Minutes for 243rd Meeting of Registration Board held on 08-09th May, 2014.

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243rd meeting of Registration Board was held on 08-09th May,2014 in the Committee Room, M/o National Health Regulation Services and Coordination, Islamabad. The meeting was chaired by Mr. Ghulam Rasool Dutani, Director, Pharmaceutical Evaluation & Registration Division. The meeting started with the recitation of Holy Verses. The meeting was attended by the following:-

1.	Lt General (R) Karamat Ahmed Karamat.	Member
2.	Brig (R). Dr. Muzammil Hasan Najmi, Associate Dean, Basic Sciences Division, Foundation Medical University, Rawalpindi.	Member
3.	Brig. Dr. Aslam Khan, Professor of Medicine, Military Hospital Rawalpindi.	Member
4.	Dr. Muhammad Arshad, President, Pakistan Veterinary Medical Council	Member
5.	Mr.Abdul Razak Director Drugs Testing Laboratory Government of Sind, Karachi.	Member
6.	Dr. Muhammad Khalid Khan Director Drugs Testing Laboratory Government of Khyber Pakhtoonkhwa, Peshawar.	Member
7.	Mr.Muhammad Jamil Anwar Director Drugs Testing Laboratory Government of Punjab, Lahore.	Member
8.	Dr.Amanullah Khan Director Drugs Testing Laboratory Government of Baluchistan, Quetta.	Member
9.	Ms.Shakira Khurshid Representative of IPO, Islamabad.	Member
10.	Sheikh Ansar Ahmad, Director Biological, DRAP	Member
11.	Dr. Noor Muhammad Shah, Director MD&MC, DRAP	Member
12.	Dr. Obaidullah, Deputy Director General (Reg.I).	Secretary/Member

Dr. Muhammad Arshad didnot attend the meeting on 09.05.2014.

Dr. Tariq Siddique (DDG), Muhammad Arif (DDC(R.I), Faisal Shahzad (DDC), Babar Khan (Incharge, PEC), Muneeb Ahmad Cheema, Ammad Zaka, Atiq ul Bari, Sara Mehreen, Muhammad Ansar, Tehreem Sara (DDC MD&MC), Asif Jalil (ADC MD&MC) and Mr.Khalid Mehmood (DDC QC) assisted relevant Directors and Secretary of the Board with agenda.

Mr.Saeed Allahwala and Mr. Hamid Raza, Mr.Nadeem Alamgeer and Dr.M.Qasim Awan attended the meeting as observer on behalf of PPMA, Pharma Beauru and PVPMA respectively.

In addition to routine agenda, the Board discussed various other matters and following decsions were also taken:

- Registration Board discussed matter regarding registration of biological drugs in detail and recommended that separate Board be constituted for registration of these products, keeping in view expertise and special nature of biological.

- Registration Board deliberated that transfer of registration from one importer to another (with no change of manufacturing site), change of brand name and change of name of manufacturer will be considered as post-registeration variation. Moreover, this approval will not be considered as renewal of the product and firm will apply for renewal of product as per procedure and will be processed as per import policy for finished drugs.

- Representative of PPMA pointed out that 10 products per section for new licensee / section is not appropriate and this criteria should be revised. The Board constituted a committee comprising of Prof.Rafi uz Zaman Saeedul Haq, Brig.Dr.Aslam Khan, Muhammad Arif and Muahmmad Amin to deliberate the matter and forward its recommendations for consideration of Registration Board within 30 days. PPMA and Pharma Beauru will be taken on board during the meeting.

Item No I: Confirmation of minutes 242nd meeting Registration Board.

242nd meeting of Registration Board was held on 24-25th February, 2014 and minutes were circulated to all members through e-mail. Deteials of comments forwarded by members are as follows:

- 06 members *viz.* Gen (R) Karamat A. Karamat ; Dr. Amanullah Khan Director, DTL, Quetta; Mr. Abdur Razzaq Director, DTL, Karachi; Dr. Khalid Khan Director, DTL, Peshawar; Mr. Jamil Anwar (Director, DTL, Lahore and Mr. A.Q.Javed Iqbal Director, QA & Lab Testing forwarded their comments on Item No.XVI (case No.1 and 2, Registration of Biological Drugs). These comments have been forwarded to Expert Committee on Biological Drugs for their opinion on each issue / question with reference from international best practice as evidence and frame recommendations. Till that time, this part of minutes was quarantined.

- **Mr. Abdur Razzaq (Director, DTL, Karachi):**

  Expert committee comment on bioequivalence study: This requirement should not be implemented since it is an expensive test, time consuming and considering the number of bioequivalence study center in ratio with the local pharmaceutical manufacturer available in Pakistan. This will only put our local industry into nuisance.

- **Mr. Jamil Anwar (Director, DTL, Lahore):**

  Item No.X: Change of Brand Name of Registered Drugs. In the decision it may be added that, as per policy decided in the 242nd meeting on this issue, the applications of manufacturers / importers for change of names will be disposed at the level of Chairman, Registration Board. The Chairman being authorized by the concerned Board to do so.

  Item No.XI: Registeration Applications for Local Manufacturing. At the serial no.874 the product 'Mefomin Tablets' was approved in the meeting

Decision: Comments of members were discussed in detail and following was concluded:

- **Quarantine part of minutes has been discussed in instant meeting.**
- **Mr. Abdur Razzaq (Director, DTL, Karachi): Comment will be referred to the committee constituted for this purpose by Registration Board.**

- **Mr. Jamil Anwar (Director, DTL, Lahore): Registration Board has already authorized its Chairman in 238th meeting to decide cases for change of brand name. However, item at serial no.874 was deferred for confirmation of me too status.**

Registration Board confirmed minutes of its 242nd meeting.

Item No II: Change of brand name of registered drugs – Referred by Director DTL, Quetta.

Under agenda Item No.X the Registration board discussed the situation for change of brand name of drug products and accordingly decided. Here I would like to share that there is another picture where the national companies take advantage by using the name of established firm with minor change. It is also our responsibility to discourage such malpractices. There may be few cases of such nature which I am not aware but one case which is brought into my knowledge needs discussion and decision.

The company S.J.& G. Fazul Ellahie (Pvt) Ltd through their letter No. SJG/GM/5866/2013 dated February 16, 2013 has informed that our firm is established in 1957 and is well known company in selling quality pharmaceutical products but unfortunately the CLB in 231st Board meeting overlooked the case and another company by the name of S.Fazalilahi & sons (Pvt) Ltd has been approved for DML.

S.Fazalilahi & sons (Pvt) Ltd name is similar to S.J.& G. Fazul Ellahie (Pvt) Ltd , therefore it is requested that all those companies which have similar names may be discussed and make decision to protect the right of the companies in the public interest . Presently my observation may be included in the forthcoming DRB meeting 243 for discussion and decision.

Decision: Registration Board referred instant reference to Licensing Division, DRAP for appropriate action at their end.

Item No III: Change of Price of Wartet Injection (Tetatus Toxoid) on available stock with M/s Hi-Warble, Pharmaceutical, Lahore.

(i) The price for Wartet Injection (Tetanus Toxoid Vaccine) was fixed by the Drug Pricing Committee in its meeting held on 08.02.2012 and notified vide SRO 328(I)/2012 dated 30.03.2012.

(ii) In a similar case of Imatet injection, M/s Amson had filed a Civil Suit before the Civil Judge, Islamabad & had obtained a restraimning order. The above said suit was dismissed and M/s Amson had requested for grant of permission for pasting stickers on the stocks of Imatet injection available with them at that time but they were not allowed, instead the company was directed to re-print the reduced price of Rs.420.00/10's with laser printing after masking the previous increased price.

(iii) In March, 2013 M/s. Hi-Warble Pharmaceuticals (Pvt.) Ltd. filed a Suit No. 9294/13 in the Court of Senior Civil Judge, Lahore in respect of price fixation of its product Wartet injection notified vide S.R.O.328(I)/2013 dated 30-03-2012 against the Secretary, NRSD, Drug Regulatory Agency of Pakistan and obtained restraining orders. After contest by the defendants by way of filing written statements & hearing arguments, the Civil Judge 1st Class, Lahore, Mr. Nadeem Anwar Ch was pleased to dismiss the temporary injunction vide order announced on 03.02.2014.

(iv) Subsequent to vacation of stay order, the Division of Costing & Pricing requested vide letter dated 7th March, 2014, DRAP field offices, Provincial Health Departments and Inspector of Drugs ICT to ensure that the said drug is available in the market at approved price and to take legal action under the Drugs Act, 1976 and rules framed there under if the firm was found selling the product at price higher than approved.

(v) Now the company has filed a request dated 28.03.2014 regarding grant of permission to affix stickers of MRP Rs.420.00/ box of 10 ampoules on all the stocks of "Wartet injections" which are available with the company & which they have recalled from the market after the stay has been vacated by the Court of Senior Civil Judge. Telephonically, the company has shown its inability to reprint the reduced MRP through laser jet printer after masking the previous increased price as they, being importers, don't have facility of laser printer & emphasized to be allowed for pasting stickers of reduced price on stocks of increased price available with them.

(vi) Meanwhile, Mr.Rana Ahsan-ul-Haq Athar, ADC, Lahore has informed the Division of Costing & Pricing vide letter dated 09.04.2014 that the company has recently imported 50,000 boxes of "Wartet injection" with MRP of Rs.495.00 printed on the boxes instead of Rs.420.00. He requested for guidance in this issue.

(vii) The matter is forwarded, as desired please, to the Division of PE&R to place before the Drug Registration Board for decision.

Decision: Keeping in view nature of the drug, the Board decided that M/s Hi-Warble, Pharmaceutical, Lahore may be permitted for inject printing of approved MRP on Wartet Injection (Tetanus Toxoid Vaccine) in any licensed manufacturing unit having facility for this purpose. The firm will provide NOC of any licensed manufacturing unit having facility for handling of cold storage items. Pricing Division will process the case for approval for issuance of letter.

Item No.IV: Manufacturing requirement for various categories of drugs:

a. Steroidal products:

Registration Board in its various meetings deferred cases for registration of steroidal preparations and constituted a committee comprising of Dr.Tariq siddique and Dr.Obaid ali for determination of the requirement. Views of PPMA and pharma Bureau were also taken by the committee. Recommendations of committee are as follows:

"Although in the state of compliance of GMP regulation and current expectation of science, handling of anti-inflamatory steroids / hormones in common manufacturing area of non-sensitive drugs with appropriate controls is acceptable, but domestic dynamics does not give reasonable space to allow across the board for handling of sensitive materials in common manufacturing facilities of different drugs. However, depending upon the level of facility compliance, material sensitivity, product dosage and demonstration of sustainable effectiveness of stringent controls to prevent cross contamination, case to case decision may be considered".

Decision: Registration Board decided to forward recommendations of the committee to Licensing Division for decision, as Schedule B-II is catered by that Division.

b. **Carbapenems:**

These are a class of β-lactam antibiotics with a broad spectrum of antibacterial activity. They have a structure that renders them highly resistant to most β-lactamases. Carbapenem antibiotics were originally developed from the carbapenem thienamycin, a naturally derived

product of *Streptomyces cattleya*. Carbapenems are one of the antibiotics of last resort for many bacterial infections, such as *Escherichia coli* (*E. coli*) and *Klebsiella pneumonia*.

Currently, there is an ambiguity whether dedicated manufacturing facilities should be mandatory for Carbapenems just like required for Cephalosporins & Penicillins or otherwise. There is a need of a lucid decision / recommendations by the Registration Board for the protection of public health in the country.

Section-1 (5.2) of Schedule-B of Drugs (L R & A), Rules, 1976 describers the requirement of Dedication / Self –contained facilities (in addition to the general facilities) for manufacturing of a particular drug (highly sensitizing material e.g., Penicillin) to minimize the risk of a serious health hazards due to cross contamination.

Regarding clarification on the requirement of separate / dedicated manufacturing facilities for Carbapenems, FDA has been mailed. Whose reply was received with the clear-cut recommendations of dedicated facilities having same level of separation requirements for manufacturing facilities and air handling systems equivalent to those required for penicillin products as mandated by 21 CFR 211.42(d), and 211.46(d). The FDA had already issued a guideline on the issue in April, 2013. This describes the cGMP framework for preventing cross-contamination with Non-Penicillin Beta-Lactam antibiotics.

The main core of the said FDA guidelines are:

a. FDA, in guidelines, has further divided the whole group beta-lactam into following five classes. They classified Carbapenems as Non-Penicillin Beta-Lactams.

- Penicillins (e.g., ampicillin, oxacillin)
- Cephalosporins (e.g., cephalexin, cefaclor)
- Penems (e.g., imipenem, meropenem)
- Carbacephems (e.g., loracarbef)
- Monobactams (e.g., aztreonam)

The FDA has used wrong term i.e.,Penems. Since the **two drugs being mentioned as an example of Penems in the referred guidelines, actually belong to Carbapenem group**. FDA has accepted the mistake.

b. As with penicillin, the section of a facility dedicated to manufacturing a sensitizing non-penicillin beta-lactam should be structurally isolated (i.e., completely and comprehensively separated) from areas in the facility in which other products are

manufactured. This control applies to each of the five classes of sensitizing beta-lactams; the area in which any class of sensitizing beta-lactam is manufactured should be separated from areas in which any other products are manufactured, including any other class of sensitizing beta-lactam or any other non-beta-lactam product.

c. FDA considers the separation of production facilities for penicillins to be current good manufacturing practice, FDA expects manufacturers to treat sensitizing non-penicillin beta-lactam-based products similarly. Specifically, FDA recommends that manufacturers establish appropriate separation and control systems designed to prevent two types of contamination: (1) the contamination of a non-penicillin beta-lactam by any other non-penicillin beta-lactam, and (2) the contamination of any other type of product by a non-penicillin beta-lactam.

d. FDA also recommends the same level of measures of control from cross-contamination for beta-lactam intermediates
and derivatives.

Decision: Registration Board deliberated the case in detail and it was decided that carbapenems are sensitive drugs and should be manufactured in dedicated facilities. Moreover, all manufacturers having registration of these drugs will be issued notices for establishment of dedicated facilities within 06 months time.

Item No: V. Applications for registration of drugs (Local Manufacturing).

Following are the applications which have been evaluated by the Pharmaceutical Evaluation Cell. The applications have been divided into following six sub-categories.

a) Application for registration of drugs, missed in 242nd meeting (05 Applications)

b) Applications for grant of registration to new Drug Manufacturing Licenses (462 - Applications)

c) Applications for grant of registration to newly approved sections (182 - Applications)

d) Applications for grant of registration to newly approved sections whose applications are still remaining (10 products per section) (34 Applications)

e) Deferred cases of previous meeting M-242 in which codal-formalities / Form-5 has been completed (30 Applications)

f) Already considered cases in which correction is required (4 - Applications)

Registration Board discussed registration applications in above categories and decided that for applications in which some deficiencies are yet to be rectified by the applicant and formulation is OK, then in such cases products are approved subject to rectification of shortconings as mentioned in agenda and subsequent approval by Chairman, Registration Board.

Registration Board authorized its Chairman for constitution of panel for taking expert opinions in consultation with Prof.Dr.M.H.Najmi and Brig.Dr.Aslam Khan.

a) Application for registration of Drugs which were missed in M-242 meeting of Registration Board: (6 - Applications)

For following application, the firm requested for more time to submit the reply. Now, it has submitted the same.

S/N	Name and address of manufacturer /Applicant	1. Brand Name 2. Dosage Form 3. Composition 4. Finished Product specifications	1.Type of Form 2. Type of application 3. Demanded Price / Pack size 4. Initial date, diary. 5. Date on which fee becomes complete according to type of application /or Form (total Fee)	1. Me-too status	Decision
1.	M/s Mediate Pharmaceuticals Pvt. Ltd. 150-151, Sector 24, Korangi Industrail Area, Karachi	1.Medidox 2.Capsule 3.Each capsule contains: Doxycycline Hyclate..…100 mg 4.USP	1.Form5 2.Fast Track 3. Rs.400/100's 4.20-05-2013 Dy.No.499 Rs.20,000/- 23-5-2013 Rs.40,000/-	Alpodox of M/s Medicaids.	Approved

Evaluator-II

2.	**Name and address of manufacturer/Applicant**	**Brand Name Dosage Form Composition (pharmacological Group)** **Finished product specification**	**Demanded Price / Pack size**	**1. Type of Form** **2. Initial date, diary.** **3. Date on which fee becomes complete according to type of application /or Form (total Fee)**	**1. International status in stringent regulatory agencies** **2. Me-too status** **3.GMP status as depicted in inspection report (dated)**	**Decision**
3.	M/s Kanel Pharma, Plot No. 6, Road SS3, National Industrial Zone, Rawat, Rawalpindi.	Pan-Care 40mg Tablets Each enteric coated tablet contains:- Pantoprazole as Sodium sesquihydrate ……40mg (Anti-Ulcer) U.S.P	As per SRO/14's	1. Form-5 2. 21/11/2013, (7404) 3. 21/11/2013 (Rs.60,000)	**1.BNF 61: Pantoprazole** (Non-proprietary) Tablets, e/c, pantoprazole 20 mg; 40 mg) **2. Aptizole(**Global Pharmaceuticals**)** [Pantoprazole:40mg] Tabs (R.No. 033392) 3.Good	Approved
4.	-do-	Tram-P 37.5/325mg Tablets Each film coated tablet contains:- Tramadol HCl ……..37.5mg Paracetamol ……..325mg (Analgesic) (USP Spec.s)	As per SRO/10's	1. Form-5 2. 21-11-2013 Dy.No.7403 3. 21-11-2013 (Rs.60,000/-)	1. **Tramacet** (Gru¨nenthal) Tablets, f/c, yellow, tramadol hydrochloride 37.5 mg, paracetamol 325 mg 2. Tonoflex-P (Sami Pharmaceuticals (Pvt) Ltd.) [Paracetamol:325mg,Tramadol (HCl):37.5mg]Tab	Approved

					3. Good	
5.	-do-	Stagmet 50/500mg Tablets Each film coated tablet contains:- Sitagliptin as Phosphate Monohydrate……….50mg Metformin HCl (B.P)…….500mg (Dipeptidyl Peptidase-4 Inhibitor (DPP-4) and biguanide. (Manufacturer's Specs)	As per SRO/10's	1.Form-5 2. 21-11-2013 Dy.No.7405 3. 21-11-2013 (Rs.60,000/)	1 **FDA: JANUMET(MERCK SHARP DOHME) (**Metformin Hydrochloride; Sitagliptin Phosphate 500mg; Eq 50mg Base) Tablet;Oral 2. **Treviamet(**Getz Pharma Pakistan (Pvt) Ltd.**)** [Metformin (HCl): 500mg, Sitagliptin:50mg]Tab 3. Good	Approved
6.	-do-	Telmis-A 5/80mg Tablets Each film coated tablet contains:- Amlodipine as Besylate ……..……5mg Telmisartan ……80mg (Calcium channel blocker and an angiotensin II Antagonist)	As per SRO/14's	1.Form-5 2. 21-11-2013 Dy.No.7406 3. 21-11-2013(Rs.60,000/)	1. Twynsta (Boehringer Ingelheim) amlodipine besylate; telmisartan eq 5mg base; 80mg multilayer tablet;oral 2. Amtas (Getz Pharma Pakistan (pvt) ltd.) [Amlodipine (Besylate): 5mg,Telmisartan:80mg] Tab 3. Good	Deferred for following 1. Complete details regarding international availability especially in FDA, EMA, Health Canada, TGA & MHLW for same generic, dosage form & strength with reference are required. Clarification is required as Twynsta (FDA approved) is multilayered. 2. Stepwise details of manufacturing process including

						Precautions/Control required to produce specified quantities of the drug applied for registration and demonstration of cleaning validation procedures, Identification & description of Critical steps which may alter the results and tests for IPQC including weight variation, hardness, friability, water content, etc are required. 3. List of particular equipments used showing its model and capacities along with their status of cGMP compliance is required. 4. Reference of manufacturer's Specifications of finished product are required. 5. The Firm has requested time for proper reply of the observations.

b) Applications of Newly approved Drug Manufacturing Licenses (462 - Applications)

Evaluator – I

S/N	Name and address of manufacturer/Applicant	Brand Name Dosage Form Composition (pharmacological Group) Finished product specification	Demanded Price / Pack size	1. Type of Form 2. Initial date, diary. 3. Date on which fee becomes complete according to type of application /or Form (total Fee)	1. International status in stringent regulatory agencies 2. Me-too status 3.GMP status as depicted in inspection report (dated)	Decision
1-	Wimits Pharmaceuticals Plot # 129 Sundar Industrial Estate,Raiwind Road Lhr Pakistan.	1.Cipromit 500mg 2.Tablet 3.Each Film Coated tablet contains: Ciprofloxacin as Hydrochloride…500mg 4.Antibiotic,Quinolone 5.USP specifications	As per SRO/ 10's	1. Form 5 2.Normal 3. 1347.23-12-2013, 4.Rs.20,000/-	1.Ciproxin (Bayer) 2.Ciproxin (Bayer) 3.Firm is new licence as per penal inspection dated 26.11.2013	Approved
2	Wimits Pharmaceuticals Plot # 129 Sundar Industrial Estate,Raiwind Road Lhr Pakistan.	1.Cipromit 250mg 2.Tablet 3.Each Film Coated tablet contains: Ciprofloxacin as Hydrochloride …250mg 4. Antibiotic, Quinolone 5. USP Specifications	As per SRO/10's	1. Form 5 2.Normal 3. 1346.23-12-2013 4.Rs.20,000/-	1.Ciproxin (Bayer) 2.Ciproxin (Bayer) 3.Firm is new licence as per penal inspection dated 26.11.2013	Approved

3	Wimits Pharmaceuticals Plot # 129 Sundar Industrial Estate,Raiwind Road Lahore.	1. Levomit 250mg 2. Tablet 3. Each Film Coated tablet contains: Levofloxacin as Hemihydrate..250mg 4. Antibiotic, Quinolone 5. Manufacturer Specs	As per SRO/ 10's	1. Form 5 2.Normal 3. 1351.23-12-2013 4. Rs.20,000/-	1.Tavanic (Sanofi) 2.Tavanic (Sanofi) 3.Firm is new licence as per penal inspection dated 26.11.2013	Approved
4	Wimits Pharmaceuticals Plot # 129 Sundar Industrial Estate,Raiwind Road Lhr Pakistan.	1.Levomit 500mg 2.Tablet 3. Each Film Coated tablet contains: Levofloxacin as Hemihydrate..500mg 4.Antibiotic, Quinolone 5.Manufacturer Specs	As per SRO/10's	1. Form 5 2.Normal 3.1352. 23-12-2013 4.Rs.20,000	1.Tavanic (Sanofi) 2.Tavanic (Sanofi) 3. Firm is new licence as per penal inspection dated 26.11.2013	Approved
5	Wimits Pharmaceuticals Plot # 129 Sundar Industrial Estate,Raiwind Road Lhr Pakistan.	1. Clarimax 250 mg 2. Tablet 3. Each Film Coated tablet contains: Clarithromycin B.P..250mg 4.Macrolide 5.B.P specs	As per SRO/ 10's	1. Form 5 2.Normal 3. 1348. 23-12-2013 4. 20,000/-	1.Klaricid (Abbott) 2.Klaricid (Abbott) 3.Firm is new licence as per penal inspection dated 26.11.2013	Approved

6	Wimits Pharmaceuticals Plot # 129 Sundar Industrial Estate,Raiwind Road Lhr Pakistan.	1. Omnidol 2. Tablet 3. Each tablet contains: Paracetamol B.P…500mg Caffeine…65mg Chlorphenaramine maleate…2mg 4. NSAID, 5. Wimits specs	As per SRO/ 100's	1. Form 5 2.Normal 3. 326.10-01-2014 4. Rs.20,000/-	1. 2.Amidol (Bloom) Firm is new licence as per penal inspection dated 26.11.2013	Approved with name change
7	Wimits Pharmaceuticals Plot # 129 Sundar Industrial Estate,Raiwind Road Lhr Pakistan.	1. Levic 250 mg 2. Tablet 3. Each Film Coated tablet contains: Levetiracetam ….. 250mg Antiepileptic 4. Anticonvulsants 5. USP Specs	As per SRO/ 30's	1. Form 5 2.Normal 3. 330.10-01-2014 4. Rs.20,000/-	1.Keppra (UCB Pharma) 2.Keppra (GSK) 3.Firm is new licence as per penal inspection dated 26.11.2013	Approved
8	Wimits Pharmaceuticals Plot # 129 Sundar Industrial Estate,Raiwind Road, Lahore.	1. Levic 500 mg 2. Tablet 3. Each Film Coated tablet contains: Levetiracetam ….. 500mg Antiepileptic 4. Anticonvulsants 5. USP Specs	As per SRO/ 30's	1. Form 5 2.Normal 3. 331.10-01-2014 4. Rs.20,000/-	1.Keppra (UCB Pharma) 2.Keppra (GSK) 3.Firm is new licence as per penal inspection dated 26.11.2013	Approved

9	Wimits Pharmaceuticals Plot # 129 Sundar Industrial Estate,Raiwind Road Lahore.	1. Ratadine 5mg 2. Tablet 3. Each film coated tablet contains Desloratadine….5 mg 4. Antihistamine 5. Manufacturer's specifications.	As per SRO/10's	1.Form-5 2. 411, 13-03-2014 3.Rs.20,000, 13-03-2014	1. **Clarinex tablet 5mg** 2. Destina tablet 3. Firm was inspected on 26-11-2013 for grant of DML by Formulation.	Approved
10	Wimits Pharmaceuticals Plot # 129 Sundar Industrial Estate,Raiwind Road Lhr Pakistan.	1. Fenbid 2. Tablet 3. Each Film Coated tablet contains: Flurbiprofen B.P….100mg 4.Analgesic,Antipyretic NSAID 5.B.P specs	As per SRO/ 30's	1. Form 5 2.Normal 3. 325.10-01-2014 4. Rs.20,000/	1.Froben (Abbott) 2.Ansaid (Pfizer) 3.Firm is new licence as per penal inspection dated 26.11.2013	Approved
11	Wimits Pharmaceuticals Plot # 129 Sundar Industrial Estate, Raiwind Road Lhr Pakistan.	Omezole 20mg Capsule Each Capsule contains: Omeprazole USP (Enteric Coated Pellets)……20 mg (source Vision Pharma Islamabad) Proton Pump Inhibitor, Proton Pump Inhibitor, USP Specs	As per SRO 14's	1. Form 5 2.Normal 3. 1372.23-12-2013 4.Rs.20,000	1.Losec (Astrazeneca) 2.Omega(Ferozsons) 3.Firm is new licence as per penal inspection dated 26.11.2013	Approved

12	Wimits Pharmaceuticals Plot # 129 Sundar Industrial Estate, Raiwind Road Lhr Pakistan.	1.Omezole 40mg 2.Capsule 3.Each Capsule contains: Omeprazole USP (Enteric Coated Pellets)……40 mg (source Spansules formulations, situated at Sy. No.172 plot No.154 IDA, Bollaram, Village, Jinnaram Mandal, Medak, District, Andhra Pradesh, India) 4.Proton Pump Inhibitor 5.USP Specifications	As per SRO/ 14's	1. Form 5 2.Normal 3.1373. 23-12-2013 4.120,000/-	1.Losec (Astrazeneca) 2.Omega(Ferozsons) 3.Firm is new licence as per penal inspection dated 26.11.2013	Approved. Firm will provide legalized GMP certificate, COA and stability data of pellets from the manufacturer
13	Wimits Pharmaceuticals Plot # 129 Sundar Industrial Estate, Raiwind Road Lhr Pakistan.	1. Essolax 20mg 2. Capsule 3. Each Capsule contains: Enteric-coated pellets of Esomeprazole Magnesium Trihydrate equivalent to Esomeprazole ……20 mg (Source Vision Pharmaceuticals Islamabad) 4. Proton Pump Inhibitor 5. Manufacturer's Specs	As per SRO/ 14's	1.Form 5 2.Normal 3.1373.23-12-2013 4. Rs.20,000/-	1. Emozul (Consilient) 2.Esso(Shaigan) 3.Firm is new licence as per panel inspection dated 26.11.2013	Approved

14	Wimits Pharmaceuticals Plot # 129 Sundar Industrial Estate, Raiwind Road Lhr Pakistan.	Essolax 40mg Capsule Each Capsule contains: Enteric-coated pellets of Esomeprazole Magnesium Trihydrate equivalent to Esomeprazole ……40 mg (source Spansules formulations, situated at Sy. No.172 plot No.154 IDA, Bollaram, Village, Jinnaram Mandal, Medak, District, Andhra Pradesh, India) Proton Pump Inhibitor Manufacturer Specs	As per SRO/ 14's	1. Form 5 2.Normal 3. 1374.23-12-2013 4.Rs.120,000/28.04 .2014	1. Emozul (Consilient) 2.Esso(Shaigan) 3.Firm is new licence as per panel inspection dated 26.11.2013	Approved. Firm will provide legalized GMP certificate, COA and stability data of pellets from the manufacturer
15	Wimits Pharmaceuticals Plot # 129 Sundar Industrial Estate, Raiwind Road Lhr Pakistan.	1. Azilex 250mg 2. Capsule 3. Each Capsule contains: Azithromycin Dihydrate USP equivalent to Azithromycin….250mg 4. Macrolide 5. USP Spec	As per SRO 6's	1. Form 5 2.Normal 3. 1377. 23-12-2013 4.Rs.20,000	1.Zithromax (Pfizer) 2.Azomax (Sandoz) 3. Firm is new licence as per penal inspection dated 26.11.2013	Approved
16	Wimits Pharmaceuticals Plot # 129 Sundar Industrial Estate, Raiwind Road Lhr Pakistan.	1. Dyclofen SR 100mg 2. Capsule 3.Each Capsule contains: Diclofenac Sodium as enteric coated pellets ….. 100mg (Source Spansules	As per SRO/ 20's	1. Form 5 2.Normal 3.1376. 23-12-2013 4. 120,000/-	1.BNF UK 2.Phlogin (Brookes) 3.Firm is new licence as per penal inspection dated 26.11.2013	Approved

		formulations, situated at Sy. No.172 plot No.154 IDA, Bollaram, Village, Jinnaram Mandal, Medak, District, Andhra Pradesh, India) 4.Analgesic, Anti Inflammatory 5. Manufacturer Specs				
17	Wimits Pharmaceuticals Plot # 129 Sundar Industrial Estate, Raiwind Road Lhr Pakistan.	1. D-Dox 100mg 2. Capsule 3. Each Capsule contains: Doxycycline Hyclate USP .. 100mg 4. Broad Spectrum Antibiotic 5. USP Specs	As per SRO/ 100's	1. Form 5 2.Normal 3. 650.09-04-2014 4.Rs.20,000/-	1.**Doxycyclate Hyclate. (West Ward Pharmaceutical corp)** 2.Vibramycin (Pfizer) 3. Firm is new licence as per penal inspection dated 26.11.2013	Approved
18	Wimits Pharmaceuticals Plot # 129 Sundar Industrial Estate, Raiwind Road Lhr Pakistan.	1. Gabamit 150mg 2. Capsule 3. Each Capsule contains: Pregabalin ….. 150mg 4. Anticonvulsant 5. Wimits Specs	As per SRO/ 14's	1. Form 5 2.Normal 3.407,13-03-2014 4. Rs.20,000	1.Lyrica (Parke-Davis Div of Pfizer Inc) 2.Gavica (Getz) 3.Firm is new licence as per penal inspection dated 26.11.2013	Approved

19	Wimits Pharmaceuticals Plot # 129 Sundar Industrial Estate, Raiwind Road Lhr Pakistan.	1. APO 20mg 2. Capsule 3. Each Enteric Coated Pellets contains: Duloxetine HCl …. 20mg (Vision Pharmaceuticals Islamabad) 4. Serotonine & Norepinephrene Reuptake Inhibitor 5. Manufacturer's Specs	As per SRO/ 14's	1. Form 5 2.Normal 3. 410.13-03-2014 4.20,000/-	1.Cymbalta (Lilly) 2.Dulan (Hilton) 3.Firm is new licence as per penal inspection dated 26.11.2013	Approved
20	Wimits Pharmaceuticals Plot # 129 Sundar Industrial Estate, Raiwind Road Lhr Pakistan.	1. APO 30mg 2. Capsule 3. Each Enteric Coated Pellets contains: Duloxetine HCl …. 30mg (source Spansules formulations, situated at Sy. No.172 plot No.154 IDA, Bollaram, Village, Jinnaram Mandal, Medak, District, Andhra Pradesh, India) 4.Serotonine & Norepinephrene Reuptake Inhibitor 5. USP Specs	As per SRO/ 14's	1. Form 5 2.Normal 3. 409.13-03-2014 4.Rs.120,000.28.04 .2014	1.Cymbalta (Lilly) 2. Dulan (Hilton) 3.Firm is new licence as per penal inspection dated 26.11.2013	Approved

21	Wimits Pharmaceuticals Plot # 129 Sundar Industrial Estate, Raiwind Road Lhr Pakistan.	1. Ibumet Suspension 2. Oral Liquid Suspension 3. Each 5ml Contains: Ibuprofen BP….100mg Analgesics, Antipyretic, 4. Anti-Inflammatory 5. B.P Specs	As per SRO/ 90 ml	1. Form 5 2.Normal 3. 1364.23-12-2013 4. Rs.20,000/-	1.IBU (Abbott) 2.Brufen (abbott) 3.Firm is new licence as per penal inspection dated 26.11.2013	Approved
22	Wimits Pharmaceuticals Plot # 129 Sundar Industrial Estate, Raiwind Road Lhr Pakistan.	1.Metrofena 2. suspension Oral Suspension 3. Each 5ml Contains: Furazolidone BP..25mg Metronidazole as Benzoate ….. 75mg 4. Anti-Amoebic 5. Manufacturer's Specs	As per SRO/ 60ml	1. Form 5 2.Normal 3. 1365 .23-12-2013 4. Rs.20,000/-	1. 2.Dependal-M (GSK) 3.Firm is new licence as per penal inspection dated 26.11.2013	Approved
23	Wimits Pharmaceuticals Plot # 129 Sundar Industrial Estate, Raiwind Road Lhr Pakistan.	1. Melenium 2. Suspension 3. Each ml Contains: Domperidone …1mg 4. Anti dopamenergic 5. Manufacturer's Specs	As per SRO 60, 120 ml	1. Form 5 2.Normal 3. 1367.23-12-2013 4. Rs.20,000/-	1. 2.Dome-One (Shrooq) 3.Firm is new licence as per penal inspection dated 26.11.2013	Approved

24	Wimits Pharmaceuticals Plot # 129 Sundar Industrial Estate, Raiwind Road Lhr Pakistan.	1. Maltoplex Syrup 2. Syrup 3. Each 5ml Contains: Iron III Hydroxide Polymaltose Complex eq to elemental iron …. 50mg 4. Anti-Anaemics, Haematinic 5. Manufacturer Specs	As per SRO/ 120 ml	1. Form 5 2.Normal 3. 1369. 23-12-2013 4.Rs.20,000/-	1. 2.Maltofer (Vifer) 3.Firm is new licence as per penal inspection dated 26.11.2013	Approved
25	Wimits Pharmaceuticals Plot # 129 Sundar Industrial Estate, Raiwind Road Lhr Pakistan.	1. Appetizer Syrup 2. Syrup 3. Each 5ml Contains: Pizotifen as Hydrogen Maleate ……. 0.25mg 4. Appetite Stimulant 5. Manufacturer Specs	As per SRO 120 ml	1. Form 5 2.Normal 3. 336.10-01-2014 4.Rs.20,000/-	1.Asked 2.Mosegar (Novartis) 3.Firm is new licence as per penal inspection dated 26.11.2013	Rejected being non-establised / wrong indication i.e appetite stimulent
26	Wimits Pharmaceuticals Plot # 129 Sundar Industrial Estate, Raiwind Road Lhr Pakistan.	1. Levic Oral Solution 2. Oral Solution 3. Each ml Contains: Levetiracetam ...100mg 4. Antiepileptics 5. USP Specs	As per SRO/ 120 ml	1. Form 5 2.Normal 3. 334. 10-01-2014 4.Rs.20,000/-	1.Keppra (UCB Pharma) 2.Levtral (Shrooq) 3. Firm is new licence as per penal inspection dated 26.11.2013	Approved

27	Wimits Pharmaceuticals Plot # 129 Sundar Industrial Estate, Raiwind Road Lahore Pakistan.	1. IPS-120 Syrup 2. Syrup 3. Each 15 ml Contains: Iron Protein Succinylate ...800mg eq to elemental Iron 40mg 4. Anti-Anaemics, Haemantinic 5. Manufacturer Specs	As per SRO/ 120 ml	1. Form 5 2.Normal 3. 1371.23-12-2013 4.Rs20,000	1. 2.Heamocare (Himont) 3.Firm is new licence as per penal inspection dated 26.11.2013	Approved with change of brand name
28	Wimits Pharmaceuticals Plot # 129 Sundar Industrial Estate, Raiwind Road Lhr Pakistan.	1.Ossovit-D Suspension 2. Oral Liquid Suspension 3. Each 5ml contains: Ossein Mineral Complex MS ...250mg corresponding to Calcium……..53.5mg Phosphorous…24.8mg Residual Mineral Salt…..7.50mg Collagen……67.50mg Other Proteins…..20mg Trace Elements …..F'Mg,Fe,Zn,Cu,Ni Corresponding to approx 132mg hydroxyapatite 4. Vitamins and calcium supplementary 5. Wimits Specs	As per SRO/ 60 ml	1. Form 5 2.Normal 3. 1370.23-12-2013 4.Rs.20,000/-	1. 2.Intig (sami) 3. Firm is new licence as per penal inspection dated 26.11.2013	Deferrd for confirmation of Atomoc Absorption by Area FID

29	Wimits Pharmaceuticals Plot # 129 Sundar Industrial Estate, Raiwind Road Lhr Pakistan.	1. Actopil 2. Syrup 3. Each 5ml Contains: Piracetam ... 1gm 4. Nootropics Neuronal metabolic modulator 5. Wimits Specs	As per SRO/ 120 ml	1. Form 5 2.Normal 3. 648. 09-04-2014, 4.Rs.20,000	1. 2.Nootropil (GSK) 3.Firm is new licence as per penal inspection dated 26.11.2013	Referred to review committee for review of formulation
30	M/s. Wimits Pharmaceuticals, Plot No.129, Sunder Industrial Estate (P.I.E) Raiwind Road, Lahore.	1. Ratadine 2. Syrup 3. Each ml contains Desloratadine...0.5 mg 4. Antihistamine 5. Manufacturer's specifications.	As per SRO/60ml pack	1.Form-5 2. 412, 13-03-2014 3. Rs.20,000, 13-03-2014	1. **Clarinex syrup 0.5mg/ml** 2. Delergia Syrup 0.5mg/ml 3. Firm was inspected on 26-11-2013 for grant of DML by Formulation.	Approved
31	Wimits Pharmaceuticals Plot # 129 Sundar Industrial Estate, Raiwind Road Lhr Pakistan.	1.Dyclofen 2.Injection 3.Each 3ml Ampoule Contains: Diclofenac Sodium …..75mg 4.Non Steroidal Anti Inflammatory Drug 5.Manufacturer's Specs	As per SRO/ 5's	1. Form 5 2.Normal 3. 1363/23-12-2013 4.20,000/-	1. 2.Dicloran (Sami) 3.3.Firm is new licence as per penal inspection dated 26.11.2013	Approved with change in brand name

32	Wimits Pharmaceuticals Plot # 129 Sundar Industrial Estate, Raiwind Road Lhr Pakistan.	1. Methovit 2. Injection 3. Each ml Ampoule Contains: Mecobalamin ...500mcg 4. Coenzyme-type vitamin B 12 5. Manufacturer Specs	As per SRO/ 10's	1. Form 5 2.Normal 3. 1362.23-12-2013 4. 20,000/-	1.Methylcobalamin 2.Methycobal (Hilton) 3.Firm is new licence as per penal inspection dated 26.11.2013	Approved
33	Wimits Pharmaceuticals Plot # 129 Sundar Industrial Estate, Raiwind Road Lhr Pakistan.	1. Irofer 2. Injection IV 3. Each 5ml Ampoule Contains: Iron Sucrose (equivalent to elemental iron).....100mg 4. Haematinic 5.BP Specs	As per SRO/ 5's	1. Form 5 2.Normal 3. 1361.23-12-2013 4.20,000/-	1.Venofer (Vifor) 2.Bisleri-S (Sami) 3.Firm is new licence as per penal inspection dated 26.11.2013	Approved
34	Wimits Pharmaceuticals Plot # 129 Sundar Industrial Estate, Raiwind Road Lhr Pakistan.	1. Buphine 2. Injection 3. Each ml Ampoule Contains: Nalbuphine HCl...10mg 4. Synthetic opioid agonist-antagonist analgesic 5. Manufacturer's Specs	As per SRO/ 5's	1. Form 5 2.Normal 3.649. 09-4-2014 4.Rs.20,000/-	1.Naulbuphine Hydrochloride (Cardinal Health) 2.Buphaine (Macter) 3.Firm is new licence as per penal inspection dated 26.11.2013	Approved

35	Wimits Pharmaceuticals Plot # 129 Sundar Industrial Estate, Raiwind Road Lhr Pakistan.	1. Dee 2. Injection 3. Each 1ml Ampoule Contains: Cholecalciferol.....5mg 4. Vitamin D Analogue 5. USP Specifications	As per SRO/ 1's	1. Form 5 2.Normal 3. 1359.23-12-2013 4. Rs.20,000/-	Calciferol (Global) 3.Firm is new licence as per penal inspection dated 26.11.2013	Approved
36	Wimits Pharmaceuticals Plot # 129 Sundar Industrial Estate, Raiwind Road Lhr Pakistan.	1. Artemet 2.Injection IM 3. Each 1ml Ampoule Contains: Artemether...80mg 4. Antimalarial 5. Manufacturer's Specs	As per SRO/ 6's	1. Form 5 2.Normal 3. 1358.23-12-2013 4.20,000/-	1.Artemether 2.Artem (Hilton) 3.Firm is new licence as per penal inspection dated 26.11.2013	Approved
37	Wimits Pharmaceuticals Plot # 129 Sundar Industrial Estate, Raiwind Road, Lahore.	1. Dyclofen Plus 2. Injection 3. Each 2 mL contains Diclofenac sodium…. 75mg Lignocaine HCl… 20mg 4. NSAID/Anesthetic 5.Manufacturer's Specs	As per SRO/2mlx 5 ampoules	1. Form 5 2.Normal 3. 1360, 23-12-2013 4. Rs.20,000, 23-12.2013	Aaram (Bosch) 3.Firm is new licence as per penal inspection dated 26.11.2013	Approved
38	Wimits Pharmaceuticals Plot # 129 Sundar Industrial Estate, Raiwind Road Lhr Pakistan.	1. K-Lac 2. Injection IM 3. Each ml Ampoule Contains: Ketorolac Trometamol …....30mg 4. Non Steroidal Anti Inflammatory Drug 5.USP Specs	As per SRO/ 10's	1. Form 5 2.Normal 3. 1357.23-12-2013 4.20,000/-	1.Toradol (Roche) 2.Toradol (Martin Dow) 3.Firm is new licence as per panel inspection dated 26.11.2013	Approved with change of name

39	Wimits Pharmaceuticals Plot # 129 Sundar Industrial Estate, Raiwind Road Lhr Pakistan.	Femvil Injection Each 2mL contains Pheniramine Maleate 22.7mg equivalent to 25mg Pheniramine salicylate Antihistamine. Manufacturer's Specs	As per SRO/ 25 x 2ml	1. Form 5 2.Normal 3. 1355.23-12-2013 4.Rs.20,000/- (Original)	2. Avil (Sanofi) 3. Firm is new licence as per panel inspection dated 26.11.2013	Deferred for confirmation of salt form of API
40	Wimits Pharmaceuticals Plot # 129 Sundar Industrial Estate, Raiwind Road Lhr Pakistan.	1. Calwim 2. IV Injection 3. Each ml contains Calcitriol …… 1 mcg 4. Vitamin D Analogue 5. USP Specs	As per SRO/ 10 x 1ml	1. Form 5 2.Normal 3. 488.21-03-2014 4. 20,000/-	1.Calcijex 2.Bonky (RG Pharma) 3.Firm is new licence as per penal inspection dated 26.11.2013	Deferred for PSI by Director DTL Lahore and area FID DRAP
41	M/s Genesis Pharmaceuticals (pvt) Ltd., Plot No.25 Sundar Industrial Estate, Raiwind Road, Lahore	1.Omegene 20mg 2.Capsule 3.Each capsule contains, Omeprazole as enteric coated pellets……20mg (Source: Vision Pharma) 4.Antipeptic Ulcerant/PPI 5. USP Specifications	195.00/ 2x7 capsules	1.Form 5 2.656/01-04-2014 3.Rs.20000,01-04-2014	1. Losec (Astrazeneca) 2.Omega (Ferozsons) 3.Firm is GMP compliant as per panel inspection dated03-02-2014	Approved

42	M/s Genesis Pharmaceuticals (pvt) Ltd., Plot No.25 Sundar Industrial Estate, Raiwind Road, Lahore	1.Essogene 40mg 2.Capsule 3.Each capsule contains, Esomeprazole Megnasium Trihydrate as enteric coated pellets……40mg (Source: Vision Pharma) 4.Antipeptic Ulcerant/PPI 5. USP Specifications	323.00/ 2x7 capsules	1.Form 5 2.652/01-04-2014 3.Rs.20000,01-04-2014	1. Emozul (Consilient) 2.Esso (Shiagan) 3.Firm is GMP compliant as per panel inspection dated03-02-2014	Approved
43	M/s Genesis Pharmaceuticals (pvt) Ltd., Plot No.25 Sundar Industrial Estate, Raiwind Road, Lahore	1.Flucogene 150mg 2.Capsule 3.Each capsule contains, Fluconazole……150mg 4.Antifungal/ Triazole 5.Manufacturer's Specification	172.00/ 1x1 capsules	1.Form 5 2.649/01-04-2014 3.Rs.20000,01-04-2014	1.Diflucan (Pfizer) 2.Diflucan 3.Firm is GMP compliant as per panel inspection dated03-02-2014	Approved
44	M/s Genesis Pharmaceuticals (pvt) Ltd., Plot No.25 Sundar Industrial Estate, Raiwind Road, Lahore	1.Omegene 40mg 2.Capsule 3.Each capsule contains, Omeprazole as enteric coated pellets……40mg (Source: Vision Pharma) 4.Antipeptic Ulcerant/PPI 5. USP Specifications	295.00/ 2x7 capsules	1.Form 5 2.655/01-04-2014 3.Rs.20000,01-04-2014	1. Losec (Astrazeneca) 2.Omega (Ferozsons) 3.Firm is GMP compliant as per panel inspection dated03-02-2014	Approved
45	M/s Genesis Pharmaceuticals (pvt) Ltd., Plot No.25 Sundar Industrial Estate, Raiwind Road, Lahore	1.Itragene 100mg 2.Capsule 3.Each capsule contains, Itraconazole……100mg 4.Antifungal/ Triazole 5.Manufacturer's Specification	300.00/ 2x7 capsules	1.Form 5 2.648/01-04-2014 3.Rs.20000,01-04-2014	1.Sporanox (Janssen) 2.Icon (Ferozsons) 3.Firm is GMP compliant as per panel inspection dated03-02-2014	Approved

46	M/s Genesis Pharmaceuticals (pvt) Ltd., Plot No.25 Sundar Industrial Estate, Raiwind Road, Lahore	1.Lanzogene 30mg 2.Capsule 3.Each capsule contains, Lansoprazole as enteric coated pellets……30mg (Source: Vision Pharma) 4.Antipeptic Ulcerant/PPI 5. USP Specifications	400.40/ 2x7 capsules	1.Form 5 2.650/01-04-2014 3.Rs.20000,01-04-2014	1.Lansoperazole (BNF) 2.Caralans(Caraway) 3.Firm is GMP compliant as per panel inspection dated03-02-2014	Approved
47	M/s Genesis Pharmaceuticals (pvt) Ltd., Plot No.25 Sundar Industrial Estate, Raiwind Road, Lahore	1.Azogen 250mg 2.Capsule 3.Each capsule contains, Azithromycin as dihydrate ……250mg 4.Macrolide Antibiotic 5. USP Specification	380.00/ 2x6 capsules	1.Form 5 2.659/01-04-2014 3.Rs.20000,01-04-2014	1.Zithromax (Pfizer) 2.Azomexin(Paramount 3.Firm is GMP compliant as per panel inspection dated03-02-2014	Approved
48	M/s Genesis Pharmaceuticals (pvt) Ltd., Plot No.25 Sundar Industrial Estate, Raiwind Road, Lahore	1.Essogene 20mg 2.Capsule 3.Each capsule contains, Esomeprazole Megnasium Trihydrate as enteric coated pellets……20mg (Source: Vision Pharma) 4.Antipeptic Ulcerant/PPI 5.Manufacturer's Specifications	126.00/ 2x7 capsules	1.Form 5 2.654/01-04-2014 3.Rs.20000,01-04-2014	1. Emozul (Consilient) 2.Esso (Shiagan) 3.Firm is GMP compliant as per panel inspection dated03-02-2014	Approved

49	M/s Genesis Pharmaceuticals (pvt) Ltd., Plot No.25 Sundar Industrial Estate, Raiwind Road, Lahore	1.Transagene 500mg 2.Capsule 3.Each capsule contains, Tranexamic acid……500mg 4. Fibrinolytic 5. Manufacturer's Specifications	300.00/ 2x10 capsules	1.Form 5 2.651/01-04-2014 3.Rs.20000,01-04-2014	Brino (Sami) 3.Firm is GMP compliant as per panel inspection dated03-02-2014	Approved
50	M/s Genesis Pharmaceuticals (pvt) Ltd., Plot No.25 Sundar Industrial Estate, Raiwind Road, Lahore	1.Tamsugene 0.4mg 2.Capsule 3.Each capsule contains, Tamsulosin HCL as SR pellets……0.4mg (Source: Vision Pharma) 4.Alpha 1 Adrenoceptor in the Prostate 5. USP Specifications	550.00/ 1x10 capsules	1.Form 5 2.653/01-04-2014 3.Rs.20000,01-04-2014	1.Flowmax (**Boehringer**) 2.Maxflow(CCL) 3.Firm is GMP compliant as per panel inspection dated03-02-2014	Approved
51	Ameer & Adnan Pharmaceuticals (Pvt.) Ltd, Plot No. 47, Sundar Industrial Estate, Raiwand Road, Lahore	1. Adzithro. 2. Capsule. 3.Each capsule contains, Azithromycin as Dihydrate…..250mg. 4. Macrolide 5. USP Specifications	As per SRO/ 6's capsules	1. Form - 5. 2.1119, 16.12.2013. 3.Rs.20000, 16.12.2013	1. Zithromax (Pfizer) 2.Azomax (Novartis) 3. Firm is a new licence as recommended by the panel of experts dated 23.10.2013	Approved

52	Ameer & Adnan Pharmaceuticals (Pvt.) Ltd, Plot No. 47, Sundar Industrial Estate, Raiwand Road, Lahore	1. Adizol 2. Capsule. 3. Each capsule contains, Fluconazole…150mg. 4. Antifungal Triazole 5. Manufacturer's Specifications	As per SRO/4s capsules	1. Form – 5. 2. 1118, 16.12.2013 3.Rs.20000, 16.12.2013	1. Diflucan (Pfizer) 2. Diflucan (Pfizer) 3. Firm is a new licence as recommended by the panel of experts dated 23.10.2013	Approved
53	Ameer & Adnan Pharmaceuticals (Pvt.) Ltd, Plot No. 47, Sundar Industrial Estate, Raiwand Road, Lahore	1. Advita. 2. Capsule. 3. Each capsule contains Vitamin A ……5500units Vitamin D3 ……...500units Vitamin E...10mg Vitamin C..100mg Vitamin B1...10mg Vitamin B2...10mg Vitamin B6...5mg Vitamin B12...8mcg Folic Acid...200mcg Nicotinamide...30mg Calcium Pantothenate ...20mg. 4. Vitamins 5. Manufacturer's Specifications	As per SRO/2x10 capsules	1. Form – 5. 2.1123, 16.12.2013 3.Rs.20000, 16.12.2013	2.Multibionta (Merck) 3. Firm is a new licence as recommended by the panel of experts dated 23.10.2013	Deferred for Vitamin policy

54	Ameer & Adnan Pharmaceuticals (Pvt.) Ltd, Plot No. 47, Sundar Industrial Estate, Raiwand Road, Lahore	1. Eucid. 2. Capsule. 3. Each capsule contains, Esomeprazole as Enteric Coated pellets equivalent to esomeprazole …..40mg. (Source Vision Pharmaceuticals Islamabad) 4. Proton Pump Inhibitor 5. Manufacturer's specifications	As per SRO/14's capsules	1. Form – 5. 2. 1128, 16.12.2013 3.Rs.20000, 16.12.2013	1. Emozul (Consilient) 2.Esso (Shiagan) 3. Firm is a new licence as recommended by the panel of experts dated 23.10.2013	Approved
55	Ameer & Adnan Pharmaceuticals (Pvt.) Ltd, Plot No. 47, Sundar Industrial Estate, Raiwand Road, Lahore	1. Fibromic. 2. Capsule. 3. Each capsule contains, Tranexamic Acid …….500mg. 4. Fibrinolytic 5. Manufacturer's Specifications	As per SRO/1x10 capsules	1. Form – 5. 2.1120, 16.12.2013 3.Rs.20000, 16.12.2013	2.Btrol (Bosch) 3. Firm is a new licence as recommended by the panel of experts dated 23.10.2013	Approved
56	Ameer & Adnan Pharmaceuticals (Pvt.) Ltd, Plot No. 47, Sundar Industrial Estate, Raiwand Road, Lahore	1. Fibromic. 2. Capsule. 3. Each capsule contains, Tranexamic Acid …….250mg. 4. Fibrinolytic 5. Manufacturer's Specifications	As per SRO/30's capsules	1. Form – 5. 2.1126, 16.12.2013. 3.Rs.20000, 16.12.2013	2.Btrol (Bosch) 3. Firm is a new licence as recommended by the panel of experts dated 23.10.2013	Approved

57	Ameer & Adnan Pharmaceuticals (Pvt.) Ltd, Plot No. 47, Sundar Industrial Estate, Raiwand Road, Lahore	1. Linkup. 2. Capsule. 3. Each capsule contains, Lincomycin HCL…500mg. 4. Lincosamide 5. BP Specifications	As per SRO/14's capsules	1. Form – 5. 2.1122, 16.12.2013 3.Rs.20000, 16.12.2013	1. Lincocin (Pharmacia & Upjohn) 2.Lincocin (Pfizer) 3. Firm is a new licence as recommended by the panel of experts dated 23.10.2013	Approved
58	Ameer & Adnan Pharmaceuticals (Pvt.) Ltd, Plot No. 47, Sundar Industrial Estate, Raiwand Road, Lahore	1. Ulcid 20mg . 2. Capsule. 3. Each capsule contains, Omeprazole as Enteric Coated Pellets equivalent to omeprazole …20mg. (Source Vision Pharmaceuticals Islamabad) 4. Proton Pump Inhibitor 5. USP Specifications	As per SRO/14's capsules	1. Form - 5. 2. 1125, 16.12.2013 3.Rs.20000, 16.12.2013	1. Losec (Astrazeneca) 2.Omega (ferozsons) 3. Firm is a new licence as recommended by the panel of experts dated 23.10.2013	Approved with change of name
59	Ameer & Adnan Pharmaceuticals (Pvt.) Ltd, Plot No. 47, Sundar Industrial Estate, Raiwand Road, Lahore	1. Ulcid 40mg. 2. Capsule. 3. Each capsule contains, Omeprazole as Enteric Coated Pellets equivalent to omeprazole …40mg. (Source Vision Pharmaceuticals Islamabad) 4. Proton Pump Inhibitor 5. USP Specifications	As per SRO/14's capsules	1. Form – 5. 2.1124, 16.12.2013. 3.Rs.20000, 16.12.2013	1. Losec (Astrazeneca) 2.Omega (ferozsons) 3. Firm is a new licence as recommended by the panel of experts dated 23.10.2013	Approved with change of name

60	Ameer & Adnan Pharmaceuticals (Pvt.) Ltd, Plot No. 47, Sundar Industrial Estate, Raiwand Road, Lahore	1. Diclocap SR 100mg. 2. Capsule. 3. Each capsule contains, Diclofenac Sodium sustained release Pellets equivalent to Diclofenac Sodium …100mg. (Source Vision Pharmaceuticals Islamabad) 4. NSAID 5. Manufacturer's Specifications	As per SRO/10's capsules	1. Form – 5. 2.1124, 16.12.2013. 3.Rs.20000, 16.12.2013	1. Diclomax SR (Galen) 2.Diclogesic (Wilson's) 3. Firm is a new licence as recommended by the panel of experts dated 23.10.2013	
61	Ameer & Adnan Pharmaceuticals (Pvt.) Ltd, Plot No. 47, Sundar Industrial Estate, Raiwand Road, Lahore	1. Adesil (Chewable). 2. Tablet. 3.Each chewable tablet contains, Magnesium Trisilicate...500mg Aluminium Hydroxide Dried Gel ……..250mg. 4. Antacid, Anti flatulent 5. USP Specifications	As per SRO/10x1000 tablets	1. Form – 5. 2. 1115, 16.12.2013 3.Rs20000, 16.12.2013	2.Trisil (Efroz) 3. Firm is a new licence as recommended by the panel of experts dated 23.10.2013	Approved
62	Ameer & Adnan Pharmaceuticals (Pvt.) Ltd, Plot No. 47, Sundar Industrial Estate, Raiwand Road, Lahore	1. Adfenic 2. Tablet. 3. Each enteric coated tablet contains Diclofenac Sodium…50mg. 4. NSAID 5. USP Specifications	As per SRO/2x10 tablets	1) Form - 5. 2) 16/12/2013 & 1109. 3) 16/12/2013 & 20000	1. Motifene (Daiichi) 2.Artifen (Abbott) 3. Firm is a new licence as recommended by the panel of experts dated 23.10.2013	Approved

63	Ameer & Adnan Pharmaceuticals (Pvt.) Ltd, Plot No. 47, Sundar Industrial Estate, Raiwand Road, Lahore	1. Adfenic 2. TABLETS. 3. Each enteric coated tablet contains diclofenac sodium.…75mg. 4. NSAID 5. USP Specifications	As per SRO/2x10 tablets	1. Form - 5. 2.1101, 16.12.2013 3.Rs.20000, 16.12.2013	1.Voltral (Novartis) 2.Arnil (Brookes) 3. Firm is a new licence as recommended by the panel of experts dated 23.10.2013	Approved as enteric coated tablet
64	Ameer & Adnan Pharmaceuticals (Pvt.) Ltd, Plot No. 47, Sundar Industrial Estate, Raiwand Road, Lahore	1. Adfenic SR 2. Tablet. 3. Each sustained release contains Diclofenac Sodium…100mg. 4. NSAID 5. USP Specifications	As per SRO/2x10 tablets	1. Form – 5. 2.1108, 16.12.2013 3.Rs.20000, 16.12.2013	1.Voltral Retard (Novartis) 2.Ardfenac (Ardin) 3. Firm is a new licence as recommended by the panel of experts dated 23.10.2013	Approved
65	Ameer & Adnan Pharmaceuticals (Pvt.) Ltd, Plot No. 47, Sundar Industrial Estate, Raiwand Road, Lahore	1. Adfenic-P. 2. Tablet. 3. Each film coated tablet contains Diclofenac Potassium…50mg. 4. NSAID 5. USP Specifications	As per SRO/2x10 tablets	1. Form - 5. 2. 1129, 16.12.2013 3. Rs.20000, 16.12.2013	1. Cambia (Depomed) 2. Caflam (Novartis) 3. Firm is a new licence as recommended by the panel of experts dated 23.10.2013	Approved

66	Ameer & Adnan Pharmaceuticals (Pvt.) Ltd, Plot No. 47, Sundar Industrial Estate, Raiwand Road, Lahore	1. Adformin. 2. Tablet. 3.Each film coated tablet contains Metformin HCl…500mg. 4. Biguanide 5. BP Specifications	As per SRO/2x10 tablets	1. Form - 5. 2.1106, 16.12.2013 3.Rs.20000, 16.12.2013	1. Glucophage (Merck) 2.Glucophage (Merck) 3. Firm is a new licence as recommended by the panel of experts dated 23.10.2013	Approved
67	Ameer & Adnan Pharmaceuticals (Pvt.) Ltd, Plot No. 47, Sundar Industrial Estate, Raiwand Road, Lahore	1. Moonkast 2 Tablet. 3.Each film coated tablet contains, Montelukast as Sodium…5mg. 4. Leukotriene Receptor Antagonist 5. Manufacturer's Specifications	As per SRO/14 tablets	1. Form - 5. 2.1107, 16.12.2013 3.Rs.20000, 16.12.2013	2.Beasy (Bosch) 3. Firm is a new licence as recommended by the panel of experts dated 23.10.2013	Approved
68	Ameer & Adnan Pharmaceuticals (Pvt.) Ltd, Plot No. 47, Sundar Industrial Estate, Raiwand Road, Lahore	1. Progesic 2. Tablet. 3. Each film coated tablet contains Naproxen as Sodium…500mg. 4. NSAID 4. BP Specifications	As per SRO/2x10 tablets	1. Form – 5. 2. 1130, 16.12.2013 3.Rs.20000, 16.12.2013	1. Anaprox DS (Hoffman La Roch) 2.Anex (Pharmevo) 3. Firm is a new licence as recommended by the panel of experts dated 23.10.2013	Approved with change of name

69	Ameer & Adnan Pharmaceuticals (Pvt.) Ltd, Plot No. 47, Sundar Industrial Estate, Raiwand Road, Lahore	1. Ranitac. 2. Tablet. 3.Each film coated tablet contains Ranitidine as HCl…150mg. 4. H2 Blockers 5. BP Specs	As per SRO/2x10 tablets	1. Form – 5. 2. 1117, 16.12.2013 3.Rs.20000, 16.12.2013	1. Zentac (GSK) 2.Zentac (GSK) 3. Firm is a new licence as recommended by the panel of experts dated 23.10.2013	Approved with change of name
70	Ameer & Adnan Pharmaceuticals (Pvt.) Ltd, Plot No. 47, Sundar Industrial Estate, Raiwand Road, Lahore	1. Temedol 2. Tablet 3. Each film coated tablet contains, Tramadol HCl ……100mg. 4. Opiate analogue 5. Manufacturer's Specifications	As per SRO/2x10 tablets	1. Form - 5. 2. 1105, 16.12.2013 3.Rs20000, 16.12.2013	1. Rayzolt (Purde Pharma) 2.Tonoflex SR (Sami) 3. Firm is a new licence as recommended by the panel of experts dated 23.10.2013	Approved with change of name
71	Ameer & Adnan Pharmaceuticals (Pvt.) Ltd, Plot No. 47, Sundar Industrial Estate, Raiwand Road, Lahore DML #000787	1. Ademol 2. Infusion 3. Each 100ml contains, Paracetamol…1g. 4. Analgesic, antipyretic 5. Manufacturer's Specifications	As per SRO/100ml x1 Bottle Pack	1. Form – 5. 2. 1102, 16.12.2013 3.Rs.20000, 16.12.2013	1. BNF 2. Bosch 3. Firm is a new licence as recommended by the panel of experts dated 23.10.2013	Approved with change of name

72	Ameer & Adnan Pharmaceuticals (Pvt.) Ltd, Plot No. 47, Sundar Industrial Estate, Raiwand Road, Lahore	1. Adicobal Injection. 2. Injection. 3.Each ml contains, Mecobalamin …..…500mcg. 4.Co-Enzyme type Vitamin B12 5.Manufacturer's Specifications	As per SRO/1mlx 10 ampoules	1. Form – 5. 2.1103, 16.12.2013 3.Rs.20000, 16.12.2013	2.Methycobal (Hilton) 3. Firm is a new licence as recommended by the panel of experts dated 23.10.2013	Approved
73	Ameer & Adnan Pharmaceuticals (Pvt.) Ltd, Plot No. 47, Sundar Industrial Estate, Raiwand Road, Lahore	1. Adelak 2. Injection. 3.Each ml contains, Ketorolac Tromatamol…30mg 4.NSAID 5.USP Specifications	As per SRO/1mlx 5 ampoules	1. Form – 5. 2. 1131, 16.12.2013 3.Rs.20000, 16.12.2013	1. Toradol (Roche) 2. Toradol (Martin Dow) 3. Firm is a new licence as recommended by the panel of experts dated 23.10.2013	Approved
74	Ameer & Adnan Pharmaceuticals (Pvt.) Ltd, Plot No. 47, Sundar Industrial Estate, Raiwand Road, Lahore	1. Adfenac 2. Injection. 3. Each 3ml contains, Diclofenac Sodium…75mg. 4. NSAID 5. Manufacturer's Specifications	As per SRO/3mlx 5 ampoules	1. Form – 5. 2. 1114, 16.12.2013 3.Rs.20000, 16.12.2013	2. Dicloran (Sami) 3. Firm is a new licence as recommended by the panel of experts dated 23.10.2013	Approved

75	Ameer & Adnan Pharmaceuticals (Pvt.) Ltd, Plot No. 47, Sundar Industrial Estate, Raiwand Road, Lahore	1. Cyanocobalamin. 2. Injection. 3. Each 2ml contains, Cyanocobalamin …..…500mcg. 4. Vitamin 5. USP Specifications	As per SRO/2mlx 25 ampoules	1. Form - 5. 2. 1112, 16.12.2013 3. Rs20000, 16.12.2013	2. Cyanamin (Lawrence) 3. Firm is a new licence as recommended by the panel of experts dated 23.10.2013	Approved
76	Ameer & Adnan Pharmaceuticals (Pvt.) Ltd, Plot No. 47, Sundar Industrial Estate, Raiwand Road, Lahore	1. Ferrevin. 2. Injection. 3. Each 5ml contains, Iron sucrose e.q to elemental iron....100mg. 4. Haematinic 5. Manufacturer's Specifications	As per SRO/5mlx 5 ampoules	1. Form - 5. 2. 1127, 16.12.2013 3. Rs.20000, 16.12.2013	1. Venofer (Vifor) 2. Bisleri (Sami) 3. Firm is a new licence as recommended by the panel of experts dated 23.10.2013	Approved with change of name
77	Ameer & Adnan Pharmaceuticals (Pvt.) Ltd, Plot No. 47, Sundar Industrial Estate, Raiwand Road, Lahore	1. Lidocaine. 2. Injection. 3. Each ml contains, Lidocaine HCl ....20mg. 4. Local Anaesthetic 5. USP Specifications	As per SRO/10ml x25 ampoules	1. Form – 5. 2.1111, 16.12.2013 3.Rs.20000, 16.12.2013	2.Licain (Epoch) 3. Firm is a new licence as recommended by the panel of experts dated 23.10.2013	Approved
78	Ameer & Adnan Pharmaceuticals (Pvt.) Ltd, Plot No. 47, Sundar Industrial Estate, Raiwand Road, Lahore	1. Vitadrop. 2. Injection 3. Each ml contains Cholecalciferol.. 200000IU/5mg. 4. Vitamin D 5. USP Specifications	As per SRO/1mlx 1 ampoule	1. Form – 5. 2. 1116. 16.12.2013 3. Rs.20000 16.12.2013	Indrop D (Neutro) 3. Firm is a new licence as recommended by the panel of experts dated 23.10.2013	Approved with change of name

79	Ameer & Adnan Pharmaceuticals (Pvt.) Ltd, Plot No. 47, Sundar Industrial Estate, Raiwand Road, Lahore	1. Water for Injection 2. Injection. 3. Water For Injection 5ml 4. Solvent/diluent 5. USP Specifications	As per SRO/5mlx 100 ampoules	1. Form – 5. 2.1104, 16.12.2013 3.Rs.20000, 16.12.2013	3. Firm is a new licence as recommended by the panel of experts dated 23.10.2013	Approved
80	Ameer & Adnan Pharmaceuticals (Pvt.) Ltd, Plot No. 47, Sundar Industrial Estate, Raiwand Road, Lahore	1. Adivil. 2. Injection. 3. Each 2ml contains, Pheniramine Maleate ....50mg. 4. Anti Histamine 5. Manufacturer's Specifications	As per SRO/2mlx 100 ampoules	1. Form - 5. 2.1113, 16.12.2013 3.Rs.20000, 16.12.2013	2.Avil (Sanofi) 3. Firm is a new licence as recommended by the panel of experts dated 23.10.2013	Approved with change of name

Evaluator – II

81.	M/s Wisdom Pharmaceuticals Industry, 78-A, Industrial Estate Hayatabad, Peshawar. (Capsule Cephalosporin Section) No. F.3-5/2004-Lic(M-232) dated 12-09-13	Zocef Capsules Each capsule contains:- Cephradine (U.S.P) (anhydrous)…….....500mg (Cephalosporin) (U.S.P)	As per SRO/10's	1. Form5 2. 10-9-2013 Dy.No.2878 3. 10-9-2013 (Rs.20000/-)	1. BNF 58: Velosef (Squibb) 2.Geosef(Geofman PharmaceuticALS) [Cephradine:500mg]Cap 3.Grant of DML recommended (25-04-13)	Approved
82.	-do-	Zocef Capsules Each capsule contains:- Cephradine (anhydrous)…….....250mg (Cephalosporin) (U.S.P)	10's/As per SRO	1. Form5 2. 10-9-2013 Dy.No.2876 3. 10-9-2013 (Rs.20000/-)	1.BNF 61. Cefradine (Non-proprietary) Capsules, cefradine 250 mg, ; 500 mg, Brands include Nicef 2.Geosef (Geofman Pharmaceuticals) [Cephradine:250mg]Cap 3.Grant of DML recommended (25-04-13)	Approved
83.	-do-	Opazet Capsules Each capsule contains:- Cefaclor Monohydrate ≡ Cefaclor (U.S.P)...500mg (Cephalosporin) (U.S.P)	10's/As per SRO	1. Form5 2. 10-9-2013 Dy.No.2875 3. 10-9-2013 (Rs.20000/-)	1. BNF 58: Cefaclor (Non-proprietary) Capsules, cefaclor (as monohydrate) 250 mg, ; 500 mg, Brands include Keftid 2. Hiclor(Hilton Pharma (Pvt) Limited)	Approved

					[Cefaclor (Monohydrate):500mg]cap 3.Grant of DML recommended (25-04-13)	
84.	-do-	Opazet Capsule Each capsule contains:- Cefaclor Monohydrate eq. to Cefaclor (U.S.P)..250mg (Cephalosporin) (U.S.P)	10's/ As per SRO	1. Form5 2. 10-9-2013 Dy.No.2877 3. 10-9-2013 (Rs.20000/-)	1. BNF 58: Cefaclor (Non-proprietary) Capsules, cefaclor (as monohydrate) 250 mg, 2. Hiclor (Hilton Pharma (Pvt) Limited) [Cefaclor (Monohydrate):250mg] cap 3.Grant of DML recommended (25-04-13)	Approved
85.	-do-	Rodaxil Capsules Each capsule contains:- Cefadroxil Monohydrate eq. to Cefadroxil (U.S.P)…500mg (Cephalosporin) (U.S.P)	10's/ As per SRO	1. Form5 2. 10-9-2013 Dy.No.2874 3. 10-9-2013 (Rs.20000/-)	1. BNF 58: Baxan (Bristol-Myers Squibb) Capsules, cefadroxil (as monohydrate) 500 mg, 2. Evacef (Highnoon Laboratories Ltd.) [Cefadroxil:500mg] Cap 3.Grant of DML recommended (25-04-13)	Approved

86.	-do-	Lordex Capsules Each capsule contains:- Cefpodoxime Proxetil ≡ Cefpodoxime (U.S.P)…100mg (Cephalosporin) (Manufacturer's)	10's/ As per SRO	1. Form5 2. 10-9-2013 Dy.No.2872 3. 10-9-2013 (Rs.20000/-)	1. Breen (Goodman International) [Cefpodoxime:100mg] Cap 3.Grant of DML recommended (25-04-13)	Deferred for confirmation of international availability.
87.	-do-	Zofim Capsules Each capsule contains:- Cefixime Trihydrate ≡ Cefixime (U.S.P)..400mg (Cephalosporin) (Manufacturer's)	5's/ As per SRO	1. Form5 2. 10-9-2013 Dy.No.2873 3. 10-9-2013 (Rs.20000/-)	1. FDA Suprax (Lupin Ltd) 2. Cefiget(Getz Pharma Pakistan (PVT) LTD.) [Cefixime:400mg]cap 3.Grant of DML recommended (25-04-13)	Approved
88.	-do- (Dry Powder Suspension, Cephalosporin) No. F.3-5/2004-Lic(M-232) dated 12-09-13	Lordex Dry Powder Suspension Each 5ml contains:- Cefpodoxime Proxetil ≡ Cefpodoxime (U.S.P)…….40mg (Cephalosporin) (U.S.P)	60ml/As per SRO	1. Form5 2. 10-9-2013 Dy.No.2912 3. 10-9-2013 (Rs.20000/-)	1. BNF 58: Oreloxc (Hoechst Marion Roussel) Tablets, f/c, cefpodoxime 100 mg (as proxetil), Oral suspension, cefpodoxime (as proxetil) for reconstitution with water, 40 mg/5 mL, Cefpomed(Medicraft Pharmaceutic Als (Pvt) Ltd.)	Approved

					[Cefpodoxime:40mg/5ml] susp 3.Grant of DML recommended (25-04-13)	
89.	-do-	Zocef Dry Powder Suspension Each 5ml contains:- Cephradine (anhydrous)…..…..250mg (Cephalosporin) (U.S.P)	60ml/As per SRO	1. Form5 2. 10-9-2013 Dy.No.2909 3. 10-9-2013 (Rs.20000/-)	1. BNF 58 Velosef (Squibb) Syrup, cefradine 250 mg/5 mL when reconstituted with water. 2. Geosef(Geofman Pharmaceuticals) [Cephradine:250mg/5ml] Susp 3.Grant of DML recommended (25-04-13)	Approved
90.	-do-	Zocef Dry Powder Suspension Each 5ml contains:- Cephradine (anhydrous) ……..125mg Cephalosporin (U.S.P)	60ml/As per SRO	1. Form5 2. 10-9-2013 Dy.No.2913 3. 10-9-2013 (Rs.20000/-)	1.FDA (**ANSPOR**) 2. Geosef(Geofman Pharmaceuticals) [Cephradine:125mg/5ml] Susp 3.Grant of DML recommended (25-04-13)	Approved

91.	-do-	Opazet Dry powder Suspension Each 5ml contains:- Cefaclor Monohydrate ≡ Cefaclor(U.S.P)...250mg (Cephalosporin) (U.S.P)	60ml/As per SRO	1. Form5 2. 10-9-2013 Dy.No.2916 3. 10-9-2013 (Rs.20000/-)	1. BNF 58: Distaclor (Flynn) 2. Hiclor (Hilton Pharma (Pvt) Limited) [Cefaclor (Monohydrate):250mg/5 ml] susp 3.Grant of DML recommended (25-04-13)	Approved
92.	-do-	Opazet Dry Powder Suspension Each 5ml contains:- Cefaclor Monohydrate ≡ Cefaclor(U.S.P)…125mg Cephalosporin (U.S.P)	60ml/As per SRO	1. Form5 2. 10-9-2013 Dy.No.2910 3. 10-9-2013 (Rs.20000/-)	1. BNF 58: Distaclor (Flynn) 2. Hiclor(Hilton Pharma (Pvt) Limited) [Cefaclor (Monohydrate):125mg/5 ml] susp 3.Grant of DML recommended (25-04-13)	Approved
93.	-do-	Opazet Dry Powder Drops Each 1ml contains:- Cefaclor Monohydrate eq. to Cefaclor….50mg (Cephalosporin) (U.S.P)	15ml/ As per SRO	1. Form5 2. 10-9-2013 Dy.No.2918 3. 10-9-2013 (Rs.20000/-)	1.BNF 61(Cefaclor (Non-proprietary) Suspension, cefaclor (as monohydrate) for reconstitution 125 mg/5 mL, ; 250 mg/5 mL) 2. Hiclor (Hilton Pharma (Pvt) Limited) [Cefaclor	Approved

					(Monohydrate):50mg/5ml] drops 3.Grant of DML recommended (25-04-13)	
94.	-do-	Zofim Dry powder Suspension Each 5ml contains:- Cefixime Trihydrate ≡ Cefixime(U.S.P)……200mg (Cephalosporin) (U.S.P)	30ml,60ml/ As per SRO	1. Form5 2. 10-9-2013 Dy.No.2914 3. 10-9-2013 (Rs.20000/-)	1.FDA (**SUPRAX**) 2. Cefiget(Getz Pharma Pakistan (Pvt) Ltd.) [Cefixime:200mg/5ml]susp 3.Grant of DML recommended (25-04-13)	Approved
95.	-do-	Zofim Dry Powder Suspension Each 5ml contains:- Cefixime Trihydrate ≡ Cefixime……100mg (Cephalosporin) (U.S.P)	30ml,60ml/As per SRO	1. Form5 2. 10-9-2013 Dy.No.2915 3. 10-9-2013 (Rs.20000/-)	1. BNF 58: Suprax (Rhoˆne-Poulenc Rorer) 2. Cefiget (Getz Pharma Pakistan (Pvt) Ltd.) [Cefixime:100mg/5ml]susp 3.Grant of DML recommended (25-04-13)	Approved

96.	-do-	Rodaxil Dry Powder Suspension Each 5ml contains:- Cefadroxil Monohydrate eq. to Cefadroxil (U.S.P)…….….250mg (Cephalosporin) (U.S.P)	60ml/ As per SRO	1. Form5 2. 10-9-2013 Dy.No.2911 3. 10-9-2013 (Rs.20000/-)	1. BNF 58: Baxanc (Bristol-Myers Squibb)A Capsules, cefadroxil (as monohydrate) 500 mg, 2. Ag-Drox(Saydon Pharmaceutical Industries (Pvt) Ltd.) [Cefadroxil:250mg/5ml]susp 3.Grant of DML recommended (25-04-13)	Approved
97.	-do-	Rodaxil Dry Powder Suspension Each 5ml contains:- Cefadroxil Monohydrate eq. to Cefadroxil……….125mg (Cephalosporin) (U.S.P)	60ml/As perSRO	1. Form5 2. 10-9-2013 Dy.No.2917 3. 10-9-2013 (Rs.20000/-)	1. BNF 58: Baxan (Bristol-Myers Squibb) 2.Ag-Drox(Saydon Pharmaceutical Industries (Pvt) Ltd.) [Cefadroxil:125mg/5ml]susp 3.Grant of DML recommended (25-04-13)	Approved
98.	-do- (Liquid Syrup General Section) No. F.3-5/2004-Lic(M-232) dated 12-09-13	Lomozole Suspension Each 5ml contains:- Metronidazole Benzoate eq. to Metronidazole (B.P)……100mg Diloxanide Furoate (B.P)..125mg	60ml/As perSRO	1. Form5 2. 10-9-2013 Dy.No.2904 3. 10-9-2013 (Rs.20000/-)	Entamizole(Abbott Laboratories (Pakistan) Limited.) [Metronidazole:100mg/5ml,Diloxanide (Furoate):125mg/5ml] Susp 3.Grant of DML recommended (25-04-13)	Approved

		(Amoebicide) (Manufacturer's)				
99.	-do-	Moradil Suspension Each 5ml contains:- Metronidazole Benzoate eq. to Metronidazole (B.P)……40mg Furazolidone (B.P)……..25mg (Amoebicide) (Manufacturer's)	60ml/As perSRO	1. Form5 2. 10-9-2013 Dy.No.2905 3. 10-9-2013 (Rs.20000/-)	2. Dependal-M (Glaxosmithkline) [Metronidazole:75mg/5ml,Furazolidone:25mg/5ml] susp 3.Grant of DML recommended (25-04-13)	Approved with change of name
100.	-do-	Zolin Syrup Each 5ml contains:- Ammonium Chloride..30mg Diphenhydramine HCl…..8mg Aminophylline……..32mg Menthol……0.98mg (Xanthine, antihistamine) (Manufacturer's)	120ml/As perSRO	1. Form5 2. 10-9-2013 Dy.No.2906 3. 10-9-2013 (Rs.20000/-)	2. Cosome E Syrup (Merck Private Ltd.) 3.Grant of DML recommended (25-04-13)	Approved

101.	-do-	Frodine Syrup Each 5ml contains:- Pholcodine (B.P)…5mg Chlorphheniramine Maleate (B.P)...2mg (Antitpyretic, Histamine H1-receptor antagonist) (Manufacturer's)	60ml,120ml/ As per SRO	1. Form5 2. 10-9-2013 Dy.No.2902 3. 10-9-2013 (Rs.20000/-)	Decorex Syp (Obsons Pharmaceuticals) 3.Grant of DML recommended (25-04-13)	Deferred for confirmation of controlled drug section and international availability.
102.	-do-	Zoramid Suspension Each 5ml contains:- Domperidone Maleate eq. to Domperidone (B.P)…..5mg (Antidopaminergic) (Manufacturer's)	60ml,120ml/As per SRO	1. Form5 2. 10-9-2013 Dy.No.2899 3. 10-9-2013 (Rs.20000/-)	1. BNF 58: Domperidone (Non-proprietary) Tablets, 10 mg (as maleate), net price 30-tab pack = 2. Avifix (Shrooq Pharmaceuticals)susp 3.Grant of DML recommended (25-04-13)	Approved
103.	-do-	Romogel Suspension Each 5ml contains:- Aluminium Hydroxide (U.S.P)…..215mg Magnesium Hydroxide	120ml/As per SRO	1. Form5 2. 10-9-2013 Dy.No.2901 3. 10-9-2013 (Rs.20000/-)	Geocone(Lisko Pakistan (Pvt) Ltd) [Simethicone:25mg/5ml, Magnesium Oxides and Hydroxides:80mg/5ml,Aluminium Hydroxide and Oxide:215mg/5ml] 3.Grant of DML	Approved .

		(U.S.P)……80mg Simethicone (U.S.P)……..25mg (Antacid) (U.S.P)			recommended (25-04-13)	
104.	-do-	Lozim Syrup Each 5ml contains:- Iron (III) Hydroxide Polymaltose Complex ≡ Elemental Iron……50mg (Iron Supplement) (Manufacturer's)	60ml,120ml/ As per SRO	1. Form5 2. 10-9-2013 Dy.No.2908 3. 10-9-2013 (Rs.20000/-)	Ferosoft(Hilton Pharma (Pvt) Limited) [Iron Hydroxide Poly Maltose Complex:50mg/5ml] Syrup 3.Grant of DML recommended (25-04-13)	Approved
105.	-do-	Infagel Suspension Each 1ml contains:- Simethicone (U.S.P)……40mg (Deflatulent) (U.S.P)	30ml/as per SRO	1. Form5 2. 10-9-2013 Dy.No.2900 3. 10-9-2013 (Rs.20000/-)	Minicol (Libra Pharmaceuticals (Pvt) Ltd) [Simethicone:40mg/ml] Drops 3.Grant of DML recommended (25-04-13)	Approved
106.	-do-	Rofim Suspension Each 5ml contains:- Paracetamol…….120mg Chlorpheniramine Maleate..1mg (Antipyretic,	60ml/as per SRO	1. Form5 2. 10-9-2013 Dy.No.2907 3. 10-9-2013 (Rs.20000/-)	Tempramine (W.Woodward Pakistan) R. No. 011423 3.Grant of DML recommended (25-04-13)	Approved

		Antihistamine) (Manufacturer's)				
107.	-do-	Omafed Syrup Each 5ml contains:- Ammonium Chloride (B.P)…131.5mg Diphenhydramine HCl (B.P)….13.5mg Sodium Citrate (B.P)…55mg Chloroform(B.P)…22mg Menthol(B.P)…1mg (Antussive, decongestant) (Manufacturer's)	120ml/As per SRO	1. Form5 2. 10-9-2013 Dy.No.2903 3. 10-9-2013 (Rs.20000/-)	Benadryl (Pfizer Laboratories Ltd.) [Ammonium Chloride:131.5mg/5ml,Chloroform:22mg/5ml,Menthol:1mg/5ml,Diphenhydramine:13.5mg/5ml,Sodium Citrate:55mg/5ml] 3.Grant of DML recommended (25-04-13)	Approved
108.	-do- (Ointment/Cream Steroid Section) No. F.3-5/2004-Lic(M-232) dated 12-09-13	Solimet Cream Each gram contains:- Fusidic Acid (B.P) …20 mg Betamethasone as Valerate (B.P).....1	5gm,15gm/As per SRO	1. Form5 2. 10-9-2013 Dy.No.2886 3. 10-9-2013 (Rs.20000/-)	1. BNF 58: Fucibet (LEO) Cream, betamethasone (as valerate) 0.1%, fusidic acid 2%, 2.Fucicort (Leo/Zam Zam)	Approved

		mg (Antibacterial+corti costeroid) (Manufacturer's)			3.Grant of DML recommended (25-04-13)	
109.	-do-	Rentagen- H Cream Each gram contains:- Miconazole Nitrate (B.P)…20 mg Hydrocortisone Acetate (B.P)…..10 mg (Antifungal+ Corticosteroid) (B.P)	10gm,15gm/As per SRO	1. Form5 2. 10-9-2013 Dy.No.2880 3. 10-9-2013 (Rs.20000/-)	1. BNF 58: Daktacort (Janssen-Cilag) Cream, hydrocortisone 1%, miconazole nitrate 2%, Daktacort(Janssen-Cilag) [Miconazole (Nitrate):2%w/w,Hydrocortisone:1%w/w] 3.Grant of DML recommended (25-04-13)	Approved
110.	-do-	Loramol NN Ointment Each gram contains:- Neomycin Sulphate (B.P)….5 mg Clobetasol Propionate (B.P)…….0.5 mg Nystatin (B.P)…….. 100,000 units (Antibacterial+ corticosteroid+Anti	5gm/As per SRO	1. Form5 2. 10-9-2013 Dy.No.2879 3. 10-9-2013 (Rs.20000/-)	Dermovate-NN (Glaxosmithkline) Oint[Nystatin:100000IU/g,Neomycin:0.5%w/w, Clobetasol (Propionate):0.05%w/w] 3.Grant of DML recommended (25-04-13)	Approved

		fungal) (Manufacturer's)				
111.	-do-	Romabet-N Ointment Each gram contains:- Neomycin Sulphate(B.P)...5 mg Betamethasone as Valerate ester (B.P)…….1 mg (Antibacterial, corticosteroid) (Manufacturer's)	5gm,15gm/As per SRO	1. Form5 2. 10-9-2013 Dy.No.2888 3. 10-9-2013 (Rs.20000/-)	1. BNF 58: Betnovate-N (Chemidex) Cream, betamethasone (as valerate) 0.1%, neomycin sulphate 0.5%, 2. Betacin-N(Geofman Pharmaceuticals) [Neomycin:0.5%w/w,Betamethasone:0.1%w/w] Cream and oint (both) 3.Grant of DML recommended (25-04-13)	Approved
112.	-do-	Zolim Cream Each gram contains:- Gentamicin (as Sulphate)(B.P)...1 mg, Hydrocortisone Acetate (B.P)…10 mg (Antibacterial, corticosteroid)	15gm/As per SRO	1. Form5 2. 10-9-2013 Dy.No.2887 3. 10-9-2013 (Rs.20000/-)	Genticyn HC Cream (Macter International) 3.Grant of DML recommended (25-04-13)	Approved change of name

		(Manufacturer s)				
113.	-do-	Mosigen-H Cream Each gram contains:- Fusidic Acid ……20mg Hydrocortisone acetate……10mg (Antibacterial, Corticosteroid) (Manufacturer's)	15gm/As per SRO	1. Form5 2. 10-9-2013 Dy.No.2881 3. 10-9-2013 (Rs.20000/-)	1. BNF 58: Fucidin H (LEO) Cream, hydrocortisone acetate 1%, fusidic acid 2%, 2. Fucidin-H(Zam Zam Corporation) [Fusidic Acid:2%w/w,Hydrocortisone:1%w/w]Cream 3.Grant of DML recommended (25-04-13)	Approved with change of name
114.	-do-	Romasol Cream Each gram contains:- Clobetasol Propionate (B.P)…..0.5mg (Corticosteroid) (B.P)	10gm,15gm/ As per SRO	1. Form5 2. 10-9-2013 Dy.No.2882 3. 10-9-2013 (Rs.20000/-)	1. BNF 58: Dermovate (GSK) Cream, clobetasol propionate 0.05%, 2.V-Derm(Vega Pharmaceuticals Ltd.) [Clobetasol (Propionate):0.05%w/w] Cream 3.Grant of DML recommended (25-04-13)	Approved with change of name

115.	-do-	Zovin-H Cream Each gram contains:- Clotrimazole (U.S.P)……10 mg Hydrocortisone (U.S.P)…10 mg (Antifungal+Corticosteroid) (Manufacturer's)	10gm,20gm/ AS per SRO	1. Form5 2. 10-9-2013 Dy.No.2884 3. 10-9-2013 (Rs.20000/-)	1. BNF 58: Canesten HC (Bayer Consumer Care)A Cream, hydrocortisone 1%, clotrimazole 1%, 2.Clozole-H (Pearl) R. No. 059418 3.Grant of DML recommended (25-04-13)	Approved with change of name
116.	-do-	Relamin Cream Each gram contains:- Gentamicin (as Sulphate) (B.P)…..1 mg Betamethasone (as Dipropionate) (B.P)…….0.5 mg (Antibacterial, Corticosteroid) (Manufacturer's)	15gm/ As per SRO	1. Form5 2. 10-9-2013 Dy.No.2883 3. 10-9-2013 (Rs.20000/-)	1. 2.Mysoderm Cream (AGP) 3.Grant of DML recommended (25-04-13)	Approved

117.	-do-	Lomazine Cream Each gram contains:- Gentamicin (as Sulphate) (B.P)……1 mg Betamethasone (as Dipropionate) (B.P)…….0.5 mg Clotrimazole (B.P)…….10 mg (Antibacterial+corticosteroid+Antifungal) (Manufacturer's)	15gm/ AS per SRO	1. Form5 2. 10-9-2013 Dy.No.2885 3. 10-9-2013 (Rs.20000/-)	1. 2. Lotricort G(Dermagen Pharma Pakistan (PVT) LIMITED) [Clotrimazole:1%w/w,Betamethasone:0.05%w/w, Gentamicin:0.1%w/w] 3.Grant of DML recommended (25-04-13)	Approved with name change .
118.	-do- (Ointment/Cream General Section) No. F.3-5/2004-Lic(M-232) dated 12-09-13	Rovel Cream Each gram contains:- Miconazole Nitrate (B.P)…20 mg (Antifungal) (B.P)	10gm,15gm/As per SRO	1. Form5 2. 10-9-2013 Dy.No.2892 3. 10-9-2013 (Rs.20000/-)	1. BNF 58: Daktarin (Janssen-Cilag) Cream, miconazole nitrate 2%, 2.Micoden (Danas Pharmaceuticals (Pvt) Ltd) [Miconazole (Nitrate):2%w/w] Cream 3.Grant of DML recommended (25-04-13)	Approved
119.	-do-	Frogen Cream Each gram contains:- Clotrimazole (U.S.P).....10m	20gm/As per SRO	1. Form5 2. 10-9-2013 Dy.No.2893 3. 10-9-2013 (Rs.20000/-)	1. BNF 58: Canesten (Bayer Consumer Care) Cream 2.Clotrim(Zafa Pharmaceutical	Approved with change of brand name

		g (Antifungal) (U.S.P)			Laboratories (Pvt) Ltd.) [Clotrimazole:1%w/w]Cream 3.Grant of DML recommended (25-04-13)	
120.	-do-	Laptrovin Ointment Each gram contains:- Mupirocin (B.P)..20 mg (Broad Spectrum Antibiotic) (B.P)	10gm, 15gm, 20gm/ As per SRO	1. Form5 2. 10-9-2013 Dy.No.2898 3. 10-9-2013 (Rs.20000/-)	1. BNF 58: Bactroban (GSK) Ointment, mupirocin 2%, 2. Bactroban oint (GSK) Reg No. (010399) 3.Grant of DML recommended (25-04-13)	Approved
121.	-do-	Trofin Cream Each gm contains:- Terbinafine HCl (B.P)…10 mg (Antifungal) (Manufacturer's)	10gm/As per SRO	1. Form5 2. 10-9-2013 Dy.No.2894 3. 10-9-2013 (Rs.20000/-)	1. BNF 58: Lamisil (Novartis Consumer Health) Cream 2.EXINOFIN (BROOKES PHARMACEUTICAL LABORATORIES (PAK.) LTD.) [Terbinafine (HCl):0] Cream 3.Grant of DML recommended (25-04-13)	Approved

122.	-do-	Limtazin Vaginal Cream Each gram contains:- Clotrimazole (U.S.P)……20 mg (Antifungal) (U.S.P)	35gm/As per SRO	1. Form5 2. 10-9-2013 Dy.No.2896 3. 10-9-2013 (Rs.20000/-)	1. BNF 58: Canesten (Bayer Consumer Care) Vaginal cream (10% VC), clotrimazole 10%. 2. Gynosporin(Nabiqasim Industries (Pvt) Ltd.) [Clotrimazole:2%w/w] Vag Cream 3.Grant of DML recommended (25-04-13)	Approved
123.	-do-	Silmazin Cream Each gram contains:- Silver Sulfadiazine (U.S.P)…….10 mg (Antibacterial) (USP)	25gm,50gm/ As per SRO	1. Form5 2. 10-9-2013 Dy.No.2895 3. 10-9-2013 (Rs.20000/-)	1. BNF 58: Flamazine (S&N Hlth.) Cream 2. Dermazin(Novartis Pharma (Pak) Ltd) [Silver Sulphadiazine:1%w/w] cream 3.Grant of DML recommended (25-04-13)	Approved
124.	-do-	Prozin Cream Each gram contains:- Fusidic Acid (B.P)……20 mg (Antibacterial) (B.P)	15gm,20gm/ AS per SRO	1. Form5 2. 10-9-2013 Dy.No.2889 3. 10-9-2013 (Rs.20000/-)	1. BNF 58: Fucidin (LEO) Cream 2. Amfic (Amros Pharmaceuticals.) [Fusidic Acid: 2%w/w]cream 3.Grant of DML recommended (25-04-13)	Approved

125.	-do-	Lomovin Cream Each gram contains:- Nitrofurazone (U.S.P)…… 2 mg (Antibacterial) (Manufacturer's)	28gm/ As per SRO	1. Form5 2. 10-9-2013 Dy.No.2890 3. 10-9-2013 (Rs.20000/-)	Furacin(Glaxosmithkline) [Nitrofurazone:0.2%w/w]cream 3.Grant of DML recommended (25-04-13)	Approved .
126.	-do-	Pentarin Cream Each gram contains:- Permethrin (M.S)…….50 mg (Pediculicide, Scabicide) (Manufacturer's)	30gm/ As per SRO	1. Form5 2. 10-9-2013 Dy.No.2891 3. 10-9-2013 (Rs.20000/-)	1. BNF 58: Lyclear Dermal Cream (Chefaro UK) Dermal cream, permethrin 5%, 2. Lotrix (Glaxosmithkline) [Permethrin:5%w/w]cream 3.Grant of DML recommended (25-04-13)	Approved with name change
127.	-do-	Moled Gel Each gram contains:- Piroxicam (B.P)……5 mg (Analgesic) (B.P)	25gm/ AS per SRO	1. Form5 2. 10-9-2013 Dy.No.2897 3. 10-9-2013 (Rs.20000/-)	1. BNF 58: Feldene (Pfizer) Gel, piroxicam 0.5%, Excipients include benzyl alcohol, propylene glycol 2. Feldene (Pfizer Laboratories Ltd.) [Piroxicam:0.5%w/w]gel 3.Grant of DML recommended (25-04-13)	Approved

128.	M/s Herbion Pakistan (Pvt.) Ltd., Kahuta Road, Industrial Triangle, Humak, Rawalpindi-Islamabad. New Licence, Sections approved vide letter No. F.6-3/2014-Lic (M-234) dated 27th March, 2014 (i) Tab (Gen) (ii) Cap (Gen) (iii) Syrup (Gen) (iv) Cream/Oint (Gen) (v) Plaster	Evofen 400mg Tablets Each sugar-coated tablet contains:- Ibuprofen (BP)…….400mg (Analgesic/Antipyretic) (B.P Spec.s)	Rs.460.00 /25x10's	Form 5 24-02-2014 Dy.No.202 Rs.20,000	1. BNF 61: (Ibuprofen (Non-proprietary) Tablets, coated, ibuprofen 200 mg ; 400 mg; 600 mg 2.Brufen (Abbott Laboratories (Pakistan) Limited.) [Ibuprofen:400mg]Tab 3.Grant of DML recommended (23-24th January 2014)	Approved with name change
129.	-do-	Montecast 5mg Chewable Tablets Each chewable tablet contains:- Montelukast Sodium BP eq. to Montelukast…….5mg (Antiasthmatic Agent (Leukotriene Receptor antagonist) (Manufacturer's Spec.s)	Rs.400.00/ 14's	Form 5 24-02-2014 Dy.No.201 Rs.20,000	1. BNF 61: (Singulair (MSD) Chewable tablets, montelukast (as sodium salt) 5 mg ; 5 mg 2.Aerokast (Barrett Hodgson) Chewable Tab 4mg 3.Grant of DML recommended (23-24th January 2014)	Deferred for correction in master formulation.

130.	-do-	Montecast 10mg Chewable Tablets Each chewable tablet contains:- Montelukast Sodium BP eq. to Montelukast…….10mg (Antiasthmatic Agent (Leukotriene Receptor antagonist) (Manufacturer's Spec.s)	Rs.460.00/ 14's	Form 5 24-02-2014 Dy.No.197 Rs.20,000	1. BNF 61: (Singulair (MSD) Chewable tablets, montelukast (as sodium salt) 4 mg ; 5 mg 2.Aerokast (Barrett hodgson) Chewable Tab 10mg 3.Grant of DML recommended (23-24th January 2014)	Deferred for correction in master formulation and confirmation of international availability
131.	-do-	Metodil 200mg Tablets Each film coated tablet contains:- Metronidazole BP……200mg (Antiamoebic and anti-infective) (B.P Spec.s)	Rs.230.00/ 20x10's	Form 5 24-02-2014 Dy.No.198 Rs.20,000	1. BNF 61: (Flagyl (Winthrop) Tablets, both f/c, ivory, metronidazole 200 mg ; 400 mg 2. Flagyl(Sanofi Aventis (Pakistan) Ltd.) [Metronidazole:200mg]Tab 3.Grant of DML recommended (23-24th January 2014)	Approved with change of brand name
132.	-do-	Metodil 400mg Tablets Each film coated tablet contains:- Metronidazole BP……400mg	Rs.345.00/ 20x10's	Form 5 24-02-2014 Dy.No.195 Rs.20,000	1. BNF 61: (Flagyl (Winthrop) Tablets, both f/c, ivory, metronidazole 200 mg ; 400 mg 2. Flagyl(Sanofi Aventis	Approved with change of brand name

		(Antiamoebic and anti-infective) (B.P Spec.s)			(Pakistan) Ltd.) [Metronidazole:400mg]Tab 3.Grant of DML recommended (23-24th January 2014)	
133.	-do-	Evoflox 250mg Tablets Each film coated tablet contains:- Levofloxacin hemihydrates USP eq. to Levofloxacin…….250mg (quinolone / antibiotic)	Rs.230.00/ 1x10's	Form 5 24-02-2014 Dy.No.199 Rs.20,000	1. BNF 61: (Tavanic (Sanofi-Aventis) Tablets, yellow-red, f/c, scored, levofloxacin 250 mg; 500 mg) 2. Tavanic (Sanofi-Aventis) 3.Grant of DML recommended (23-24th January 2014)	Approved
134.	-do-	Evoflox 500mg Tablets Each film coated tablet contains:- Levofloxacin hemihydrates USP eq. to Levofloxacin…….500mg (quinolone / antibiotic)	Rs.230.00/ 1x10's	Form 5 24-02-2014 Dy.No.196 Rs.20,000	1. BNF 61: (Tavanic (Sanofi-Aventis) Tablets, yellow-red, f/c, scored, levofloxacin 250 mg; 500 mg) 2. Tavanic (Sanofi-Aventis) 3.Grant of DML recommended (23-24th January 2014)	Approved

135.	-do-	Zetrol 10mg Tablets Each film coated tablet contains:- Cetirizine dihydrochloride BP……10mg (Antihistamine/Anti allergic)	Rs.138.00/ 3x10's	Form 5 24-02-2014 Dy.No.193 Rs.20,000	1. BNF 61 (Cetirizine (Non-proprietary) Tablets, cetirizine hydrochloride 10 mg) Alerid (Pharmatec Pakistan (Pvt) Ltd.) [Cetirizine:10mg]Tab 3.Grant of DML recommended (23-24th January 2014)	Approved
136.	-do- (Capsule Section)	Coxicap 100mg Capsules Each capsule contains:- Celecoxib (BP)…….100mg (Cox-2 inhibitor / antirhemuatic) (Manufacturer's Spec.s)	Rs. 225.00/2×10's	Form 5 17-03-2014 Dy.No.255 Rs.20,000	1. BNF 61 (Celebrex (Pharmacia) Capsules, celecoxib 100 mg; 200 mg) 2. Celbexx (Getz) 3.Grant of DML recommended (23-24th January 2014)	Approved
137.	-do-	Coxicap 200mg Capsules Each capsule contains:- Celecoxib (BP)…….200mg (Cox-2 inhibitor / antirhemuatic) (Manufacturer's Spec.s)	Rs. 365.00/2×10's	Form 5 17-03-2014 Dy.No.257 Rs.20,000	1. BNF 61 (Celebrex (Pharmacia) Capsules, celecoxib 100 mg; 200 mg) 2. Celbexx (Getz) 3.Grant of DML recommended (23-24th January 2014)	Approved

138.	-do-	Azovant 250mg Capsules Each capsule contains:- Azithromycin dihydrate eq. to Azithromycin……..250mg (Macrolides / systemic Anti-infectives) (USP)	Rs. 415/2×6's	Form 5 17-03-2014 Dy.No.258 Rs.20,000	1. BNF 61 (Zithromax (Pfizer) Capsules, azithromycin (as dihydrate) 250 mg) 2. Zitamax/ Zithromax(Pfizer Laboratories Ltd.) [Azithromycin:250mg] Caps 3.Grant of DML recommended (23-24th January 2014)	Approved
139.	-do- (Syrup General Section)	Cosodril Syrup Each 5ml contains:- Aminophylline (BP)……..32mg Diphenhydramine HCl (BP)…8mg Ammonium Chloride (BP)….30mg (Cough Expectorant) (Manufacturer's Spec.s)	Rs.41.50/ 120ml	Form 5 26-02-2014 Dy.No.206 Rs.20,000	2. Hydrillin (Searle) 3.Grant of DML recommended (23-24th January 2014)	Approved
140.	-do-	Mucol 15mg Syrup Each 5ml contains:- Ambroxol HCl (BP)….15mg (Expectorant) (Manufacturer's Spec.s)	Rs.62.00/ 60ml	Form 5 26-02-2014 Dy.No.212 Rs.20,000	MUCOSOLVAN (MERCK PRIVATE LTD.) [Ambroxol (HCl):15mg/5ml] Syrup 3.Grant of DML recommended (23-24th January 2014)	Approved

141.	-do-	Metodil 200mg Suspension Each 5ml of suspension contains:- Metronidazole benzoate (BP) eq. to Metronidazole….200mg (Antimaoebic and Anti-infective) (B.P Spec.s)	Rs.37.00/ 60ml	Form 5 26-02-2014 Dy.No.204 Rs.20,000	1.BNF 61 (Flagyl S (Winthrop) Suspension, orange- and lemon-flavoured, metronidazole (as benzoate) 200 mg/5 mL) 2. Flagyl (Sanofi) 3.Grant of DML recommended (23-24th January 2014)	Approved
142.	-do-	Evofen 100mg Suspension Each 5ml contains:- Ibuprofen (BP)……100mg (Antipyretic Analgesic and anti Inflammatory) (B.P Spec.s)	Rs.41.50/ 90ml	Form 5 26-02-2014 Dy.No.207 Rs.20,000	1.BNF 61 (Brufen (Abbott) Syrup, orange, ibuprofen 100 mg/5 mL, net price 500 mL (orange-flavoured)) 2. (Brufen (Abbott) 3.Grant of DML recommended (23-24th January 2014)	Approved

143.	-do-	Maxilax 3.35g Syrup Each 5ml contains:- Lactulose (BP)……3.35g (Laxative) (B.P Spec.s)	Rs.170.00/ 120ml	Form 5 26-02-2014 Dy.No.208 Rs.20,000	1.BNF 61 (Lactulose (Non-proprietary) Solution, lactulose 3.1–3.7 g/5mLwith other ketoses.) 2. Duphalac (Highnoon Laboratories Ltd.) [Lactulose:3.35g/5ml] Syrup 3.Grant of DML recommended (23-24th January 2014)	Deferred for confirmation of : 1. Source & fee. 2. Testing facility by DDG DRAP and FID
144.	-do-	Zetrol 5mg Oral Solution Each 5ml contains:- Cetirizine Dihydrochloride (BP)…….5 mg (Antihistamine / Anti Allergic) (B.P Spec.s)	Rs.53.00/ 60ml	Form 5 26-02-2014 Dy.No.209 Rs.20,000	1.BNF 61 (Cetirizine (Non-proprietary) Oral solution, cetirizine hydrochloride 5 mg/5 mL) 2. Rigix (agp (private) limited) [Cetirizine:5mg/5ml] Oral Soln 3.Grant of DML recommended (23-24th January 2014)	Approved
145.	-do-	Evamol 120mg Suspension Each 5ml contains:- Paracetamol (BP)…….120mg (Non-Narcotic Analgesics)	Rs.63.00/ 120ml	Form 5 26-02-2014 Dy.No.210 Rs.20,000	1.BNF 61 Paracetamol (Non-proprietary) Oral suspension 120 mg/5 mL (Paediatric Mixture), paracetamol 120 mg/5 mL	Approved

		(B.P Spec.s)			2. Calpol (GSK) 3.Grant of DML recommended (23-24th January 2014)	
146.	-do-	Sinosil Junior Nasal Drops Contains:- Xylometazoline HCl (USP)……. 0.05% w/v (Sympathomimetic) (USP Spec.s)	Rs.25.30 15ml	Form 5 26-02-2014 Dy.No.205 Rs.20,000	1.BNF 61. (Xylometazoline (Non-proprietary) Paediatric nasal drops, xylometazoline hydrochloride 0.05%) 2. Xlomet (Karachi Chemical Industries) [Xylometazoline (HCl):0.05%w/v] Nasal Drops 3.Grant of DML recommended (23-24th January 2014)	Rejected as the firm does not possess the manufacturing facility.
147.	-do-	Sinosil 0.1% Nasal Spray Contains:- Xylometazoline HCl (USP)……. 0.1% w/v (Sympathomimetic) (Manuf Spec.s)	Rs.34.00 15ml	Form 5 26-02-2014 Dy.No.203 Rs.20,000	1.BNF 61. (Xylometazoline (Non-proprietary) Nasal spray, xylometazoline hydrochloride 0.1%) 2. Xynosine (Zafa Pharmaceutical Laboratories (Pvt) Ltd.) [Xylometazoline (HCl):0.1%w/v] Nasal Spray	Rejected as the firm does not possess the manufacturing facility

					3.Grant of DML recommended (23-24th January 2014)	
148.	-do- (Cream/Oint General Section)	Activion Cream Contains:- Methyl Salicylate (BP)..15% w/w Menthol (BP)…….10% w/w (Analgesic / counter irritant / rubefacient) (Manufacturer's Spec.s)	Rs. 180/60gm	Form 5 17-03-2014 Dy.No.259 Rs.20,000	Pain-Gay (Marvi) 3.Grant of DML recommended (23-24th January 2014)	Approved
149.	-do-	Dermic Cream Each 1g of cream contains:- Micronized Silver Sulphadiazine (USP)….1% (in a hydrophilic cream base) (Antibacterial) (U.S.P Spec.s)	Rs. 100/25gm	Form 5 17-03-2014 Dy.No.254 Rs.20,000	1. BNF 58: Flamazine (S&N Hlth.) Cream, silver sulfadiazine 1% 2. Dermazin(Novartis Pharma (Pak) Ltd) [Silver Sulphadiazine: 1%w/w] cream 3.Grant of DML recommended (23-24th January 2014)	Approved

150.	-do-	Dyclop 1.16% Gel Each 1gm of gel contains:- Diclofenac diethylamine (BP)……1.16% w/w (Phenylacetic Acid / Topical Anti-Rheumatics) (BP Spec.s)	As Per SRO/ N.A.	Form 5 17-03-2014 Dy.No.252 Rs.20,000	Voltral Emulgel (Novartis) 3.Grant of DML recommended (23-24th January 2014)	Approved
151.	-do-	Metodil Vaginal Gel Each 5g (applicatorful) contains:- Metronidazole (USP)….37.5mg (Antibacterial / antiprotozoal)	Rs. 126/75gm	Form 5 17-03-2014 Dy.No.256 Rs.20,000	2. Metni V 0.75% Gel (Shaigan) 3.Grant of DML recommended (23-24th January 2014)	Approved with change in brand name
152.	-do- (Plaster Section)	Neemplast Plaster Contains:- Acrinol……10.4% (Disinfectant and Antiseptic) (Manufacturer's)	Rs. 25/ 19×72mm (10 strips) Rs. 35/19×72mm (20 strips) Rs. 160/19×72mm (100 strips) Rs. 720/19×72mm	Form 5 17-03-2014 Dy.No.251 Rs.20,000	1. Required 2. Required 3.Grant of DML recommended (23-24th January 2014)	Deferred for confirmation of me too status and international availability.

			(500 strips)			
153.	-do-	Neemplast Plus Plaster Contains:- Neem extract…….15mg Tea tree oil…….0.03ml (Antiseptic & Disinfectant) (Manufacturer's)	Rs. 28/ 19×72mm (10 strips) Rs. 38/19×72mm (20 strips) Rs. 175/19×72mm (100 strips) Rs. 750/19×72mm (500 strips)	Form 5 17-03-2014 Dy.No.253 Rs.20,000	1. Required 2. Required 3.Grant of DML recommended (23-24th January 2014)	Referred to H&OTC Division
154.	-do-	Montecast 4mg Granules Each sachet contains:- Montelukast sodium BP eq. to Montelukast Sodium (B.P) equiv to Montelukast……4mg (Antiasthmatic Agent (Leukotriene Receptor	Rs.345.00/ 14's sachets	Form 5 24-02-2014 Dy.No.200 Rs.20,000	1. BNF 61. (Singulair (MSD) Granules, montelukast (as sodium salt) 4 mg) 2. Beasy (Bosch Pharmaceuticals (Pvt) Ltd.) [Montelukast:4mg] Sachet 3.Grant of DML recommended (23-24th January 2014)	Rejected as firm does not possess the manufacturing facility for sachet dosage form

		antagonist)) (Manufacturer's Spec.s)				

Evaluator – III

155.	M/s Wenovo Pharmaceuticals Taxila. **Tablet General**	Ciprovo 250mg Tablets Each film coated tablet contains:- Ciprofloxacin as HCl…..250mg (Fluoroquiolones) USP	As per SRO/1x10 's	Form 5 New License Dy No 8908 dated 17-01-2014 17-01-2014 Rs.20,000	Cipro(film coated tablet) of Bayer Health care Novidat of Sami Pharmaceuticals Karachi Firm was inspected on 19-11-2013 by the panel of inspectors and recommended grant of DML by the way of formulation	Approved
156.	-do-	Ciprovo 500mg Tablets Each film coated tablet contains:- Ciprofloxacin as HCl…..500mg (Fluoroquiolones) USP	As per SRO/1x10 's	Form 5 New License Dy No 8914 dated 17-01-2014 17-01-2014 Rs.20,000/-	Cipro(film coated tablet) of Bayer Health care Novidat of Sami Pharmaceuticals Karachi Firm was inspected on 19-11-2013 by the panel of inspectors and recommended grant of DML by the way of formulation	Approved

157.	-do-	Wenold 250mg Tablets Each film coated tablet contains:- Levofloxacin as Hemihydrate….250mg (Fluoroquinolones) Manufacturer	As per SRO/1x10's	Form 5 New License Dy No 8906 dated 17-01-2014 17-01-2014 Rs.20,000/-	Levaquin of Janssen Pharmaceuticals Inc Leflox of Getz Pharma Karachi Firm was inspected on 19-11-2013 by the panel of inspectors and recommended grant of DML by the way of formulation.	Approved with Japanese pharmacopeia
158.	-do-	Wenold 500mg Tablets Each film coated tablet contains:- Levofloxacin as Hemihydrate…….500mg (Fluoroquinolones) Manufacturer	As per SRO/1x10's	Form 5 New License Dy No 8905dated 17-01-2014 17-01-2014 Rs.20,000/-	Levaquin of Janssen Pharmaceuticals Inc Leflox of Getz Pharma Karachi Firm was inspected on 19-11-2013 by the panel of inspectors and recommended grant of DML by the way of formulation.	Approved with Japanese pharmacopeia
159.	-do-	Wenamol 37.5/325mg Tablets Each film coated tablet contains:- Tramadol HCl…….37.5 mg Acetaminophen……325mg (Opioid Analgesic and antipyretic)	As per SRO/1x10's	Form 5 New License Dy No 235 dated 13-02-2014 13-02-2014 Rs.20,000	**Acetaminophen; Tramadol Hydrochloride of Mylan Inc** **Tonoflex-P of Sami Pharmaceuticals Karachi.** Firm was inspected on 19-11-2013 by the panel of inspectors and recommended grant of	Approved

		Manufacturer			DML by the way of formulation.	
160.	-do-	Sofovir 400 mg tablets Each tablet contains sofosbuvir 400mg (Wenovo spec's) Nucleotide analogue inhibitor of HCV NS5B polymerase Manufacturer specs	85000/- per tablet/ pack of 10's	Form 5-D New License Dy No 932 dated 07-03-2014 07-03-2014 50,000/-	SOVALDI of Gilead Sciences, Inc Firm was inspected on 19-11-2013 by the panel of inspectors and recommended grant of DML by the way of formulation.	Deferred for: a) Expert opinion by Dr Najam, Shifa International Hospital, Islambad, Dr Tasawar , Fauji Foundation Rawalpindi, Dr Pervaiz b) Product specific inspection by Dr Muzamil Hassan Najmi, Member RB, Director QA & Lab testing and area FID c) Source of API
161.	-do-	Sarlozide Tablet Tablet Each film coated tablet contains Amlodipine…5mg Valsartan….160mg Hydrochlorthiazide….12.5 CCB, ARB and Diuretic	As per SRO/3x10's	Form 5 New License Dy No 807 dated 10-03-2014 10-03-2014 20,000/-	Exforge HCT of Novartis Corporation Co-Extor of Searle Pakistan Karachi Firm was inspected on 19-11-2013 by the panel of inspectors and recommended grant of DML by the way of formulation	Approved

162.	-do-	Sarlozide Tablet Tablet Each film coated tablet contains Amlodipine…10 mg Valsartan….160m g Hydrochlorthiazid e….12.5 CCB, ARB and Diuretic	As per SRO/3x10 's	Form 5 New License Dy No 806 dated 10-03-2014 10-03-2014 20,000/-	Exforge HCT of Novartis Corporation Co-Extor of Searle Pakistan Karachi Firm was inspected on 19-11-2013 by the panel of inspectors and recommended grant of DML by the way of formulation	Approved
163.	-do-	Sarlozide Tablet Tablet Each film coated tablet contains Amlodipine…10 mg Valsartan….160m g Hydrochlorthiazid e….25 CCB, ARB and Diuretic	As per SRO/3x10 's	Form 5 New License Dy No 808 dated 10-03-2014 10-03-2014 20,000/-	Exforge HCT of Novartis Corporation Co-Extor of Searle Pakistan Karachi Firm was inspected on 19-11-2013 by the panel of inspectors and recommended grant of DML by the way of formulation	Approved
164.	-do-	Sarlozide Tablet Tablet Each film coated tablet contains Amlodipine…10 mg Valsartan….320m g Hydrochlorthiazid	As per SRO/3x10 's	Form 5 New License Dy No 809 dated 10-03-2014 10-03-2014 20,000/-	Exforge HCT of Novartis Corporation Co-Extor of Searle Pakistan Karachi Firm was inspected on 19-11-2013 by the panel of inspectors and	Approved

		e….25 CCB, ARB and Diuretic			recommended grant of DML by the way of formulation	
165.	-do- **Capsule Gen.** (12 files)	Isotriwen 20mg Capsules Each capsule contains:- Isotritinoin…20mg (Cystic Acne)	As per SRO/Pack of 10's	Form 5 New License Dy No 8911 dated 17-01-2014 17-01-2014 20,000/-	Absorica™ (isotretinoin) of Ranbaxy Inc Each hard gelatin capsule contains isotretinoin USP, stearoyl macrogolglycerides, soybean oil, sorbitan monooleate and propyl gallate however the formulation of the applied product is different from formulation approved by stringent regulatory agencies Acnewine capsule of Wnsfield Pharmaceuticals Hattar Firm was inspected on 19-11-2013 by the panel of inspectors and recommended grant of DML by the way of	Referred for review of formulation by review committee.

					formulation	
166.	-do-	Azrovo 250mg Capsules Each capsule contains:- Azithromycin….. 250mg (Macrolide antibiotics) USP	As per SRO/Pack of 10's	Form 5 New License Dy No 8910 dated 17-01-2014 17-01-2014 20,000/-	Zithromax of Pfizer Azrowin of Wnsfield Pharmaceuticals Hattar Firm was inspected on 19-11-2013 by the panel of inspectors and recommended grant of DML by the way of formulation	Approved
167.	-do-	Azrovo 500mg Capsules Each capsule contains:- Azithromycin…500mg (Macrolide antibiotics) USP	As per SRO/Pack of 10's	Form 5 New License Dy No 8909 dated 17-01-2014 17-01-2014 20,000/-	Not found Azrowin of Wnsfield Pharmaceuticals Hattar Firm was inspected on 19-11-2013 by the panel of inspectors and recommended grant of DML by the way of formulation	Deferred for confirmation of international availability
168.	-do-	Esowen 20mg Capsules Each capsule contains:- Esomeprazole enteric coated Pellets eq. to Esomeprazole…. ……20mg	As per SRO/Pack of 2x7's	Form 5 New License Dy No 8896 dated 17-01-2014 17-01-2014 20,000/-	NEXIUM (esomeprazole magnesium) capsule, delayed release of AstraZeneca Esso of Shaigan Pharmaceuticals Islamabad	Approved

		(Proton Pump Inhibitor) (Manufacturer Specs) Source: Esomeprazole magnesium enteric coated pellets 22.5% of Vision Pharmaceuticals Islamabad			Firm was inspected on 19-11-2013 by the panel of inspectors and recommended grant of DML by the way of formulation	
169.	-do-	Esowen 40mg Capsules Each capsule contains:- Esomeprazole enteric coated Pellets eq. to Esomeprazole…..……40mg (Proton Pump Inhibitor) (Manufacturer Specs) Source: Esomeprazole magnesium	As per SRO/Pack of 2x7's	Form 5 New License Dy No 8894 dated 17-01-2014 17-01-2014 20,000/-	NEXIUM (esomeprazole magnesium) capsule, delayed release of AstraZeneca Esso of Shaigan Pharmaceuticals Islamabad Firm was inspected on 19-11-2013 by the panel of inspectors and recommended grant of DML by the way of formulation	Approved

		enteric coated pellets 22.5% of Vision Pharmaceuticals Islamabad				
170.	-do-	Wenozole 20mg Capsules Each capsule contains:- Omeprazole enteric coated Pellets eq. to Omeprazole……20mg (Proton Pump Inhibitor) USP Source: Omeprazole enteric coated pellets 8.5% of Vision Pharmaceuticals Islamabad	As per SRO/Pack of 2x7's	Form 5 New License Dy No 8897 dated 17-01-2014 17-01-2014 20,000/-	OMEPRAZOLE capsule, delayed release pellets [Watson Pharma, Inc.] Risek of Getz Pharma Karachi Firm was inspected on 19-11-2013 by the panel of inspectors and recommended grant of DML by the way of formulation	Approved

171.	-do-	Wenozole 40mg Capsules Each capsule contains:- Omeprazole enteric coated Pellets eq. to Omeprazole……40mg (Proton Pump Inhibitor) USP Source: Omeprazole enteric coated pellets 8.5% of Vision Pharmaceuticals Islamabad	As per SRO/Pack of 2x7's	Form 5 New License Dy No 8904 dated 17-01-2014 17-01-2014 20,000/-	OMEPRAZOLE capsule, delayed release pellets [Watson Pharma, Inc.] Risek of Getz Pharma Karachi Firm was inspected on 19-11-2013 by the panel of inspectors and recommended grant of DML by the way of formulation	Approved
172.	-do-	Flovo 150mg Capsules Each capsule contains:- Fluconazole….150mg (A Zole) (Manufacturer Specs)	As per SRO/Pack of 2x7's	Form 5 New License Dy No 8912 dated 17-01-2014 17-01-2014 20,000/-	Diflucan of Pfizer Inc Diflucan of Pfizer Firm was inspected on 19-11-2013 by the panel of inspectors and recommended grant of DML by the way of formulation	Approved

173.	-do-	Lansodex 30mg Capsuels Each capsule contains:- Dexlansoprazole …30mg (Proton Pump Inhibitor) Manufacturer specs Source: dexlansoprazole delayed release pellets 17% of Vision Pharmaceuticals Islamabad	As per SRO/Pack of 2x7's	Form 5 New License Dy No 233 dated 13-02-2014 13-02-2014 20,000/-	DEXILANT (dexlansoprazole) capsule, delayed release (Takeda Pharmaceuticals America, Inc) Not provided	Deferred till expert opinion and Form 5D, fee
174.	-do-	Lansodex 60mg Capsuels Each capsule contains:- Dexlansoprazole ….60mg PPI Manufacturer Specs Source: dexlansoprazole	As per SRO/Pack of 2x7's	Form 5 New License Dy No 234 dated 13-02-2014 13-02-2014 20,000/-	Dexilant (dexlansoprazole) capsule, delayed release (Takeda Pharmaceuticals America, Inc) Not provided	Deferred till expert opinion and Form 5D, fee

		delayed release pellets 17% of Vision Pharmaceuticals Islamabad				
175.	-do- Oral Dry Powder Suspension (General)	Wedexi Suspension Each 5ml contains:- Dexibuprofen …….100mg (non-steroidal anti-inflammatory drug with analgesic action)	As per SRO/60ml	Form 5 New License Dy No 8953 dated 20-01-2014 20-01-2014 Rs.20,000/-	Not found in stringent regulatory authorities but the firm has submitted reference regarding availability in India Dexib of Tabros Pharma Karachi .	Deferred for confirmation international availability in stringent DRA's.
176.	-do-	Novotem 15/90mg Suspension Each 5ml contains:- Artemether…… ……..15mg Lumefantrine… ……..90mg (Anti Malarial) Specs of pending monograph of USP	As per SRO/30ml	Form 5 New License Dy No 8953 dated 03-02-2014 03-02-2014 Rs.20,000	Co-Artesian Oral of Dafra Pharma International Belgium Bio Lumefer of Bio Labs Islamabad Firm was inspected on 19-11-2013 by the panel of inspectors and recommended grant of DML by the way of formulation.	Approved

177.	-do-	Wenlevo 125mg Suspension Each 5ml contains:- Levofloxacin as hemihydrate…… …..125mg (Anti-Infective, Quinolone)	As per SRO/60ml	Form 5 New License Dy No 27 dated 03-02-2014 03-02-2014 Rs.20,000	Ambiguous details provided (formulation is in solution approved by stringent regulatory agencies) Levanic of Global Pharmaceuticals Islamabad	Deferred for clarification of formulation as applied formulation is approved in solution form in stringents DRA's
178.	-do-	Wenlevo 250mg Suspension Each 5ml contains:- Levofloxacin as hemihydrate…… …..250mg (Anti-Infective, Quinolone)	As per SRO/60ml	Form 5 New License Dy No 28 dated 03-02-2014 03-02-2014 Rs.20,000	Ambiguous details provided (formulation is in solution approved by stringent regulatory agencies Levanic of Global Pharmaceuticals Islamabad	Deferred for clarification of formulation as applied formulation is approved in solution form in stringents DRA's
179.	-do-	Montewen Dry Suspension Each 5ml contains:- Montelukast Sodium…….5mg (Bronchodilators, Anti-Asthmatic) MAnufacturer	As per SRO/60ml	Form 5 New License Dy No 8936 dated 20-01-2014 20-01-2014 Rs.20,000	Not provided/Not found in stringent regulatory agencies Montair suspension of CCL Labs Lahore(approved in 242nd meeting of DRB)	Deferred for review of formulation by review committee

180.	-do-	Novocin 200mg Dry Suspension Ech5ml contains:- Azithromycin as dihydrate……..200mg (Macrolide Antibiotics) Manufacturer	As per SRO/15ml	Form 5 New License Dy No 8939 dated 20-01-2014 20-01-2014 Rs.20,000	Zithromax of Pfizer Inc Azomax of Novartis Karachi	Approved
181.	-do-	Novoclark 125mg Dry Suspension Each 5ml contains:- Clarithromycin……125mg (Macrolide Antibiotics)	As per SRO/60ml	Form 5 New License Dy No 8937 dated 20-01-2014 20-01-2014 Rs.20,000	BIAXIN(granules for oral suspension) of AbbVie Inc Klaracid of Abbot Karachi	Approved
182.	-do-	Nozin Dry Suspension Each 5ml contains:- Zinc Sulphate as Monohydrate equivalent to elemental zinc …20mg Manufacturer	As per SRO/60ml	Form 5 New License Dy No 8938 dated 20-01-2014 20-01-2014 Rs.20,000/-	Not found internationally (Indian reference is submitted by the firm) Winzinc of Winbrain Pharmaceuticals Hattar	Approved

183.	-do-	Novocip 125mg Dry Suspension Each 5ml contains:- Ciprofloxacin as HCl……125mg (Anti-bacterial Quinolones)	As Per SRO/60ml	Form 5 New License Dy No 26 dated 03-02 -2014 20-01-2014 Rs.20,000/-	Not provided Ciprin of Werrick Pharmaceuticals Islamabad Firm was inspected on 19-11-2013 by the panel of inspectors and recommended grant of DML by the way of formulation	Deferred for confirmation of approval of formulation in 125 mg strength by Stringent Regulatory Agencies.
184.	-do-	Novocip 250 mg Dry Suspension Each 5ml contains:- Ciprofloxacin as HCl……250 mg (Anti-bacterial Quinolones)	As Per SRO/60ml	Form 5 New License Dy No 25 dated 03-02 -2014 20-01-2014 Rs.20,000/-	Not provided Ciprin of Werrick Pharmaceuticals Islamabad Firm was inspected on 19-11-2013 by the panel of inspectors and recommended grant of DML by the way of formulation	Approved subject to correction of formulation as per originator.
185.	-do- Capsule Cephlosporin (07 files)	Wenoxime 200mg Capsules Each capsule contains:- Cefixime ……200mg Antibiotic, Cephalosporine)	As per SRO/1x5's	Form 5 New License Dy No 8899 dated 17-01-2014 17-01-2014 Rs.20,000/-	Not provided/Not found in stringent regulatory agencies Cefim of Hilton Pharma Karachi	Deferrred for confirmation of international availability in stringent DRA's.

		manufacturer				
186.	-do-	Wenoxime 400mg Capsules Each capsule contains:- Cefixime ……400mg (Antibiotic, Cephalosporine) Manufacturer	As per SRO/1x5's	Form 5 New License Dy No 8898 dated 17-01-2014 17-01-2014 Rs.20,000/-	Suprax® (cefixime) Capsules of Lupin Inc Cefim of Hilton Pharma Karachi	Approved
187.	-do-	Cefdox 250mg Capsules Each capsule contains:- Cefadroxil……..250mg (Antibiotic, Cephalosporine) Mannufacturer	As Per SRO 2x6's	Form 5 New License Dy No 8902 dated 17-01-2014 17-01-2014 Rs.20,000/-	Not available internationally Wnsoxil of Wnsfield Pharmaceuticals Hattar	Deferrred for confirmation of international availability in stringent DRA's.
188.	-do-	Cefdox 500mg Capsules Each capsule contains:- Cefadroxil……..500mg (Antibiotic, Cephalosporine)	As Per SRO 2x6's	Form 5 New License Dy No 8903 dated 17-01-2014 17-01-2014 Rs.20,000/-	Cefadroxil capsules 500mg Of Teva Inc C-Doxil of Nova Med Pharma Lahore	Approved

189.	-do-	Cefdox 1gm Capsules Each capsule contains:- Cefadroxil……….1gm (Antibiotic, Cephalosporine)	As Per SRO 2x6's	Form 5 New License Dy No 8894 dated 17-01-2014 17-01-2014 Rs.20,000/-	Not provided/Not found Wnsoxil of Wnsfield Pharmaceuticals Hattar	Deferrred for confirmation of international availability in stringent DRA's.
190.	-do-	Cefnowen 250mg Capsules Each capsule contains:- Cephradine……..250mg (Antibiotic, Cephalosporine) USP	As per SRO 2x6's	Form 5 New License Dy No 8901 dated 17-01-2014 17-01-2014 Rs.20,000	Valosef of BMS USA Bactocef of Swiss Pharma Karachi	Approved
191.	-do-	Cefnowen 500mg Capsules Each capsule contains:- Cephradine……..500mg (Antibiotic, Cephalosporine)	As per SRO/ 2x6's	Form 5 New License Dy No 8900 dated 17-01-2014 17-01-2014 Rs.20,000	Valosef of BMS USA Bactocef of Swiss Pharma Karachi	Approved
192.	-do- Sachet	Montewen 4mg Sachet Each sachet contains:- Montelukast Sodium	As per SRO/7's,14's20's28's30's	Form 5 New License Dy No 8934 dated 20-01-2014 20-01-2014 Rs.20,000	SINGULAIR (montelukast sodium) granule of Merck Sharp & Dohme Corp. SINGULAIR	Approved

		Granules…… …4mg (Bronchodilators, Anti-Asthmatic)			(montelukast sodium) granules of OBS Karachi	
193.	M/s Agror Pharma, Rawat. Capsules (Ceph.) (10 files)	Nirocef 300mg Capsules Each capsule contains:- Cefdinir…300mg (Cephalosporin) USP Specs	As per SRO pack of 10's	Form 5 New License Dy No 9065 dated 23-01-2014 23-01-2014 Rs.20,000	CEFDINIR (cefdinir) capsule Lupin Pharmaceuticals Inc Dinacor of Hilton Karachi Inspection of the firm was conducted by the panel of inspectors on 24-12-2013 and recommend for grant of DML by the way of formulation for sections namely cephalosporin dry powder for suspension, cephalosporin capsule section and cephalosporin dry powder for injection	Approved
194.	-do-	Agrodine 250mg Capsules Each capsule contains:- Cephradine……	As per SRO/Pack of 12's	Form 5 New License Dy No 9073 dated 23-01-2014 23-01-2014	Valosef of BMS Inc Valosef of GSK	Approved

		…250mg (First Generation Cephalosporins) USP Specs		Rs.20,000		
195.	-do-	Agrodine 500mg Capsules Each capsule contains:- Cephradine…… …500mg (First Generation Cephalosporins) USP Specs	As per SRO/Pack of 12's	Form 5 New License Dy No 9063 dated 23-01-2014 23-01-2014 Rs.20,000	Valosef of BMS Inc Valosef of GSK	Approved
196.	-do-	Agrofix 200mg Capsules Each capsule contains:- Cefixime (as trihydrate)….200 mg (Third Generation Cephalosporins) Manufacturer	As per SRO/Pack of 10's	Form 5 New License Dy No 9074 dated 23-01-2014 23-01-2014 Rs.20,000	Reference is not found in stringent regulatory bodies but the firm has submitted references regarding availability in India, Korea and Indonesia Icef of ICI	Deferrred for confirmation of international availability in stringent DRA's.

197.	-do-	Agrofix 400mg Capsules Each capsule contains:- Cefixime (as trihydrate)….400 mg (Third Generation Cephalosporins) Manufacturer	As per SRO/Pack of 5's	Form 5 New License Dy No 9074 dated 23-01-2014 23-01-2014 Rs.20,000	Suprax Capsules of Lupin Inc Icef of ICI	Approved
198.	-do-	Lexin 250mg Capsules Each capsule contains:- Cephalexin (as monohydrate)……250mg (1st Generation Cephalosporins) USP	As per SRO/Pack of 12's	Form 5 New License Dy No 9068 dated 23-01-2014 23-01-2014 Rs.20,000	Cephalexin Capsule of Ranbaxy Pharmaceuticals Inc. Ceporex of GSK Karachi	Approved
199.	-do-	Lexin 500mg Capsules Each capsule contains:- Cephalexin (as monohydrate)……500mg (1st Generation Cephalosporins)	As per SRO/Pack of 12's	Form 5 New License Dy No 9075 dated 23-01-2014 23-01-2014 Rs.20,000	Cephalexin Capsule **of** Ranbaxy Pharmaceuticals Inc. Ceporex of GSK Karachi	Approved

		USP				
200.	-do-	Cefrox 250mg Capsules Each capsule contains:- Cefuroxime (as Axitel)….250mg (2nd Generation Cephalosporins) Manufacturer specs	As per SRO/Pack of 10's	Form 5 New License Dy No 9109 dated 23-01-2014 23-01-2014 Rs.20,000	Reference is not found in stringent regulatory bodies but the firm has submitted references regarding availability in Malaysia, Philippines Trucef of Synchro Pharma Lahore	Deferred for confirmation of international availability in stringent DRA's.
201.	-do-	Rinox 100mg Capsules Each capsule contains:- Cefpodoxime (as Proxitell)…….. 100mg (2nd Generation Cephalosporins)	As per SRO/Pack of 2x6's	Form 5 New License Dy No 9108 dated 23-01-2014 23-01-2014 Rs.20,000	Reference is not found in stringent regulatory bodies but the firm has submitted references regarding availability in India, Kenya, Vietnam and Turkey Cefporite of Shrooq Pharma Lahore	Deferred for confirmation of international availability in stringent DRA's.
202.	-do-	Rinox 200mg Capsules Each capsule contains:-	As per SRO/Pack of 2x6's	Form 5 New License Dy No 9108 dated 23-01-2014	Not found internationally Not found	Deferred for confirmation of international availability in stringent DRA's and confirmation

		Cefpodoxime (as Proxitell)……..200mg (2nd Generation Cephalosporins)		23-01-2014 Rs.20,000		of me-too status.
203.	-do- **Dry Powder Susp. (Ceph.)**	Cefoxil 250mg Dry Suspension Each 5ml contains:- Cefadroxil (as monohydrate)…….250mg (1st Generation Cephalosporin USP	As per SRO/ Pack of 60ml	Form 5 New License Dy No 9080 dated 23-01-2014 23-01-2014 Rs.20,000	**CEFADROXIL (cefadroxil monohydrate) powder, for suspension** (Ranbaxy Pharmaceuticals Inc) Duricef of GSK Karachi	Approved
204.		Nirocef 125mg Dry Suspension Each 5ml contains:- Cefdinir……..125mg (Cephalosporins) USP	As per SRO/ Pack of 60ml	Form 5 New License Dy No 9071 dated 23-01-2014 23-01-2014 Rs.20,000	CEFDINIR (cefdinir) powder, for suspension (Lupin Pharmaceuticals Inc) Dinacor of Hilton Pharma Karachi	Approved

205.	-do-	Rinox 40mg Suspension Each 5ml contains:- Cefpodoxime (as Proxitell)….40mg (2nd Generation Cephalosporins) (USP)	As per SRO/Pack of 50ml	Form 5 New License Dy No 9070 dated 23-01-2014 23-01-2014 Rs.20,000	CEFPODOXIME PROXETIL granule, for suspension of Sandoz Inc Orelox of Sanofi Aventis Karachi	Approved
206.	-do-	Cefrox 125mg Dry Suspension Each 5ml contains:- Cefuroxime (as Axitel Granules)……. .125mg (2nd Generation Cephalosporins) USP	As per SRO/Pack of 50 ml	Form 5 New License Dy No 9056 dated 23-01-2014 23-01-2014 Rs.20,000	Cefuroxime Axetil For Oral Suspension [Ranbaxy Pharmaceuticals Inc] Zinacef of GSK	Approved
207.	-do-	Agrodine 125mg Dry Suspension Each 5ml contains:- Cephradine (as Monohydrate)… ……..125mg (1st Generation Cephalosporin)	As per SRO/Pack of 60ml	Form 5 New License Dy No 9062 dated 23-01-2014 23-01-2014 Rs.20,000	Velosef of BMS Inc Velosef of GSK .	Approved

		USP				
208.	-do-	Agrodine 250mg Dry Suspension Each 5ml cotnaions:- Cephradine (as Monohydrate)…….250mg (1st Generation Cephalosporins) USP	As per SRO/Pack of 60ml	Form 5 New License Dy No 9053 dated 23-01-2014 23-01-2014 Rs.20,000	Velosef of BMS Inc Velosef of GSK	Approved
209.	-do-	Lexin 125mg Dry Suspension Each 5ml contains:- Cephalexin (as monohydrate)……..125mg (1st Generation Cephalosporins) USP	As per SRO/Pack of 60ml	Form 5 New License Dy No 9054 dated 23-01-2014 23-01-2014 Rs.20,000	Cephalexin of Ranabaxy Pharmaceuticals Inc Ceporex of GSK Karachi	Approved
210.	-do-	Lexin 250mg Dry Suspension Each 5ml contains:-	As per SRO/Pack of 60ml	Form 5 New License Dy No 9052 dated 23-01-2014	Cephalexin of Ranabaxy Pharmaceuticals Inc	Approved

		Cephalexin (as monohydrate)…….250mg (1st Generation Cephalosporins) USP		23-01-2014 Rs.20,000	Ceporex of GSK Karachi	
211.	-do-	Agrofix 100mg Dry Suspension Each 5ml contains:- Cefixime (as trihydrate)….100 mg (3rd Generation Cephalosporins) USP	As per SRO/Pack of 30ml	Form 5 New License Dy No 9050 dated 23-01-2014 23-01-2014 Rs.20,000	SUPRAX (cefixime) powder, for suspension [Lupin Pharmaceuticals, Inc.] Fixval of GSK Karachi.	Approved
212.	-do-	Agrofix 200mg Dry Suspension Each 5ml contains:- Cefixime (as trihydrate)….200 mg (3rd Generation Cephalosporins) USP	As per SRO/Pack of 30ml	Form 5 New License Dy No 9057 dated 23-01-2014 23-01-2014 Rs.20,000	SUPRAX (cefixime) powder, for suspension [Lupin Pharmaceuticals, Inc.] Fixval of GSK Karachi	Approved

213.	-do- **Dry Powder for Injection (Ceph.)**	Cefagzone 500mg Injection IV Each glass vial contains sterile powder:- Ceftriaxone (as sodium)….500mg (3rd Generation Cephalosporins) **USP**	As per SRO/ Pack of 1''s	Form 5 New License Dy No 9051 dated 23-01-2014 23-01-2014 Rs.20,000	CEFTRIAXONE (ceftriaxone sodium) injection, powder, for solution [Baxter Healthcare Corporation] Getofin of Getz Karachi	Approved
214.	-do-	Cefagzone 1gm Injection IV Each glass vial contains sterile powder:- Ceftriaxone (as sodium)….1gm (3rd Generation Cephalosporins)	As per SRO/Pack of 1's	Form 5 New License Dy No 9058 dated 23-01-2014 23-01-2014 Rs.20,000	ROCEPHIN of Hofman La Roche Getofin of Getz Karachi	Approved
215.	-do-	Cefagzone 500mg Injection IM Each glass vial contains:- Ceftriaxone (as Sodium)…..500mg (Cephalosporins)	As per SRO/Pack of 1's	Form 5 New License Dy No 329 dated 14-02-2014 14-02-2014 Rs.20,000	ROCEPHIN of Hofman La Roche Getofin of Getz Karachi	Approved

216.	-do-	Cefagzone 250mg Injection IM Each glass vial contains:- Ceftriaxone (as Sodium)…..250mg (Cephalosporins)	As per SRO/Pack of 1's	Form 5 New License Dy No 328 dated 14-02-2014 14-02-2014 Rs.20,000	ROCEPHIN of Hofman La Roche Getofin of Getz Karachi	Approved
217.	-do-	Agrocef 1gm Injection Each vial contains:- Cefoperazone (as Sodium).500mg Sulbactam (as Sodium)…..500mg (Cephalosporin + Beta Lactamase Inhibitor Manufacturer	As per SRO/Pack of 1's	Form 5 New License Dy No 9067 dated 23-01-2014 23-01-2014 Rs.20,000	Reference is not found in stringent regulatory bodies but the firm has submitted references regarding availability in India, Korea, Malaysia, Thailand and Switzerland (Novartis) Cebac of Bosch Karachi	Approved
218.	-do-	Agrocef 2gm Injection Each vial contains:- Cefoperazone (as Sodium)1000mg Sulbactam (as Sodium)….1000 mg	As per SRO/Pack of 1's	Form 5 New License Dy No 9061 dated 23-01-2014 23-01-2014 Rs.20,000	Reference is not found in stringent regulatory bodies but the firm has submitted references regarding availability in India, Korea, Malaysia, Thailand and Switzerland (Novartis	Approved

		(Cephalosporins / Beta Lactamase Inhibitor			Cebac of Bosch Karachi	
219.	-do-	Afipime 500mg Injection Each vial contains:- Cefepime (as HCl with l-arginine)……..500mg (Cephalosporin) USP	As per SRO/Pack of 1's	Form 5 New License Dy No 9060 dated 23-01-2014 23-01-2014 Rs.20,000	CEFEPIME (cefepime hydrochloride) injection [Sandoz Inc] Maxipime of GSK Karachi	Approved
220.	-do-	Afipime 1gm Injection Each vial contains:- Cefepime (as HCl with l-arginine)……..1gm (Cephalosporin) USP	As per SRO/Pack of 1's	Form 5 New License Dy No 9066 dated 23-01-2014 23-01-2014 Rs.20,000	CEFEPIME (cefepime hydrochloride) injection [Sandoz Inc] Maxipime of GSK Karachi	Approved

221.	-do-	Paradime 250mg Injection Each glass vial contains:- Ceftazidime (as ceftazidime (as pentahydrate) with sodium carbonate anhydrous)…..250mg (3rd Generation Cephalosporins) USP	As per SRO/Pack of 1's	Form 5 New License Dy No 327 dated 14-02-2014 14-02-2014 Rs.20,000	Fortum of GSK Inc Fortum of GSK Karachi	Approved
222.	-do-	Paradime 1gm Injection Each glass vial contains:- Ceftazidime (as ceftazidime / as pentahydrate) with sodium carbonate anhydrous…….1gm (3rd Generation Cephaloporins) USP	As per SRO/Pack of 1's	Form 5 New License Dy No 9059 dated 23-01-2014 23-01-2014 Rs.20,000	CEFTAZIDIME injection, powder, for solution [Sandoz Inc] Fortum of GSK Karachi	Approved

223.	M/s Nortech Pharmaceuticals (Pvt) Ltd, Islamabad. **Tablet General**	Moxinor 400mg Tablets Each film coated tablet contains:- Moxifloxacin as HCl…….400mg (Quinolone Antibiotic) (USP)	As per SRO/Pack of 1x5's	Form 5 New License Dy No 8897 dated 21-01-2014 21-01-2014 Rs.20,000	AVELOX (moxifloxacin hydrochloride) tablet, film coated [Schering Plough Corporation] Avelon of EG Pharmaceuticals Islamabad Inspection of the firm was conducted on 24-12-2013 by panel of inspectors and recommended for grant of license by the way of formulation for sections namely Tablet (general), Capsule (general), Dry suspension (general) and Skin cream/ointment/gel (non steroid) and ampoule/vial section was not recommended due to certain shortcomings, advised to rectify them and submit compliance report. The CLB also advised to get	Approved

					clarification from firm before issuance of approval. Evidence of approval of said section is provided by the firm.	
224.	-do-	Meconor 0.500mg Tablets Each film coated tablet contains:- Mecobalamin……0.500mg (Vit B12 Analogue) (Manufacturer)	As per SRO/ 2x10's 10x10's	Form 5 New License Dy No 8954 dated 21-01-2014 21-01-2014 Rs.20,000	Methycobal tablets of Eisai Co Ltd Japan Mabil of Sami Pharmaceuticals Karachi	Approved
225.	-do-	Norzin 5mg Tablets Each film coated tablet contains:- Levocetirizine 2HCl…….5mg (Anti-Histamine) (Manufacturer)	As per SRO/ 1x10's	Form 5 New License Dy No 8969 dated 21-01-2014 21-01-2014 Rs.20,000	Levocetirizine dihydrochloride) tablet, film coated [Winthrop U.S.] Allerno of Well & Well Pharmaceuticals Islamabad	Approved
226.	-do-	Artenor 80/480 Tablets Each tablet contains:- Artemether……80mg Lumefantrine……480mg (Anti-Malarial)	As per SRO/ 1x4's 1x6's	Form 5 New License Dy No 8955 dated 21-01-2014 21-01-2014 Rs.20,000	COARTEM (artemether and lumefantrine) tablet [Novartis Pharmaceuticals Corporation] Malavel of Well & Well Pharmaceuticals,	Approved

		USP			Islamabad	
227.	-do-	Cipronor 250mg Tablets Each film coated tablet contains:- Ciprofloxacin as HCl……250mg (Quinolone antibiotic) USP	As per SRO/1x10 's	Form 5 New License Dy No 8974 dated 21-01-2014 21-01-2014 Rs.20,000	CIPRO of [Bayer HealthCare Pharmaceuticals Inc.] Cipro of Bayer Healthcare Karachi	Approved
228.	-do-	Cipronor 500mg Tablets Each film coated tablet contains:- Ciprofloxacin as HCl……500mg (Quinolone antibiotic) USP	As per SRO/1x10 's	Form 5 New License Dy No 8995 dated 21-01-2014 21-01-2014 Rs.20,000	CIPRO of [Bayer HealthCare Pharmaceuticals Inc.] Cipro of Bayer Healthcare Karachi	Approved
229.	-do-	Klarinor 250mg Tablets Each film coated tablet contains:- Clarithromycin……250mg (Macrolide Antibiotic)	As per SRO/1x10 's	Form 5 New License Dy No 8983 dated 21-01-2014 21-01-2014 Rs.20,000	BIAXIN of AbbVie Inc Klaricid of Abbot Karachi	Approved

		USP				
230.	-do-	Klarinor 500mg Tablets Each film coated tablet contains:- Clarithromycin……500mg (Macrolide Antibiotic) USP	As per SRO/1x10's	Form 5 New License Dy No 8996 dated 21-01-2014 21-01-2014 Rs.20,000	BIAXIN of AbbVie Inc Klaricid of Abbot Karachi	Approved
231.	-do-	Levonor 250mg Tablets Each film coated tablet contains:- Levofloxacin (as Hemihydrate)……250mg (Quinolone antibiotic) Manufacturer	As per SRO/1x10's	Form 5 New License Dy No 8953 dated 21-01-2014 21-01-2014 Rs.20,000	Levaquin of Janssen Pharmaceutica Inc Leflox of Getz Pharma Karachi	Approved
232.	-do-	Levonor 500mg Tablets Each film coated tablet contains:- Levofloxacin (as Hemihydrate)……500mg	As per SRO/1x10's	Form 5 New License Dy No 8970 dated 21-01-2014 21-01-2014 Rs.20,000	Levaquin of Janssen Pharmaceutica Inc Leflox of Getz Pharma Karachi	Approved

		(Quinolone antibiotic) Manufacturer				
233.	-do- **Capsule General**	Isotretinor 10mg Capsules Each capsule contains:- Isotretinoin……..10mg (Vitamin A Derivative / Anti Acne Preparation) BP	As per SRO/ 1x5's 1x10's	Form 5 New License Dy No 8992 dated 21-01-2014 21-01-2014 Rs.20,000	Absorica™ (isotretinoin) of Ranbaxy Inc Each hard gelatin capsule contains isotretinoin USP, stearoyl macrogolglycerides, soybean oil, sorbitan monooleate and propyl gallate however the formulation of the applied product is different from formulation approved by stringent regulatory agencies Isonex of Sharooq Pharmaceuticals Islamabad	Referred to Review committee for review of formulation.
234.	-do-	Isotretinor 20mg Capsules Each capsule contains:- Isotretinoin……	As per SRO/ 1x5's 1x10's 3x10's	Form 5 New License Dy No 8992 dated 21-01-2014 21-01-2014	Absorica™ (isotretinoin) of Ranbaxy Inc Each hard gelatin capsule contains	Referred to Review committee for review of formulation.

		…..20mg (Vit A Derivative / Anti Acne Preparation) BP		Rs.20,000	isotretinoin USP, stearoyl macrogolglycerides, soybean oil, sorbitan monooleate and propyl gallate however the formulation of the applied product is different from formulation approved by stringent regulatory agencies Isonex of Sharooq Pharmaceuticals Islamabad	
235.	-do-	Normic 250mg Capsules Each capsule contains:- Traneximic Acid……250mg (Haemostatic / Fibrinolytic) Manufacturer	As per SRO 2x10's 10x10's	Form 5 New License Dy No 8956 dated 21-01-2014 21-01-2014 Rs.20,000	Transamin Capsules of Daiichi Sankyo Company Ltd Japan Transamine of Hilton Pharma Karachi	Approved

236.	-do-	Flunor 150mg Capsules Each capsule contains:- Fluconazole……….150mg (Anti Fungal) Manufacturer (pending monograph of USP)	As per SRO 1x1's	Form 5 New License Dy No 8959 dated 21-01-2014 21-01-2014 Rs.20,000	Diflucan of Roerig Fungvel of WELL & WELL Pharma Islamabad	Approved
237.	-do-	Celenor 200mg Capsules Each capsule contains:- Celecoxib……….200mg (Anti-Rheumatic) Manufactuere	As per SRO 1x10's	Form 5 New License Dy No 8957 dated 21-01-2014 21-01-2014 Rs.20,000	CELEBREX (celecoxib) capsule [G.D. Searle LLC Division of Pfizer Inc] Celzib of Well & Well Pharma Islamabad	Approved
238.	-do-	Rabinor 20mg Capsules Each capsule contains:- Rabeprazole (as Sodium enteric coated pellets)….20mg (Proton Pump Inhibitor) (Manufacturer)	As per SRO 1x10's	Form 5 New License Dy No 8965 dated 21-01-2014 21-01-2014 Rs.100,000	Not provided/not found Rabiton of Envoy Pharma Lahore	Deferrred for confirmation of international availability in stringent DRA's.

		Source: Spansule Formulations, Sy No 172, Plot No, 154/A4, IDA, Bollaram Village, Jinnaram Mandal,Medak District, Andra Pardesh, India				
239.	-do-	Azinor 250mg Capsules Each capsule contains:- Azithromycin (As dihydate……2 50mg (Macrolide Antibiotic) (USP)	As per SRO 1x6's 1x10's 3x12's	Form 5 New License Dy No 8984 dated 21-01-2014 21-01-2014 Rs.20,000/-	Zithromax (Pfizer) Azomax of Novartis Pharma Karachi	Approved
240.	-do-	Piroxinor 20mg Capsules Each capsule contains:- Piroxicam…… …20mg (Anti-Reumatics) BP	As per SRO/ 2x10's	Form 5 New License Dy No 8958 dated 21-01-2014 21-01-2014 Rs.20,000/-	FELDENE (piroxicam) capsule [Keltman Pharmaceuticals Inc.] Biocam of Biorex Pharma	Approved

241.	-do-	Essonor 20mg Capsules Each capsule contains:- Esomeprazole (as Magnesium Trihydrate) (Enteric Coated Pellets) eq. to …….20mg (Proton Pump Inhibitor) Manufacturer **Source**: Spansule Formulations, Sy No 172, Plot No, 154/A4, IDA, Bollaram Village, Jinnaram Mandal,Medak District, Andra Pardesh, India	As per SRO/ 2x7's	Form 5 New License Dy No 8960 dated 21-01-2014 21-01-2014 Rs.100,000/-	Nexium of AstraZeneca Esso of Shaigan Pharmaceuticals Islamabad.	Approved. Firm will provide legalized GMP certificate of Source, COA and stability data. Chairman RB will approve issuance of registration letter
242.	-do-	Essonor 40mg Capsules Each capsule contains:- Esomeprazole (as Magnesium Trihydrate) (Enteric Coated Pellets) eq. to	As per SRO/ 2x7's	Form 5 New License Dy No 8961 dated 21-01-2014 21-01-2014 Rs.100,000/-	Nexium of AstraZeneca Esso of Shaigan Pharmaceuticals Islamabad.	Approved. Firm will provide legalized GMP certificate of Source, COA and stability data. Chairman RB will approve issuance of registration letter

		…….40mg (Proton Pump Inhibitor) Manufacturer **Source**: Spansule Formulations, Sy No 172, Plot No, 154/A4, IDA, Bollaram Village, Jinnaram Mandal,Medak District, Andra Pardesh, India				
243.	-do- **Dry Powder Suspension** (07 files)	Klarinor 125mg Dry Suspension Each 5ml contains:- Clarithromycin ……..125mg (Macrolide Antibiotic) USP Claritromycin taste masked granules 27.5% Source: Vision Pharmaceuticals Islamabad	As per SRO/ 60ml	Form 5 New License Dy No 8963 dated 21-01-2014 21-01-2014 Rs.20,000/-	BIAXIN (clarithromycin) granule, for suspension [AbbVie Inc.] Klaricid Suspension of Abbot Labs Karachi.	Approved

244.	-do-	Azinor 200mg Dry Suspension Each 5ml contains:- Azithromycin as dihydrate…..200 mg (Macrolide antibiotic) USP	As per SRO/ 15ml 22.5ml	Form 5 New License Dy No 8964 dated 21-01-2014 21-01-2014 Rs.20,000	AZITHROMYCIN (Azithromycin monohydrate) powder, for suspension [Teva Pharmaceuticals USA Inc] Azomax of Novartis Pharmaceuticals Karachi	Approved
245.	-do-	Cipronor 125mg Dry Suspension Each 5ml contains:- Ciprofloxacin (as HCl)…..125mg (Quinolone Antibiotic) Ciprofloxacin taste masked pellets 25% Source: Vision Pharmaceuticals Islamabad Manufacturer	As per SRO/ 60ml	Form 5 New License Dy No 8993 dated 21-01-2014 21-01-2014 Rs.20,000	Not found in applied strength in stringent regulatory authorities Novidat dry suspension of Sami Pharmaceuticals Karachi	Deferred for confirmation of approval of formulation in 125 mg strength by Stringent Regulatory Agencies.

246.	-do-	Cipronor 250mg Dry Suspension Each 5ml contains:- Ciprofloxacin (as HCl)…..250mg (Quinolone Antibiotic) Ciprfloxacin taste masked pellets 25% Source:Vision Pharmaceuticals Islamabad Manufacturer	As per SRO/ 60ml	Form 5 New License Dy No 8994 dated 21-01-2014 21-01-2014 Rs.20,000	Not provided/Not found Novidat dry suspension of Sami Pharmaceuticals Karachi	Approved as Ciprofloxacin base in microcapsule form.
247.	-do-	Levonor 125mg Dry Suspension Each 5ml contains:- Levofloxacin (as Hemihydrate)…125mg (Quinolone antibiotic) Manufactrure	As per SRO/ 60ml	Form 5 New License Dy No 8971 dated 21-01-2014 21-01-2014 Rs.20,000	Not provided/not found Levaq dry suspension of Global Pharmaceuticals Islamabad	Deferred for clarification of formulation from Firm as applied formulation is approved as solution in stringent DRA's.

248.	-do-	Levonor 250mg Dry Suspension Each 5ml contains:- Levofloxacin (as Hemihydrate)…. …250mg (Quinolone antibiotic)	As per SRO/ 60ml	Form 5 New License Dy No 8977 dated 21-01-2014 21-01-2014 Rs.20,000	Not provided/not found Levaq dry suspension of Global Pharmaceuticals Islamabad	Deferred for clarification of formulation from Firm as applied formulation is approved as solution in stringent DRA's.
249.	-do-	Artenor 15/90 Dry Suspension Each 5ml contains:- Artemether…… …..15mg Lumefantrine… …..90mg (Anti Malarial) Proposed specs of USP pending monograph	As per SRO/ 60ml	Form 5 New License Dy No 8978 dated 21-01-2014 21-01-2014 Rs.20,000	Co-Artesian Oral of Dafra Pharma International Belgium Malavel of Well & Well Pharma Islamabad	Approved
250.	-do- **Cream/Ointment/Gel (Non Steroidal)**	Miconor 2% Cream Each gram contains:- Miconazole nitrate…….20 mg (Imidazole antifungal)	As per SRO/ 10gm 20gm	Form 5 New License Dy No 8952 dated 21-01-2014 21-01-2014 Rs.20,000	CAVILON ANTIFUNGAL (miconazole nitrate) cream [3M Health Care] Daktarin of Janssen Cilag Karachi	Approved

		(BP)				
251.	-do-	Silvenor 1% Cream Each gram contains:- Silver Sulphadiazine…..10mg (Antibacterial) USP	As per SRO/ 20gm	Form 5 New License Dy No 8975 dated 21-01-2014 21-01-2014 Rs.20,000	SILVADENE (silver sulfadiazine) cream [Pfizer Laboratories Div Pfizer Inc] Quench cream of Ferozesons Hattar	Approved
252.	-do-	Clindanor 2% Cream Each gram contains:- Clindamycin (as Phosphate)……..20mg (Antibiotic) USP	As per SRO/ 10gm	Form 5 New License Dy No 8951 dated 21-01-2014 21-01-2014 Rs.20,000	CLEOCIN (clindamycin phosphate) cream of Pharmacia and Upjohn Company Clycin V cream of Shaigan Pharmaceuticals Islamabad	Approved
253.	-do-	Clotrinor 2% Cream Each gram contains:- Clotrimazole….20mg	As per SRO/ 10gm 35gm	Form 5 New License Dy No 8982 dated 21-01-2014 21-01-2014 Rs.20,000	Canesten Cream 3 of Bayer Inc Canada Clozox vag cream of Shaigan Pharmaceuticals	Approved

		(Imidazole Antifungal) USP			Islamabad	
254.	-do-	Fusinor 2% Cream Each gram contains:- Fusidic Acid…….20mg (Antibacterial) BP	As per SRO/ 5gm 15gm	Form 5 New License Dy No 8981 dated 21-01-2014 21-01-2014 Rs.20,000	Fucidin Cream 2% of LEO Pharma Inc Canada Melas of Atco Labs Karachi.	Approved
255.	-do-	Clotrinor 10% Cream Each gram contains:- Clotrimazole……..100mg (Imidazole antifungal) USP	As per SRO/ 5gm	Form 5 New License Dy No 8972 dated 21-01-2014 21-01-2014 Rs.20,000	Canesten Cream 1 of Bayer Inc Canada Canesten Vaginal cream of Bayer Pakistan	Approved
256.	-do-	Pirxinor 0.5% Gel Each gram contains:- Piroxicam…….5mg (NSAID)	As per SRO/ 10gm 25gm	Form 5 New License Dy No 8976 dated 21-01-2014 21-01-2014 Rs.20,000	**Feldene of Pfizer** **Feldene of Pfizer Labs Karachi**	Approved

		BP				
257.	-do-	Isotretinor 0.05% Gel Each gram contains:- Isotretinoin……..0.5mg (Vitamin A Derivative) BP	As per SRO/ 10gm	Form 5 New License Dy No 8979 dated 21-01-2014 21-01-2014 Rs.20,000	Isotrex of Stiefel Inc Isotin Gel of Shiagan Pharmaceuticals Islamabad	Approved
258.	-do-	Ketonorfen 2.5% Gel Each gram contains:- Ketoprofen……25mg (Imidazole anti-Fungal) BP	As per SRO/ 25gm	Form 5 New License Dy No 8980 dated 21-01-2014 21-01-2014 Rs.20,000	Powergel of (Menarini) Fastum Topical Gel of Pharmatec Karachi	Approved
259.	-do-	Diclonor 1 % Gel Each gram contains:- Diclofenac Diethylamine….10mg (NSAID)	As per SRO/ 20gm	Form 5 New License Dy No 8973 dated 21-01-2014 21-01-2014 Rs.20,000	Voltaren Emugel of Novartis Voltaren Emugel of Novartis	Approved with change of brand name.

		BP				
260.	-do- **Ampoule/vial** (10 files)	Aqua-Nor Injection Each 5ml ampoule contains:- Water for Injection……..5ml (Solvent) (USP)	As per SRO/ 5mlx5's 5mlx10's Amp.	Form 5 New License Dy No 8966 dated 21-01-2014 21-01-2014 Rs.20,000	Aqua-p of Ipram Pharmaceuticals Islamabad	Deferred for confirmation of approval of manufacturing facility from Licensing Section.
261.	-do-	Ketonor 30mg Injection Each 1ml ampoule contains:- Ketorolac Tromethamine...30mg (NSAID) USP	As per SRO/ 1mlx5's 1mlx10's Amp.	Form 5 New License Dy No 8991 dated 21-01-2014 21-01-2014 Rs.20,000	Toradol of Roche Tromit of Standpharm	Deferred for confirmation of approval of manufacturing facility from Licensing Section.
262.	-do-	Tropinor 5mg Injection Each 5ml ampoule contains:- Tropisetron as HCl…….5mg	As per SRO/ 5mlx1's Amp.	Form 5 New License Dy No 8967 dated 21-01-2014 21-01-2014 Rs.20,000	Navoban injection of Novartis Pharmaceuticals Australia Navoban injection of Novartis	Deferred for confirmation of approval of manufacturing facility from Licensing Section.

		(5HT3-antagonist) Manufacturer			Pharmaceuticals Karachi Pakistan	
263.	-do-	Ayron 100mg Injection Each 5ml ampoule contains:- Iron (as Iron Sucrose)……100 mg (Anti-Anaemics) USP	As per SRO/ 5mlx5's Amp.	Form 5 New License Dy No 8990 dated 21-01-2014 21-01-2014 Rs.20,000	Venofer ® (iron sucrose injection, USP) of LUITPOLD (American Regent Inc) Besleri-S of Sami Pharmaceuticals Karachi	Deferred for confirmation of approval of manufacturing facility from Licensing Section.
264.	-do-	Zonor 50mg Injection Each 2ml ampoule contains:- Ranitidine (as HCl)…..50mg (Antipeptic Ulcerants) USP	As per SRO/ 2mlx5's 2mlx10's Amp.	Form 5 New License Dy No 8989 dated 21-01-2014 21-01-2014 Rs.20,000	RANITIDINE injection of [Bedford Laboratories] Zantac of GSK Karachi	Deferred for confirmation of approval of manufacturing facility from Licensing Section.
265.	-do-	Vitanor-D Injection Each 1ml ampoule contains:- Colecalciferol…	As per SRO/ 1mlx1's 1mlx5's Amp.	Form 5 New License Dy No 8988 dated 21-01-2014 21-01-2014 Rs.20,000	Not provided/Not found Calciferol of Global Pharmaceuticals Islamabad	Deferred for confirmation of approval of manufacturing facility from Licensing Section.

		……5mg (Vitamin-D Analogue) BP				
266.	-do-	Vominor 10mg Injection Each 2ml ampoule contains:- Metoclopramide (as HCl)…10mg (Antidopaminergic) USP	As per SRO/ 2mlx10's Amp.	Form 5 New License Dy No 8986 dated 21-01-2014 21-01-2014 Rs.20,000	Reglan of Ani Pharms Clopan of Siza Pharmaceuticals Lahore	Deferred for confirmation of approval of manufacturing facility from Licensing Section.
267.	-do-	Piroxinor 20mg Injection Each 1ml ampoule contains:- Piroxicam……20 mg (anti-Rheumatics) Manufacturer	As per SRO/ 1mlx5's Amp.	Form 5 New License Dy No 8985 dated 21-01-2014 21-01-2014 Rs.20,000	Feldene Injection of Pfizer France (needs confirmation) Mobicam of Global Pharmaceuticals Islamabad	Deferred for confirmation of approval of manufacturing facility from Licensing Section.
268.	-do-	Normic 250mg Injection Each 5ml ampule contains:- Tranexamic Acid……..250mg (Anti-	As per SRO/ 5mlx5's 5mlx10's Amp.	Form 5 New License Dy No 8987 dated 21-01-2014 21-01-2014 Rs.20,000	Azeptil of Medochemie Ltd Cyprus Brino of Sami Pharmaceuticals Karachi	Deferred for confirmation of approval of manufacturing facility from Licensing Section.

		haemorrhagics/Anti-haemophillics) BP				
269.	-do-	Meconor 500mcg Injection Each 1ml ampoule contains:- Mecobalamin…….500mcg (Coenzyme-type vitamin B12) Manufacturer	As per SRO/ 1mlx10's Amp.	Form 5 New License Dy No 8987 dated 21-01-2014 21-01-2014 Rs.20,000	Methycobal Injection 500ug of Eiasi Co. Ltd Tokyo Japan (provided by firm from manufacturer website , needs confirmation) Neuromin of EG Pharma Islamabad.	Deferred for confirmation of approval of manufacturing facility from Licensing Section.

Evaluator – IV

270.	M/s Hiranis Pharmaceutical Pvt. Ltd. Plot.No. E-145-149, North western Industrial Zone, Port Qasim, Karachi. **(Tablet General)**	Gastopride Tablet Each tablet contains: Cinitapride as Acid Tartrate MS 1mg (Prokinetic) Finished product specifications are Manufacturer.	As per PRC	1.Form-5 2. 09-10-2013 3. 09-10-2013 Dy.No.892 Rs.20,000/-	1.Not found in reference drug agencies 2. Cinita 1mg 3. Firm was inspected on 17th & 23rd September 2013, for grant of DML by way of formulation	Referred to Review Committee for review of formulation.
271.	-do- **(Tablet General)**	Mytind Tablet Each film coated tablet contains: Tinidazole USP 500 mg (Antiprotozoal and antibacterial) Finished product specifications are Manufacturer.	10's/ As per PRC	1.Form-5 2. 09-10-2013 Dy.No. 895 3. 09-10-2013 Rs.20,000/-	1. Tindamax Tablet 500 mg 2. Fasigyn Tablet 500 mg 3. Firm was inspected on 17th & 23rd September 2013, for grant of DML by way of formulation	Approved
272.	-do- **(Tablet General)**	PAINOFF-IR Tablet Each film coated tablet contains: Naproxen Sodium USP 550 mg eq to Naproxen 500mg (NSAID)	As per PRC	1.Form-5 2.24-10-2013 Dy.No. 928 3. 24-10-2013 Rs.20,000/-	1. Anaprox 500mg 2. Xaprox 550mg 3. Firm was inspected on 17th & 23rd September 2013, for grant of DML by way of formulation	Approved

		Finished product specifications are USP				
273.	-do- **(Tablet General)**	PROMOX Tablet Each film coated tablet contains: Moxifloxacin BP 400mg (Quinolone) Finished product specifications are USP Non-US Monograph	As per PRC	1.Form-5 2.28-10-2013 Dy.No. 943 3. 28-10-2013 Rs.20,000/-	1. Avelox 400mg 2. Avelox 400mg 3. Firm was inspected on 17th & 23rd September 2013, for grant of DML by way of formulation	Approved
274.	-do- **(Tablet General)**	Roflu **(NEW MOLECULE)** Tablet Each film coated tablet contains: Roflumilast……..500mcg (Inhibitor of the enzyme PDE-4) Finished product specifications are Manufacturer.	Rs.270/10's Rs.378/14's	1.Form-5D 2. 28-10-2013 Dy.No. 940 3. 28-10-2013 Rs.50,000/-	1. Daliresp Tablet 500 mcg 2. New Molecule 3. Firm was inspected on 17th & 23rd September 2013, for grant of DML by way of formulation	Deferred for expert opinion of Brig Dr. Aslam, Dr.Shazli Manzoor and Dr. Rehana Kauser PIMS
275.	-do-**(Tablet General)**	Caterol Tablet Each tablet contains:- Procatero MS 50mcg (Bronchodilator)	As per PRC	1.Form-5 2.07-11-2013 Dy.No. 1000 3. 07-11-2013 Rs.20,000/-	1. Meptin Tablet 50 mcg by M/s Otsuka Pharmaceuticals Ltd. Hong Kong 2. Meptin Tablet 50 mcg	Approved as firm has removed the following observation & submitted the revised formulation.

		Finished product specifications are Manufacturer.			3. Firm was inspected on 17th & 23rd September 2013, for grant of DML by way of formulation	1. Adjustment of difference in quantity of Procaterol HCl to be done by Microcrystalline cellulose
276.	-do- **(Tablet General)**	Levopearl Tablet Each film coated tablet contains:- Levofloxacin (as hemi hydrate) USP 250 mg (Quinolone) Finished product specifications are Manufacturer.	As per PRC	1.Form-5 2.16-12-2013 Dy.No. 2066 3. 16-12-2013 Rs.20,000/-	1. Levaquine 250mg 2. Axolev 250mg 3. Firm was inspected on 17th & 23rd September 2013, for grant of DML by way of formulation	Approved
277.	-do- **(Tablet General)**	Levopearl Tablet Each film coated tablet contains:- Levofloxacin (as hemi hydrate) USP 500 mg (Quinolones) Finished product specifications are Manufacturer.	As per PRC	1.Form-5 2. 16-12-2013 3.16-12-2013 Dy.No. 2068 Rs.20,000/-	1. Levaquine tablet 500mg 2. Axolev tablet 500mg 3. Firm was inspected on 17th & 23rd September 2013, for grant of DML by way of formulation	Approved
278.	-do- **(Tablet General)**	Myotec Tablet Each sugar coated tablet contains: Eeperis one HCl MS 50mg	As per PRC	1.Form-5 2.16-12-2013 Dy.No. 2061 3. 16-12-2013	1. Not found in reference drug agencies however, Myonal 50mg manufactured by	Deferred for international availability status.

		(Antispasmodic) Manufacturer Specifications		Rs.20,000/-	Eisai China Inc. is available internationally 2. Myonal 50mg 3. Firm was inspected on 17th & 23rd September 2013, for grant of DML by way of formulation	
279.	-do- **Capsules (General)**	Hiclind Capsule Each capsule contains: Clindamycin (as HCl) USP 300 mg (Antibiotic) Finished product Specifications are USP	As per PRC	1.Form-5 2.09-10-2013 Dy.No. 889 3.09-10-2013 Rs.20,000/-	1. Cleocin Capsule 300 mg 2. Dalacin-C 300mg 3. Firm was inspected on 17th & 23rd September 2013, for grant of DML by way of formulation	Approved
280.	-do- **Capsules (General)**	Acebro Capsule **(NEW MOLECULE)** Each capsule contains: Acebrophylline MS 100mg (An airway mucoregulator and anti-inflammatory agent) Finished product Specifications are Manufacturer.	As per PRC	1.Form-5D 2. 24-10-2013 Dy.No. 931 3.24-10-2013 Rs.50,000/-	1. Not found in reference drug agencies while AB Phylline Capsule 100mg manufactured by M/s Sun Pharma is available in India. 2. New drug 3. Firm was inspected on 17th & 23rd September 2013, for grant of DML by way of	Rejected as safety & efficacy of formulation has not been established in Stringent Regulatory Authorities.

					formulation	
281.	-do- **Capsules (General)**	Rivamine Capsule Each capsule contains:- Rivastigmine as Tartrate USP 3.0mg (Cholinesterase Inhibitor, Used for dementia of Alzheimer Type) Finished product specifications are USP	As per PRC	1.Form-5 2.07-11-2013 Dy.No. 999 3.07-11-2013 Rs.20,000/-	1. Exelon Capsule 3mg 2. Exelon Capsule 3mg 3. Firm was inspected on 17th & 23rd September 2013, for grant of DML by way of formulation	Approved
282.	-do- **Capsules (General)**	Rivamine Capsule Each capsule contains:- Rivastigmine as Tartrate USP 1.5mg (Cholinesterase Inhibitor, Used for dementia of Alzheimer Type) Finished product specifications are USP	As per PRC	1.Form-5 2.07-11-2013 Dy.No. 1001 3.07-11-2013 Rs.20,000/-	1. Exelon Capsule 1.5 mg 2. Exelon Capsule 1.5 mg 3 Firm was inspected on 17th & 23rd September 2013, for grant of DML by way of formulation	Approved
283.	-do- **Capsules (General)**	Ferrital Capsule Each capsule contains:- Polysaccharide-Iron Complex eq. to Elemental Iron MS 150mg (Iron Supplement) Finished product	As per PRC	1.Form-5 2.16-12-2013 Dy.No. 2062 3.16-12-2013 Rs.20,000/-	1. Not found in reference drug agencies, however, Polysaccharide Iron Complex syrup available internationally. 2.Ferricure Capsule	Deferred for me too status

		specifications are Manufacturer			1.5 mg 3.Firm was inspected on 17th & 23rd September 2013, for grant of DML by way of formulation	
284.	-do- **Dry Powder Suspension (General).**	INFEXO Dry Suspension Each 5ml contains: Ciprofloxacin USP 125mg (Quinolone) Finished product specifications are Manufacturer	60ml/As per PRC	1.Form-5 2.24-10-2013 Dy.No. 934 3.24-10-2013 Rs.20,000/-	1. Cipro Internationally available in strength of 250 & 500mg/5ml. FDA approved Ciprofloxacin microcapsules for dry suspension 2. Hiflox 125mg/5ml 3.Firm was inspected on 17th & 23rd September 2013, for grant of DML by way of formulation	Deferred for confirmation of approval of formulation in 125 mg strength by Stringent Regulatory Agencies.
285.	-do- **Dry Powder Suspension (General).**	INFEXO DS Dry Suspension Each 5ml contains: Ciprofloxacin USP 250mg (Quinolones) Finished product specifications are Manufacturer	60ml/As per PRC	1.Form-5 2.24-10-2013 Dy.No. 933 3. 24-10-2013 Rs.20,000/-	1. Cipro 250mg/5ml. FDA approved Ciprofloxacin microcapsules for dry suspension 2. Hiflox 250mg/5ml 3.Firm was inspected on 17th & 23rd September 2013, for grant of	Deferred for confirmation / clarification of formulation.

					DML by way of formulation	
286.	-do- **Dry Powder Suspension (General).**	Atizor Dry Suspension Each 5ml contains: Azithromycin Dihydrate eq. to Azithromycin USP 200 mg (Macrolide) Finished product specifications are USP	As per PRC	1.Form-5 2.24-10-2013 Dy.No. 932 3. 24-10-2013 Rs.20,000/-	1. Zithromycin for oral suspension 200mg/5ml 2. Zomax Suspension 200mg/5ml 3.Firm was inspected on 17th & 23rd September 2013, for grant of DML by way of formulation	Approved
287.	-do- **Dry Powder Suspension (General).**	Levopearl Dry Suspension Each 5ml contains:- Levofloxacin USP 125 mg Quinolone Finished product specifications are Manufacturer.	As per PRC	1.Form-5 2.16-12-2013 Dy.No. 2067 3. 16-12-2013 Rs.20,000/-	1. Levaquine 250mg/10ml 2. Leva Q 125mg/5ml 3.Firm was inspected on 17th & 23rd September 2013, for grant of DML by way of formulation	Deferred for confirmation of formulation.
288.	-do- **Dry Powder Suspension (General).**	Erdozet Suspension Each 5ml contains:- Erdosteine MS 175mg (Fludifying Agent) Finished product	As per PRC	1.Form-5 2.26-11-2013 Dy.No. 2035 3. 26-11-2013 Rs.20,000/-	1. Suspension form not found in reference drug agencies, EMA approved Erdosteine Sachet only for Lead	Approved

		specifications are Manufacturer.			& Mercury Toxicity. Erdosteine dry suspension is present Internationally. 2. Dostin 175mg/5ml Suspension 3.Firm was inspected on 17th & 23rd September 2013, for grant of DML by way of formulation	
289.	-do- **Dry Powder Suspension (General).**	Levopearl -DS Dry Suspension Each 5ml contains:- Levofloxacin USP 250 mg Quinolone Finished product specifications are Manufacturer.	As per PRC	1.Form-5 2.16-12-2013 Dy.No. 2059 3.16-12-2013 Rs.20,000/-	1. Internationally available as Levaquine 250mg/10 ml, not in DS 2. Leva Q DS 250mg/5ml 3.Firm was inspected on 17th & 23rd September 2013, for grant of DML by way of formulation	Deferred for confirmation of formulation.
290.	-do- **Sachet Section (General)**	Purgo Sachet Each sachet contains: Montelukast Sodium eq. to Montelukast MS 4mg (Leukotriene receptor	As per PRC	1.Form-5 2.22-10-2013 Dy.No. 909 3.22-10-2013 Rs.20,000/-	1. Singulair Sachet 4mg 2. Singulair Sachet 4mg 3.Firm was inspected on 17th & 23rd September	Approved

		antagonists) Manufacturer Specifications			2013, for grant of DML by way of formulation	
291.	-do- **Sachet Section (General)**	Fosfon Sachet Each sachet contains:- Fosfomycin Trometamol eq. To Fosfomycin (Ph.Eur) 3gm (Antibiotic/Bactericidal) Finished product Specifications are Manufacturer.	1's/As per PRC	1.Form-5 2.22-10-2013 Dy.No. 910 3.22-10-2013 Rs.20,000	1. Monurol Sachet 3 g 2. Monurol Sachet 3 g 3. Firm was inspected on 17th & 23rd September 2013, for grant of DML by way of formulation	Approved
292.	-do- **Sachet Section (General)**	HIPOLIV Sachet Each sachet contains:- L-Ornthine L- Aspartate MS 3g (Amino Acid) Finished product specifications are Manufacturer.	5'sx5 Sachet/As per PRC	1.Form-5 2.24-10-2013 Dy.No. 929 3. 24-10-2013 Rs.20,000/-	1. Not found in reference drug agencies 2. Hepa Merz sachet 3g 3.Firm was inspected on 17th & 23rd September 2013, for grant of DML by way of formulation	Approved.
293.	-do- **Sachet Section (General)**	ARTI-Q Sachet Each sachet contains Dihydroartemisinin USP 15mg Piperaquine Phosphate USP 120mg (Anti-malarial)	As per PRC	1.Form-5 2.07-11-2013 Dy.No. 996 3.07-11-2013 Rs.20,000/-	1. Darte- Q Sachet manufactured by M/s Chemospecialty Ltd., Taiwan 2. Neo Fansidar Sachet 3.Firm was inspected on 17th &	Approved

		Finished product Specifications are Manufacturer.			23rd September 2013, for grant of DML by way of formulation	
294.	-do- **Sachet Section (General)**	Erdozet Sachet Each sachet contains:- Erdosteine MS 225.00mg (Fludifying Agent) Finished product specifications are Manufacturer.	As per PRC	1.Form-5 2.26-11-2013 Dy.No. 2032 3.26-11-2013 Rs.20,000/-	1. EMA approved Erdosteine Sachet 225mg for Lead & Mercury toxicity 2. Dostin Sachet 225mg 3.Firm was inspected on 17th & 23rd September 2013, for grant of DML by way of formulation	Approved
295.	-do- **Sachet Section (General)**	Prostant Sachet Each sachet contains:- Strontium Ranelate MS 2 gm (Antiosteoporotic) Finished product specifications are Manufacturer.	As per PRC	1.Form-5 2.16-12-2013 Dy.No. 2064 3.16-12-2013 Rs.20,000/-	1. Protelos Sachet 2g 2. Onita Sachet 2g 3.Firm was inspected on 17th & 23rd September 2013, for grant of DML by way of formulation	Approved
296.	-do- **Liquid Syrup (General)**	Zincad Syrup Each 5 ml contains Zinc Gluconate USP (elemental zinc) 20mg (Mineral) Finished product	30ml, 60ml, 90ml/ As per PRC	1.Form-5 2.09-10-2013 Dy.No. 891 3.09-10-2013 Rs.20,000/-	1.Not found in reference drug agencies 2. E- Zinc syrup 20mg/5ml 3.Firm was inspected on 17th &	Approved

		specifications are Manufacturer.			23rd September 2013, for grant of DML by way of formulation	
297.	-do- **Liquid Syrup (General)**	Gastopride Syrup Each 5ml contains:- Cinitapride as acid Tartrate MS 1mg (Prokinetic) Finished product specifications are Manufacturer.	As per PRC	1.Form-5 2.09-10-2013 Dy.No. 896 3.09-10-2013 Rs.20,000/-	1.Not found in reference drug agencies 2. Cinita syrup 1mg/5ml 3.Firm was inspected on 17th & 23rd September 2013, for grant of DML by way of formulation	Deferred for review of formulation.
298.	-do- **Liquid Syrup (General)**	HIPOLIV Syrup Each 5ml Contains:- L-Ornithine L-Aspartate MS 300mg Nicotinamide BP 24mg Riboflavin BP 0.76mg (Amino Acid) Finished product specifications are Manufacturer.	As per PRC	1.Form-5 2.24-10-2013 Dy.No. 930 3. 24-10-2013 Rs.20,000/-	1. Not found in reference drug agencies 2. Hepa Merz 3.Firm was inspected on 17th & 23rd September 2013, for grant of DML by way of formulation	Approved.
299.	-do- **Liquid Syrup (General)**	ACEBRO **(NEW MOLECULE)** SYRUP Each 5ml contains Acebrophylline MS 50mg (An airway mucoregulator and anti-inflammatory	Rs. 120/120ml	1.Form-5D 2.28-10-2013 Dy.No. 942 3.28-10-2013 Rs.50,000/-	1. Not found in reference drug agencies while available Abrofyll Syrup 50mg/5ml in India, manufactured by M/s Alkerm	Rejected as safety & efficacy of formulation has not been established in Stringent Regulatory Authorities.

		agent) Finished product specifications are Manufacturer.			Laboratories, India. 2. New drug 3.Firm was inspected on 17th & 23rd September 2013, for grant of DML by way of formulation	
300.	-do- **Liquid Syrup (General)**	Lekra Oral Solution Each ml contains:- Levetiracetam USP 100mg (Anti-epileptic) Finished product specifications are USP.	As per PRC	1.Form-5 2.05-12-2013 Dy.No. 2044 3.05-12-2013 Rs.20,000/-	1. Keppra Oral solution 100mg/ml 2. Klevra Oral solution 100mg/ml 3.Firm was inspected on 17th & 23rd September 2013, for grant of DML by way of formulation	Approved
301.	-do- **Liquid Syrup (General)**	Caterol Syrup Each 5ml contains Procaterol HCl MS 25mcg (Bronchodilator) Finished product specifications are Manufacturer.	As per PRC	1.Form-5 2.07-11-2013 Dy.No. 1002 3.07-11-2013 Rs.20,000/-	1. Meptin syrup 25mcg/5ml by M/s Otsuka Pharmaceuticals Ltd. Hong Kong 2. Meptin syrup 25mcg/5ml 3.Firm was inspected on 17th & 23rd September 2013, for grant of DML by way of formulation	Approved

302.	-do- **Liquid Syrup (General)**	Crateral Oral Suspension Each 5ml contains:- Sucralfate USP 1g (Cytoprotective) Finished product specifications are Manufacturer.	As per PRC	1.Form-5 2.26-11-2013 Dy.No. 2037 3.26-11-2013 Rs.20,000/-	1. Carafate oral suspension available in strength of **1g/10ml** while firm applied for 1g/5ml 2. Cidifen oral suspension 1g/5ml 3.Firm was inspected on 17th & 23rd September 2013, for grant of DML by way of formulation	Approved
303.	-do- **Liquid Syrup (General)**	Ferrital Syrup Each 5ml contains: Polysaccharide-Iron Complex MS 217.4 mg equivalent to elemental Iron MS 100mg Iron Supplement Finished product specifications are Manufacturer.	As per PRC	1.Form-5 2.16-12-2013 Dy.No. 2063 3.16-12-2013 Rs.20,000/-	1. Not found in reference drug agencies, however, Polysaccharide Iron Complex syrup available internationally. 2. Ferricure Syrup 100mg 3.Firm was inspected on 17th & 23rd September 2013, for grant of DML by way of formulation	Approved
304.	-do- **Mouth Wash (General)**	Curadent Mouthwash Each ml contains:- Chlorhexidine Gluconate (BP) 0.2 mg	As per PRC	1.Form-5 2. 22-10-2013 Dy.No. 914 3. 22-10-	1. Not found in reference drug agencies, however, Curasept 0.2% mouth wash	Deferred for me too status

		0.2% w/v Sodium Fluoride (BP) 0.5mg 0..5% w/v (Anti-bacterial/ Antiseptic)		2013 Rs.20,000/-	manufactured by Curaden Swiss Australia is available internationally. 2. Me too 3.Firm was inspected on 17th & 23rd September 2013, for grant of DML by way of formulation	
305.	-do- **Mouth Wash (General)**	Benzicept Mouthwash Each 100ml contains:- Benzydamine HCl BP 0.15gm Cetylpyridinium Choloride. BP 0.05gm NSAID+Antiseptic Finished product specifications are Manufacturer	As per PRC	1.Form-5 2.06-02-2014 Dy.No. 36 3. 06-02-2014 Rs.20,000/-	1. Not found in reference drug agencies, however Difflam C mouth rinse by Meda Health Sales Ireland Limited, is available internationally 2. Benzirin C Mouth wash 3.Firm was inspected on 17th & 23rd September 2013, for grant of DML by way of formulation	Deferred for me too status
306.	-do- **Effervescent Tablet (General)**	Megacal-D Tablet Each effervescent tablet contains:- Calcium Lactate Gluconate MS 1000mg	As per PRC	1.Form-5 2.06-02-2014 Dy.No. 41 3.06-02-2014 Rs.20,000/-	1. Not found internationally 2. 3. Firm was inspected on 17th & 23rd September	Deferred for vitamin policy

		Calcium Carbonate BP 327mg Vitamin C BP 500mg Vitamin D_3 BP 4mg Vitamin B_6 BP 10mg (Calcium+Vitmain B+ Vitamin D) Finished product specifications are manufacturer			2013, for grant of DML by way of formulation	
307.	-do- **Tooth Paste (General)**	Curadent Tooth Paste Each gm Contains:- Chlorhexidine Gluconate 0.2 mg 0.2% w/w (Anti-bacterial/ Antiseptic) Finished product specifications are Manufacturer.	As per PRC	1.Form-5 2.22-10-2013 Dy.No. 913 3. 22-10-2013 Rs.20,000/-	1. Not found in reference drug agencies 2. Clinica 0.2% tooth paste 3.Firm was inspected on 17th & 23rd September 2013, for grant of DML by way of formulation Chlorhexidine Gluconate 0.2% tooth paste is not available internationally. Instead strengths 0.05% & 0.12% Chlorhexidine Gluconate tooth paste is available internationally.	Deferred for me too status

308.	-do- **Tooth Paste (General)**	Texadent Tooth Paste Each gram contains:- Sodium Chloride B.P 160mg 16% w/w Tranexamic Acid B.P 0.5 mg 0.05% w/w (Stokatologicals, Dentifrics, Haemostatic Fibronolytic) Finished product specifications are Manufacturer.	As per PRC	1.Form-5 2.22-10-2013 Dy.No. 911 3.22-10-2013 Rs.20,000/-	1. Not found in reference drug agencies however present in Japan as Lion dent health medicinal toothpaste manufactured by The Lion Co., Ltd. Japan 2. Hi Salz tooth paste 3.Firm was inspected on 17th & 23rd September 2013, for grant of DML by way of formulation	Deferred for me too status
309.	-do- **Cream / Ointment/ Gel (General)**	Curadent Gel Contains:- Chlorhexidine Gluconate BP 0.2%w/w (Anti-bacterial/ Antiseptic) Finished product specifications are BP	As per PRC	1.Form-5 2.22-10-2013 Dy.No. 912 3.22-10-2013 Rs.20,000/-	1. Not found in reference drug agencies however **Bexident Gel Chlorhexidine Gel 0.2%** is available internationally. TGA approved Chlorhexidine Oral Gel 0.2% in combination with Sodium Fluoride. 2. Clinica Gel 0.2% 3.Firm was	Deferred for me too status

					inspected on 17th & 23rd September 2013, for grant of DML by way of formulation	
310.	-do- **Cream / Ointment/ Gel (General)**	Tacrozemus 0.1% Ointment Each gm Contains:- Tacrolimus (as Monohydrate) USP 1mg (Macrolide, Immuno modulating agent) Finished product specifications are Manufacturer	As per PRC	1.Form-5 2. 06-02-2014 Dy.No. 42 3.06-02-2014 Rs.20,000/-	1. Protopic Ointment 0.1% 2. Eczemus Ointment 0.1% 3.Firm was inspected on 17th & 23rd September 2013, for grant of DML by way of formulation	Deferred for clarification that whether separate manufacturing facility is required for immunosuppresent or otherwise.
311.	-do- **Cream / Ointment/ Gel (General)**	Noitch Lotion Each ml contains:- Permethrin MS 50.0mg (Scabicide) Finished product specifications are Manufacturer.	As per PRC	1.Form-5 2.06-02-2014 Dy.No. 39 3.06-02-2014 Rs.20,000/-	1. Zeroscab 5% lotion manufactured by M/s Palsons Drugs, India. 2. Permite 5% Lotion 3.Firm was inspected on 17th & 23rd September 2013, for grant of DML by way of formulation Firm states that lotion will be manufactured in cream/ointment/gel section.	Approved

312.	-do- **Cream / Ointment/ Gel (General)**	Noitch Cream Each 100 gram contains: Permethrin MS 5.0gm (Scabicide) Finished product specification are Manufacturer	As per PRC	1.Form-5 2.06-02-2014 Dy.No. 35 3. 06-02-2014 Rs.20,000/-	1. Elimite Cream 5% 2. Elemite Cream 5% 3.Firm was inspected on 17th & 23rd September 2013, for grant of DML by way of formulation	Approved
313.	-do- **Cream / Ointment/ Gel (General)**	Tacrozemus 0.03% Ointment Each gm Contains:- Tacrolimus (as Monohydrate) USP 0.3mg (Macrolide, Immunomodulating agent) Finished product specifications are Manufacturer	As per PRC	1.Form-5 2.06-02-2014 Dy.No. 32 06-02-2014 Rs.20,000/-	1. Protopic Ointment 0.03% 2. Eczemus Ointment 0.03% 3.Firm was inspected on 17th & 23rd September 2013, for grant of DML by way of formulation	Deferred for clarification that whether separate manufacturing facility is required for immunosuppresent or otherwise.
314.	-do- **Cream / Ointment/ Gel (General)**	Fucibact Cream Each gm Contains:- Fusidic Acid 20mg Antibiotic Finished product specifications are Manufacturer	As per PRC	1.Form-5 2. 30-10-2013 Dy.No. 954 3. 30-10-2013 Rs.20,000/-	1. Not found in reference drug agencies however Fucidin Cream is being manufactured by M/s Leo Pharma Inc., Canada 2. Fudic 2% Cream 3. Firm was inspected on 17th & 23rd September 2013, for grant of DML by way of	Approved

					formulation	
315.	-do- **Cream / Ointment/ Gel (General)**	Avogel-V Gel Each gram contains:- Metronidazole BP 7.5 mg 0.75%w/w (Anti bacterial) Finished product specifications are BP.	As per PRC	1.Form-5 2.16-12-2013 Dy.No. 2060 3.16-12-2013 Rs.20,000/-	1. Metrogel- V 2. Metni- V 3. Firm was inspected on 17th & 23rd September 2013, for grant of DML by way of formulation	Approved
316.	-do- **Tablet Steroides**	Terzhinan Vaginal Tablet Each tablet contains:- Ternidazole MS 200mg Neomycin Suphate USP 100mg Nystatin USP 100000units Prednisolone USP 3mg (Antimicrobial, anti-inflammatory, anti-protozoa and anti-fungal)	As per PRC	1.Form-5 2.06-02-2014 Dy.No. 34 06-02-2014 Rs.20,000/-	1. Not found in reference drug agencies however being manufactured by M/s Bouchara Recordati, Russia 2. 3.Firm was inspected on 17th & 23rd September 2013, for grant of DML by way of formulation The firm applied the formulation containing Ternidazole. While alredy approved formulation contains Tnidazole. Clarification is required whether active ingredient is Ternidazole or	Deferred for confirmation of me too status and international availability.

					Tinidazole as Tergynan is available in Tinidazole. Druginfosys and Pharma Guide are mentioning product Tergynan as Tinidazole.	
317.	-do- **Ointment /Gel/ Cream Steroids**	DENTAMAX Dental Paste Each gm contains Demeclocycline HCl USP 30.00mg Triamcinolone acetonide USP 10.00mg (Stomatologicals, Dentifrices) Finished product specifications are Manufacturer.	As per PRC	1.Form-5 2.22-10-2013 Dy.No. 915 3.22-10-2013 Rs.20,000/-	1. Not found in reference drug agencies however, Ledermix past is available in UK manufactured by M/s Henry Schein UK holdings Limited. 2. Me too 3.Firm was inspected on 17th & 23rd September 2013, for grant of DML by way of formulation	Deferred for me too status
318.	-do- **Ointment /Gel/ Cream Steroids**	DENTALOG Ointment Each gm contains Triamcinolone acetonide USP 1 mg (Stomatologicals, Dentifrices)	As per PRC	1.Form-5 2.22-10-2013 Dy.No. 916 3. 22-10-2013 Rs.20,000/-	1. Kenalog Ointment 0.1% 2. Kenalog Ointment 0.1% 3.Firm was inspected on 17th & 23rd September 2013, for grant of	Approved

		Finished product specifications are USP			DML by way of formulation	
319.	-do- **Ointment /Gel/ Cream Steroids**	Fungocort Cream Each 100 gram contains: Miconazole Nitrate 2gm Hydrocortisone 1gm (Antifungal +Steroid) Finished product specifications are BP	As per PRC	1.Form-5 2.06-02-2014 Dy.No. 40 3.06-02-2014 Rs.20,000/-	1. Not found in reference drug agencies however, Daktacort in UK by M/s Janssen – Cilag Ltd. 2. Mycon-H cream 3.Firm was inspected on 17th & 23rd September 2013, for grant of DML by way of formulation	Approved
320.	-do- **Ointment /Gel/ Cream Steroides**	Dermacort Cream Each gm contains:- Fluticasone Propionate BP 0.5mg (Corticosteroid) Finished product specifications are BP	As per PRC	1.Form-5 2.06-02-2014 Dy.No. 37 3.06-02-2014 Rs.20,000/-	1. Cutivate 0.05% Cream 2. Cutivate 0.05% Cream 3.Firm was inspected on 17th & 23rd September 2013, for grant of DML by way of formulation	Approved
321.	-do- **Ointment /Gel/ Cream Steroides**	ISOCORT Cream Each gram contains: Isoconazole Nitrate BP 10mg	As per PRC	1.Form-5 2.06-02-2014 Dy.No. 38 3.06-02-2014 Rs.20,000/-	1. Not found in reference drug agencies however Travocort cream by M/s Schering	Approved

		Diflucortolone Valerate BP 1mg (Antibiotic +Steroid) Manufacturer Specification			Plough, Ltd, Germany is available 2. Travocort Cream 3.Firm was inspected on 17th & 23rd September 2013, for grant of DML by way of formulation	
322.	-do- **Ointment /Gel/ Cream Steroides**	Fucibact –H Cream Each gm Contains:- Fusidic Acid 20mg Hydrocortisone Acetate 10mg (Antibiotic + Steroid) Finished product specifications are Manufacturer.	As per PRC	1.Form-5 2.30-10-2013 Dy.No. 955 3. 30-10-2013 Rs.20,000/-	1. Not found in reference drug agencies however Fucidin H Cream is being manufacture by M/s Leo Pharma Inc., Canada 2. Fsid H Cream 3.Firm was inspected on 17th & 23rd September 2013, for grant of DML by way of formulation	Approved
323.	-do- **Ointment /Gel/ Cream Steroides**	Fucibact –B Cream Each gm Contains:- Fusidic Acid BP 20mg Betamethasone BP 1mg (Antibiotic + Steroid) Finished product specifications are Manufacturer.	As per PRC	1.Form-5 2.30-10-2013 Dy.No. 956 3.30-10-2013 Rs.20,000/-	1. Not found in reference drug agencies however Fucibet Cream is being manufacture by M/s Leo Pharma Inc., Canada 2. Fucicort Cream 3.Firm was	Approved

					inspected on 17th & 23rd September 2013, for grant of DML by way of formulation	
324.	-do- **Ointment /Gel/ Cream Steroides**	Diprosone –G Cream Each gm Contains:- Betamethasone Dipropionate 0.64mg equivalent to Betamethasone BP 0.5mg Gentamicin Sulphate 1.70mg Eq. to Gentamicin BP 1mg (Antibiotic + Steroid) Finished product specification are Manufacturer	As per PRC	1.Form-5 2.07-11-2013 Dy.No. 997 3.07-11-2013 Rs.20,000/-	1. Not found in reference drug agencies however Betagentam cream by M/s Schering Plough, Ltd, Germany is available 2. Betawis G Cream 3.Firm was inspected on 17th & 23rd September 2013, for grant of DML by way of formulation	Approved
325.	-do- **Capsule Steroides**	Brethease 100mcg/6mcg Capsule Each capsule contains:- Formoterol Fumarate BP 6mcg Budesonide BP 100mcg (anti-inflammatory corticosteroid+ selective beta$_2$-adrenergic agonist) Finished product	As per PRC	1.Form-5 2.28-10-2013 Dy.No. 939 3.28-10-2013 Rs.20,000/-	1. Same strength Formoterol fumarate 6mcg + Budesonide 100mcg has not been approved by US FDA, however, Foracort Rotacaps 100/6mcg is available in India manufactured by M/s Cipla Pharmaceuticals.	Deferred for Product specific inspection by Director DTL Karachi alongwith FID alongwith following verifications: 1. Confirmation of approval of formulation by the

		specifications are Manufacturer			FDA approved Formoterol fumarate 4.5mcg + Budesonide160mcg and Formoterol fumarate 4.5mcg + Budesonide 80mcg 2. Combivair 100mcg+6mcg	stringent regulatory agencies. 2. Confirmation of API in ultramicronized form.
326.	-do- **Capsule Steroides**	Brethease 200mcg/6mcg Capsule Each capsule contains:- Formoterol Fumarate BP 6mcg Budesonide BP 200mcg (anti-inflammatory corticosteroid+ selective beta$_2$-adrenergic agonist) Finished product specifications are Manufacturer	As per PRC	1.Form-5 2.28-10-2013 Dy.No. 939 3.28-10-2013 Rs.20,000/-	1. Same strength Formoterol fumarate 6mcg + Budesonide 200mcg has not been approved by US FDA, however, Foracort Rotacaps 200/6mcg is available in India manufactured by M/s Cipla Pharmaceuticals. FDA approved Formoterol fumarate 4.5mcg + Budesonide160mcg and Formoterol fumarate 4.5mcg + Budesonide 80mcg 2. Combivair 400mcg+6mcg	Deferred for Product specific inspection by Director DTL Karachi alongwith FID alongwith following verifications: 1. Confirmation of approval of formulation by the stringent regulatory agencies. 2. Confirmation of API in ultramicronized form

327.	-do- **Capsule Steroides**	Brethease 400mcg/6mcg Capsule Each capsule contains:- Formoterol Fumarate. BP 6mcg Budesonide BP 400mcg (anti-inflammatory corticosteroid+ selective beta$_2$-adrenergic agonist) Finished product specifications are Manufacturer	As per PRC	1.Form-5 2.28-10-2013 Dy.No. 939 3.28-10-2013 Rs.20,000/-	1. Same strength Formoterol fumarate 6mcg + Budesonide 400mcg has not been approved by US FDA, however, Foracort Rotacaps 400/6mcg is available in India manufactured by M/s Cipla Pharmaceuticals. FDA approved Formoterol fumarate 4.5mcg + Budesonide160mcg and Formoterol fumarate 4.5mcg + Budesonide 80mcg 2. Combivair 400mcg+6mcg	Deferred for Product specific inspection by Director DTL Karachi alongwith FID alongwith following verifications: 1. Confirmation of approval of formulation by the stringent regulatory agencies. 2. Confirmation of API in ultramicronized form
328.	M/s. Wimits Pharmaceuticals, Plot No.129, Sunder Industrial Estate (P.I.E) Raiwind Road,	Methampyrone Injection Liquid Injection Each ml of liquid injection contains:- **Methampyrone**	Decontrolled\ pack size 10ml 50ml 100ml	1.Form-5 2.03-01-2014 Dy. No.02 3.03-01-2014 Rs.20,000/-	1. Not found in reference drug agencies 2. Vet Pyron Injection	Rejected as the formulation contains already banned drug metamizole.

	Lahore.	**BP**…….200mg **Aminopyrine**…….50mg Caffeine BP ….20mg Sodium benzoate BP…...20mg Chlorpheniramine Maleate USP …2mg (Non Steroidal Anti-Inflammatory drug) Finished product specifications are Manufacturer.			3. Firm was inspected on 26-11-2013 for grant of DML by Formulation.	
329.	M/s. Wimits Pharmaceuticals, Plot No.129, Sunder Industrial Estate (P.I.E) Raiwind Road, Lahore.	Meprawits Injection Each ml of liquid injection contains Mepyramine Maleate BP …..50mg (Antihistamine) Finished product specifications are	Decontrolled\ pack size 10ml 50ml	1.Form-5 2.01-03-2014 Dy. No.195 3.13-31-2014 Rs.20,000/-	1. Not found in reference drug agencies, however, Mepyramine Maleate Injection 50mg/ ml available in South Africa, Newzealand. 2. Mepran Injection	Approved
330.	M/s. Wimits Pharmaceuticals, Plot No.129, Sunder Industrial Estate (P.I.E) Raiwind Road, Lahore.	Wimtox Injection Liquid Injection Each ml of liquid injection contains:- Novaminsulfon 40mg Etilefrin B.P 0.2mg Calcium Gluconate B.P 100mg Magnesium Gluconate B.P 10mg	Decontrolled\ pack size 100ml 250ml 500ml	1.Form-5 2.03-01-2014 Dy. No.03 3. 03-01-2014 Rs.20,000/-	1. Not found in reference drug agencies, however, Novacoc Solution for Infusion containing Metamizole, caffeine, calcium gluconate, magnesium	Deferred for expert opinion .

		Sodium Salicylate B.P 7mg Nicotinamide B.P 0.3mg Caffeine B.P 10mg Boric Acid B.P 10mg (Analgesic and Antipyretic) Finished product specifications are Manufacturer.			gluconate, sodium dihydrogen phosphate dihydrate, acetylmethionine, glucose, is present internationally. 2. Aminox Injection 3. Firm was inspected on 26-11-2013 for grant of DML by Formulation.	
331.	M/s. Wimits Pharmaceuticals, Plot No.129, Sunder Industrial Estate (P.I.E) Raiwind Road, Lahore.	Sulphamit Injection 33.33% Liquid Injection Each ml contains:- Sulphadimidine Sodium 333.3mg (Sulfonamide Antibacterial) Finished product specifications are BP	Decontrolled\ pack size 50ml 100ml	1.Form-5 2.03-01-2014 Dy. No.04 3.03-01-2014 Rs.20,000/-	1. Sulfadimidine Injection is available internationally 2. Demicon Injection 33.33% 3. Firm was inspected on 26-11-2013 for grant of DML by Formulation.	Approved
332.	M/s. Wimits Pharmaceuticals, Plot No.129, Sunder Industrial Estate (P.I.E) Raiwind Road, Lahore.	Loxitar Injection 10mg/ml Liquid Injection Each ml of liquid injection contains:- Meloxicam BP 10mg (NSAID) Finished product specifications are BP.	Decontrolled\ pack size 50ml 100ml	1.Form-5 2.03-01-2014 Dy. No.05 3.03-01-2014 Rs.20,000/-	1. Meloxicam injection 2. Loxicon Injection 3. Firm was inspected on 26-11-2013 for grant of DML by Formulation.	Approved
333.	M/s. Wimits Pharmaceuticals,	Trizine Injection Liquid Injection	Decontrolled\ pack size	1.Form-5 2.03-01-2014	1. Tribrissen 48% Injection	Approved (with change in brand

	Plot No.129, Sunder Industrial Estate (P.I.E) Raiwind Road, Lahore.	(Suspension). Each ml of liquid injection contains:- Trimethoprim BP 80mg Sulfadiazine BP 400mg (Dihydrofolate Reducatse Inhibitor; Antibacterial, Antibiotc) Finished product specifications are BP Firm applied for both IV & IM	10ml 50ml 100ml	Dy. No.06 3.03-01-2014 Rs.20,000/-	2. Tribex Injection 3. Firm was inspected on 26-11-2013 for grant of DML by Formulation.	name)
334.	M/s. Wimits Pharmaceuticals, Plot No.129, Sunder Industrial Estate (P.I.E) Raiwind Road, Lahore.	Oxyfast-50 Injection Liquid Injection Each ml contains:- Oxytetracycline HCI BP 50mg Lignocaine HCL 10 mg (Antibiotic) Finished product specifications are Manufacturer.	Decontrolled\ pack size 10ml 50ml 100ml	1.Form-5 2.03-01-2014 Dy. No.07 3.03-01-2014 Rs.20,000/-	1. Terramycin Injection 2. Oxycon Injection 3. Firm was inspected on 26-11-2013 for grant of DML by Formulation.	Approved
335.	M/s. Wimits Pharmaceuticals, Plot No.129, Sunder Industrial Estate (P.I.E) Raiwind Road, Lahore.	Enromit Injection 20% Liquid Injection Each ml contains:- Enrofloxacin BP 200mg (Fluroquinolone Antibiotic) Finished product specifications are Manufacturer.	Decontrolled\ pack size 10ml 50ml 100ml	1.Form-5 2.03-01-2014 Dy. No.08 3.03-01-2014 Rs.20,000/-	1. Same strength not available in reference drug agencies, however, Enrofloxacin 20% Injection available in China. 2. Enroquin Forte Injection	Approved (with change in brand name)

336.	M/s. Wimits Pharmaceuticals, Plot No.129, Sunder Industrial Estate (P.I.E) Raiwind Road, Lahore.	Ivertin Injection Liquid Injection Each ml contains:- Ivermectin BP 10mg (Anthelmintic) Finished product specifications are BP	Decontrolled\ pack size 10ml 50ml 100ml 250ml	1.Form-5 2.03-01-2014 Dy. No.09 3.03-01-2014 Rs.20,000/-	1. Ivomec 1% injection 2. Ivercon Injection 3. Firm was inspected on 26-11-2013 for grant of DML by Formulation.	Approved
337.	M/s. Wimits Pharmaceuticals, Plot No.129, Sunder Industrial Estate (P.I.E) Raiwind Road, Lahore.	Tylomit-G Injection Liquid Injection Each ml contains:- Tylosin Tartrate…100mg Gentamicin sulphate…..50mg (Macrolide , Aminoglycoside) Finished product specifications are Manufacturer.	Decontrolled\ pack size 10ml 50ml 100ml	1.Form-5 2.03-01-2014 Dy. No.10 3.03-01-2014 Rs.20,000/-	1. Not found in reference drug agencies, however, Tylosin Tartrate 100mg/ml + Gentamicin Sulphate 50mg/ml Injection available in Vietnam & Turkey. 2. Tylo gold Injection 3. Firm was inspected on 26-11-2013 for grant of DML by Formulation.	Approved
338.	M/s. Wimits Pharmaceuticals, Plot No.129, Sunder Industrial Estate (P.I.E) Raiwind Road, Lahore.	Colibar Water Soluble Powder Each gm contains:- Colistin Sulphate BP…….5MIU (Antibiotic) Finished product specifications are Manufacturer.	Decontrolled\ pack size 100g 250g 500g 1 Kg	1.Form-5 2.03-01-2014 Dy. No.11 3.03-01-2014 Rs.20,000/-	1. Same strength not found in reference drug agencies, however, Colistin Sulfate WSP 5 MIU/G present in Netherlands. 2. Colibak Fort WSP 3. Firm was	Approved

					inspected on 26-11-2013 for grant of DML by Formulation.	
339.	M/s. Wimits Pharmaceuticals, Plot No.129, Sunder Industrial Estate (P.I.E) Raiwind Road, Lahore.	Dairy King Granules/Powder Each Kg contains:- Vitamin A USP …….0.8gm Vitamin D_3 USP…….0.16gm Vitamin E USP …0.38gm Vitamin B_1 USP .1.0gm Vitamin B_2 USP …1.25gm Vitamin B_{12} USP …0.001gm Vitamin B_3 USP .6.25gm Copper Sulphate BP…..0.25gm Magnesium Sulphate BP …25.0gm Calcium Chloride BP 0.023gm Zinc Sulphate USP ....2.17gm Manganese Sulphate BP ……10gm Potassium Iodide BP ….0.5 g Sodium Selenite USP …..0.01gm Phosphorus BP...150gm	Decontrolled\ pack size 1Kg 5 Kg 25 Kg	1.Form-5 2.03-01-2014 Dy. No.12 3.03-01-2014 Rs.20,000/-	1. Not found in reference drug agencies, however, multivitamins & minerals for veterinary use are present internationally. 2. White Gold Powder 3. Firm was inspected on 26-11-2013 for grant of DML by Formulation.	Deferred for PSI & expert opinion on formulation.

		Sodium Chloride BP …120gm Vitamin B_6 USP 4gm (Minerals + Vitamins) Finished product specifications are Manufacturer.				
340.	M/s. Wimits Pharmaceuticals, Plot No.129, Sunder Industrial Estate (P.I.E) Raiwind Road, Lahore.	Lancer Water Soluble Powder Each 100gm contains:- Enrofloxacin BP…..10g Colistin Sulphate…….4.5g Amantadine HCI BP……..5g (Antibiotic) Finished product specifications are Manufacturer.	Decontrolled\ pack size 100g 250g 500g 1 Kg 2.5Kg	1.Form-5 2.03-01-2014 Dy. No.13 3.03-01-2014 Rs.20,000/-	1. Not found in reference drug agencies 2. EN-C WSP 3. Firm was inspected on 26-11-2013 for grant of DML by Formulation.	Approved
341.	M/s. Wimits Pharmaceuticals, Plot No.129, Sunder Industrial Estate (P.I.E) Raiwind Road, Lahore.	Trigger Water Soluble Powder Powder Each gm contains:- Doxycycline Hyclate BP 250mg Tylosin Tartrate BP 200mg (Antibiotic) Finished product specifications are Manufacturer	Decontrolled\ pack size 100g 250g 500g 1Kg 2.5Kg	1.Form-5 2.03-01-2014 Dy. No.15 3.03-01-2014 Rs.20,000/-	1. Not found in reference drug agencies, however, Doxycycline 100mg/g + Tylosin Tartrate 100mg/g WSP available in Holland 2. Macrodox WSP 3. Firm was inspected on 26-11-2013 for grant of DML by Formulation.	Approved

342.	M/s. Wimits Pharmaceuticals, Plot No.129, Sunder Industrial Estate (P.I.E) Raiwind Road, Lahore.	Anti-Diarrhea Water Soluble Powder Each gm contains:- Neomycin Sulphate BP 33.33 mg Streptomycin Sulphate BP 33.33 mg Sulphaguanidine BP 333.33 mg Kaolin USP 333.33 mg Pectin USP 33.33 mg Bismuth Sub nitrate USP 166.66 mg Vitamin A Acetate BP 2.291 mg (Anti-Diarrheal & Antibiotic) Finished product specifications are Manufacturer	Decontrolled\ pack size 12gm 250gm 500gm 1 Kg	1.Form-5 2.03-01-2014 Dy. No.16 3.03-01-2014 Rs.20,000/-	1. Not found in reference drug agencies. 2. Diarroban Powder 3. Firm was inspected on 26-11-2013 for grant of DML by Formulation.	Deferred for confirmation of me too status
343.	M/s. Wimits Pharmaceuticals, Plot No.129, Sunder Industrial Estate (P.I.E) Raiwind Road, Lahore.	Striker Water Soluble Powder Powder Each 1000gm contains:- Chlortetracycline HCI BP…..80gm Neomycin Sulphate BP……70gm Colistin Sulphate BP……..4.0gm (Antibiotic) Finished product specifications are	Decontrolled\ pack size 100g 250g 500g 1 Kg 2.5 Kg	1. Form-5 2.03-01-2014 Dy. No.17 3.03-01-2014 Rs.20,000/-	1. Not found in reference drug agencies. 2. CNC-200 WSP 3. Firm was inspected on 26-11-2013 for grant of DML by Formulation.	Approved

		Manufacturer.				
344.	M/s. Wimits Pharmaceuticals, Plot No.129, Sunder Industrial Estate (P.I.E) Raiwind Road, Lahore.	Mega Flush Water Soluble Powder Each gm contains:- Calcium Pantothenate BP 5mg Methenamine BP (Hexamethylene Tetramine) 995mg Vitamin B2 BP….10mg Nicotinamide BP…25mg (Diuretic & Minerals.) Finished product specifications are Manufacturer.	Decontrolled\ pack size 100g 250g 500g 1 Kg 2.5 Kg	1.Form-5 2.03-01-2014 Dy. No.18 3.03-01-2014 Rs.20,000/-	1. Not found in reference drug agencies 2. Filtrax WSP 3. Firm was inspected on 26-11-2013 for grant of DML by Formulation.	Deferred for confirmation of formulation.
345.	M/s. Wimits Pharmaceuticals, Plot No.129, Sunder Industrial Estate (P.I.E) Raiwind Road, Lahore.	Tycoon-D Water Soluble Powder Powder Each gm contains:- Doxycycline Hyclate BP……..200mg Tylosin Tartrate BP……100mg Colistin Sulphate BP……..25mg Bromhexine HCI BP……5mg (Antibiotic, Bronchodilator.)	Decontrolled\ pack size 100g 250g 500g 1 Kg 2.5 Kg	1.Form-5 2.03-01-2014 Dy. No.19 3.03-01-2014 Rs.20,000/-	1. Same formulation with same strength & same combination not found. 2. CRD Raze WSP 3. Firm was inspected on 26-11-2013 for grant of DML by Formulation.	Approved

		Finished product specifications are Manufacturer.				
346.	M/s. Wimits Pharmaceuticals, Plot No.129, Sunder Industrial Estate (P.I.E) Raiwind Road, Lahore.	Cocci-Close Water Soluble Powder Each gm contains:- Sulphaquinoxaline Sodium USP……200mg Sulfadimidine Sodium BP…….82.5mg Diaveridine HCI…….50mg Vitamin A BP……2500 IU Vitamin K3 BP…….2mg Colistin Sulphate BP…500,000 IU (Anticoccidial) Finished product specifications are Manufacturer.	Decontrolled\ pack size 100g 250g 500g 1 Kg 2.5 Kg	1.Form-5 2.03-01-2014 Dy. No.20 3.03-01-2014 Rs.20,000/-	1. Same formulation with same strength & same combination not found. 2. Darvicox WSP 3. Firm was inspected on 26-11-2013 for grant of DML by Formulation.	Deferred for confirmation of formulation.
347.	M/s. Wimits Pharmaceuticals, Plot No.129, Sunder Industrial Estate (P.I.E) Raiwind Road, Lahore.	Amantadine-10% Water Soluble Powder Each gm contains:- Amantadine HCI BP…….100mg (Antiviral) Finished product specifications are Manufacturer.	Decontrolled\ pack size 100g 250g 500g 1 Kg 2.5 Kg	1.Form-5 2.03-01-2014 Dy. No.21 3.03-01-2014 Rs.20,000/-	1. Not found in reference drug agencies, however, Amantadine Oral Powder available internationally. 2. Amanabak 10% WSP 3. Firm was inspected on 26-11-	Approved

					2013 for grant of DML by Formulation.	
348.	M/s. Wimits Pharmaceuticals, Plot No.129, Sunder Industrial Estate (P.I.E) Raiwind Road, Lahore.	Myquine-Bolus Each bolus contains:- Flumequine BP……350mg (Antibiotic) Finished product specifications are Manufacturer.	Decontrolled\ pack size 2 x 5's Boli Blister Pack 50 Bolus per packet	1.Form-5 2.03-01-2014 Dy. No.22 3.03-01-2014 Rs.20,000/-	1. Not found in reference drug agencies, however, Flumequine tablet 400 mg present internationally. 2. Flumequine Bolus 3. Firm was inspected on 26-11-2013 for grant of DML by Formulation.	Approved
349.	M/s. Wimits Pharmaceuticals, Plot No.129, Sunder Industrial Estate (P.I.E) Raiwind Road, Lahore.	Albamit-2500 Bolus Each bolus contains:- Albendazole BP……2500mg (Anthelmintic) Finished product specifications are Manufacturer.	Decontrolled\ pack size 2 x 5's Boli Blister Pack 50 Bolus per packet	1.Form-5 2.03-01-2014 Dy. No.24 3.03-01-2014 Rs.20,000/-	1. Albenol 2500 Bolus present internationally 2. Albensel-2500 bolus 3. Firm was inspected on 26-11-2013 for grant of DML by Formulation.	Approved
350.	M/s. Wimits Pharmaceuticals, Plot No.129, Sunder Industrial Estate (P.I.E) Raiwind Road, Lahore.	Fenbal-Bolus Each bolus contains:- Fenbendazole BP…750mg (Anthelmintic) Finished product	Decontrolled\ pack size 2 x 5's Boli Blister Pack 50 Bolus per packet	1.Form-5 2.03-01-2014 3.03-01-2014 Dy. No.25 Rs.20,000/-	1. Not found in reference drug agencies, however, Fenbendazole 750 mg Bolus is available in India	Approved

		specifications are Manufacturer			2. Fenbal Bolus 3. Firm was inspected on 26-11-2013 for grant of DML by Formulation.	
351.	M/s. Wimits Pharmaceuticals, Plot No.129, Sunder Industrial Estate (P.I.E) Raiwind Road, Lahore.	Levacloz Bolus Each bolus contains:- Oxyclozanide BP……2250mg Levamisole BP……1125mg (Anthelmintic) Finished product specifications are Manufacturer	Decontrolled\ pack size 2 x 5's Boli Blister Pack 50 Bolus per packet	1.Form-5 2.03-01-2014 Dy. No.26 3.03-01-2014 Rs.20,000/-	1. Not found in reference drug agencies, however, Oxyclozanide + Levamisole 3400mg tablets present in China. 2. Helmex Plus Bolus 3. Firm was inspected on 26-11-2013 for grant of DML by Formulation.	Approved
352.	M/s. Wimits Pharmaceuticals, Plot No.129, Sunder Industrial Estate (P.I.E) Raiwind Road, Lahore.	Levatoll-Bolus Each bolus contains:- Levamisole HCI BP……1125mg (Anthelmintic) Finished product specifications are Manufacturer	Decontrolled\ pack size 2 x 5's Boli Blister Pack 50 Bolus per packet	1.Form-5 2.03-01-2014 Dy. No.27 3.03-01-2014 Rs.20,000/-	1. FDA approved Levamisole Bolus in strengths of 0.184 g & 2.19 g, however, Levamisole bolus 1000 mg available in China. 2. Levasel Bolus 3. Firm was inspected on 26-11-2013 for grant of DML by Formulation.	Approved

353.	M/s. Wimits Pharmaceuticals, Plot No.129, Sunder Industrial Estate (P.I.E) Raiwind Road, Lahore.	Closamit-500 Bolus Each bolus contains:- Closantel BP……..500mg (Anthelmintic) Finished product specifications are Manufacturer.	Decontrolled\ pack size 2 x 5's Boli Blister Pack 50 Bolus per packet	1.Form-5 2.03-01-2014 Dy. No.28 3.03-01-2014 Rs.20,000/-	1. Not found in reference drug agencies, however, Closantel Bolus 500mg present in Iran, India. 2. Flukinil Bolus 3. Firm was inspected on 26-11-2013 for grant of DML by Formulation.	Approved
354.	M/s. Wimits Pharmaceuticals, Plot No.129, Sunder Industrial Estate (P.I.E) Raiwind Road, Lahore.	Trizine-Bolus Each bolus contains:- Trimethoprim BP……200mg Sulphadiazine USP….1000mg (Antibiotic) Finished product specifications are Manufacturer.	Decontrolled\ pack size 2 x 5's Boli Blister Pack 50 Bolus per packet	1.Form-5 2.03-01-2014 Dy. No.29 3.03-01-2014 Rs.20,000/-	1. FDA approved Trimethoprim & Sulphadiazine in strengths of 5 mg + 25 mg, 20 mg + 100 mg, 80 mg + 400 mg, 160 mg + 800 mg, however; bolus containing Trimethoprim 200 mg + Sulphadiazine 1 g is present internationally. 2. Tridin Bolus 3. Firm was inspected on 26-11-2013 for grant of DML by Formulation.	Approved

355.	M/s. Wimits Pharmaceuticals, Plot No.129, Sunder Industrial Estate (P.I.E) Raiwind Road, Lahore.	Albamit-152 Bolus Each bolus contains:- Albendazole BP ……152mg (Anthelmintic) Finished product specifications are Manufacturer	Decontrolled\ pack size 2 x 5's Boli Blister Pack 50 Bolus per packet	1.Form-5 2.03-01-2014 Dy. No.30 3.03-01-2014 Rs.20,000/-	1. Not found in reference drug agencies, however, Albendazole 152 mg available in Iran. 2. Albensel S bolus 3. Firm was inspected on 26-11-2013 for grant of DML by Formulation.	Approved
356.	M/s. Wimits Pharmaceuticals, Plot No.129, Sunder Industrial Estate (P.I.E) Raiwind Road, Lahore.	Albamit-600 Bolus Each bolus contains:- Albendazole BP 600mg (Anthelmintic) Finished product specifications are Manufacturer	Decontrolled\ pack size 2 x 5's Boli Blister Pack 50 Bolus per packet	1.Form-5 2.03-01-2014 Dy. No.31 3.03-01-2014 Rs.20,000/-	1. Not found in reference drug agencies, however, Albendazole Bolus 600mg present in India. 2. Albensel C bolus 3. Firm was inspected on 26-11-2013 for grant of DML by Formulation.	Approved
357.	M/s. Wimits Pharmaceuticals, Plot No.129, Sunder Industrial Estate (P.I.E) Raiwind Road, Lahore.	Co-Flor Liquid Liquid Each 100ml contains:- Florfenicol (CVP)....10gm Colistin Sulphate (BP)…2.50gm (Antibiotic) Finished product specifications are Manufacturer.	Decontrolled\ pack size 100ml 500ml 1000ml	1.Form-5 2.03-01-2014 Dy. No.32 3.03-01-2014 Rs.20,000/-	1. Not found in reference drug agencies, however, Florfenicol 10% Liquid is present internationally 2. Floro C Liquid 3. Firm was inspected on 26-11-2013 for grant of	Approved

					DML by Formulation.	
358.	M/s. Wimits Pharmaceuticals, Plot No.129, Sunder Industrial Estate (P.I.E) Raiwind Road, Lahore.	Oxamit-Drench Each ml contains:- Oxfendazole BP…….22.65mg (Anthelmintic) Finished product specifications are BP.	Decontrolled\ pack size 100ml 500ml 1000ml	1.Form-5 2.03-01-2014 Dy. No.33 3.03-01-2014 Rs.20,000/-	1. Synanthin Suspension 2. Oxfendacon liquid suspension 3. Firm was inspected on 26-11-2013 for grant of DML by Formulation.	Approved
359.	M/s. Wimits Pharmaceuticals, Plot No.129, Sunder Industrial Estate (P.I.E) Raiwind Road, Lahore.	Clozasol-Drench Each 100ml contains:- Levamisole HCI BP……1.50gm Oxyclozanide BP….3.00gm (Anthelmintic) Finished product specifications are Manufacturing	Decontrolled\ pack size 100ml 500ml 1000ml	1.Form-5 2.03-01-2014 Dy. No.34 3.03-01-2014 Rs.20,000/-	1. Not found in reference drug agencies, however, Levamisole + Oxyclozanide Drench is available in France, UK, India 2. Nayzan Drench 3. Firm was inspected on 26-11-2013 for grant of DML by Formulation.	Approved
360.	M/s. Wimits Pharmaceuticals, Plot No.129, Sunder Industrial Estate (P.I.E) Raiwind Road, Lahore.	Triclamex-Drench Each ml contains:- Triclabendazole……..50 mg Levamisole HCI BP……..37.50mg	Decontrolled\ pack size 100ml 500ml 1000ml	1.Form-5 2.03-01-2014 Dy. No.35 3.03-01-2014 Rs.20,000/-	1. Not found in reference drug agencies in same strength, however, Levamisole + Triclabendazole in	Approved

		(Anthelmintic) Finished product specifications are Manufacturer.			oral liquid, present internationally. 2. Trizole 8.75% oral suspension 3. Firm was inspected on 26-11-2013 for grant of DML by Formulation.	
361.	M/s. Wimits Pharmaceuticals, Plot No.129, Sunder Industrial Estate (P.I.E) Raiwind Road, Lahore.	Oxycloz-Drench Each ml contains:- Oxfendazole BP……22.65mg Oxyclozanide BP…….62.50mg (Anthelmintic) Finished product specifications are Manufacturer	Decontrolled\ pack size 100ml 500ml 1000ml	1.Form-5 2.03-01-2014 Dy. No.36 3.03-01-2014 Rs.20,000/-	1. EMA recommended formulation i.e. Oxfendazole + Oxyclozanide drench 2. Oxarex Drench 3. Firm was inspected on 26-11-2013 for grant of DML by way of formulation	Approved
362.	M/s. Wimits Pharmaceuticals, Plot No.129, Sunder Industrial Estate (P.I.E) Raiwind Road, Lahore.	Femicol Liquid Oral Liquid Each 100ml contains:- Florfenicol…23g (Antibiotic) Finished product specifications are Manufacturer	Decontrolled\ pack size 100ml 500ml 1000ml	1.Form-5 2.03-01-2014 Dy. No.37 3.03-01-2014 Rs.20,000/-	1. Not found in reference drug agencies in same strength, however, Florfenicol 23% oral solution is present internationally. 2. Baflor-23 oral solution 3. Firm was inspected on 26-11-	Approved (with change in brand name)

					2013 for grant of DML by Formulation.	
363.	M/s. Wimits Pharmaceuticals, Plot No.129, Sunder Industrial Estate (P.I.E) Raiwind Road, Lahore.	Enrolist Liquid Oral Liquid Each 100ml contains:- Enrofloxacin (BP)……20gm Colistin Sulphate (BP)……2.50gm (Antibiotic) Finished product specifications are Manufacturer.	Decontrolled\ pack size 100ml 500ml 1000ml	1.Form-5 2.03-01-2014 Dy. No.38 3.03-01-2014 Rs.20,000/-	1. Not found in reference drug agencies, however, Enrofloxacin 10g/100ml + Colistin sulfate 1200,000 IU/100ml available in Netherlands. 2. Floxa-C oral liquid 3. Firm was inspected on 26-11-2013 for grant of DML by Formulation.	Approved
364.	M/s. Wimits Pharmaceuticals, Plot No.129, Sunder Industrial Estate (P.I.E) Raiwind Road, Lahore.	Levamit-Drench Each ml contains:- Levamisole Hydrochloride (BP)…..1.5% W/V 15mg (Anthelmintic) Finished product specifications are BP.	Decontrolled\ pack size 100ml 500ml 1000ml	1.Form-5 2.03-01-2014 Dy. No.39 3.03-01-2014 Rs.20,000/-	1. Same strength not found in reference drug agencies, however, FDA approved Levamisole Liquid. 2. Levacon Drench 3. Firm was inspected on 26-11-2013 for grant of DML by Formulation.	Approved

365.	M/s. Wimits Pharmaceuticals, Plot No.129, Sunder Industrial Estate (P.I.E) Raiwind Road, Lahore.	Albatop-10% Drench Each ml contains:- Albendazole (BP)….100mg/ml (Anthelmintic) Finished product specifications are BP.	Decontrolled\ pack size 100ml 500ml 1000ml	1.Form-5 2.03-01-2014 Dy. No.40 3.03-01-2014 Rs.20,000/-	1. Valbazen 2. Albacon 10% oral suspension 3. Firm was inspected on 26-11-2013 for grant of DML by Formulation.	Approved
366.	M/s. Wimits Pharmaceuticals, Plot No.129, Sunder Industrial Estate (P.I.E) Raiwind Road, Lahore.	Anthalex Drench Oral Suspension Each ml contains:- Albendazole BP…….100mg Triclabendazole 120mg Ivermectin BP…….2.0mg (Anthelmintic) Finished product specifications are Manufacturer.	Decontrolled\ pack size 100ml 500ml 1000ml	1.Form-5 2.10-01-2014 Dy. No.46 3.10-01-2014 Rs.20,000/-	1. Not found in reference drug agencies, however, Albendazole + Ivermectin in combination present internationally. 2. Thunder Drench 3. Firm was inspected on 26-11-2013 for grant of DML by Formulation.	Approved
367.	M/s. Wimits Pharmaceuticals, Plot No.129, Sunder Industrial Estate (P.I.E) Raiwind Road, Lahore.	Oxygaurad-G SPRAY Topical Spray Each gm contains:- Oxytetracycline HCI (BP)……40mg Gentian Violet (BP)…….04mg (Tetracycline Antibiotic) Finished product specifications are Manufacturer	Decontrolled\ pack size 100ml 150ml 200ml	1.Form-5 2.10-01-2014 Dy. No.43 3.10-01-2014 Rs.20,000/-	1. Not found in reference drug agencies, however, spray containing Oxytetracycline+ Gentian violet in combination present internationally. 2. Teragen Aerosol Spray 3. Firm was inspected on 26-11-	Approved

					2013 for grant of DML by Formulation.	
368.	M/s. Wimits Pharmaceuticals, Plot No.129, Sunder Industrial Estate (P.I.E) Raiwind Road, Lahore.	Stop Spray Topical Spray Each 100ml of aerosol contains Deltamethrin BP 0.500g (Insecticide) Finished product specifications are Manufacturer.	Decontrolled\ pack size 100ml 150ml 200ml aerosol package	1.Form-5 D 2.21-03-2014 Dy. No.43 3.21-03-2014 Rs.50,000/-	1. Not found in reference drug agencies but present in India as Loc Chalk Spray 0.5% 2. New drug 3. Firm was inspected on 26-11-2013 for grant of DML by Formulation..	Deferred for expert opinion.
369.	M/s. Wimits Pharmaceuticals, Plot No.129, Sunder Industrial Estate (P.I.E) Raiwind Road, Lahore.	Defender Spray Topical Spray Each 30g of aerosol contains Neomycin Sulfate BP 150mg Clostebol Acetate 150 mg (Antiseptic & Dermatological Healer) Finished product specifications are Manufacturer.	Decontrolled\ pack size 100ml 150ml 200ml aerosol package	1.Form-5 D 2.21-03-2014 Dy. No.43 3.21-03-2014 Rs.50,000/-	1. Not found in reference drug agencies but present in Europe as Neo-Sept Spray 2. New drug 3. Firm was inspected on 26-11-2013 for grant of DML by Formulation.	Deferred for expert opinion.
370.	M/s. Wimits Pharmaceuticals, Plot No.129, Sunder Industrial Estate (P.I.E) Raiwind Road, Lahore.	Methra Spray Topical Spray Each 100ml of aerosol contains Permethrin 0.5 g (Insecticide) Finished product specifications are Manufacturer.	Decontrolled\ pack size 100ml 150ml 200ml aerosol package	1.Form-5 D 2.21-03-2014 Dy. No.43 3.21-03-2014 Rs.50,000/-	1. Not found in reference drug agencies but Repel-35 RTU 0.5% being manufactured by BioDerm Laboratories, USA. 2. New drug	Deferred for expert opinion.

					3. Firm was inspected on 26-11-2013 for grant of DML by Formulation.	
371.	M/s. Wimits Pharmaceuticals, Plot No.129, Sunder Industrial Estate (P.I.E) Raiwind Road, Lahore.	TETRA-C SPRAY Topical Spray Each ml contains:- Chlortetracycline Hydrochloride (BP)…995.3mg (Tetracycline Antibiotic) Finished product specifications are Manufacturer.	Decontrolled\ pack size 100ml 150ml 200ml	1.Form-5 2.10-01-2014 Dy. No.44 3.10-01-2014 Rs.20,000/-	1. Chlortetracycline HCL spray available internationally 2. CTC Spray 3. Firm was inspected on 26-11-2013 for grant of DML by way of formulation	Approved
372.	M/s. Wimits Pharmaceuticals, Plot No.129, Sunder Industrial Estate (P.I.E) Raiwind Road, Lahore.	CRYSTAL-S SPRAY Topical Spray Each ml contains:- **Chloramphenicol**…50mg Cetrinide…10mg Dimethy Phathalate…10mg Crystal Violet…5mg (Antibiotic, Antiseptic, Ectoparasiticide, Antiseptic dye.) Finished product specifications are Manufacturer.	Decontrolled\ pack size 100ml 150ml 200ml	1.Form-5 2.10-01-2014 Dy. No.45 3.10-01-2014 Rs.20,000/-	1. Not found in reference drug agencies, however, Chloramphenicol spray available in Germany 2. Pink Spray 3. Firm was inspected on 26-11-2013 for grant of DML by Formulation.	Deferred for PSI by director DTL Lahore and FID
373.	M/s. Wimits Pharmaceuticals,	HEALER SPRAY Topical Spray	Decontrolled\ pack size	1.Form-5 2.10-01-2014	1. Not found in reference drug	Rejected as the firm has no steroid

	Plot No.129, Sunder Industrial Estate (P.I.E) Raiwind Road, Lahore.	Each ml contains:- Oxytetracycline HCI (BP)……..5mg **Hydrocortisone** (BP)……1.6mg (Tetracycline Antibiotic, Corticosteroid) Finished product specifications are Manufacturer.	100ml 150ml 200ml	Dy. No.46 3.10-01-2014 Rs.20,000/-	agencies, however, Oxytetracycline + Hydrocortisone spray in combination present internationally 2.Oxycort Spray 3. Firm was inspected on 26-11-2013 for grant of DML by Formulation. Firm applied for product containing steroid while firm has no steroidal manufacturing facility.	manufacturing facility.
374.	M/s. Wimits Pharmaceuticals, Plot No.129, Sunder Industrial Estate (P.I.E) Raiwind Road, Lahore.	Ratadine 5mg Tablet Each film coated tablet contains Desloratadine 5 mg (Antihistamine) Finished product specifications are Manufacturer.	Alu Alu blister 10's Rs 140/- per pack Rs 14/- per tablet	1.Form-5 2.13-03-2014 Dy. No.411 3.13-03-2014 Rs.20,000/-	1. **Clarinex tablet 5mg** 2. Destina tablet 3. Firm was inspected on 26-11-2013 for grant of DML by Formulation.	Duplicate entry Ratadine 5mg tablet has already been discussed at Sr No. 9
375.	M/s. Wimits Pharmaceuticals, Plot No.129, Sunder Industrial Estate (P.I.E) Raiwind Road,	Ratadine Syrup Each ml contains Desloratadine 0.5 mg (Antihistamine) Finished product	60ml Rs 80/- per pack	1.Form-5 2.13-03-2014 Dy. No.412 3.13-03-2014 Rs.20,000/-	1. **Clarinex syrup 0.5mg/ml** 2. Delergia Syrup 0.5mg/ml 3. Firm was	Duplicate entry Ratadine 5mg tablet has already been discussed at Sr No. 30

	Lahore.	specifications are Manufacturer.			inspected on 26-11-2013 for grant of DML by Formulation.	

Evaluator – V

376.	M/s. Stallion Pharmaceuticals (Pvt) Ltd, 581- Sunder Industrial Estate, Lahore **New License** 1.Capsule.(Penicillin) 2.Dry Powder Suspension (Penicillin) 3.Dry Powder Injection (Penicillin) Vide letter No. F. 1-33/2009 – Lic dated 6th February, 2014	**Stamentin Suspension 156.25mg (B.P)** Dry Suspension Each 5ml contains:- Amoxicillin Trihydrate (BP) equivalent to Amoxicillin…..125mg Potassium clavulanate (BP) equivalent to Clavulanic acid …….. 31.25mg (Penicillin) BP Specifications	Rs.80.50 / 60ml Rs.120.75 / 90ml, Rs.134.17 / 100ml, Rs. 161 / 120ml	Form-5 25-10-2013 638 R&I Rs. 20,000/-	AUGMENTIN 125 / 31.25mg /5ml Dry Powder Suspension USFDA AUGMENTIN 125 / 31.25mg /5ml Gsk N/A (New License)	Approved
377.	-do-	**Stamentin DS Suspension 312.5 mg (B.P)** Dry Suspension Each 5ml contains:- Amoxicillin Trihydrate (BP) equivalent to Amoxicillin…..250mg Potassium clavulanate (BP) equivalent to Clavulanic acid …..62.500mg (Penicillin) BP Specifications	Rs.125.35 / 60ml Rs.188 / 90ml, Rs.209 / 100ml, Rs.250.70 / 120ml	Form-5 25-10-2013 629 R&I Rs. 20,000/-	AUGMENTIN 250 / 62.5mg /5ml Dry Powder Suspension USFDA AUGMENTIN 250 / 62.5mg /5ml Gsk N/A (New License)	Approved
378.	-do-	**Stamentin DUO Suspension**	Rs. 100.0	Form-5	APO AMOXI CLAV	Approved

		457mg (B.P) Dry powder suspension Each 5ml contains: Amoxicillin Trihydrate B.P eq. to Amoxicillin……400.00mg Potassium Clavulanate (BP) eq. to Clavulanic acid ……. 57.00mg (Penicillin) BP Specifications	/35ml, Rs. 200.0 / 70ml, Rs. 400.0 / 140ml	25-10-2013 622 R&I Rs. 20,000/-	400 / 57mg /5ml Dry Powder Suspension Health Canada AUGMENTIN BD 400 / 57mg /5ml Gsk N/A (New License)	
379.	-do-	**Stamentin Oral Drops (BP)** Dry powder Each ml contains: AmoxicillinTrihydrate (BP) eq. to Amoxicillin……..50.00mg Potassium Clavulanate (BP) eq. to Clavulanic acid……..12.5mg (Penicillin) BP Specifications	Rs. 75.0 / 10ml, Rs. 150.0 / 20ml	Form-5 25-10-2013 637 R&I Rs. 20,000/-	Augmentin Drops 50 / 12.5 mg per ml For infants GSK GmbH EMA FORTECIN 50 / 12.5mg /ml Cirin N/A (New License)	Approved
380.	-do-	**Amoxi Suspension 125mg (BP)** Dry powder suspension Each 5ml contains: Amoxicillin Trihydrate (BP) eq. to Amoxicillin……125mg (Penicillin)	Rs. 50.0 / 60ml, Rs. 75.0 / 90 ml, Rs. 100.0 / 120ml	Form-5 25-10-2013 631 R&I Rs. 20,000/-	AMOXIL 125mg /5ml Powder for oral suspension Dr. Reddy's Labs US FDA AMOXIL 125mg /5ml Gsk	Approved

		BP Specifications			N/A (New License)	
381.	-do-	**Amoxi Suspension 250mg (BP)** Dry powder suspension Each 5ml contains: Amoxicillin Trihydrate (BP) eq. to Amoxicillin……250 mg (Penicillin) BP Specifications	Rs. 66.0 / 60ml, Rs. 99.0 / 90ml, Rs. 132.0 / 120ml	Form-5 25-10-2013 646 R&I Rs. 20,000/-	AMOXIL 250mg /5ml Powder for oral suspension Dr. Reddy's Labs US FDA AMOXIL 250mg /5ml Gsk N/A (New License)	Approved
382.	-do-	**Ampi Suspension 125mg (BP)** Dry powder suspension Each 5 ml contains:- Ampicillin Trihydrate (BP) eq. to Ampicillin ……. 125mg (Penicillin) Manufacturers' Specifications	Rs. 37.0/60, Rs. 55.50/90ml, Rs. 74.0/120ml	Form-5 25-10-2013 630 R&I Rs. 20,000/-	PENBRITIN 125mg /5ml MHRA PENBRITIN 125mg /5ml Gsk N/A (New License)	Approved
383.	-do-	**Flumox Suspension 250mg (Stallion Specs.)** Dry powder suspension Each 5ml contains: Amoxicillin Trihydrate (BP) eq. to Amoxicillin ……125mg Flucloxacillin Sodium (BP) eq. to Flucloxacillin .....…125 mg	Rs. 63.0 / 45ml Rs. 84.0 / 60ml, Rs. 126.0 / 90ml, Rs. 168.0 / 120ml	Form-5 25-10-2013 648 R&I Rs. 20,000/-	Firm has provided following evidences of international availability: Suprapen S (Syrup) SmithKline Beecham Johannesburg Flamox Oral Suspension Cosmos Limited Kenya	Approved

		(Penicillin) Manufacturers' Specifications			Ultrapen Suspension Aleppo Pharmaceuticals Industries, LLC, Syria FLAMOXINE Suspension NCPI, Syria FLUMOXIPEN 125 / 125mg /5ml Lisko, Pakistan	
384.	-do-	**Staclox Oral Drops (Stallion Specs.)** Dry powder Each 0.6 ml (after reconstitution) contains: Ampicillin Trihydrate (BP) eq. to Ampicillin ……60 mg Cloxacillin Sodium (BP) eq. to Cloxacillin …… 30 mg (Penicillin) Manufacturers' Specifications	Rs. 35.0 / 8ml, Rs. 80.0 / 20ml, Rs. 120.0 / 30ml	Form-5 25-10-2013 649 R&I Rs. 20,000/-	Firm has provided following evidences of international availability: Ampiclox D SmithKline Beecham Cape Town Cosmiclox Neonatal Oral Drops Nairobi, Kenya Ampiclox Oral Drops Beecham Pharmaceuticals, Singapore AMPICLOX 60 / 30mg /0.6ml Gsk	Approved
385.	-do-	**Staclox Suspension 250mg**	Rs. 46.0 /	Form-5	Firm has provided	Approved

		(Stallion Specs.) Dry powder suspension Each 5ml contains: Ampicillin Trihydrate (BP) eq. to Ampicillin ……125mg Cloxacillin Sodium (BP) eq. to Cloxacillin ……125 mg Manufacturers' Specifications	60ml, Rs. 69.0 / 90ml, Rs. 92.0 / 120ml	25-10-2013 650 R&I Rs. 20,000/-	following evidences of international availability: Cosmiclox Dry Suspension Nairobi, Kenya Amicloxan 250mg Oral Suspension Barakat Pharmaceutical Industries Syria Ampiclox S (Syrup) SmithKline Beecham Pharmaceuticals Cape Town AMPICLOX 125 / 125mg /5ml Gsk N/A (New License)	
386.	-do-	**Ticin Injection (USP)** Dry Powder Injection Each Vial Contains: Ticarcillin Disodium (USP) eq. to Ticarcillin …….... 3000mg Clavulanate Potassium (USP) eq. to Clavulanic acid …….. 200mg	Rs. 1050.0 / 1's, Rs. 4200.0' / 4's Rs. 10,500.0 / 10's	Form -5 31-12-2013 1347 R&I Rs. 20,000/-	TIMENTIN 3.2g Vial MHRA TIMENTIN 3.2g GSK, Pakistan N/A (New License)	Approved

		(Penicillin) USP Specifications				
387.	-do-	**Stamentin Injection 600mg (BP)** Dry Powder Injection Each Vial Contains: Amoxicillin Sodium (BP) eq. to Amoxicillin … 500 mg Potassium Clavulanate (BP) eq. to Clavulanic acid …….. 100 mg (Penicillin) BP Specifications	Rs. 115.0/1's, Rs. 1150.0/10's	Form-5 25-10-2013 627 R&I Rs. 20,000/-	Co amoxiclav 500/100mg powder for solution for injection. MHRA AMOXICLAV 500/100mg Vial Novartis, Pakistan N/A (New License)	Approved
388.	-do-	**Stamentin Injection 1.2gm (BP)** Dry Powder Injection Each Vial Contains: Amoxicillin Sodium (BP) eq. to Amoxicillin …1000 mg Potassium Clavulanate (BP) eq. to Clavulanic acid …….. 200 mg (Penicillin) BP Specifications	Rs. 196.0/1's, Rs. 1960.0/10's	Form-5 25-10-2013 644 R&I Rs. 20,000/-	Co amoxiclav 1000/200mg powder for solution for injection. MHRA AMOXICLAV 1000/200mg Vial Novartis, Pakistan N/A (New License)	Approved
389.	-do-	**Tazobac Injection 2.25gm (USP)** Dry Powder Injection Each Vial Contains: Piperacillin Sodium (USP) eq. to Piperacillin …… 2.0gm Tazobactam Sodium (MS) eq.	Rs. 523.0 / 1's, Rs. 5300.0 / 10's	Form-5 25-10-2013 628 R&I Rs. 20,000/-	ZOSYN 2.25 g US FDA TAZOP 2 / 0.25g Vial Global Pharma N/A (New License)	Approved

		to Tazobactam …… 0.250gm (Penicillin) USP Specifications				
390.	-do-	**Tazobac Injection 4.5gm (USP)** Dry Powder Injection Each Vial Contains: Piperacillin Sodium USP eq. to Piperacillin …… 4.0gm Tazobactam Sodium USP eq. to Tazobactam…… 0.50gm (Penicillin) USP Specifications	Rs. 1046.0/1's, Rs. 10460.0/10's	Form-5 25-10-2013 633 R&I Rs. 20,000/-	ZOSYN 4.5 g US FDA Tazocin 4 / 0.5g Vial Pfizer, Pakistan N/A (New License)	Approved
391.	-do-	**Meropen Injection 500mg (USP)** Dry Powder Injection Each vial contains: Meropenem (USP)…500mg (Penicillin) USP Specifications	Rs. 1230.0/1's, Rs. 12300.0/10's	Form-5 25-10-2013 645 R&I Rs. 20,000/-	MERREM 500 mg US FDA Meronem 500 mg ICI Pakistan N/A (New License)	Deferred for confirmation of manufacturing facility
392.	-do-	**Meropen Injection 1gm (USP)** Dry Powder Injection Each vial contains: Meropenem (USP)…1gm (Penicillin) USP Specifications	Rs. 2300.0/1's, Rs. 23000.0/10's	Form-5 25-10-2013 636 R&I Rs. 20,000/-	MERREM 1 g US FDA Meronem 1 g ICI Pakistan N/A (New License)	Deferred for confirmation of manufacturing facility

393.	-do-	**Primaxin Injection (USP)** Dry Powder Injection Each Vial contains: Imipenem (BP)……500mg Cilastatin Sodium (BP) eq. to Cilastatin ……500mg (Penicillin) USP Specifications	Rs. 1230.0/1's, Rs. 12300.0/10's	Form-5 25-10-2013 632 R&I Rs. 20,000/-	PRIMAXIN IV 500 / 500 mg Vial US FDA STANEM 500 / 500 mg Cirin Pharma N/A (New License)	Deferred for confirmation of manufacturing facility
394.	-do-	**Sulbicin Injection (Stallion Specs.)** Dry Powder Injection Each Vial Contains: Piperacillin Sodium (USP) equivalent to Piperacillin……..…4gm Sulbactam Sodium (BP) eq.t to Sulbactam……..2gm (Penicillin) Manufacturers' Specifications	Rs. 650.0/1's, Rs. 6500.0/10's	Form-5 25-10-2013 641 R&I Rs. 20,000/-	COMBICIN 4 / 2g lyophilized powder per vial Mission Pharmaceuticals, Karachi (Manufactured by Samsung Pharm, Korea)	Approved
395.	-do-	**Erapen Injection 1 g (Stallion Specs)** Dry powder injection Each vial contains: Ertapenem Sodium (Manufacturers specs) eq. to Ertapenem …… 1 g (Penicillin) Manufacturers' Specifications	Rs. 3,500/- 1's Rs. 35,000/- 10's	Form-5 17-03-2014 450 R&I Rs,20,000/-	INVANZ 1 g US FDA INVANZ 1 g OBS N/A (New License)	Deferred for confirmation of manufacturing facility

396.	-do-	**Amoxi Capsule 250mg (BP)** Capsule Each Capsule contains: Amoxicillin Trihydrate (BP) eq. to Amoxicillin……250mg (Penicillin) BP Specifications	Rs. 80.0/20's, Rs. 400.0/100's, Rs. 800.0/200's, Rs. 4000.0/1000's	Form-5 25-10-2013 623 R&I Rs. 20,000/-	AMOXIL 250 mg US FDA AMOXIL 250 mg Gsk N/A (New License)	Approved
397.	-do-	**Amoxi Capsule 500mg (BP)** Capsule Each Capsule contains: Amoxicillin Trihydrate (BP) eq. to Amoxicillin……500mg (Penicillin) BP Specifications	Rs. 172.0 / 20's, Rs. 860.0 / 100's, Rs. 1720 / 200's, Rs. 8600.0 / 1000's	Form-5 25-10-2013 647 R&I Rs. 20,000/-	AMOXIL 500 mg US FDA AMOXIL 500 mg Gsk N/A (New License)	Approved
398.	-do-	**Fluclox Capsule 250mg (B.P)** Capsule Each Capsule contains: Flucloxacillin Sodium BP eq. to Flucloxacillin …… 250mg	Rs. 152.0/20's, Rs. 760.0/100's, Rs. 1520.0/200's, Rs. 7600.0/1000's	Form-5 25-10-2013 642 R&I Rs. 20,000/-	FLOPEN 250 mg TGA A-FLOX 250 mg Acme Laboratories N/A (New License)	Approved

		(Penicillin) BP Specifications				
399.	-do-	**Fluclox Capsule 500mg (B.P)** Capsule Each Capsule contains: Flucloxacillin Sodium (BP) eq. to Flucloxacillin …… 500mg (Penicillin) BP Specifications	Rs. 234.0/20's, Rs. 1170.0/100's, Rs. 2340.0/200's, Rs. 11,700/1000's	Form-5 25-10-2013 626 R&I Rs. 20,000/-	FLOPEN 500 mg TGA A-FLOX 500 mg Acme Laboratories N/A (New License)	Approved
400.	-do-	**Ampi Capsule 250mg (BP)** Capsule Each capsule contains:- Ampicillin Trihydrate (BP) eq. to Ampicillin ……250mg (Penicillin) BP Specifications	Rs. 100.0/20's, Rs. 500.0/100's, Rs. 1000.0/200's, Rs. 5000.0/1000's	Form-5 25-10-2013 624 R&I Rs. 20,000/-	ALPHACIN 250 mg TGA OMNIPEN 250 mg Pfizer N/A (New License)	Approved
401.	-do-	**Ampi Capsule 500mg (BP)** Capsule Each capsule contains:- Ampicillin Trihydrate (BP) eq. to Ampicillin …….. 500mg (Penicillin)	Rs. 200.0/20's, Rs. 1,000.0 /100's, Rs. 2,000.0/200's, Rs. 10,000/1000's	Form-5 25-10-2013 640 R&I Rs. 20,000/-	ALPHACIN 500 mg TGA OMNIPEN 500 mg Pfizer N/A (New License)	Approved

		BP Specifications				
402.	-do-	**Staclox Capsule 250mg (B.P)** Capsule Each Capsule contains: Ampicillin Trihydrate (BP) eq. to Ampicillin……125mg Cloxacillin Sodium (BP) eq. to Cloxacillin…. 125mg (Penicillin) B.P Specifications	Rs. 60.0/20's, Rs. 300.0/100's, Rs. 600.0/200's, Rs. 3000.0/1000's	Form-5 25-10-2013 625 R&I Rs. 20,000/-	Firm has provided following evidences of international availability: Gaclox 250 Capsules Rugal Pharmaceutical Limited, Nigeria. Anclox-LB 125 Capsules Nootan Pharmaceuticals. India AMPICLOX 125 / 125 mg Gsk, Pakistan N/A (New License)	Approved
403.	-do-	**Staclox Capsule 500mg (B.P)** Capsule Each Capsule contains: Ampicillin Trihydrate (BP) eq. to Ampicillin……250mg Cloxacillin Sodium (BP) eq. to Cloxacillin…. 250mg	Rs. 120.0/20's, Rs. 600.0/100's, Rs. 1200.0/200's, Rs. 6000.0/1000's	Form-5 25-10-2013 634 R&I Rs. 20,000/-	Firm has provided following evidences of international availability: Ampiclox 500 Capsules SmithKline Beecham Pharmaceuticals Cape Town	Approved

		(Penicillin) B.P Specifications			Cosmiclox Capsules 500mg Cosmos Limited, Nairobi, Kenya AMPICLOX 250 / 250 mg Gsk N/A (New License)	
404.	-do-	**Flumox Capsule 250mg (Stallion Specs.)** Capsule Each Capsule contains: Amoxicillin Trihydrate (BP) eq. to Amoxicillin……125mg Flucloxacillin Sodium (BP) eq. to Flucloxacillin ..…. 125mg (Penicillin) Manufacturers' Specifications	Rs.152.0/20's, Rs. 760.0/100's, Rs. 1,520/200's, Rs. 7,600/1000's	Form-5 25-10-2013 635 R&I Rs. 20,000/-	Firm has provided following evidences of international availability: Flucamox 250mg Capsules Sedico Pharmaceutical Company, Egypt FLUMOX 250 EIPICO, Egypt FLUMOXIPEN 125 / 125mg Capsules Lisko N/A (New License)	Approved
405.	-do-	**Flumox Capsule 500mg (Stallion Specs.)**	Rs. 300.0/20's, Rs.	Form-5	Firm has provided following evidences	Approved

		Capsule Each Capsule contains: Amoxicillin Trihydrate (BP) eq. to Amoxicillin……250mg Flucloxacillin Sodium (BP) eq. to Flucloxacillin ..…… 250mg (Penicillin) Manufacturers' Specifications	1,500.0/100's, Rs. 3,000.0/200's, Rs. 15,000/1000's	25-10-2013 639 R&I Rs. 20,000/-	of international availability: FLUMOX 500 Dr. Wolff Germany Suprapen 500 Capsules SmithKline Beecham Pharmaceuticals, Johannesburg Ultrapen 500mg Capsules Aleppo Pharmaceuticals Industries, LLC, Syria Flucamox 500mg Capsules Sedico Pharmaceutical Company, Egypt FLUMOXIPEN 250 / 250mg Capsules Lisko, Pakistan N/A (New License)	

406.	M/s. Wellness Pharmaceuticals (Pvt) Ltd, Plot No. 33 Sunder Industrial Estate, Lahore. **New License: -** 1. Tablet. (general) 2. Capsule (general) 3. Oral Liquid (general) 4. External Preparations Vide letter No. F. 1-51/2004 – Lic dated 7th February, 2014	**Dicwell SR 100mg** Capsule Each Capsule contains:- Diclofenac Sodium USP…100mg Analgesic, Anti-inflammatory Manufacturers' Specifications	As Per SRO (10% less than brand leader) / 2x7's	Form-5 31-07-2013 9402 R&I Rs.20,000/-	RHUMALGAN XL 100mg SR Capsule Sandoz MHRA MOBIKARE 100mg SR Capsules Barrett Hodgson Panel inspection report dated 13/05/2013.	Approved. Letter will be issued after rectification of shortcomings.
407.	-do-	**Vitacin 25mg** Capsule Each Capsule contains:- Acitretin ….25mg vitamin-A derivative Manufacturers' Specifications	As Per SRO (10% less than brand leader) / 1x10's	Form-5 31-07-2013 9406 R&I Rs.20,000/-	NEOTIGASON 25mg Capsule Actavis TGA NEOTIGASON 25mg Capsule Roche Pakistan	Approved. Letter will be issued after rectification of shortcomings.
408.	-do-	**Optadol 50mg** Capsule Each Capsule contains:- Tramadol USP….50mg Opiate analogue Manufacturers' Specifications	As Per SRO (10% less than brand leader) / 10's	Form-5 31-07-2013 9417 R&I Rs.20,000/-	TRAMEDO 50mg Capsule Alphapharm TGA TRAMAL 50mg Capsule Searle	Approved. Letter will be issued after rectification of shortcomings.

409.	-do-	**Myzit 250mg** Capsule Each Capsule contains:- Azithromycin….250mg Antibiotic Manufacturers' Specifications	As Per SRO (10% less than brand leader) / 10's	Form-5 31-07-2013 9418 R&I Rs.20,000/-	ZITHROMAX 250mg (as dihydrate) Capsule Pfizer MHRA AZOMAX 250mg Capsule Novartis	Approved. Letter will be issued after rectification of shortcomings.
410.	-do-	**Myzit 500mg** Capsule Each Capsule contains:- Azithromycin…500mg Antibiotic Manufacturers' Specifications	As Per SRO (10% less than brand leader) /6's	Form-5 31-07-2013 9438 R&I Rs.20,000/-	Internationally available as 500 mg tablet. AZOCAM 500mg Capsule Chas A. Mendoza Panel inspection report dated 13/05/2013.	Referred to review committee for review of formulation
411.	-do-	**Esomet** Capsule Each Capsule contains:- Esomeprazole magnesium….40mg Antipeptic ulcerants Manufacturers' Specifications	As Per SRO (10% less than brand leader) / 2x7's	Form-5 31-07-2013 9426 R&I Rs.20,000/-	NEXIUM 40mg Delayed release Capsule AstraZeneca USFDA NEXUM 40mg Capsule Getz	Approved. Letter will be issued after rectification of shortcomings.

					Panel inspection report dated 13/05/2013.	
412.	-do-	**Esomet** Capsule Each Capsule contains:- Esomeprazole magnesium….20mg Antipeptic ulcerants Manufacturers' Specifications	As Per SRO (10% less than brand leader) / 2x7's	Form-5 31-07-2013 9434 R&I Rs.20,000/-	NEXIUM 20mg Delayed release Capsule AstraZeneca USFDA NEXUM 20mg Capsule Getz Panel inspection report dated 13/05/2013.	Approved. Letter will be issued after rectification of shortcomings.
413.	-do-	**Diarein 50mg** Capsule Each Capsule contains:- Diacerein B.P ….50mg Anthraquinone derivative Manufacturers' Specifications	As Per SRO (10% less than brand leader) /1x10's	Form-5 31-07-2013 9427 R&I Rs.20,000/-	EMA's Pharmacovigellance Risk Assesment Committee (PRAC) has recommended the suspension of diacereine containing medicines across the EU (08/11/2013) DIORA 50mg Capsule Getz	Referred to review committee for review of formulation
414.	-do-	**Oma**	As Per SRO	Form-5	PRILOSEC	Approved. Letter will be

		Capsule Each Capsule contains:- Omeprazole Pellets….20mg Antipeptic ulcerants Manufacturers' Specifications	(10% less than brand leader) / 2x7's	31-07-2013 9429 R&I Rs.20,000/-	20mg Delayed release Capsule AstraZeneca USFDA Risek 20mg Capsule Getz Panel inspection report dated 13/05/2013.	issued after rectification of shortcomings.
415.	-do-	**Oma** Capsule Each Capsule contains:- Omeprazole Pellets….40mg Antipeptic ulcerants Manufacturers' Specifications	As Per SRO (10% less than brand leader) /2x7's	Form-5 31-07-2013 9430 R&I Rs.20,000/-	PRILOSEC 40mg Delayed release Capsule AstraZeneca USFDA Risek 40mg Capsule Getz Panel inspection report dated 13/05/2013.	Approved. Letter will be issued after rectification of shortcomings.
416.	-do-	**Ajma 250mg** Film Coated Tablet Each tablet contains:- Ciprofloxacin as HCl	As Per SRO (10% less than brand leader) /10's	Form-5 31-07-2013 9408 R&I Rs.20,000/-	CIPRO 250mg film coated tablets Bayer USFDA	Approved. Letter will be issued after rectification of shortcomings.

		……...250mg Quinolones / Antibiotic Manufacturers' Specifications			AXCIN 250mg tablet Novartis Panel inspection report dated 13/05/2013.	
417.	-do-	**Ajma 500mg** Tablet Each tablet contains:- Ciprofloxacin as HCl ……....500mg Manufacturers' Specifications	As Per SRO (10% less than brand leader) /10's	Form-5 31-07-2013 9413 R&I Rs.20,000/-	CIPRO 500mg film coated tablets Bayer USFDA AXCIN 500mg tablet Novartis Panel inspection report dated 13/05/2013.	Approved. Letter will be issued after rectification of shortcomings.
418.	-do-	**Indium 10mg** Tablet Each tablet contains:- Domperidone…..10mg Antidopaminergic / Antiemetic Manufacturers' Specifications	As Per SRO (10% less than brand leader) / 10's	Form-5 31-07-2013 9422 R&I Rs.20,000/-	TEVA – DOMEPERIDONE 12.72 mg Domperidone Maleate eq. to 10mg Domperidone Film coated tablets TEVA Health Canada	Approved. Letter will be issued after rectification of shortcomings.

					DOMEL 10mg tablet Barrett Hodgson *The CMDh, a medicines regulatory body representing the EU Member States, endorsed recommendations to restrict the use of Domperidone containing medicines to relieve symptoms of nausea and vomiting, that doses and length of treatment should be restricted and that they should be adjusted carefully by the patient's weight where available for use in children.* Panel inspection report dated 13/05/2013.	
419.	-do-	**IPF** Tablet	As Per SRO (10% less than brand leader) / 2 x 20's	Form-5 31-07-2013 9416 R&I	International availability requires confirmation	Approved. Letter will be issued after rectification of shortcomings.

		Each tablet contains:- Iron (III) hydroxyl polymaltose complex…..100mg Folic Acid…..0.35mg Haematinic Manufacturers' Specifications		Rs.20,000/-	RUBIFER - F 100 / 0.35mg chewable tablet AGP Panel inspection report dated 13/05/2013.	
420.	-do-	**Hayoona** Tablet Each tablet contains:- Escitalopram….10mg Antidepressant Manufacturers' Specifications	As Per SRO (10% less than brand leader) /2 x 7's	Form-5 31-07-2013 9414 R&I Rs.20,000/-	LEXAPRO Escitalopram (as Oxalate) 10mg film coated tablets Lundbeck USFDA CIPRALEX 10mg tablet Lundbeck Panel inspection report dated 13/05/2013.	Approved. Letter will be issued after rectification of shortcomings.
421.	-do-	**Madoon** Tablet Each tablet contains:- Priroxicam BCD USP….20mg Analgesic / Anti Inflammatory	As Per SRO (10% less than brand leader) /2 x 10's	Form-5 31-07-2013 9410 R&I Rs.20,000/-	Brexidol Cheisi BNF NYSA 20mg tablet Getz Pharma Panel inspection	Approved. Letter will be issued after rectification of shortcomings.

		Manufacturers' Specifications			report dated 13/05/2013.	
422.	-do-	**Gallium 320mg** Tablet Each tablet contains:- Gemifloxacin mesylate …….320mg Floroquinolone Manufacturers' Specifications	As Per SRO (10% less than brand leader) /1x7's	Form-5 31-07-2013 9409 R&I Rs.20,000/-	FACTIVE 320mg Film coated tablet Merus Labs US FDA GEMGLOW 320mg tablet Searle Panel inspection report dated 13/05/2013.	Approved. Letter will be issued after rectification of shortcomings.
423.	-do-	**Astatine** Tablet Each tablet contains:- Levofloxacin ….. 250mg Quinolone / Antibiotic Manufacturers' Specifications	As Per SRO (10% less than brand leader) /10's	Form-5 31-07-2013 9433 R&I Rs.20,000/-	LEVAQUIN 250mg film coated tablet Janssen Pharmaceuticals US FDA LEFLOX 250mg tablet Getz Pharma Panel inspection report dated 13/05/2013.	Approved. Letter will be issued after rectification of shortcomings.
424.	-do-	**Astatine**	As Per SRO (10% less than	Form-5	LEVAQUIN 500mg film coated	Approved. Letter will be issued after rectification of

		Tablet Each tablet contains:- Levofloxacin …..500mg Quinolone / Antibiotic Manufacturers' Specifications	brand leader) /10's	31-07-2013 9424 R&I Rs.20,000/-	tablet Janssen Pharmaceuticals US FDA LEFLOX 500mg tablet Getz Pharma Panel inspection report dated 13/05/2013.	shortcomings.
425.	-do-	**Arfaloon** Tablet Each tablet contains:- Montilukast sodium ……..... 10mg Antihistamine HI (Bronchodilator / Anti asthma) Manufacturers' Specifications	As Per SRO (10% less than brand leader) /10's	Form-5 31-07-2013 9426 R&I Rs.20,000/-	SINGULAIR 10mg film coated tablet Merck & Co. US FDA SINGULAIR 10mg tablet MSD Panel inspection report dated 13/05/2013.	Approved. Letter will be issued after rectification of shortcomings.
426.	-do-	**Zuzi** Syrup Each 5ml contains:- Zinc Sulphate …..20mg	As Per SRO (10% less than brand leader) /60ml and 100ml	Form-5 31-07-2013 9423 R&I Rs.20,000/-	International availability requires confirmation. However, WHO recommends zinc supplementation with	Approved. Letter will be issued after rectification of shortcomings.

		Zinc Supplement Manufacturers' Specifications			Zinc tablets and oral solution. ZINKLET 20mg/5ml Syrup Hilton Panel inspection report dated 13/05/2013.	
427.	-do-	**Xinal** Suspension / syrup Each 5ml contains:- Nalidixic Acid…..250mg Quinolone / Antibiotic Manufacturers' Specifications	As Per SRO (10% less than brand leader) /60ml and 120ml	Form-5 31-07-2013 9428 R&I Rs.20,000/-	BNF reference of Uriben 300mg/5ml suspension provided. However, 250mg/5ml suspension was FDA approved but now discontinued (NegGram Suspension). NALACID 250mg /5ml Pharmatec Panel inspection report dated 13/05/2013.	Approved. Letter will be issued after rectification of shortcomings.
428.	-do-	**Indium**	As Per SRO (10% less than	Form-5	Domperidone 5mg / 5ml suspension	Approved. Letter will be issued after rectification of

		Suspension Each 5ml contains:- Domperidone…..5mg Antidopaminergic / Antiemetic Manufacturers' Specifications	brand leader) /60ml & 120ml	31-07-2013 9403 R&I Rs.20,000/-	BNF DOMEL 1mg/ml Barrett Hodgson *The CMDh, a medicines regulatory body representing the EU Member States, endorsed recommendations to restrict the use of Domperidone containing medicines to relieve symptoms of nausea and vomiting, that doses and length of treatment should be restricted and that they should be adjusted carefully by the patient's weight where available for use in children.* Panel inspection report dated 13/05/2013.	shortcomings.
429.	-do-	**Welfit**	As Per SRO (10% less than	Form-5	CARAFATE 1g/5ml oral liquid	Approved. Letter will be issued after rectification of

		Suspension Each 5ml contains:- Sucralfate USP….1gm Cytoprotective Manufacturers' Specifications	brand leader) /60ml,120ml	31-07-2013 9411 R&I Rs.20,000/-	Aspen Pharmacare TGA ULSANIC 1g/5ml Highnoon Laboratories Panel inspection report dated 13/05/2013.	shortcomings.
430.	-do-	Aroos Suspension Each 5ml contains:- Divalproex sodium/sodium Valproate ……. 250mg Carboxylic Acid Derivative Manufacturers' Specifications	As Per SRO (10% less than brand leader) /60ml	Form-5 31-07-2013 9407 R&I Rs.20,000/-	BNF reference of Epilium (Sodium Valproate) 200mg / 5ml syrup has been provided Depakene Valproic Acid (as sodium salt) 250mg / 5ml US FDA EPIVAL 250mg / 5ml Abbott Panel inspection report dated 13/05/2013.	Approved. Letter will be issued after rectification of shortcomings.
431.	-do-	**Brunac**	As Per SRO	Form-5	Brufen Syrup	Approved. Letter will be

		Suspension Each 5ml contains:- Ibuprofen USP….100mg Anti Rheumatics – Propionic acid Manufacturers' Specifications	(10% less than brand leader) / 60ml, 120ml	31-07-2013 9404 R&I Rs.20,000/-	100mg / 5ml BNF Brufen 100mg / 5ml Abbott Panel inspection report dated 13/05/2013.	issued after rectification of shortcomings.
432.	-do-	**Wefen** Suspension Each 5ml contains:- Iron (III) Hydroxy polymaltose complex ……. 50mg Folic acid …… 0.35mg Haematinic Manufacturers' Specifications	As Per SRO (10% less than brand leader) / 60ml, 120ml	Form-5 31-07-2013 9432 R&I Rs.20,000/-	MALCIFER – F 0.35 / 50mg / 5ml Martin Dow Panel inspection report dated 13/05/2013.	Approved. Letter will be issued after rectification of shortcomings.
433.	-do-	**Pitil** Syrup Each 10ml contains:- Pizotifen (as hydrogen maleate) …..0.5mg	As Per SRO (10% less than brand leader) / 60ml, 120ml	Form-5 31-07-2013 9435 R&I Rs.20,000/-	Sanomigran Pizotifen (as hydrogen malate) 250mcg/5ml BNF MOSEGOR 0.25mg / 5ml	Approved. Letter will be issued after rectification of shortcomings.

		Appetite stimulant Manufacturers' Specifications			Novartis Panel inspection report dated 13/05/2013.	
434.	-do-	**Hydin** Syrup Each 5ml contains:- Diphenhydramine Hcl ……. 13.5mg Ammonium chloride ……..... 131.5 mg Sodium Citrate…..55mg Menthol ……..… 1mg Antihistamine / Expectorant / Demulcent Manufacturers' Specifications	As Per SRO (10% less than brand leader) / 60ml, 120ml	Form-5 31-07-2013 9436 R&I Rs.20,000/-	International availability requires confirmation CHLOROHIST LCPW Panel inspection report dated 13/05/2013.	Approved. Letter will be issued after rectification of shortcomings.
435.	-do-	**Acetam** Solution Each 5ml contains:- Levetiracetam USP….100mg Pyrrolidine Derivative	As Per SRO (10% less than brand leader) / 60ml, 100ml	Form-5 31-07-2013 9419 R&I Rs.20,000/-	Internationally 100mg / ml available. Keppra 100mg/ml BNF LEVOTAM 100mg / ml	Approved. Letter will be issued after rectification of shortcomings.

		Manufacturers' Specifications			Platinum Panel inspection report dated 13/05/2013.	
436.	-do-	**Welldin Scrub** External Liquid Each contains:- Chlorhexidine gluconate USP…….. 1.5% w/v Cetrimide B.P….. 15%w/v Disinfectant Manufacturers' Specifications	As Per SRO (10% less than brand leader) / 60ml, 450ml and 1000ml	Form-5 31-07-2013 9405 R&I Rs.20,000/-	SEP GARD 1.5 / 15% W/V ZAFA Panel inspection report dated 13/05/2013.	Approved. Letter will be issued after rectification of shortcomings.
437.		**Kezol 2%** Lotion External Liquid Each contains:- Ketoconazole…..2% Antifungal Manufacturers' Specifications	As Per SRO (10% less than brand leader) /60ml & 90ml	Form-5 31-07-2013 9412 R&I Rs.20,000/-	SPIKE 2 % Solution Highnoon Panel inspection report dated 13/05/2013.	Approved. Letter will be issued after rectification of shortcomings.
438.		**Povinol Scrub** External Liquid	As Per SRO (10% less than brand leader) / Different	Form-5 31-07-2013 9415 R&I	To be referred to HOTC Division? Surgical Scrub	Deferred for confirmation of testing facility

		Each contains:- Povidon-iodine…..7.5% Antiseptic Manufacturers' Specifications	packaging	Rs.20,000/-	Povidone – Iodine in aqueous solution BNF ABODINE 7.5% W/W Abbott Panel inspection report dated 13/05/2013.	
439.		**Welldin Solution** Solution External Liquid Each contains:- Chlorhexidine gluconate USP……..1.5% W/V Disinfectant Manufacturers' Specifications	As Per SRO (10% less than brand leader) /500ml, 1000ml, 60ml and 112 ml.	Form-5 31-07-2013 9421 R&I Rs. 20,000/-	To be referred to HOTC Division? HEXALON 1.5 % W/V Polyfine Panel inspection report dated 13/05/2013.	Approved. Letter will be issued after rectification of shortcomings.
440.		**Wexol** Solution External Liquid Each contains:- Cresol and Soap solution……50% Disinfectant	As Per SRO (10% less than brand leader) /60ml	Form-5 31-07-2013 9425 R&I Rs.20,000/-	To be referred to HOTC Division? Panel inspection report dated 13/05/2013.	Approved. Letter will be issued after rectification of shortcomings.

		Manufacturers' Specifications				
441.		**Povinol** External Liquid Each contains:- Povidone-Iodine……10% Antiseptic Manufacturers' Specifications	As Per SRO (10% less than brand leader) / Different packaging	Form-5 31-07-2013 9437 R&I Rs.20,000/-	Antiseptic Solution, Povidone Iodine 10% in aqueous solution. To be referred to HOTC Division?	Deferred for confirmation of testing facility
442.		**Wiptol** External Liquid Each contains:- Parachlorometaxylenol …….. 1.44%w/v Terpineol …..... 1.8% Antiseptic Manufacturers' Specifications	As Per SRO (10% less than brand leader) /50ml, 100ml, 250ml, 500ml, 1000ml & 4500ml.	Form-5 31-07-2013 9437 R&I Rs.20,000/-	To be referred to HOTC Division?	Deferred for confirmation of testing facility
443.	M/s Wisdom Pharmaceutical Industry, 78 – A, Industrial Estate, Peshawar New License:	**Mofed tablets** Tablet Each film coated tablet contains:-	As Per SRO / 10's & 20's	Form-5 09-09-2013 70 R&I Rs.20,000/-	International availability requires confirmation FLAGYL PLUS 500 / 400mg tablets	Approved. Letter will be issued after rectification of shortcomings.

	Dry Powder Suspension (Ceph) Capsule (Ceph) Capsule (Gen) Liquid Syrup (Gen) Tablet (Gen) Ointment / Cream Steroid Ointment / Cream (Gen) Vide letter No. F. 3-5/2004 – Lic (M-232) dated 12th September, 2013	Diloxanide Furoate …….. 500mg Metronidazole …….400mg Amoebicide Manufacturers' Specifications			Sanofi Aventis	
444.	-do-	**Zolev tablets** Tablet Each tablet contains:- Levofloxacin Hemihydrate eq. Levofloxacin …….. 250mg Quinolone Manufacturers' Specifications	As Per SRO / 10's	Form-5 09-09-2013 72 R&I Rs.20,000/-	LEVAQUIN 250mg f/c tablets US FDA LEFLOX 250mg tablets Getz, Pakistan	Approved as the firm has corrected the Assay method.
445.	-do-	**Zolev tablets** Tablet Each tablet contains:- Levofloxacin Hemihydrate eq. Levofloxacin …….. 500mg	As Per SRO / 10's	Form-5 09-09-2013 71 R&I Rs.20,000/-	LEVAQUIN 500mg f/c tablets US FDA LEFLOX 500mg tablets Getz, Pakistan	Approved as the firm has corrected the Assay method.

		Quinolone Manufacturers' Specifications				
446.	-do-	**Locip tablets** Tablet Each tablet contains:- Ciprofloxacin Hcl eq. Ciprofloxacin …….250mg Quinolone Manufacturers' Specifications	As Per SRO / 10's	Form-5 09-09-2013 75 R&I Rs.20,000/-	CIPRO 250mg f/c tablet Bayer US FDA CIPROXIN 250mg tablet Bayer, Pakistan	Approved
447.	-do-	**Locip tablets** Each tablet contains:- Ciprofloxacin Hcl eq. Ciprofloxacin …….500mg Quinolone Manufacturers' Specifications	As Per SRO / 10's	Form-5 09-09-2013 74 R&I Rs.20,000/-	CIPRO 500mg f/c tablet Bayer US FDA CIPROXIN 500mg tablet Bayer, Pakistan	Approved
448.	-do-	**Lozim - F tablets** Chewable tablet Each chewable tablet contains:- Iron (III) Hydroxide Polymaltose complex eq. to	As Per SRO / 3 x 10's	Form-5 09-09-2013 76 R&I Rs.20,000/-	International availability requires confirmation RUBIFER – F 100 / 0.35 mg chewable tablet AGP, Pakistan	Deferred for Product Specific Inspection by Director DTL Quetta, Area FID and Area ADC

		elemental Iron …….100mg Folic Acid …….. 0.35mg Haematinic Manufacturers' Specifications				
449.	-do-	**Rofim Extra tablets** Tablet Each tablet contains:- Paracetamol …….500mg Chlorpheniramine maleate ……... 2mg Caffeine ……. 65mg Analgesic Manufacturers' Specifications	As Per SRO / 10 x 10's	Form-5 09-09-2013 73 R&I Rs.20,000/-	International availability requires confirmation AXADOL PLUS 500 / 65 / 2mg tablet Medisure, pakistan	Approved(as the firm has rectified the shortcomings)
450.	-do-	**Brolem tablets** Tablet Each tablet contains:- Orphenadrine Citrate …….35mg Paracetamol …… 450mg Analgesic	As Per SRO / 100's	Form-5 09-09-2013 68 R&I Rs.20,000/-	International availability requires confirmation NORGESIC 35/450mg tablet Searle, Pakistan	Approved(as the firm has rectified the shortcomings)

		Manufacturers' Specifications				
451.	-do-	**Cardel tablets** Tablet Each tablet contains:- Piroxicam Betacyclodextrin ……. 20mg Analgesic Anti-inflammatory Manufacturers' Specifications	As Per SRO / 100's	Form-5 09-09-2013 66 R&I Rs.20,000/-	BREXIN 20mg tablet Cheisi / Taro Intl., Israel Brexidol BNF BCD 20mg tablet Genome, Pakistan	Approved(as the firm has rectified the shortcomings)
452.	-do-	**Romed tablets** Tablet Each tablet contains:- Moxifloxacin Hcl eq. to Moxifloxacin……. 400mg Quinolone Manufacturers' Specifications	As Per SRO / 10's	Form-5 09-09-2013 69 R&I Rs.20,000/-	AVELOX 400mg f/c tablet Bayer, USA AVELOX 400mg Bayer, Pakistan	Approved
453.	-do-	**Lomep Capsules** Capsule Each capsule contains:-	As Per SRO / 2x7's & 10's	Form-5 09-09-2013 58 R&I	PRILOSEC 20mg Capsules (Delayed Release Pellets) US FDA	Approved (as the firm has rectified the shortcomings)

		Omeprazole……. 20mg Proton pump inhibitor Manufacturers' Specifications **Source:** Omeprazole enteric coated pellets 8.5% of M/s Vision Pharmaceuticals, Plot No. 224, Street No. 1, I-10/3, Industrial Area, Islamabad.		Rs.20,000/-	RISEK 20mg Capsules Getz Pharma, Pakistan	
454.	-do-	**Lomep Capsules** Capsule Each capsule contains:- Omeprazole……. 40mg Proton pump inhibitor Manufacturers' Specifications **Source:** Omeprazole enteric coated pellets 8.5% of M/s Vision Pharmaceuticals, Plot No. 224, Street No. 1, I-10/3, Industrial Area, Islamabad.	As Per SRO / 2x7's & 10's	Form-5 09-09-2013 57 R&I Rs.20,000/-	PRILOSEC 40mg Capsules (Delayed Release Pellets) US FDA RISEK 40mg Capsules Getz Pharma, Pakistan	Approved(as the firm has rectified the shortcomings)

455.	-do-	**Dolem Capsules** Capsule Each capsule contains:- Lansoprazole……. 30mg Proton pump inhibitor Manufacturers' Specifications Source: Lansoprazole enteric coated 22.5% from M/s Vision Pharmaceuticals, Plot No. 224, Street No. 1, I-10/3, Industrial Area, Islamabad.	As Per SRO / 2x7's & 10's	Form-5 09-09-2013 63 R&I Rs.20,000/-	PREVACID 30mg Capsules (Delayed Release Pellets) US FDA INDPRO 30mg capsule Indus Pharma	Approved(as the firm has rectified the shortcomings)
456.	-do-	**Zorel Capsules** Capsule Each capsule contains:- Esomeprazole……. 20mg Proton pump inhibitor Manufacturers' Specifications Source: Esomeprazole magnesium enteric coated pellets 22.5% of M/s Vision Pharmaceuticals, Plot No. 224, Street No. 1, I-10/3, Industrial Area, Islamabad.	As Per SRO / 2x7's & 10's	Form-5 09-09-2013 60 R&I Rs.20,000/-	NEXIUM 20mg Capsules (Delayed Release Pellets) US FDA NEXUM 20mg capsule Getz Pharma	Approved(as the firm has rectified the shortcomings)

457.	-do-	**Zorel Capsules** Capsule Each capsule contains:- Esomeprazole……. 40mg Proton pump inhibitor Manufacturers' Specifications Source: Esomeprazole magnesium enteric coated pellets 22.5% of M/s Vision Pharmaceuticals, Plot No. 224, Street No. 1, I-10/3, Industrial Area, Islamabad.	As Per SRO / 2x7's & 10's	Form-5 09-09-2013 59 R&I Rs.20,000/-	NEXIUM 40mg Capsules (Delayed Release Pellets) US FDA NEXUM 40mg capsule Getz Pharma	Approved(as the firm has rectified the shortcomings).
458.	-do-	**Lofin Capsules** Capsule Each capsule contains:- Celecoxib……. 100mg NSAIDS Manufacturers' Specifications	As Per SRO / 1 x 10's & 2 x 10's	Form-5 09-09-2013 64 R&I Rs.20,000/-	CELEBREX 100mg capsule US FDA CELBEXX 100mg capsule Getz Pharma	Approved(as the firm has rectified the shortcomings)
459.	-do-	**Lofin Capsules** 898Capsule Each capsule contains:- Celecoxib……. 200mg NSAIDS	As Per SRO / 1 x 10's & 2 x 10's	Form-5 09-09-2013 61 R&I	CELEBREX 200mg capsule US FDA CELBEXX	Approved(as the firm has rectified the shortcomings)

		Manufacturers' Specifications		Rs.20,000/-	200mg capsule Getz Pharma	
460.	-do-	**Nemrocin Capsules** Capsule Each capsule contains:- Azithromycin dihydrate eq. to Azithromycin …… 250mg Macrolide USP Specifications	As Per SRO / 1 x 5's & 1 x 10's	Form-5 19-09-2013 137 R&I Rs.20,000/-	ZITHROMAX 250mg Capsules Pfizer BNF AZOMAX 250mg capsule Novartis	Approved
461.	-do-	**Flozed Capsules** Capsule Each capsule contains:- Fluconazole …… 150mg Antifungal Manufacturers' Specifications	As Per SRO / 1's	Form-5 09-09-2013 65 R&I Rs.20,000/-	DIFLUCAN 150mg capsule Pfizer BNF DIFLUCAN 150mg capsule Pfizer	Approved
462.	-do-	**Rocam Capsules** Capsule Each capsule contains:- Piroxicam ……. 20mg Analgesic Anti - inflammatory Manufacturers' Specifications	As Per SRO / 20's	Form-5 09-09-2013 62 R&I Rs.20,000/-	FELDENE 20mg capsule US FDA FELDENE 20mg capsule Pfizer	Approved

c) Applications of Newly approved sections (182 - Applications)

Evaluator – II

S/N	Name and address of manufacturer/Applicant	Brand Name Dosage Form Composition (pharmacological Group) Finished product specification	Demanded Price / Pack size	1. Type of Form 2. Initial date, diary. 3. Date on which fee becomes complete according to type of application /or Form (total Fee)	1. International status in stringent regulatory agencies 2. Me-too status 3.GMP status as depicted in inspection report (dated)	Decision
1.	M/s Searle IV Solutions (Pvt.) Ltd, 1.5 km Manga Raiwind Road, Manga Mandi, Lahore (Formeraly M/s Mac & Rains Pharmaceuticals (Pvt.) Ltd, 1.5 km Manga Raiwind Road, Manga Mandi, Lahore. Company Name was changed vide letter No. F.1-34/2003-Lic (Vol-III) dated 18th February, 2014) Section Approved vide letter No. F.6-	Onsetron 8mg Tablets Each film coated tablet contains:- Ondansetron HCl 2HO eq. to Ondansetron…8mg (Antiemetic) (USP Spec.s)	Rs.3795.79 /10's	1. Form-5 2. 18-12-2013 3. 18-12-2013 (Rs.20,000/-)	1. **BNF 61. Zofran** (GSK) Tablets, yellow, f/c, ondansetron (as hydrochloride) 4 mg, 8 mg, 2. **ZOFRAN(**GLAXOSMITHKLINE**)** [Ondansetron (HCl):8mg]Tabs 3. Grants of additional sections recommended (14-10-2013)	Approved

	2/2013-Lic (M-233) dated 3rd Feb, 2014. 1. Tab (Gen) 2. Cap (Gen) 3. Sachet (Gen) Dry Susp(Gen) 5. Liq injVial (Gen) 6. Liq injAmp (Gen) 7. Cream/Oint (Gen) 8. Eye Drops (Gen)					
2.	-do-	Ranoline SR 1000mg Tablets Each sustained release film coated tablet contains:- Ranolazine….1000 mg (Anti-anginal) (Manufacturer's Spec.s)	Rs.330.00/ 14's	1. Form-5 2. 18-12-2013 3. 18-12-2013 (Rs.20,000/-)	1. FDA: Ranexa By Gilead ranolazine 1gm tablet, extended release;oral 2. Razin er(getz pharma pakistan (pvt) ltd.) [Ranolazine:1g]Tab 3. Grants of additional sections recommended (14-10-2013)	Approved
3.	-do-	Ranoline SR 500mg Tablets Each film coated tablet contains:- Ranolazine….500m g (Anti-Anginal)	Rs.196.00/ 14's	1. Form-5 2. 18-12-2013 3. 18-12-2013(Rs.20,000/-)	1. FDA: **RANEXA by GILEAD** RANOLAZINE 500MG TABLET, EXTENDED RELEASE;ORAL 2. Ranzol XR(Maple PHARMA)	Approved

		(Manufacturer's Spec.s)			[Ranolazine:500mg]Tab 3. Grants of additional sections recommended (14-10-2013)	
4.	-do-	Trample Tablets Each film coated tablet contains:- Paracetamol…..325 mg Tramadol HCl….37.5mg (NSAID + Opioid analgesic) USP	Rs. 200.00/20's	1. Form-5 2. 18-12-2013 3.18-12-2013 Rs.20,000/-	1. BNF 61.**Tramacet** (Gru¨nenthal) Tablets, f/c, yellow, tramadol hydrochloride 37.5 mg, paracetamol 325 mg 2. TONOFLEX-P(SAMI PHARMACEUTICALS (PVT) LTD.) [Paracetamol:325mg,Tramadol (HCl):37.5mg]Tab 3. Grants of additional sections recommended (14-10-2013)	Approved (with USP specs fpr finished product)
5.	-do-	Protide Tablets Each film coated tablet contains:- Itopride HCl….50mg (gastrokinetic) (Manufacturer's)	Rs.150.00/ 10's	1. Form-5 2. 18-12-2013 (1188) 3. 18-12-2013 (Rs.20,000/-)	1. Ganaton (Japan) 2. GANATON By ABBOTT LABORATORIES (PAKISTAN) LIMITED. 3. Grants of additional sections recommended (14-10-2013)	Deferred for review of formulation by the review committee

6.	-do-	Protide SR Tablets Each film coated sustained release tablet contains:- Itopride HCl….150mg (Gastrokinetic) (Manufacturer's Spec.s)	Rs.330.00/ 10's	1. Form-5 2. 18-12-2013 (1186) 3. 18-12-2013 (Rs.20,000/-)	1. Ganaton (India) 2. Ganaton (Abbott) Tab OD 150mg (R.No. 058549) 3. Grants of additional sections recommended (14-10-2013)	1. Deferred for review of formulation by the review committee
7.	-do-	Ciroxin 500mg Tablets Each film coated tablet contains:- Ciprofloxacin HCl eq. to ciprofloxacin…500 mg (Antibiotic) (BP Spec.s)	Rs.281.53/ 10's	1. Form-5 2. 18-12-2013 (1185) 3. 18-12-2013 (Rs.20,000/-)	1.BNF 61. Ciproxin (Bayer Schering) Tablets, all f/c, ciprofloxacin (as hydrochloride) 250 mg (scored); 500 mg (scored); 750 mg. 2. NOVIDAT by SAMI PHARMACEUTICALS (PVT) LTD 3. Grants of additional sections recommended (14-10-2013)	Approved with correction of master formulation
8.	-do-	Ciroxin 250mg Tablet Each film coated tablet contains:- Ciprofloxacin HCl eq. to ciprofloxacin….250 mg (Antibiotic)	Rs.151.00/ 10's	1. Form-5 2. 18-12-2013 (1174) 3. 18-12-2013 (Rs.20,000/-)	1.BNF 61. Ciproxin (Bayer Schering) Tablets, all f/c, ciprofloxacin (as hydrochloride) 250 mg (scored); 500 mg (scored); 750 mg. 2. NOVIDAT by SAMI PHARMACEUTICALS	Approved with correction of master formulation

		(BP Spec.s)			(PVT) LTD 3. Grants of additional sections recommended (14-10-2013)	
9.	-do-	Neurocare 500mg Tablets Each film coated tablet contains:- Citicoline sodium eq. to Citicoline….500mg (Nootropics &Neurotonic)	Rs.655.00/ 10's	1. Form-5 2. 09-01-2014 (311) 3. 09-01-2014 (Rs.20,000/-)	1.(According to the firm) Ceraxon Tablet by Ferrer Pharma , Maxico 2.Cercolin (Schazoo) 3. Grants of additional sections recommended (14-10-2013)	Deferred for review of formulation by review committee
10.	-do-	Serlpride 25mg Tablets Each film coated tablet contains:- Levosulpiride….25 mg (Benzamides antipsychotics) (Manufacturer's Spec.s)	206.62/2x1 0's	1. Form-5 2. 09-01-2014 (306) 3. 09-01-2014 (Rs.20,000/-)	1. (According to the firm)Dislep Tablet by Ferrer Pharma , Maxico 2. LEVOPRAID (PACIFIC PHARMACEUTICALS LTD.) [Levosulpiride:25mg]Tab 3. Grants of additional sections recommended (14-10-2013)	Deferred for review of formulation by review committee
11.	-do- (Capsule General Section)	Afcon Capsules 150mg Each capsule contains:- Fluconazole (U.S.P)…150mg (Antifungal triazole	Rs. 150.00/1's	1. Form-5 2. 18-12-2013 3. 18-12-2013 (Rs.20,000/-)	1. **BNF 61.** Diflucan (Pfizer) Capsules, fluconazole 50 mg (blue/white) ; 150 mg (blue), single-capsule; 200 mg (purple/white).	Approved

		(Systemic)) (Manufacturer's Spec.s)			2. DIFLUCAN (PFIZER LABORATORIES LTD.) [Fluconazole:150mg]Cap 3. Grants of additional sections recommended (14-10-2013)	
12.	-do-	Diquin Capsule Each capsule contains:- Dihydroartemisinin …..40mg Piperaquine phosphate…..320mg (Antimalarial) (Manufacturer's Spec.s)	Rs.380/8's Rs. 47.50/per cap	1. Form-5 2. 09-01-2014 (319) 3. 09-01-2014 (Rs.20,000/-)	1.Eurartesim (Italy) 2. NEO FANSIDAR MARTIN DOW PHARMACEUTICALS (PAK) LTD. [Dihydroartemisinin:40mg ,Piperaquine Phosphate:320mg]Cap 3. Grants of additional sections recommended (14-10-2013)	Approved
13.	-do-	Dutam Capsule Each capsule contains:- Dutasteride….0.5mg Tamsulosin HCl…..0.4mg (5-Alpha-reductase inhibitor + alpha 1A adrenoceptor combination) (Manufacturer's Spec.s)	Rs.2970.00 /30's	1. Form-5 2. 09-01-2014(314) 3. 09-01-2014 (Rs.20,000/-)	1. Jalyn (USA) 2. Duodart (GSK) 3. Grants of additional sections recommended (14-10-2013)	Deferred for verification/ clarification of formulation as per originator

14.	-do-	MuGo 375mg Capsule Each capsule contains:- Carbocisteine…375 mg (Mucolytic) (Manufacturer's Spec.s)	Rs.147.00/ 3x10's	1. Form-5 2. 09-01-2014 (316) 3. 09-01-2014 (Rs.20,000/-)	1. Carbocisteine (Sanofi-Aventis) Capsules, carbocisteine 375 mg, Brands include Mucodyne 2. RHINATHIOL (SANOFI AVENTIS (PAKISTAN) LTD.) [Carbocysteine:375mg]Cap 3. Grants of additional sections recommended (14-10-2013)	Approved
15.	-do-	Exoib 60mg Capsule Each capsule contains:- Etoricoxib….60mg (Antirheumatics) (Manufacturer's Spec.s)	Rs.490.00/ 1x14's	1. Form-5 2. 09-01-2014 (309) 3. 09-01-2014 (Rs.20,000/-)	1. Required 2. Required 3. Grants of additional sections recommended (14-10-2013)	Deferred for me too and international availability
16.	-do-	Obestat 120mg Capsules Each capsule contains:- Orlistat….120mg (Antiobesity) (USP Spec.s)	Rs.1200/30 's, Rs.40/1's	1. Form-5 2. 25-2-2014(294) 3.25-2-2014 (Rs.20,000/-)	1. BNF 61 (Xenical(Roche)) 2. Fabecal (Highnoon) 3. Grants of additional sections recommended (14-10-2013)	Deferred for verification/ clarification of formulation with originator

17.	-do-	Piropain Capsule Each Capsule contains:- Piroxicam (as betacyclodextrin)…. 20mg (Anti inflammatory analgesic) (Manufacturer's)	Rs.175/30's, Rs.8.75/1's	1. Form-5 2. 25-2-2014(295) 3. 25-2-2014 (Rs.20,000/-)	1. BNF (Brexidol (Chiesi)) 2. Boshcam-B (Bosch) 3. Grants of additional sections recommended (14-10-2013)	Approved
18.	-do- (Sachet General Section)	Infalyte-R Powder Sachet Each sachet of powder contains:- Rice powder (pre-cooked)….6.0gm Sodium Citrate…..0.58gm Sodium Chloride….0.35gm Potassium Chloride…..0.30gm (Oral rehydration salts) (Manufacturer's Spec.s)	Rs.140.00/ 10's sachet	1. Form-5 2. 18-12-2013(1190) 3. 18-12-2013 (Rs.20,000/-)	1. Ricetral Powder India (Export to USA) FDC Limited, Mambai , Indai (According to Firm. BNF 61. **UK Formulation. Dioralyte Relief** (Sanofi-Aventis) Oral powder, sodium chloride 350 mg, potassium chloride 300 mg, sodium citrate 580 mg, cooked rice powder 6 g/sachet. (in 200ml of water) **WHO formulation** Oral Rehydration Salts (Non-proprietary) Oral powder, sodium chloride 2.6 g, potassium chloride 1.5 g, sodium citrate 2.9 g, anhydrous glucose	Approved

					13.5 g. To be dissolved in sufficient water to produce 1 litre (providing Na+ 75 mmol, K+ 20 mmol, Cl– 65 mmol, citrate 10 mmol, glucose 75 mmol/litre) Note Recommended by the WHO and the United Nations Children's Fund but not commonly used in the UK. 2. Gastrolyte Rice Powder (Sanofi) 3. Grants of additional sections recommended (14-10-2013)	
19.	-do-	Infalyte L Powder Sachet Each sachet of powder contains:- Sodium chloride….2.60gm Potassium chloride…..1.50gm Glucose….13.50gm Sodium citrate….2.90gm (Oral rehydration salts) (Manufacturer's Spec.s)	Rs.100.00/ 20's Sachet	1. Form-5 2. 18-12-2013(1194) 3. 18-12-2013 (Rs.20,000/-)	1.**WHO formulation** Oral Rehydration Salts (Non-proprietary) Oral powder, sodium chloride 2.6 g, potassium chloride 1.5 g, sodium citrate 2.9 g, anhydrous glucose 13.5 g. To be dissolved in sufficient water to produce 1 litre (providing Na+ 75 mmol, K+ 20 mmol, Cl– 65 mmol, citrate 10 mmol, glucose 75 mmol/litre) Note: Recommended by	Approved

					the WHO and the United Nations Children's Fund but not commonly used in the UK. 2. FEROLYTEL(FEROZSONS LABORATOIES LTD.) [Sodium Chloride:2.6g,Potassium Chloride:1.5g,Glucose:13.5g, Sodium Citrate:2.9g] Sachet 3. Grants of additional sections recommended (14-10-2013)	
20.	-do-	Monar Paediatric 4mg Sachet Each sachet of powder contains:- Montelukast sodium eq. to montelukast …….4mg (Anti-asthma) (Manufacturer's Spec.s)	Rs.1900.00 /28's sachet	1. Form-5 2. 18-12-2013 (1195) 3. 18-12-2013 (Rs.20,000/-)	1. Singulair (MSD) Granules, montelukast (as sodium salt) 4 mg, 2. BEASY (BOSCH PHARMACEUTICALS (PVT) LTD.) [Montelukast:4mg] Sachet 3. Grants of additional sections recommended (14-10-2013)	Approved
21.	-do-	Diquin Powder Sachet Each powder of sachet contains:- Dihydroartemisinin …..15mg	Rs.380.00/ 16's Sachet	1. Form-5 2. 09-01-2014(312) 3. 09-01-2014 (Rs.20,000/-)	1. Required 2. NEO FANSIDAR (MARTIN DOW PHARMACEUTICALS (PAK) LTD.) [Dihydroartemisinin:15mg	Approved

		Piperaquine phosphate…120mg (Antimalarial) (Manufacturer's Spec.s)			,Piperaquine Phosphate:120mg]Sachet 3. Grants of additional sections recommended (14-10-2013)	
22.	-do-	Lecta Powder Sachet Each sachet of powder contains:- Dioctahedral smectite….3.00gm (Absorbant antidiarrhoeals) (Manufacturer's Spec.s)	Rs.318.00/ 30's Sachet	1. Form-5 2. 09-01-2014(313) 3. 09-01-2014 (Rs.20,000/-)	1. Required 2. Diosecta (Woodwards) 3. Grants of additional sections recommended (14-10-2013)	Deferred for review of formulation by review committee
23.	-do-	Nocons Powder Sachet Each sachet of powder contains:- Macrogol….13.125 gm Sodium bicarbonate….178.5 mg Sodium chloride….350.7mg Potassium chloride….46.6mg (Osmotic laxative) (Manufacturer's Spec.s)	Rs.225.00/ 10's sachet	1. Form-5 2. 09-01-2014(307) 3. 09-01-2014 (Rs.20,000/-)	1. Apo-Macrogol Plus Electrolyte (Australia) 2. Required 3. Grants of additional sections recommended (14-10-2013)	Deferrred for confirmation of me too status

24.	-do-	Bonistro Powder sachet Each sachet of Powder contains:- Strontium ranelate….2gm (For osteoporosis) (Manufacturer's Spec.s)	Rs.770.00/ 7's	1. Form-5 2. 09-01-2014(309) 3. 09-01-2014 (Rs.20,000/-)	1. Protos (Australia) 2. Onita (Pharmevo) 3. Grants of additional sections recommended (14-10-2013)	Approved
25.	-do-	MuGo C Powder Sachet Each sachet of powder contains:- Acetylcysteine….20 0mg (Mucolytic agent) (Manufacturer's Spec.s)	Rs.320.32/ 30's sachet	1. Form-5 2. 09-01-2014(304) 3. 09-01-2014 (Rs.20,000/-)	1. Required 2. Mucolator (Abbot) 3. Grants of additional sections recommended (14-10-2013)	Approved
26.	-do- (Dry Susp General Section)	Armeth Dry Suspension Each 5ml (when reconstituted) contains:- Artemether…15mg Lumefantrine….90m g (Anti malarial) (Manufacturer's Spec.s)	Rs.180.00/ 60ml	1. Form-5 2. 18-12-2013(1223) 3. 18-12-2013 (Rs.20,000/-)	1. Required 2. Artem Plus (Hilton) 3. Grants of additional sections recommended (14-10-2013)	Approved

27.	-do-	Ciroxin 250mg Dry Suspension Each 5ml (when reconstituted) contains:- Ciprofloxacin (as hydrochloride) BP….250mg (Quinolone (anti-infective, systemic) (Manufacturer's Spec.s)	Rs.160.00/ 60ml	1. Form-5 2. 18-12-2013 (1220) 3. 18-12-2013 (Rs.20,000/-)	1. Cipro (Bayer) 2.Novidat (Sami) 3. Grants of additional sections recommended (14-10-2013)	Approved with ciprofloxacin base in microcapsule form and change of name.
28.	-do-	Ciroxin 125mg Dry Suspension Each 5ml (when reconstituted) contains:- Ciprofloxacin (as hydrochloride) BP….125mg (Quinolone (anti-infective, systemic) (Manufacturer's Spec.s)	Rs.90.00/60ml	1. Form-5 2. 18-12-2013(1204) 3. 18-12-2013 (Rs.20,000/-)	1. Cipro (Bayer) 2.Novidat (Sami) 3. Grants of additional sections recommended (14-10-2013)	Deferred for confirmation of approval of formulation in 125 mg strength by Stringent Regulatory Agencies.
29.	-do-	Lariza Dry Suspension Each 5ml (when reconstituted) contains:- Clarithromycin….125mg	Rs.222.00/ 60ml	1. Form-5 2. 18-12-2013 (1216) 3. 18-12-2013 (Rs.20,000/-)	1. BNF 61. (Klaricid (Abbott)) 2. (Klaricid (Abbott)) 3. Grants of additional sections recommended (14-10-2013)	Approved

		(Macrolide antibiotic) (USP Spec.s)				
30.	-do-	Monar Dry Suspension Each 5ml(when reconstituted) contains:- Montelukast sodium eq.to montelukast…..5mg (anti-asthmatic) (Manufacturer's Spec.s)	Rs.200/60 ml	1. Form-5 2. 09-01-2014 (317) 3. 09-01-2014 (Rs.20,000/-)	1. Required 2. Synkast (Synchro) 3. Grants of additional sections recommended (14-10-2013)	Referred to review committee for review of formulation
31.	-do-	Esteine Dry Suspension Each 5ml (when reconstituted) contains:- Erdosteine….175mg (Mucolytic) (Manufacturer's Spec.s)	Rs.160/100 ml	1. Form-5 2. 09-01-2014(318) 3. 09-01-2014 (Rs.20,000/-)	1. Required 2. Dostin (Brookes) 3. Grants of additional sections recommended (14-10-2013)	Deferred for confirmation of me too status and international availability

32.	-do-	Afcon Dry Suspension Each 5ml(when reconstituted) contains:- Fluconazole….50mg (Anti fungal) (Manufacturer's Spec.s)	Rs.935.00/ 35ml	1. Form-5 2. 09-01-2014(320) 3. 09-01-2014 (Rs.20,000/-)	1. BNF 61. (Diflucanc (Pfizer)) 2. (Diflucanc (Pfizer)) 3. Grants of additional sections recommended (14-10-2013)	Approved
33.	-do-(Liq Inj Vial General Section)	Linzo IV Injection Each ml contains:- Linezolid….2mg (Antibacterial agent) (Manufacturer's Spec.s)	Rs.600.00/ 300ml vial	1. Form-5 2. 18-12-2013 (1182) 3. 18-12-2013 (Rs.20,000/-)	1. BNF 61. (Zyvox (Pharmacia)) 2. Zolrest (Bosch) 3. Grants of additional sections recommended (14-10-2013)	Approved. (Confirmation of Liquid particle counter and TOC availability by area FID)
34.	-do-	ISO Mac IV Injection Each 100ml contains:- (Total amino acids…..10.641g) L-Isoleucine…..0.56g L-Leucine…..1.25g L-Lysine HCl…..1.10g L-Methionine…..0.35 g L-phenylalanine….0.9	Rs.317.00/ 500ml vial	1. Form-5 2. 09-01-2014 (321) 3. 09-01-2014 (Rs.20,000/-)	1. Required 2. Nutriamin (Geofman) 3. Grants of additional sections recommended (14-10-2013)	Deferred for PSI by Director DTL Peshawar, area FID and ADC

		35 g L-Threonine….0.65 g L-Tryptophan...0.13 g L-valine….0.45g L-Alanine…0.62g L-Arginine HCl…..0.955g L-Aspartic acid……0.38g L-Cysteine HCl (H2O)….0.145g L-Glutamic acid…..0.65g L-Histidine HCl(H2O)….0.811 g L-Proline…..0.33g L-Serine….0.22g L-Tyrosine……0.035 g Amino acetic acid…..1.07g (Amino acids) (Manufacturer's Spec.s)				

35.	-do-	Amino Rib IV Injection Each 1000ml contains:- (Amino acids (L-form)…..50.0g) L-Isoleucine…..3.20g L-Leucine…..2.40g L-Lysine HCl……..2.50g L-Methionine…..3.00g L-Phenylalanine….4.00g L-Threonine…..2.00g L-tryptophan……1.00g L-Valine…..3.20g L-Alanine…..6.00g L-Arginine HCl……2.66 g L-Arginine….4.00g L-Histidine HCl .H_2O…..1.35g L-Proline….2.00 g Glycine (amino acetic acid)….14.0g D-Sorbitol….100.00g	Rs.375.00/ 500ml vial	1. Form-5 2. 09-01-2014 (315) 3. 09-01-2014 (Rs.20,000/-)	1. Required 2. Aminovel 600 (Otsuka) 3. Grants of additional sections recommended (14-10-2013)	Deferred for PSI by Director DTL Peshawar, area FID and ADC

		Vitamin C…..400.00mg Inositol…..500mg Nicotinamide….60.00mg Pyridoxine HCl…..40.00mg Riboflavin sodium phosphate….2.50mg Water for injection ….q.s Electrolytes (mEq/L) Sodium…..35 Potassium…..25 Magnesium…..5 Acetate….35 Malate….22 Chloride…..38 (Amino acids, vitamins & sorbitol) (Manufacturer's Spec.s)				
36.	-do-	Ciroxin 50ml IV Injection Each ml contains:- Ciprofloxacin (as lactate)….2mg (Anti-biotic) (USP Spec.s)	Rs.95.00/50ml vial	1. Form-5 2. 09-01-2014 (310) 3. 09-01-2014 (Rs.20,000/-)	1.BNF 61. Ciproxin(Bayer Schering) 2.Ciprok (Swiss) 3. Grants of additional sections recommended (14-10-2013)	Approved with change of brand name

37.	-do-	Eptide IV Injection Each ml contains:- Eptifibatide…0.75mg (Antiplatelet) (Manufacturer's Spec.s)	Rs.660.00/ 100ml	1. Form-5 2. 18-12-2013(1211) 3. 18-12-2013 (Rs.20,000/-)	1.BNF 61. Integrilin(GSK 2. Integrilin (OBS) 3. Grants of additional sections recommended (14-10-2013)	Referred to Biological Division
38.	-do-	Zoldric IV Injection Each 100ml contains:- Zoledronic acid ….5mg (Bisphosphonates for tumour-related calcium disorders) (Manufacturer's Spec.s)	Rs.24000/100ml vial	1. Form-5 2. 09-01-2014 (305) 3. 09-01-2014 (Rs.20,000/-)	1. BNF 61. Aclasta (Novartis) 2. Aclasta (Novartis) 3. Grants of additional sections recommended (14-10-2013)	Approved
39.	-do-	Modimac IV Injection Each 50ml contains:- Nimodipine ……10mg (Calcium channel blocker) (Manufacturer's Spec.s)	Rs.840.00/ 1vialx50ml	1. Form-5 2. 25-2-2014(295) 3. 25-2-2014 (Rs.20,000/-)	1.BNF 61. Nimotop(Bayer Schering) 2. Nimotop(Bayer) 3. Grants of additional sections recommended (14-10-2013)	Approved with finished product specs as per pharmacopiea

40.	-do- (Liq Inj Amp General Section)	Onsetron 4mg Injection Each 2ml contains:- Ondansetron HCl $2H_2O$ eq. to Ondansetron…..4mg (Antiemetic) (USP Spec.s)	Rs.2700.00 /5ampx2ml	1. Form-5 2. 18-12-2013(1213) 3. 18-12-2013 (Rs.20,000/-)	1. BNF 61. Zofran (GSK) 2. Zofran (GSK) 3. Grants of additional sections recommended (14-10-2013)	Approved
41.	-do-	Onsetron 8mg Injection Each 4ml contains:- Ondansetron HCl $2H_2O$ eq. to Ondansetron…8mg (Antiemetic) (USP Spec.s)	Rs.4525.66 /5amp x4ml	1. Form-5 2. 18-12-2013(1193) 3. 18-12-2013 (Rs.20,000/-)	1. BNF 61. Zofran (GSK) 2. Zofran (GSK) 3. Grants of additional sections recommended (14-10-2013)	Approved
42.	-do-	VD3 Injection Each ml contains:- Cholecalciferol….5. 0mg (Vitamin D) (USP Spec.s)	Rs.140.00/ 1.0ampx1 ml	1. Form-5 2. 18-12-2013(1209) 3. 18-12-2013 (Rs.20,000/-)	1. Required 2. Calciferol (Global) 3. Grants of additional sections recommended (14-10-2013)	Deferred for PSI by Director DTL Peshawar, area FID and ADC
43.	-do-	Armeth 80mg Injection Each ml contains:- Artemether….80mg (Antimalarial) (Manufacturer's Spec.s)	Rs.755.04/ 6ampx1ml	1. Form-5 2. 18-12-2013(1207) 3. 18-12-2013 (Rs.20,000/-)	1. Required 2. Artem 80 (Hilton) 3. Grants of additional sections recommended (14-10-2013)	Approved

44.	-do-	Armeth 40mg Injection 3.Each ml contains:- Artemether……40mg (Antimalarial) (Manufacturer's Spec.s)	Rs.600.00/ 10amx1ml	1. Form-5 2. 18-12-2013(1200) 3. 18-12-2013 (Rs.20,000/-)	1. Required 2. Artem 40 (Hilton) 3. Grants of additional sections recommended (14-10-2013)	Approved
45.	-do-	Torolac Injection Each ml contains:- Ketorolac trometamol….30mg (NSAID) (USP Spec.s)	Rs. 430/5amp Rs. 86/1ml amp	1. Form-5 2. 18-12-2013(1189) 3. 18-12-2013 (Rs.20,000/-)	1.BNF 61. Toradol (Roche) 2. Toralac (Global) 3. Grants of additional sections recommended (14-10-2013)	Approved
46.	-do-	Pramol L Injection Each 2ml contains:- Paracetamol….300mg Lignocaine HCl….20mg (Analgesic & anti-pyretic) (Manufacturer's Spec.s)	Rs.130.00/ 10amp x 2ml	1. Form-5 2. 18-12-2013(1191) 3. 18-12-2013 (Rs.20,000/-)	1. Required 2. Fevenor (Global) 3. Grants of additional sections recommended (14-10-2013)	Approved
47.	-do-	Vepamil Injection Each 2ml contains:- Verapamil HCl….5mg (Calcium channel blocker)	Rs.19.79/1's Rs.98.93/5 amp x2ml	1. Form-5 2. 18-12-2013(1188) 3. 18-12-2013 (Rs.20,000/-)	1. BNF 61. Securon (Abbott) 2. Isoptin (Abbot) 3. Grants of additional sections recommended (14-10-2013)	Approved

		(USP Spec.s)				
48.	-do-	1. Neurocare 250mg 2. Injection 3. Each 2ml contains:- Citicoline sodium eq. to Citicoline…250mg (Nootropics & Neurotonic) (Manufacturer's Spec.s)	Rs.750.00/ 5ampx2ml	1. Form-5 2. 09-01-2014 (308) 3. 09-01-2014 (Rs.20,000/-)	1. Required 2. Citolin (Global) 3. Grants of additional sections recommended (14-10-2013)	Referred to review committee for review of formulation
49.	-do-	Fenac-L Injection Each 2ml contains:- Diclofenac Sodium….75mg Lignocaine HCl…..20mg (NSAID, local anesthetic) (Manufacturer's Spec.s)	Rs.240.00/ 10ampx2ml	1. Form-5 2. 18-12-2013(1196) 3. 18-12-2013 (Rs.20,000/-)	1. Required 2. Articure (Global) 3. Grants of additional sections recommended (14-10-2013)	Approved

50.	-do- (Cream/Oint General Section)	Benestine Cream 1% Each gram contains:- Clotrimazole USP…..10mg (Imidazole anti-fungal) (USP Spec.s)	Rs. 32.00/10gm	1. Form-5 2. 18-12-2013(1218) 3. 18-12-2013 (Rs.20,000/-)	1. BNF 58: Canesten (Bayer Consumer Care) Cream 2. CLOTRIM(ZAFA PHARMACEUTICAL LABORATORIES (PVT) LTD.) [Clotrimazole:1%w/w]Cream 3. Grants of additional sections recommended (14-10-2013)	Approved
51.	-do-	Bicrole Cream 2% Each gram contains:- Miconazole (as Nitrate) BP…..20mg (Antifungal) (BP Spec.s)	Rs.73.29/10gm	1. Form-5 2. 18-12-2013(1214) 3. 18-12-2013 (Rs.20,000/-)	1. BNF 58: Daktarin (Janssen-Cilag) Cream, miconazole nitrate 2%, 2. MICODEN(DANAS PHARMACEUTICALS (PVT) LTD) [Miconazole (Nitrate):2%w/w]Cream 3. Grants of additional sections recommended (14-10-2013)	Approved with correction of formulation/strength
52.	-do-	Bizrole Cream 2 % Each gm contains:- Ketoconazole USP…..20mg (Antifungal) (Manufacturer's Spec.s)	Rs.95.77/10gram tub	1. Form-5 2. 18-12-2013(1186) 3. 18-12-2013 (Rs.20,000/-)	1. Nizoral Cream(Janssen-Cilag) UK 2. Nizoral Cream(Janssen-Cilag) 3. Grants of additional sections recommended (14-10-2013)	Approved

53.	-do-	Binafine Cream 1% Each gm contains:- Terbinafine HCl B.P….1% w/w (Antifungal) (Manufacturer's Spec.s)	Rs.170.00/ 10gm	1. Form-5 2. 18-12-2013(1178) 3. 18-12-2013 (Rs.20,000/-)	1. BNF 58: Lamisil (Novartis Consumer Health) Cream 2. Exinofin(brookes pharmaceutical laboratories (pak.) Ltd.) [Terbinafine (HCl):0] Cream 3. Grants of additional sections recommended (14-10-2013)	Approved
54.	-do-	Burnazine Cream 1% Each gm contains:- Silver Sulphadiazine USP….10mg (Dermatological Antibacterial) (USP Spec.s)	Rs.81.35/10gm	1. Form-5 2. 18-12-2013 (1175) 3. 18-12-2013 (Rs.20,000/-)	1. BNF 58: Flamazine (S&N Hlth.) Cream 2. Dermazin(Novartis Pharma (Pak) Ltd) [Silver Sulphadiazine:1%w/w] cream 3. Grants of additional sections recommended (14-10-2013)	Approved
55.	-do-	Bramacin Eye Ointment Each gm contains:- Tobramycin….0.3% w/w (Antibiotic) (USP Spec.s)	Rs.162.05/ 3.5gm tube	1. Form-5 2. 18-12-2013(1221) 3. 18-12-2013 (Rs.20,000/-)	1. Tobrex (FDA) 2. Eyebrex (Barret Hodgson) 3. Grants of additional sections recommended (14-10-2013)	Rejected as the firm does not possess the manufacturing facility for ophthalmic preparation

56.	-do-	Bcivor Eye Ointment Each gm contains:- Acyclovir…..5% w/w (Antiviral) (USP Spec.s)	Rs.242.00/ 4.5gm tube	1. Form-5 2. 18-12-2013(1192) 3. 18-12-2013 (Rs.20,000/-)	1. Required. 2. Zovirax (GSK) 3. Grants of additional sections recommended (14-10-2013)	Rejected as the firm does not possess the manufacturing facility for ophthalmic preparation
57.	-do-	Busidin Ointment Each contains:- Fusidic acid…..2% w/w (Antibacterial) (B.P)	Rs.135.00/ 15gm	1. Form-5 2. 18-12-2013(1177) 3. 18-12-2013 (Rs.20,000/-)	1. BNF 58: Fucidin (LEO) Cream 2. Amfic(Amros Pharmaceuticals.) [Fusidic Acid:2%w/w]cream 3. Grants of additional sections recommended (14-10-2013)	Approvrd with change of brand name
58.	-do-	Brim Gel Each contains:- Adapalene ……0.1% w/w (Retinoids) (Manufacturer's Spec.s)	Rs.140.00/ 15gm tube	1. Form-5 2. 18-12-2013(1199) 3. 18-12-2013 (Rs.20,000/-)	1. BNF 61. (Differin (Galderma) 2. Adapco (Atco) 3. Grants of additional sections recommended (14-10-2013)	Approved
59.	-do-	Scarlet Gel Each 20gm contains:- Ext.cepae…….2.0g m Heparin Sodium…..1000 I.U	Rs.143.91/ 20gm tube	1. Form-5 2. 18-12-2013(1201) 3. 18-12-2013 (Rs.20,000/-)	1. Required 2. Contractubex (Brookes) 3. Grants of additional sections recommended (14-10-2013)	Refrerred to the biological division

		Allantoin……0.2gm (Skin softening agent/anti-scar) (Manufacturer's Spec.s)				
60.	-do- (Eye Drops General Section)	Levogan Eye Drops Each ml contains:- Levobunolol HCl….0.5 % w/v (Anti-glaucoma) (U.S.P Spec.s)	Rs.102.00/ 5ml	1. Form-5 2. 18-12-2013(1222) 3. 18-12-2013 (Rs.20,000/-)	1. BNF 61 (Betagan (Allergan)) 2. Levosan (Sante) 3. Grants of additional sections recommended (14-10-2013)	Approved
61.	-do-	Ciroxin Eye Drops Each 5ml contains:- Ciprofloxacin HCl eq. to Ciprofloxacin…..0.3 % w/v (Antibiotic) (USP Spec.s)	Rs.115.00/ 5ml	1. Form-5 2. 18-12-2013(1219) 3. 18-12-2013 (Rs.20,000/-)	1. BNF 61. (Ciloxan (Alcon)) 2. Rocip(Remington) 3. Grants of additional sections recommended (14-10-2013)	Approved
62.	-do-	Moxi Eye Drops Each 5ml contains:- Moxifloxacin HCl eq.to Moxifloxacin….0.5 % w/v (Antibiotic) (Manufacturer's Spec.s)	Rs. 425.00/5ml in dropper bottle	1. Form-5 2. 18-12-2013(1197) 3. 18-12-2013 (Rs.20,000/-)	1. BNF 61. Moxivig (Alcon) 2. Vigamox (Novartis) 3. Grants of additional sections recommended (14-10-2013)	Approved

63.	-do-	Timbro 2. Eye Drops 3.Each ml contains:- Timolol maleate eq. to Timolol….0.5 % w/v Brimonidine Tartrate eq. to Brimonidine…0.2% w/v (Anti-glaucoma) (Manufacturer's)	Rs.350.00/ 5ml	1. Form-5 2. 18-12-2013(1215) 3. 18-12-2013 (Rs.20,000/-)	1. Combigan (FDA) 2.Brytim (Remington) 3. Grants of additional sections recommended (14-10-2013)	Approved
64.	-do-	Oculozine Eye Drops Each ml contains:- Antazoline HCl…..0.05% w/v (Antihistamine) (Manufacturer's Spec.s)	Rs.90.26/10ml bottle	1. Form-5 2. 18-12-2013(1203) 3. 18-12-2013 (Rs.20,000/-)	1. Required 2. Spersallerg (Novartis) 3. Grants of additional sections recommended (14-10-2013)	Approved
65.	-do-	Trava Eye Drops Each ml contains:- Travoprost…..40mcg (Prostaglandin analogue) (Manufacturer's Spec.s)	Rs.950.00/ 2.5ml Bottle	1. Form-5 2. 18-12-2013(1205) 3. 18-12-2013 (Rs.20,000/-)	1. BNF 61. (Travatan (Alcon) 2. Travatan (Novartis) 3. Grants of additional sections recommended (14-10-2013)	Approved

66.	-do-	Oculacil Eye Drops Each ml contains:- Tropicamide….1% w/v (Antimuscarinic) (USP Spec.s)	Rs.115.00/ 15ml	1. Form-5 2. 18-12-2013(1206) 3. 18-12-2013 (Rs.20,000/-)	1. BNF 61. (Mydriacyl (Alcon)) 2. Mydriacyl (Novartis) 3. Grants of additional sections recommended (14-10-2013)	Approved
67.	-do-	Melose Eye Drops Each ml contains:- Hypromellose….3mg (Lubricant) (USP Spec.s)	Rs.165.00/ 10ml Bottle	1. Form-5 2. 18-12-2013(1198) 3. 18-12-2013 (Rs.20,000/-)	1. Required 2. Required 3. Grants of additional sections recommended (14-10-2013)	Deferred for confirmation of me too status and international availability
68.	-do-	Oculain Eye Drops Each ml contains:- Proparacaine HCl……0.5% w/v (Anaesthetic) (USP Spec.s)	Rs. 87.00/15ml	1. Form-5 2. 18-12-2013(1176) 3. 18-12-2013 (Rs.20,000/-)	1. Required 2. Alcaine (Alcon) 3. Grants of additional sections recommended (14-10-2013)	Approved.
69.	-do-	Bexalol Eye Drops (Suspension) Each 5ml contains:- Betaxolol HCl eq. to Betaxolol…..0.25 % w/v (Beta Blocker) (USP Spec.s)	Rs.236.78/ 5ml	1. Form-5 2. 18-12-2013(1173) 3. 18-12-2013 (Rs.20,000/-)	1. BNF 61. (Betoptic (Alcon) 2. Betoptic-S(Novartis) 3. Grants of additional sections recommended (14-10-2013)	Approved
70.	M/s. Medisearch Pharmacal (Pvt) ltd, 5-Km,	Molus Dry Suspension When reconstituted	As per SRO/60ml	Form-5 20-12-2013(1308) Rs.20,000/-	1. Required 2. Synkast (Synchro) 3. Grant of additional	Approved. Letter will be issued after rectification of shortcomings.

	Raiwind Manga Road, Lahore. Additional Sections 1.Dry Powder Suspension (General) 2.Dry Powder Suspension (Cephalosporin) 3. Capsule (Cephalosporin) Vide letter No. 6-2/2013-Lic (M-233) dated 3rd Feb, 2014	Each 5ml contains:- Montelukast Sodium…..5mg (anti-asthmatic) (Manufacturer's Spec.s)			sections recommended (07-11-2013)	
71.	-do-	Flucose 50mg Suspension Each 5ml contains:- Fluconazole…..50mg (Antifungal triazole) (Manufacturer's Spec.s)	As per SRO/35ml	Form-5 20-12-2013 Rs.20,000/-	1. BNF 61. (Diflucan (Pfizer)) 2. (Diflucan (Pfizer)) 3. Grant of additional sections recommended (07-11-2013)	Approved. Letter will be issued after rectification of shortcomings.
72.	-do-	Arti-Puls Suspension Each 5ml contains:- Artemether….15mg Lumefantrine…..90 mg (Synthetic antimalarial) (Manufacturer's	As per SRO/60ml	Form-5 20-12-2013 Rs.20,000/-	1. Required 2. Artem Plus (Hilton) 3. Grant of additional sections recommended (07-11-2013)	Approved. Letter will be issued after rectification of shortcomings.

		Spec.s)				
73.	-do-	Becip 125mg Suspension Each 5ml contains:- Ciprofloxacin HCl eq. to Ciprofloxacin……125mg (Quinolone) (Manufacturer's Spec.s)	As per SRO/60ml	Form-5 20-12-2013 Rs.20,000/-	1. Cipro (Bayer) 2.Novidat (Sami) 3. Grant of additional sections recommended (07-11-2013)	Deferred for confirmation of approval of formulation in 125 mg strength by Stringent Regulatory Agencies.
74.	-do-	Becip Suspension Each 5ml contains:- Ciprofloxacin HCl eq. to Ciprofloxacin……250mg (Quinolone) (Manufacturer's Spec.s)	As per SRO/60ml	Form-5 20-12-2013(1328) Rs.20,000/-	1. Cipro (Bayer) 2.Novidat (Sami) 3. Grant of additional sections recommended (07-11-2013)	Approved. Letter will be issued after rectification of shortcomings.
75.	-do-	Levosrch 125mg Supension Each 5ml contains:- Levofloxacin Hemihydrates eq to Levofloxacin …125mg	As per SRO/60ml	Form-5 20-12-2013(1331)` Rs.20,000/-	1.Required 2.Levocure (Hygeia) 3. Grant of additional sections recommended (07-11-2013)	Deferred for clarification of formulation by firm as the applied product is in solution form in stringent DRA's

		(Quinolone/antibiotics, systemic) (Manufacturer's Spec.s)				
76.	-do-	Levosrch 250mg Suspension Each 5ml contains:- Levofloxacin Hemihydrates eq to Levofloxacin …250mg (Quinolone/antibiotics, systemic) (Manufacturer's Spec.s)	As per SRO/60ml	Form-5 20-12-2013(1333) Rs.20,000/-	1.Required 2.Levocure (Hygeia) 3. Grant of additional sections recommended (07-11-2013)	Deferred for clarification of formulation by firm as the applied product is in solution form in stringent DRA's
77.	-do-	Erymed 200mg Granules Each 5ml contains:- Erythromycin ethylsuccinate eq. to erythromycin…200 mg (Macrolide) (B.P)	As per SRO/60ml	Form-5 20-12-2013(1319) Rs.20,000/-	1.Arbor Pharms Inc 2.Erythrocin (Abbot) 3. Grant of additional sections recommended (07-11-2013)	Approved. Letter will be issued after rectification of shortcomings.

78.	-do-	Clariglod Suspension Each 5ml contains:- Clarithromycin…..125mg (Macrolide) (USP Spec.s)	As per SRO/60ml	Form-5 20-12-2013(1310) Rs.20,000/-	1.BNF 61. Klaricid (Abbott) 2. . Klaricid (Abbott) 3. Grant of additional sections recommended (07-11-2013)	Approved. Letter will be issued after rectification of shortcomings.
79.	-do-	Nagra 200mg Suspension Each 5ml contains:- Azithromycin dihydrate eq. to Azithromycin …..200mg (Macrolide) (USP)	As per SRO/15ml	Form-5 20-12-2013(1332) Rs.20,000/-	1.BNF 61. (Zithromax (Pfizer)) 2.Acasia (Nexpharm) 3. Grant of additional sections recommended (07-11-2013)	Approved. Letter will be issued after rectification of shortcomings.
80.	-do- Dry Powder Suspension (Cephalosporin) Section	Chemidroxil 125mg Suspension Each 5ml contains:- Cefadroxil Monohydrate eq. to Cefadroxil (U.S.P)…….…….125mg (Cephalosporin) (U.S.P)	As per SRO/60ml	Form-5 20-12-2013(1326) Rs.20,000/-	1. BNF 58: Baxan (Bristol-Myers Squibb) 2.Ag-Drox(Saydon Pharmaceutical Industries (Pvt) Ltd.) [Cefadroxil:125mg/5ml]susp 3. Grant of additional sections recommended (07-11-2013)	Approved. Letter will be issued after rectification of shortcomings.
81.	-do-	Cemidroxil 250mg Suspension Each 5ml contains:- Cefadroxil Monohydrate eq. to Cefadroxil	As per SRO/60ml	Form-5 20-12-2013(1325) Rs.20,000/-	1. BNF 58: Baxan (Bristol-Myers Squibb) 2.Ag-Drox(Saydon Pharmaceutical Industries (Pvt) Ltd.)	Approved. Letter will be issued after rectification of shortcomings.

		(U.S.P)……..….250mg (Cephalosporin) (U.S.P)			[Cefadroxil:250mg/5ml]susp 3. Grant of additional sections recommended (07-11-2013)	
82.	-do-	Azidine 250mg Suspension Each 5ml contains:- Cephradine (anhydrous) ……..250mg Cephalosporin (U.S.P)	As per SRO/60ml	Form-5 20-12-2013(1327) Rs.20,000/-	1. BNF 58 Velosef (Squibb) Syrup, cefradine 250 mg/5 mL when reconstituted with water. 2. Geosef (Geofman Pharmaceuticals) [Cephradine:250mg/5ml] Susp 3. Grant of additional sections recommended (07-11-2013)	Approved. Letter will be issued after rectification of shortcomings.
83.	-do-	Azidine 125mg Suspension Each 5ml contains:- Cephradine (anhydrous) ……..125mg Cephalosporin (U.S.P)	As per SRO/60ml	Form-5 20-12-2013 (1328) Rs.20,000/-	1.FDA (Anspor) 2. Geosef (Geofman Pharmaceuticals) [Cephradine:125mg/5ml] Susp 3. Grant of additional sections recommended (07-11-2013)	Approved. Letter will be issued after rectification of shortcomings.
84.	-do-	Medicef Suspension Each 5ml contains:- Cefixime Trihydrate ≡ Cefixime(U.S.P)…… ……200mg	As per SRO/30ml	Form-5 20-12-2013(1323) Rs.20,000/-	1.FDA (Suprax) 2. Cefiget (Getz Pharma Pakistan (Pvt) Ltd.) [Cefixime:200mg/5ml]susp 3. Grant of additional sections recommended	Approved. Letter will be issued after rectification of shortcomings.

		(Cephalosporin) (U.S.P)			(07-11-2013)	
85.	-do-	Medicef Suspension Each 5ml contains:- Cefixime Trihydrate ≡ Cefixime(U.S.P)……100mg (Cephalosporin) (U.S.P)	As per SRO/30ml	Form-5 20-12-2013(1324) Rs.20,000/-	1. BNF 58: Suprax (Rhoˆne-Poulenc Rorer) 2. Cefiget(Getz Pharma Pakistan (Pvt) Ltd.) [Cefixime:100mg/5ml]susp 3. Grant of additional sections recommended (07-11-2013)	Approved. Letter will be issued after rectification of shortcomings.
86.	-do-	F-Clor Suspension Each 5ml contains:- Cefaclor Monohydrate ≡ Cefaclor(U.S.P)...125mg (Cephalosporin) (U.S.P)	As per SRO/60ml	Form-5 20-12-2013(1322) Rs.20,000/-	1. BNF 58: Distaclor (Flynn) 2. Hiclor(Hilton Pharma (Pvt) Limited) [Cefaclor (Monohydrate):125mg/5ml] susp 3. Grant of additional sections recommended (07-11-2013)	Approved. Letter will be issued after rectification of shortcomings.
87.	-do-	F-Clor Suspension Each 5ml contains:- Cefaclor Monohydrate ≡ Cefaclor(U.S.P)...125mg (Cephalosporin) (U.S.P)	As per SRO/60ml	Form-5 20-12-2013(1321) Rs.20,000/-	1. BNF 58: Distaclor (Flynn) 2. Hiclor(Hilton Pharma (Pvt) Limited) [Cefaclor (Monohydrate):250mg/5ml] susp 3. Grant of additional sections recommended (07-11-2013)	Approved. Letter will be issued after rectification of shortcomings.

88.	-do-	Cefix 125mg Suspension Each 5ml contains:- Cefuroxime (as axetil)….125mg (Anti-infective cephalosporin)	As per SRO/50ml	Form-5 20-12-2013 (1311) Rs.20,000/-	1.BNF 61. Zinnat (GSK) 2.Daycef (Shrooq) 3. Grant of additional sections recommended (07-11-2013)	Approved. Letter will be issued after rectification of shortcomings.
89.	-do- Capsule (Cephalosporin) Section	Chemidroxil 500mg Capsule Each capsule contains:- Cefadroxil Monohydrate eq. to Cefadroxil (U.S.P)…500mg (Cephalosporin) (U.S.P)	As per SRO/10's	Form-5 20-12-2013(1307) Rs.20,000/-	1. BNF 58: Baxan (Bristol-Myers Squibb) Capsules, cefadroxil (as monohydrate) 500 mg, 2. Evacef(Highnoon Laboratories Ltd.) [Cefadroxil:500mg] Cap 3. Grant of additional sections recommended (07-11-2013)	Approved. Letter will be issued after rectification of shortcomings.
90.	-do-	Chemidroxil 250mg Capsule Each capsule contains:- Cefadroxil Monohydrate eq. to Cefadroxil (U.S.P)…250mg (Cephalosporin) (U.S.P)	As per SRO/10's	Form-5 20-12-2013(1314) Rs.20,000/	1.FDA approved. 2.Neutrocef (Neutro) 3. Grant of additional sections recommended (07-11-2013)	Approved. Letter will be issued after rectification of shortcomings.

91.	-do-	Chemidroxil 1gm Capsule Each capsule contains:- Cefadroxil Monohydrate eq. to Cefadroxil (U.S.P)…1gm (Cephalosporin) (U.S.P)	As per SRO/10's	Form-5 20-12-2013 (1316) Rs.20,000/-	1. Not provided. 2.C-doxil (Novamed) 3. Grant of additional sections recommended (07-11-2013)	Deferred for confirmation of international availability
92.	-do-	Azidine 500mg Capsules Each capsule contains:- Cephradine (U.S.P) (anhydrous)……...500mg (Cephalosporin) (U.S.P)	As per SRO/10's	Form-5 20-12-2013 (1320) Rs.20,000/-	1. BNF 58: Velosef (Squibb) 2. Geosef(Geofman Pharmaceuticals) [Cephradine:500mg]Cap 3. Grant of additional sections recommended (07-11-2013)	Approved. Letter will be issued after rectification of shortcomings.
93.	-do-	Azidine 250mg Capsules Each capsule contains:- Cephradine (U.S.P) (anhydrous)……...250mg (Cephalosporin) (U.S.P)	As per SRO/10's	Form-5 20-12-2013(1315) Rs.20,000/-	1. BNF 58: Velosef (Squibb) 2. Geosef(Geofman Pharmaceuticals) [Cephradine:250mg]Cap 3. Grant of additional sections recommended (07-11-2013)	Approved. Letter will be issued after rectification of shortcomings.

94.	-do-	Medicef 200mg Capsule Each capsule cotnains:- Cefixime Trihydrate ≡ Cefixime (U.S.P)..200mg (Cephalosporin) (Manufacturer's)	As per SRO/10's	Form-5 20-12-2013(1318) Rs.20,000/-	1.Required 2.Cefim (Hilton) 3. Grant of additional sections recommended (07-11-2013)	Deferred for confirmation of international availability in stringent DRA's
95.	-do-	Medicef 400mg Capsules Each capsule contains:- Cefixime Trihydrate ≡ Cefixime (U.S.P)..400mg (Cephalosporin) (Manufacturer's)	As per SRO/10's	Form-5 20-12-2013 (1312) Rs.20,000/-	1. FDA Suprax (Lupin Ltd) 2. Cefiget(Getz Pharma Pakistan (Pvt) Ltd.) [Cefixime:400mg]cap 3. Grant of additional sections recommended (07-11-2013)	Approved. Letter will be issued after rectification of shortcomings.
96.	-do-	F-Clor 500mg Capsule Each cpaule contains:- Cefaclor Monohydrate ≡ Cefaclor (U.S.P)...500mg (Cephalosporin) (U.S.P)	As per SRO/12x2's	Form-5 20-12-2013(1317) Rs.20,000/-	1. BNF 58: Cefaclor (Non-proprietary) Capsules, cefaclor (as monohydrate) 250 mg, ; 500 mg, Brands include Keftid 2. Hiclor(Hilton Pharma (Pvt) Limited) [Cefaclor (Monohydrate):500mg]cap 3. Grant of additional sections recommended (07-11-2013)	Approved with change of name. Letter will be issued after rectification of shortcomings.

97.	-do-	F-Clor 250mg Capsule Each capusle contains:- Cefaclor Monohydrate ≡ Cefaclor (U.S.P)...500mg (Cephalosporin) (U.S.P)	As per SRO/12x2's	Form-5 20-12-2013(1313) Rs.20,000/-	1. BNF 58: Cefaclor (Non-proprietary) Capsules, cefaclor (as monohydrate) 250 mg, ; 500 mg, Brands include Keftid 2. Hiclor(Hilton Pharma (Pvt) Limited) [Cefaclor (Monohydrate):250mg]cap 3. Grant of additional sections recommended (07-11-2013)	Approved with change of name. Letter will be issued after rectification of shortcomings.
98.	M/s. Sunrise Pharma (Pvt) Ltd, 594-A sunder industrial Estate, Raiwind Road, Lahore. Additional Section Dry Powder Injectable (Cephalosporin) vide letter No. F.6-2/2013-Lic (M-233) dated 3rd Feb, 2014.	Mac Cepime 1gm Injection Each vial contains:- Cefepime HCl eq. to Cefepime….1gm (Cephalosporin) (USP)	Rs.730.00/ 1's	Form-5 18-12-2013(1229) Rs.20,000/-	1. FDA: MAXIPIME by HOSPIRA INC (Cefepime Hydrochloride Eq 1gm Base/Vial) Injection Original Approval or Tentative Approval Date: January 18, 1996 2. MAXIPIME (GLAXOSMITHKLINE) [Cefepime:1gm] Inj 3. Grant of additional section recommended (13-11-2013)	Approved with change of brand name

99.	-do-	Mac Cepime 500mg Injection Each vial contains:- Cefepime HCl eq. to Cefepime….500mg (Cephalosporin) (USP)	Rs.387.51/ 1's	Form-5 18-12-2013 (1226) Rs.20,000/-	1.FDA: Maxipime By Hospira Inc (Cefepime Hydrochloride Eq 500mg Base/Vial) Injection Original Approval or Tentative Approval Date: January 18, 1996 2. MAXIPIME (GLAXOSMITHKLINE) [Cefepime:500mg] Inj 3. Grant of additional section recommended (13-11-2013)	Approved with change of brand name
100.	-do-	Furains 1gm Powder for injection Injection Each vial contains:- Cefuroxime Sodium eq. to Cefuroxime….1gm (Cephalosporin) (USP Spec.s)	Rs.125.00/ 1's	Form-5 18-12-2013 (1230) Rs.20,000/-	1. Required not found in BNF and FDA in same strength 2. Trucef(Synchro Pharmaceuticals) [Cefuroxime:1g] Inj Vial 3. Grant of additional section recommended (13-11-2013)	Defrerred for confirmation of international availability
101.	-do-	Furains 250mg Powder for Injection Each vial contains:- Cefuroxime (as Sodium)….250mg (Cephalosporin) (USP Spec.s)	Rs.28.00/1's	Form-5 31-03-2014 (596) Rs.20,000/-	1. BNF 61. (Zinacef(GSK) Injection, powder for reconstitution, cefuroxime (as sodium salt). 250-mg vial; 750-mg vial ; 1.5-g vial) 2. TRUCEF(SYNCHRO PHARMACEUTICALS)	Approved

					[Cefuroxime:250mg] Inj Vial 3. Grant of additional section recommended (13-11-2013)	
102.	-do-	Trimac 2.0gm Powder for Injection Each vial contains:- Ceftriaxone (as Sodium)….2.0gm I/V (Cephalosporin/Antibiotic) (USP Spec.s)	Rs.450.00/ 1's	Form-5 31-03-2014 (595) Rs.20,000/-	1. BNF 61. (Rocephin (Roche) Injection, powder for reconstitution, ceftriaxone (as sodium salt) 250-mg vial; 1-g vial ; 2-g vial) 2. Sporcef(Lowitt Pharmaceuticals (Pvt) Ltd) [Ceftriaxone (Na):250mg,500mg, 1g , 2g] Inj Vial 3. Grant of additional section recommended (13-11-2013)	Approved
103.	-do-	Trimac 1.0gm Powder for Injection Each vial contains:- Ceftriaxone (as Sodium)….1.0gm I/V (Cephalosporin/Antibiotic) (USP Spec.s)	Rs.260.00/ 1's	Form-5 31-03-2014 (589) Rs.20,000/-	1. BNF 61. (Rocephin (Roche) Injection, powder for reconstitution, ceftriaxone (as sodium salt) 250-mg vial; 1-g vial ; 2-g vial) 2. Sporcef(Lowitt Pharmaceuticals (Pvt) Ltd) [Ceftriaxone	

					(Na):250mg,500mg, 1g , 2g] Inj Vial 3. Grant of additional section recommended (13-11-2013)	
104.	-do-	Trimac 500mg Powder for Injection Each vial contains:- Ceftriaxone (as Sodium)….500mg I/V (Cephalosporin/Antibiotic) (USP Spec.s)	Rs.120.00/ 1's	Form-5 31-03-2014 (591) Rs.20,000/-	1. BNF 61. (Rocephin (Roche) Injection, powder for reconstitution, ceftriaxone (as sodium salt) 250-mg vial; 1-g vial ; 2-g vial) 2. Sporcef(Lowitt Pharmaceuticals (Pvt) Ltd) [Ceftriaxone (Na):250mg,500mg, 1g , 2g] Inj Vial 3. Grant of additional section recommended (13-11-2013)	Approved
105.	-do-	Trimac 250mg Powder for Injection Each vial contains:- Ceftriaxone (as Sodium)….250mg (I/V) (Cephalosporin/Antibiotic) (USP Spec.s)	Rs.95.00/1's	Form-5 31-03-2014 (592) Rs.20,000/-	1. BNF 61. (Rocephin (Roche) Injection, powder for reconstitution, ceftriaxone (as sodium salt) 250-mg vial; 1-g vial ; 2-g vial) 2. Sporcef(Lowitt Pharmaceuticals (Pvt) Ltd) [Ceftriaxone	

					(Na):250mg,500mg, 1g , 2g] Inj Vial 3. Grant of additional section recommended (13-11-2013)	
106.	-do-	Peramac 1gm Powder for Injection Each vial contains:- Cefoperazone (as Sodium)….0.5 gm Sulbactam (as Sodium)…0.5gm (Cephalosporin/Antibiotic) (Manufacturer's)	Rs.250.00/ 1's	Form-5 31-03-2014 (594) Rs.20,000/-	1. Required 2. Cebac (Bosch) 3. Grant of additional section recommended (13-11-2013)	Approved
107.	-do-	Peramac 2gm Powder for Injection Each vial contains:- Cefoperazone (as Sodium)….1 gm Sulbactam (as Sodium)…1gm (Cephalosporin/Antibiotic) (Manufacturer's)	Rs.350.00/ 1's	Form-5 31-03-2014 (593) Rs.20,000/-	1. Required 2. Cebac (Bosch) 3. Grant of additional section recommended (13-11-2013)	Approved

108.	M/s Healthtek Pvt. Ltd. Plot No.14, Sector No.19, Korangi Industrial Area, Karachi **Liquid Ampoule Section (Water for injection with diluents) vide letter No. F.6-2/2013-Lic (M-233) dated 3rd Feb 2014.**	Water for Injection Liquid Injection Each ampoule contains: Sterile water for injection…….. 10 ml (Diluent) (USP Spec.s)	As per PRC	Form-5 04-11-2013 Dy.No. 980 Rs.20,000/-	1. BNF 61: Water for Injections 1-mL amp; 2-mL amp; 5-mL amp; 10-mL amp; 20-mL amp; 50-mL amp; 2.Water for Injection (Getz) Regn. No. 053043) 3.Grant of additional section recommended. (20 & 26th November, 2013)	Approved
109.	-do-	Water for Injection Liquid Injection Each ampoule contains: Sterile water for injection……..…….…..5 ml Diluent (USP Spec.s)	As per PRC	Form-5 04-11-2013 Dy.No. 982 Rs.20,000/-	1. BNF 61: Water for Injections 1-mL amp; 2-mL amp; 5-mL amp; 10-mL amp; 20-mL amp; 50-mL amp; 2. Water for Injection 5ml (Getz) Regn. No. 053041) 3. Grant of additional section recommended. (20 & 26th November, 2013)	Approved
110.	-do-	Water for Injection Liquid Injection Each ampoule contains: Sterile water for injection…….. 4 ml (Diluent) (USP Spec.s)	As per PRC	Form-5 04-11-2013 Dy.No. 983 Rs.20,000/-	1. 2. Water for Injection 4ml (Getz) Regn. No. 053040) 3. Grant of additional section recommended. (20 & 26th November, 2013)	Approved

111.	-do-	Water for Injection Liquid Injection Each ampoule contains: Sterile water for injection…….. 3 ml (Diluent) (USP Spec.s)	As per PRC	Form-5 04-11-2013 Dy.No. 979 Rs.20,000/-	1. 2. Water for Injection 3ml (Zafa) Regn. No. 047219) 3. Grant of additional section recommended. (20 & 26th November, 2013)	Approved
112.	-do-	Water for Injection Liquid Injection Each ampoule contains: Sterile water for injection…….. 2 ml (Diluent) (USP Spec.s)	As per PRC	Form-5 04-11-2013 Dy.No. 978 Rs.20,000/-	1. BNF 61: Water for Injections 1-mL amp; 2-mL amp; 5-mL amp; 10-mL amp; 20-mL amp; 50-mL amp; 2. Water for Injection 2ml (Getz) Regn. No. 053039) 3. Grant of additional section recommended. (20 & 26th November, 2013)	Approved
113.	-do-	Water for Injection Liquid Injection Each ampoule contains: Sterile water for injection…….. 1 ml (Diluent) (USP Spec.s)	As per PRC	Form-5 04-11-2013 Dy.No. 976 Rs.20,000/-	1. BNF 61: Water for Injections 1-mL amp; 2-mL amp; 5-mL amp; 10-mL amp; 20-mL amp; 50-mL amp; 2. Water for Injection 1ml (Pharmatec) Regn. No. 070918) 3. Grant of additional section recommended. (20 & 26th November, 2013)	Approved

114.	-do-	Lidocain HCl 1% Injection IM Each 5ml contains: Lidocaine Hydrochloride (USP)…….50 mg (Local anesthesia) (USP Spec.s)	As per PRC	Form-5 04-11-2013 Dy.No. 981 Rs.20,000/-	1.BNF 61: Lidocaine (Non-proprietary) Injection, lidocaine hydrochloride 5 mg/mL (0.5%), 10-mL amp; 10 mg/mL (1%), 2-mL amp, 5-mL amp, 10-mL amp, 10- mL prefilled syringe; 20-mL amp; 20 mg/mL (2%), 2-mL amp, 5-mL amp 2.Painil (Sami) R. No. 023072 3. Grant of additional section recommended. (20 & 26th November, 2013)	Approved
115.	-do-	Lidocain HCl 1% Injection Each 2ml contains: Lidocaine Hydrochloride (USP)…….20 mg (Local anesthesia) (USP Spec.s)	As per PRC	Form-5 04-11-2013 Dy.No. 977 Rs.20,000/-	1. BNF 61: Lidocaine (Non-proprietary) Injection, lidocaine hydrochloride 5 mg/mL (0.5%), 10-mL amp; 10 mg/mL (1%), 2-mL amp, 5-mL amp, 10-mL amp, 10- mL prefilled syringe; 20-mL amp; 20 mg/mL (2%), 2-mL amp, 5-mL amp 2.Painil (Sami) R. No. 023072	Approved

					3. Grant of additional section recommended. (20 & 26th November, 2013)	

Evaluator – III

i) Humans

116.	M/s Hygeia Pharmaceuticals, 295 Industrial Triangle, Kahuta Road, Islamabad Dry Powder Injection(Ceph)	PERA-S 2gm Injection IV Dry powder injection Each injection contains Cefeoparazone sodium …1gm Sulbactum sodium….1gm Cephlosporin+ Beta lactam inhibitor Manufacturer	As per SRO/pack of 1's	Form 5 Additional section Dy No 984 dated 19-03-2014 19-03-2014 Rs.20,000	Magnex injection of Pfizer Inc India Toxirid of Global Pharmaceuticals Islamabad. The inspection of the firm was conducted on 14-02-2014 by panel of inspectors and recommended the grant of two additional sections namely dry powder cephalosporin and cream/ointment (general	Approved
117.	-do-	PERA-S 1gm Injection IV Dry powder injection Each injection contains Cefeoparazone sodium …500mg Sulbactum sodium….500mg Cephlosporin+ Beta lactam inhibitor	As per SRO/pack of 1's	Form 5 Additional section Dy No 985 dated 19-03-2014 19-03-2014 Rs.20,000	Magnex injection of Pfizer Inc USA Toxirid of Global Pharmaceuticals Islamabad.	Approved

		Manufacturer				
118.	-do-	PIME 500mg Injection IV Dry powder Injection Each injection contains Cefepime hydrochloride with L-arginine…..500mg Fourth generation cephalosporin USP	As per SRO/pack of 1's	Form 5 Additional section Dy No 1000 dated 19-03-2014 19-03-2014 Rs.20,000	Maxipime of Hospira Inc Zepim of Global Pharmaceuticals Islamabad.	Approved
119.	-do-	PIME 1g Injection IV Dry powder Injection Each injection contains Cefepime hydrochloride with L-arginine…..1g Fourth generation cephalosporin USP	As per SRO/pack of 1's	Form 5 Additional section Dy No 999 dated 19-03-2014 19-03-2014 Rs.20,000	Maxipime of Hospira Inc Zepim of Global Pharmaceuticals Islamabad.	Approved
120.	-do-	Cef-One 500mg Injection IM Each injection contains:- Ceftriaxone Sodium……500	As Per SRO/ 1's vial	Form 5 Additional section Dy No 986 dated 19-03-2014	Rociphen of Roche USA Oxidil injection of Sami Pharmaceuticals Islamabad.	Approved with change of brand name.

		mg Cephlosporin USP		19-03-2014 Rs.20,000		
121.	-do-	Cef-One 1gm Injection IM Each injection contains:- Ceftriaxone Sodium……1gm Cephlosporin USP	As Per SRO/ 1's vial	Form 5 Additional section Dy No 1007 dated 19-03-2014 19-03-2014 Rs.20,000	Rociphen of Roche USA Oxidil injection of Sami Pharmaceuticals Islamabad.	Approved with change of brand name.
122.	-do-	Cef-One 500mg Injection IV Each injection contains:- Ceftriaxone Sodium ……500mg Cephlosporin USP	As Per SRO/ 1's vial	Form 5 Additional section Dy No 987 dated 19-03-2014 19-03-2014 Rs.20,000	Rociphen of Roche USA Oxidil injection of Sami Pharmaceuticals Islamabad.	Approved with change of brand name.
123.	-do-	Cef-One 1gm Injection IV Each injection contains:- Ceftriaxone Sodium ……1gm Cephlosporin USP	As Per SRO/ 1's vial	Form 5 Additional section Dy No 1006 dated 19-03-2014 19-03-2014 Rs.20,000	Rociphen of Roche USA Oxidil injection of Sami Pharmaceuticals Islamabad.	Approved with change of brand name.

124.	-do-	Fusid 2.0% Ointment Each tube contains:- Fusidic Acid…….2.0% Anti-infective Manufacturer	As Per SRO/ 15gm	Form 5 Additional section Dy No 988 dated 19-03-2014 19-03-2014 Rs.20,000	Fucid Ointment of Leo France Fudic of Shaigan Pharmaceuticals Islamabad	Approved with change of brand name.
125.	-do-	Fusid 2.0% Cream Each tube contains:- Fusidic Acid……..2.0% Anti-infective BP	As per SRO/ 15gm	Form 5 Additional section Dy No 1001 dated 19-03-2014 19-03-2014 Rs.20,000	Fucid cream of Leo France Fudic cream of Shaigan Pharmaceuticals Islamabad	Approved with change of brand name.
126.	-do- Cream/Ointment (general)	Tretin 0.05 % Cream Each tube contains:- Tretinoin ……..0.05% Vitamin A derivative USP	As per SRO/ 15gm	Form 5 Additional section Dy No 1002 dated 19-03-2014 19-03-2014 Rs.20,000	Solange of Stiefel Labs Inc USA Skin A cream of Atco Laboratories Karachi	Approved

127.	-do-	Binate 1% Cream Each tube contains:- Terbinafine HCl ……1% Allyamine Antifungal USP	As per SRO/ 10gm	Form 5 Additional section Dy No 1003 dated 19-03-2014 19-03-2014 Rs.20,000	Lamisil Novartis USA Lamisil Topical	Approved with change of brand name.
128.	-do-	Aroleen 0.1% Cream Each tube contains:- Adapalene …… 0.1% Antiacne Manufacturer	As per SRO/ 15gm	Form 5 Additional section Dy No 1004 dated 19-03-2014 19-03-2014 Rs.20,000	Defferin of Galderma Labs USA Acne Lene cream of Valor Pharmaceuticals Islamabad	Approved
129.	-do-	Soretin Cream Each tube contains:- Isotretinoin…….0.05% Vitamin A derivative Manufacturer	As per SRO/ 10gm	Form 5 Additional section Dy No 1005 dated 19-03-2014 19-03-2014 Rs.20,000	Acutane of Roche USA Isotrol cream of Valor Pharmaceuticals Islamabad	Approved

ii) Veterinary

130.	M/s. D-Maarson Pharmaceuticals, Plot # 17, Street # SS-2, National Industrial Zone Rawat, Islamabad.	VITA FOS DM INJECTION Liquid Injection Each ml contains:- Toldimfos Sodium……100mg Vitamin B12 USP……50ug Mineral and Vitamin Supplement Manufacturer	Decontrolled/pack size 50ml	Form 5 Additional section Dy No 793 dated 10-03-2014 10-03-2014 Rs.20,000	Not provided Fosfa Plus Injection of Attabak Pharmaceuticals Islamabad (50 & 100ml) The inspection of the firm was conducted on 08-01-2014 by panel of inspectors and recommended grant of additional sections namely Bolus & Liquid vials injectable section (veterinary)	Approved
131.	-do-	GENTA DM 10% INJECTION BP Liquid Injection Each ml contains:- Gentamycin Sulphate (BP)…….100mg/ml Antibiotic BP	Decontrolled/pack size 100ml	Form 5 Additional section Dy No 794 dated 10-03-2014 10-03-2014 Rs.20,000	Genta-ject of Bayer Health Care Animal Health Division USA. Gentbak of Attabak Pharmaceuticals Islamabad 30ml, 50ml & 100ml	Approved
132.	-do-	MELOX DM INJECTION (BP) Liquid Injection Each ml contains:-	Decontrolled/pack size 50ml	Form 5 Additional section Dy No 795 dated 10-03-2014	Not provided Meloxibak of Attabak Pharmaceuticals Islamabad	Approved

		Meloxicam BP…….7.5mg Antibiotic BP		10-03-2014 Rs.20,000		
133.	-do-	VITA DM INJECTION Liquid Injection Each ml contains:- Vitamin-A…..80,000 I.U Vitamin-D3……40,000 I.U Vitamin-E……20mg Vitamin supplement Manufacturer	Decontrolled/pack size 50ml	Form 5 Additional section Dy No 786 dated 10-03-2014 10-03-2014 Rs.20,000	Vitamin A, D3, E of Dechra Veterinary products UK VAD3 Injection of Breeze Pharmaceuticals Islamabad	Deferred for Product Specific Inspection by (i) Director DTL Peshawar (ii) Area FID
134.	-do-	IVER GN INJECTION Liquid Injection Each ml contains:- Ivermectin……..10mg Anthelmentic BP	Decontrolled/pack size 50ml	Form 5 Additional section Dy No 792 dated 10-03-2014 10-03-2014 Rs.20,000	Iqvalan Injection of Merial Ltd USA Ivobak injection of Attabak Pharmaceuticals Islamabad	Approved

135.	-do-	NOVA DM INJECTION Liquid Injection Each 100ml contains:- Novaminsulfon….4g Etilefrin……0.02g Calcium Gluconate……10g Magnesium gluconate……1.0g Sodium salicylate…..0.700g Nicotinamide……0.3g Caffeine……1.0g Boric acid……1.0g Analgesic, Antipyretic	Decontrolled/pack size 450ml	Form 5 Additional section Dy No 787 dated 10-03-2014 10-03-2014 Rs.20,000	Not provided Aminogesic Injection of Nawal Pharma Taxila.	Deferred for expert opinion
136.	-do-	SULPHA DM INJECTION Injection Each 100ml contains:- Sulfadimidine Sodium BP……..33.33% Antibacterial	Decontrolled/pack size 100ml	Form 5 Additional section Dy No 788 dated 10-03-2014 10-03-2014 Rs.20,000	Not provided Super Sulf Injection of Nawal Pharmaceuticals Taxila	Approved

		BP				
137.	-do-	PYRO DM INJECTION Injection Each ml contains:- Methampyrone…200mg Aminopyrine…..50mg Caffeine USP…..20mg Sodium Benzoate USP…20mg Chlorpheniramine Maleate BP…2mg Analgesic, Antipyretic Manufacturer	Decontrolled\pack size 50ml	Form 5 Additional section Dy No 789 dated 10-03-2014 10-03-2014 Rs.20,000	Not provided Vetpyrone of Vetcon Pharmaceuticals Mirpur	Rejected as the formulation contains already banned drug metamizole. The Registration Board decided to review already registed formulation containing metamizole.
138.	-do-	FLORAMEC INJECTION Injection Each ml contains:- Ivermectin (B.P)…….20mg Anthelmentic BP	Decontrolled\pack size 50ml	Form 5 Additional section Dy No 790 dated 10-03-2014 10-03-2014 Rs.20,000	Ivermection injection 2% of Hebei New Centaury Pharmaceuticals China(not found in stringent regulatory authorities) Ivomek of Nawal Pharmaceuticals Taxila	Approved
139.	-do-	TRI DM INJECTION	Decontrolled/pack	Form 5 Additional section	Tribrissen of Schering-Plough Animal Health Limited, New Zealand	Approved

		Injection Each ml contains:- Trimethoprim BP……..80mg Sulfadiazine BP……400 mg Antibacterial BP	size 50ml	Dy No 791 dated 10-03-2014 10-03-2014 Rs.20,000	Sulfaprime Injection of Attabak Pharmaceuticals Islamabad	
140.	M/s. D-Maarson Pharmaceuticals, Plot # 17, Street # SS-2, National Industrial Zone Rawat, Islamabad.	BENDA-2500 BOLUS Bolus Each bolus contains:- Albendazole……2500mg Anthelmentic USP	Decontrolled\pack size 50 Bolus 100 Bolus 200 Bolus	Form 5 Additional section Dy No 800 dated 10-03-2014 10-03-2014 Rs.20,000	Albendazole 2500mg of Alfasan Spain Zoben bolus of Prix Pharma Lahore	Approved
141.	M/s. D-Maarson Pharmaceuticals, Plot # 17, Street # SS-2, National Industrial Zone Rawat, Islamabad.	SULFADIMDINE-DM BOLUS Bolus Each bolus contains:- Sulfadimidine BP……2.50g Anthelmentic BP	Decontrolled\pack size 50 Bolus 100 Bolus 200 Bolus	Form 5 Additional section Dy No 799 dated 10-03-2014 10-03-2014 Rs.20,000	Sulmet Oblets of Boheringer Vetmedica Inc Sulfapri Bolus of Prix Pharmaceuticals Lahore	Approved

142.	M/s. D-Maarson Pharmaceuticals, Plot # 17, Street # SS-2, National Industrial Zone Rawat, Islamabad.	CLOSANTEL DM-500 BOLUS Bolus Each bolus contains:- Closantel sodium hihydrate…….500mg Anthelmentic Manufacturer	Decontrolled\pack size 50 Bolus 100 Bolus 200 Bolus	Form 5 Additional section Dy No 805 dated 10-03-2014 10-03-2014 Rs.20,000	Closal 500 of Behrood Atrak Priclosan of Prix Pharmaceuticals Lahore	Approved
143.	M/s. D-Maarson Pharmaceuticals, Plot # 17, Street # SS-2, National Industrial Zone Rawat, Islamabad.	FLUCIN BOULS Bolus Each bolus contains:- Flumequine…… ……..350mg Colistin Sulphate BP……300mg Antibiotic Manufacturer	Decontrolled\pack size 50 Bolus 100 Bolus 200 Bolus	Form 5 Additional section Dy No 804 dated 10-03-2014 10-03-2014 Rs.20,000	Not provided Colis-Q of Prix Pharmaceuticals Lahore	Approved
144.	M/s. D-Maarson Pharmaceuticals, Plot # 17, Street # SS-2, National Industrial Zone Rawat, Islamabad.	WAN DM-250 BOLUS Bolus Each bolus contains:- Albendazole USP……..250mg Anthelmentic USP	Decontrolled\pack size 50 Bolus 100 Bolus 200 Bolus	Form 5 Additional section Dy No 803 dated 10-03-2014 10-03-2014 Rs.20,000	Albendazole 250mg bolus of Alfasan Spain Bendol 250 of Breeze Pharmaceuticals Islamabad	Approved

145.	M/s. D-Maarson Pharmaceuticals, Plot # 17, Street # SS-2, National Industrial Zone Rawat, Islamabad.	ALBA DM-152 bolus Bolus Each bolus contains:- Albendazole……….152mg Anthelmentic USP	Decontrolled\pack size 50 Bolus 100 Bolus 200 Bolus	Form 5 Additional section Dy No 802 dated 10-03-2014 10-03-2014 Rs.20,000	Albazole 152 of Behrood Atrak Animal Health Zoben of prix Pharmaceuticals Lahore	Approved
146.	M/s. D-Maarson Pharmaceuticals, Plot # 17, Street # SS-2, National Industrial Zone Rawat, Islamabad.	PARA-DM BOLUS Bolus Each bolus contains:- Oxyclozanide.2.250g Levamisole HCI (USP)……...1.125 g Anthelmentic Manufacturer	Decontrolled\pack size 50 Bolus 100 Bolus 200 Bolus	Form 5 Additional section Dy No 798 dated 10-03-2014 10-03-2014 Rs.20,000	Not provided Paranil Bolus of Breeze Pharmaceuticals Lahore	Approved
147.	M/s. D-Maarson Pharmaceuticals, Plot # 17, Street # SS-2, National Industrial Zone Rawat, Islamabad.	FLU WAN DM BOLUS Bolus Each bolus contains:- Flumequine…….350mg Anthelmentic Manufacturer	Decontrolled\pack size 50 Bolus 100 Bolus 200 Bolus	Form 5 Additional section Dy No 797 dated 10-03-2014 10-03-2014 Rs.20,000	Not provided Dart-350 of Breeze Pharmaceuticals Lahore	Approved

148.	M/s. D-Maarson Pharmaceuticals, Plot # 17, Street # SS-2, National Industrial Zone Rawat, Islamabad.	BERSEN-DM BP BOLUS Bolus Each bolus contains:- Trimethoprim BP……200mg Sulfadiazine BP……..1000mg Antibiotic BP	Decontrolled\pack size 50 Bolus 100 Bolus 200 Bolus	Form 5 Additional section Dy No 796 dated 10-03-2014 10-03-2014 Rs.20,000	Norodin bolus tablets of Norbrook Laboratories UK Trimodin of Nawan Laboratories Karachi	Approved
149.	M/s. D-Maarson Pharmaceuticals, Plot # 17, Street # SS-2, National Industrial Zone Rawat, Islamabad.	NICLOSAMIDE BOLUS Bolus Each bolus contains:- Niclosamide BP…….1250 mg Anthelmentic	Decontrolled\pack size 50 Bolus 100 Bolus 200 Bolus	Form 5 Additional section Dy No 801 dated 10-03-2014 10-03-2014 Rs.20,000	Niclosamide of Behroo Atrak Pritap bolus of Prix Pharmaceuticals Lahore	Approved

Evaluator – IV

150.	M/s Vega Pharmaceuticals (Pvt.) Limited. Plot No. 4, 30 Km Pharma City Multan Road, Lahore.	Diosef Capsules Each capsule contains Cephradine USP 250mg (Cephalosporin) Finished Product specifications are USP	2 × 6's Rs 100/-	1. Form 5 2. 09-09-13 3. 09-09-13 Rs 20,000/-	1.Anspor Capsule 250mg 2. Me too Anasef Cap 250mg 3. Firm was inspected on 24-06-13 for grant of additional section for manufacturing of Cephalosporin (dry powder for injectable, capsule, dry powder for suspension).	Approved
151.	M/s Vega Pharmaceuticals (Pvt.) Limited. Plot No. 4, 30 Km Pharma City Multan Road, Lahore.	Diosef Capsules Each capsule contains Cephradine USP 500mg (Cephalosporin) Finished Product specifications are USP	2 × 6's Rs 200/-	1. Form 5 2. 09-09-13 3. 09-09-13 Rs 20,000/-	1. Anspor Capsule 500mg 2. Me too Anasef Cap 500mg 3. Firm was inspected on 24-06-13 for grant of additional section for manufacturing of Cephalosporin (dry powder for injectable, capsule, dry powder for suspension).	Approved
152.	M/s Vega Pharmaceuticals (Pvt.) Limited. Plot No. 4, 30 Km Pharma City Multan Road, Lahore.	Vegalex Capsules Each capsule contains Cephalexin monohydrate eq. to Anhydrous Cephalexin USP 250mg (Cephalosporin) Finished Product	2 × 6's Rs 80/ pack	1. Form 5 2. 09-09-13 3. 09-09-13 Rs 20,000/-	1.Keflex Cap 250mg 2. Me-too Keflex Cap 250mg 3. Firm was inspected on 24-06-13 for grant of additional section for manufacturing of Cephalosporin (dry powder for injectable, capsule, dry powder for	Approved

		specifications are USP			suspension).	
153.	M/s Vega Pharmaceuticals (Pvt.) Limited. Plot No. 4, 30 Km Pharma City Multan Road, Lahore.	1. Vegalex 2. Capsules 3. Each capsule contains Cephalexin monohydrate eq. to Anhydrous Cephalexin USP 500mg (Cephalosporin) Finished Product specifications are USP	2 × 6's Rs 170/ pack	1. Form 5 2. 09-09-13 3. 09-09-13 Rs 20,000/-	1. Keflex Cap 500mg 2. Me-too Keflex Cap 500mg 3. Firm was inspected on 24-06-13 for grant of additional section for manufacturing of Cephalosporin (dry powder for injectable, capsule, dry powder for suspension).	Approved
154.	M/s Vega Pharmaceuticals (Pvt.) Limited. Plot No. 4, 30 Km Pharma City Multan Road, Lahore.	Vestaclor Capsules Each capsule contains Cefaclor monohydrate eq. to Anhydrous Cefaclor USP 250mg (Cephalosporin) Finished Product specifications are USP	3. 2 × 6's Rs 230/ pack	1. Form 5 2. 09-09-13 3. 09-09-13 Rs 20,000/-	1.Cefaclor Cap 250mg 2. Me too Cavaclor Cap 250mg 3. Firm was inspected on 24-06-13 for grant of additional section for manufacturing of Cephalosporin (dry powder for injectable, capsule, dry powder for suspension).	Approved
155.	M/s Vega Pharmaceuticals (Pvt.) Limited. Plot No. 4, 30 Km Pharma City Multan Road, Lahore.	Vestaclor Capsules Each capsule contains Cefaclor monohydrate eq. to Anhydrous Cefaclor USP 500mg (Cephalosporin) Finished Product specifications are	2 × 6's Rs 460/	1. Form 5 2. 09-09-13 3. 09-09-13 Rs 20,000/-	1. Cefaclor Cap 500mg 2. Me too Cavaclor Cap 500mg 3. Firm was inspected on 24-06-13 for grant of additional section for manufacturing of Cephalosporin (dry powder for injectable, capsule, dry powder for	Approved

		USP			suspension).	
156.	M/s Vega Pharmaceuticals (Pvt.) Limited. Plot No. 4, 30 Km Pharma City Multan Road, Lahore.	Vestaclor 187.5mg/5ml dry suspension Dry powder suspension After reconstitution each 5ml contains Cefaclor monohydrate eq. to Cefaclor USP 187.5mg (Cephalosporin) Finished Product specifications are USP	60ml Rs 220/ pack	1. Form 5 2. 09-09-13 3. 09-09-13 Rs 20,000/-	1.Cefaclor dry suspension 187mg/5ml 2. Me too Ceclor Susp- BD 187mg 3. Firm was inspected on 24-06-13 for grant of additional section for manufacturing of Cephalosporin (dry powder for injectable, capsule, dry powder for suspension).	Approved
157.	M/s Vega Pharmaceuticals (Pvt.) Limited. Plot No. 4, 30 Km Pharma City Multan Road, Lahore.	Vestaclor 250mg/5ml dry suspension Dry powder suspension After reconstitution each 5ml contains Cefaclor monohydrate eq. to Cefaclor USP 250mg (Cephalosporin) Finished Product specifications are USP	60ml Rs 260/ pack	1. Not mentioned 2. 09-09-13 3. 09-09-13 Rs 20,000/-	1. Cefaclor dry suspension 250mg/5ml 2. Me too Cavaclor Susp 250mg/5ml 3. Firm was inspected on 24-06-13 for grant of additional section for manufacturing of Cephalosporin (dry powder for injectable, capsule, dry powder for suspension).	Approved
158.	M/s Vega Pharmaceuticals (Pvt.) Limited.	Vestaclor 125mg/5ml dry suspension	60ml Rs 150/ pack	1. Not mentioned 2. 09-09-13 3. 09-09-13	1. Cefaclor dry suspension 125mg/5ml 2. Me too	Approved

	Plot No. 4, 30 Km Pharma City Multan Road, Lahore.	Dry powder suspension After reconstitution each 5ml contains Cefaclor monohydrate eq. to Cefaclor USP 125mg Cephalosporin Finished Product specifications are USP		Rs 20,000/-	Cavaclor Susp 125mg/5ml 3. Firm was inspected on 24-06-13 for grant of additional section for manufacturing of Cephalosporin (dry powder for injectable, capsule, dry powder for suspension).	
159.	M/s Vega Pharmaceuticals (Pvt.) Limited. Plot No. 4, 30 Km Pharma City Multan Road, Lahore.	Vegalex 125mg Dry Suspension Dry Powder Suspension After reconstitution each 5ml contains Cephalexin (as monohydrate) USP 125mg (Cephalosporin) Finished Product specifications are USP	60 ml Rs 53/ pack	1. Form 5 2. 09-09-13 3. 09-09-13 Rs 20,000/-	1.Cephalexin for Suspension 125mg/5ml 2. Me-too Keflex Susp 125mg/5ml 3. Firm was inspected on 24-06-13 for grant of additional section for manufacturing of Cephalosporin (dry powder for injectable, capsule, dry powder for suspension).	Approved
160.	M/s Vega Pharmaceuticals (Pvt.) Limited. Plot No. 4, 30 Km Pharma City Multan Road, Lahore.	Vegalex 250mg Dry spension Dry Powder Suspension After reconstitution each 5ml contains Cephalexin (as monohydrate) USP 250mg (Cephalosporin) Finished Product	60 ml Rs 89/ pack	1. Form 5 2. 09-09-13 3. 09-09-13 Rs 20,000/-	1. Cephalexin for Suspension 250mg/5ml 2. Me-too Keflex Susp 250mg/5ml 3. Firm was inspected on 24-06-13 for grant of additional section for manufacturing of Cephalosporin (dry powder for injectable, capsule, dry powder for	Approved

		specifications are USP			suspension).	
161.	M/s Vega Pharmaceuticals (Pvt.) Limited. Plot No. 4, 30 Km Pharma City Multan Road, Lahore.	Diosef 250mg Dry Suspension Dry Powder Suspension After reconstitution each 5ml contains Cephradine 250mg (Cephalosporin) Finished Product specifications are USP	60 ml Rs 120/ pack	1. Form 5 2. 09-09-13 3. 09-09-13 Rs 20,000/-	1. FDA discontinued marketing of Cephradine of all registered brands & all dosage forms 2. Me too Anasef Susp 250mg/5ml 3. Firm was inspected on 24-06-13 for grant of additional section for manufacturing of Cephalosporin (dry powder for injectable, capsule, dry powder for suspension).	Approved
162.	M/s Vega Pharmaceuticals (Pvt.) Limited. Plot No. 4, 30 Km Pharma City Multan Road, Lahore.	Diosef 125mg Dry Suspension Dry Powder Suspension After reconstitution each 5ml contains Cephradine 125mg (Cephalosporin) Finished Product specifications are USP	60 ml Rs 70/ pack	1. Form 5 2. 09-09-13 3. 09-09-13 Rs 20,000/-	1. FDA discontinued marketing of Cephradine of all registered brands & all dosage forms 2. Me too Anasef Susp 125mg/5ml 3. Firm was inspected on 24-06-13 for grant of additional section for manufacturing of Cephalosporin (dry powder for injectable, capsule, dry powder for suspension).	Approved
163.	M/s Vega Pharmaceuticals (Pvt.) Limited. Plot No. 4, 30 Km Pharma City	Prozil 250mg Dry Suspension Dry Powder Suspension After reconstitution	50 ml Rs 300/ pack	1. Not mentioned 2. 09-09-13 3. 09-09-13 Rs 20,000/-	1.Cefprozil for Suspension 250mg/5ml 2. Me-too 3. Firm was inspected on 24-06-13 for grant of	Approved

	Multan Road, Lahore.	each 5ml contains Cefprozil (as monohydrate) 250mg (Cephalosporin) Finished Product specifications are USP			additional section for manufacturing of Cephalosporin (dry powder for injectable, capsule, dry powder for suspension).	
164.	M/s Vega Pharmaceuticals (Pvt.) Limited. Plot No. 4, 30 Km Pharma City Multan Road, Lahore.	Prozil 125mg Dry Suspension Dry Powder Suspension After reconstitution each 5ml contains Cefprozil (as monohydrate) 125mg (Cephalosporin) Finished Product specifications are USP	50 ml Rs 150/ pack	1. Not mentioned 2. 09-09-13 3. 09-09-13 Rs 20,000/-	1. Cefprozil for Suspension 125mg/5ml 2. Me-too 3. Firm was inspected on 24-06-13 for grant of additional section for manufacturing of Cephalosporin (dry powder for injectable, capsule, dry powder for suspension).	Approved
165.	M/s Vega Pharmaceuticals (Pvt.) Limited. Plot No. 4, 30 Km Pharma City Multan Road, Lahore.	Xipodox 40mg Dry Suspension Dry Powder Suspension After reconstitution each 5ml contains Cefpodoxime Proxetil eq. to Cefpodoxime 40 mg (Cephalosporin) Finished Product specifications are USP	50 ml Rs 200/ pack	1. Form 5 2. 09-09-13 3. 09-09-13 Rs 20,000/-	1. FDA approved Cefpodoxime dry suspension 50mg/5ml while firm applied for 40mg/5ml 2. Me-too Apodox Susp 40mg/5ml 3. Firm was inspected on 24-06-13 for grant of additional section for manufacturing of Cephalosporin (dry powder for injectable, capsule, dry powder for suspension).	Approved

166.	M/s Vega Pharmaceuticals (Pvt.) Limited. Plot No. 4, 30 Km Pharma City Multan Road, Lahore.	Verox 125mg Dry Suspension Dry Powder Suspension After reconstitution each 5ml contains Cefuroxime axetil eq. to Cefuroxime 125 mg (Cephalosporin) Finished Product specifications are USP	50 ml Rs 190/ pack	1. Form 5 2. 09-09-13 3. 09-09-13 Rs 20,000/-	1.Ceftin for Suspension 125mg base/5ml 2. Me too Dowcef Susp 125mg/5ml 3. Firm was inspected on 24-06-13 for grant of additional section for manufacturing of Cephalosporin (dry powder for injectable, capsule, dry powder for suspension).	Approved
167.	M/s Vega Pharmaceuticals (Pvt.) Limited. Plot No. 4, 30 Km Pharma City Multan Road, Lahore.	Vezid 250mg dry Injection Injection Each vial contains Ceftazidime (as pentahydrate) 250mg (Cephalosporin) Finished Product specifications are USP	1's Rs 100/ injection	1. Form 5 2. 09-09-13 3. 09-09-13 Rs 20,000/-	1. Same strength as Ceftazidime 250mg not found in reference drug agencies, while, Ceftazidime 250 mg Inj registered by MHRA. 2. Me too Ceftaz Inj 250mg 3. Firm was inspected on 24-06-13 for grant of additional section for manufacturing of Cephalosporin (dry powder for injectable, capsule, dry powder for suspension).	Approved
168.	M/s Vega Pharmaceuticals (Pvt.) Limited. Plot No. 4, 30 Km Pharma City Multan Road, Lahore.	Vezid 500mg dry Injection Injection Each vial contains Ceftazidime (as pentahydrate) 500mg	1's Rs 180/ injection	1. Form 5 2. 09-09-13 3. 09-09-13 Rs 20,000/-	1.Fortaz Injectable 500mg 2. Me too Ceftaz Inj 500mg 3. Firm was inspected on 24-06-13 for grant of additional section for manufacturing of	Approved

		Cephalosporin Finished Product specifications are USP			Cephalosporin (dry powder for injectable, capsule, dry powder for suspension).	
169.	M/s Vega Pharmaceuticals (Pvt.) Limited. Plot No. 4, 30 Km Pharma City Multan Road, Lahore.	Vezid 1 g dry Injection Injection Each vial contains Ceftazidime (as pentahydrate) 1G (Cephalosporin) Finished Product specifications are USP	1's Rs 300/ injection	1. Form 5 2. 09-09-13 3. 09-09-13 Rs 20,000/-	1. Fortaz Injectable 1g 2. Me too Ceftaz Inj 1g 3. Firm was inspected on 24-06-13 for grant of additional section for manufacturing of Cephalosporin (dry powder for injectable, capsule, dry powder for suspension).	Approved
170.	M/s Vega Pharmaceuticals (Pvt.) Limited. Plot No. 4, 30 Km Pharma City Multan Road, Lahore.	V-pime 500mg dry Injection Injection Each vial contains Cefepime hydrochloride eq. to Cefepime 500mg (Cephalosporin) Finished Product specifications are USP	1's Rs 300/ injection	1. Form 5 2. 09-09-13 3. 09-09-13 Rs 20,000/-	1.Maxipime Injectable 500mg 2. Me too Medipime 500mg Inj 3. Firm was inspected on 24-06-13 for grant of additional section for manufacturing of Cephalosporin (dry powder for injectable, capsule, dry powder for suspension).	Approved
171.	M/s Vega Pharmaceuticals (Pvt.) Limited. Plot No. 4, 30 Km Pharma City Multan Road, Lahore.	V-pime 1g dry Injection Injection Each vial contains Cefepime hydrochloride eq. to Cefepime 1g (Cephalosporin) Finished Product	1's Rs 600/ injection	1. Form 5 2. 09-09-13 3. 09-09-13 Rs 20,000/-	1. Maxipime Injectable 1g 2. Me too Medipime 1g Inj 3. Firm was inspected on 24-06-13 for grant of additional section for manufacturing of Cephalosporin (dry powder for injectable,	Approved

		specifications are USP			capsule, dry powder for suspension).	
172.	M/s Vega Pharmaceuticals (Pvt.) Limited. Plot No. 4, 30 Km Pharma City Multan Road, Lahore.	Cefopraz 250mg dry Injection Injection Each vial contains Cefoperazone sodium 250mg (Cephalosporin) Finished Product specifications are USP	1's Rs 100/ injection	1. Form 5 2. 09-09-13 3. 09-09-13 Rs 20,000/-	1. Same strength not present in reference drug agencies, while, Cefoperazone Injction 250 mg available in India. 2. Me-too Aricef Inj 250mg 3. Firm was inspected on 24-06-13 for grant of additional section for manufacturing of Cephalosporin (dry powder for injectable, capsule, dry powder for suspension).	Approved
173.	M/s Vega Pharmaceuticals (Pvt.) Limited. Plot No. 4, 30 Km Pharma City Multan Road, Lahore.	Cefopraz 500mg dry Injection Injection Each vial contains Cefoperazone sodium 500mg (Cephalosporin) Finished Product specifications are USP	1's Rs 180/ injection	1. Not mentioned 2. 09-09-13 3. 09-09-13 Rs 20,000/-	1. 2. Me-too Aricef Inj 500mg 3. Firm was inspected on 24-06-13 for grant of additional section for manufacturing of Cephalosporin (dry powder for injectable, capsule, dry powder for suspension).	Approved
174.	M/s Vega Pharmaceuticals (Pvt.) Limited. Plot No. 4, 30 Km Pharma City Multan Road, Lahore.	Cefopraz 1g dry Injection Injection Each vial contains Cefoperazone sodium 1g (Cephalosporin)	1's Rs 250/ injection	1. Form 5 2. 09-09-13 3. 09-09-13 Rs 20,000/-	1.Cefobid Injectable 1g FDA describes marketing status as discontinued 2. Me-too Aricef Inj 1g 3. Firm was inspected on 24-06-13 for grant of	Approved

		Finished Product specifications are USP			additional section for manufacturing of Cephalosporin (dry powder for injectable, capsule, dry powder for suspension).	
175.	M/s Vega Pharmaceuticals (Pvt.) Limited. Plot No. 4, 30 Km Pharma City Multan Road, Lahore.	Cefobact 500mg dry Injection Injection Each vial contains Cefoperazone as sodium 250mg & Sulbactam as sodium 250mg (Cephalosporin) Finished Product specifications are Manufacturer	1's Rs 150/ vial	1. Form 5 2. 09-09-13 3. 09-09-13 Rs 20,000/-	1. Not found in reference drug agencies, however, present in India in combination of 250mg + 250 Cefoperazone Sodium + Sulbactam respectively. 2. Me too Paratam 500mg Inj 3. Firm was inspected on 24-06-13 for grant of additional section for manufacturing of Cephalosporin (dry powder for injectable, capsule, dry powder for suspension).	Approved
176.	M/s Vega Pharmaceuticals (Pvt.) Limited. Plot No. 4, 30 Km Pharma City Multan Road, Lahore.	Cefobact 1g dry Injection Injection Each vial contains Cefoperazone as sodium 500mg & Sulbactam as sodium 500mg (Cephalosporin) Finished Product specifications are Manufacturer	1's Rs 250/ vial	1. Form 5 2. 09-09-13 3. 09-09-13 Rs 20,000/-	1. Not found in reference drug agencies, however, present in India in combination of 500mg + 500 & 1g + 1g of Cefoperazone Sodium + Sulbactam respectively. 2. Me too Paratam 1g Inj 3. Firm was inspected on 24-06-13 for grant of additional section for manufacturing of Cephalosporin (dry	Approved

					powder for injectable, capsule, dry powder for suspension).	
177.	M/s Vega Pharmaceuticals (Pvt.) Limited. Plot No. 4, 30 Km Pharma City Multan Road, Lahore.	Cefobact 2g dry Injection Injection Each vial contains Cefoperazone as sodium 1g & Sulbactam as sodium 1g (Cephalosporin) Finished Product specifications are Manufacturer	1's Rs 350/ vial	1. Form 5 2. 09-09-13 3. 09-09-13 Rs 20,000/-	1. Not found in reference drug agencies, however, present in India in combination of 500mg + 500 & 1g + 1g of Cefoperazone Sodium + Sulbactam respectively. 2. Me too Paratam 2g Inj 3. Firm was inspected on 24-06-13 for grant of additional section for manufacturing of Cephalosporin (dry powder for injectable, capsule, dry powder for suspension).	Approved

Evaluator – V

178.	M/s. Vision Pharmaceuticals, Plot No. 22 & 23, Industrial Triangle Kahuta Road, Islamabad **Additional Section:** Large Volume and Small Volume Parenterals Vide letter No. F. 6-3/2014 – Lic (M-234) dated 10th April, 2014	**Dexsol 5% IV Infusion** Each 100ml contains: - Dextrose USP …. 5% Carbohydrate caloric solution	As fixed by Govt. 1000ml	Form-5 13-03-2014 877 R&I Rs.20,000/-	5% Dextrose Injection B. Braun, USA (250, 500 & 1000ml) PLADEX 5 5% w/v (100, 500 & 1000ml) Otsuka	Approved. (Confirmation of Liquid particle counter and TOC availability by area FID)
179.	-do-	**Visoline IV Infusion** Each 100ml contains: - Sodium Chloride USP …….. 0.9% Electrolyte	As fixed by Govt. / 1000ml	Form-5 13-03-2014 881 R&I Rs.20,000/-	0.9% Sodium Chloride Injection B. Braun, USA (250, 500 & 1000ml) PLASALINE 0.9% w/v (100, 500 & 1000ml) Otsuka	Approved. (Confirmation of Liquid particle counter and TOC availability by area FID)
180.	-do-	**Dexsol – DS IV Infusion** Each 100ml contains: - Dextrose USP …. 5% Sodium Chloride USP …….. 0.9% Electrolyte	As fixed by Govt. / 1000ml	Form-5 13-03-2014 884 R&I Rs.20,000/-	5% Dextrose and 0.9% Sodium Chloride Injection B. Braun, USA (500 & 1000ml) PLADEXSAL 5% / 0.9% w/v (500 & 1000ml) Otsuka	Approved. (Confirmation of Liquid particle counter and TOC availability by area FID)

181.	-do-	**Visolact IV Infusion** Each 1000ml contains: - Calcium Chloride 2H2O USP …… 0.2g Potassium Chloride USP ……. 0.3g Sodium Chloride USP ……. 6.0g Sodium Lactate USP …….3.1g Electrolyte	As fixed by Govt. 1000ml	Form-5 13-03-2014 890 R&I Rs.20,000/-	Lactated Ringer's Injection USP RINGOLACT 500 & 1000ml Otsuka	Approved. (Confirmation of Liquid particle counter and TOC availability by area FID)
182.	-do-	**Visolact - D IV Infusion** Each 1000ml contains: Calcium Chloride USP ……..…… 0.2g Potassium Chloride USP ……. 0.3g Sodium Chloride USP ……. 6.0g Sodium Lactate USP ……. 3.1g Dextrose USP ….. 50g Electrolyte / Carbohydrate	As fixed by Govt. 1000ml	Form-5 13-03-2014 889 R&I Rs.20,000/-	Lactated Ringers and 5% Dextrose Baxter, USA RINGOLACT – D Otsuka	Approved. (Confirmation of Liquid particle counter and TOC availability by area FID)

d) Applications of Newly approved sections whose applications are still remaining according to 10 per section policy as they got registrations less than 10 per section in the previous meetings of the Registration Board (34 Applications)

Evaluator – II

S/N	Name and address of manufacturer/Applicant	Brand Name Dosage Form Composition (pharmacological Group) Finished product specification	Demanded Price / Pack size	1. Type of Form 2. Initial date, diary. 3. Date on which fee becomes complete according to type of application /or Form (total Fee)	1. International status in stringent regulatory agencies 2. Me-too status 3.GMP status as depicted in inspection report (dated)	Decision
1.	M/s Martin Dow Ltd. Plot. No.37, Sector 19, Korangi Industrial Area, Karachi-47900. Dry Powder Suspension (General) Section vide letter No. F. 2-6/86-Lic (Vol.v) dated 12-06-2011	Rythro Oral Granules for Suspension Each 5ml contains: Erythromycin as ethyl succinate (U.S.P)…….200 mg (Antibiotic) (U.S.P)	Rs.40.70/60ml	1. Form-5 2. 11-04-2013 Dy.No.231 3. 11-04-2013 (Rs.20,000/-)	1.FDA E.E.S. SUSPENSION; ORAL (ARBOR PHARMS INC) ERYTHROMYCIN ETHYLSUCCINATE GRANULE;ORAL EQ 200MG BASE/5ML 2.Erythrocin (Indus Pharma) Susp 200mg 3. Good (08-01-14)	Approved

2.	M/s Sante (Pvt) Ltd, A-97, S.I.T.E. Super Highway Karachi. Cream/ointment (General) section vide letter no F.2-12/2006-lic dated 25-02-2011	Mupicin Cream Each gm contains: Mupirocin (as calcium) (U.S.P)……..…20 mg (Antibiotic) (USP)	Rs.140/15gm	1.Form-5 2. 09-07-2012 Rs.8000/- Dy.No.1264 3. 08-04-2013 Rs.12,000/-	1. BNF 58: Bactroban (GSK) Cream, mupirocin (as mupirocin calcium) 2%, 2. Bactroban cream (GSK) 3.Acceptable level of GMP (09-05-13)	Approved
3.	-do- Ear/Nasal drops (General) section vide letter no F.2-12/2006-lic dated 25-02-2011	Xenase Nasal Spray Each100 micro liter contains: Olopatadine hydrochloride……..665mcg / 0.6% w/v (Anti Allergic)	Rs.800/15ml Plastic Bottle	1.Form-5D 2. 23-11-2011 Dy.No.379 Rs.15000/- 3. 08-04-2013 Rs.35,000/-	1. PATANASE (ALCON PHARMS LTD) SPRAY, METERED;NASAL OLOPATADINE HYDROCHLORIDE 0.665MG/SPRAY 2. 3.Acceptable level of GMP (09-05-13)	Deferred for (i) expert opinion (ii) Product Specific Inspection for manufacturing facility.
4.	-do-	Rhinase Nasal Spray Each ml contains: Naphazoline Nitrate…….1.25 mg Ephedrine Hydrochloride.5.00 mg, 9 alpha-Fluoroprednisolone-21 acetate……..…0.025 mg	Rs.100/Per Pack	1.Form5 2. 28-02-2011 Dy.No.545 Rs.8000/- 3. 08-04-2013 Rs.12,000/-	1.Not provided 2.Rhinosone (Schazoo Pharma) 3. Acceptable level of GMP (09-05-13)	Deferred for clarification of manufacturing facility (steroid and Controlled Drug) from Licensing Section.

		(Allergy Nasal Spray) (Manufacturer's Spec.s)				
5.	-do-	Flutisin Nasal Spray Each spray contains: Fluticasone Propionate…..50 mcg (Nasal corticosteroid)	Rs,420/Per Pack	1.Form5 2. 28-02-2011 Dy.No.544 Rs.8000/- 3. 08-04-2013 Rs.12,000/-	1. BNF 58: Flixotide (A&H) Evohaler aerosol inhalation, fluticasone propionate 50 micrograms/metered inhalation ; 250 micrograms/ metered inhalation. 2. Flexosone (Schazoo Pharma) 3.	Deferred for confirmation of manufacturing facility (steroid).
6.	M/s. Hansel Pharmaceuticals (Pvt.) Ltd. Plot # 2, Pharma city, 30th Km., Multan Road, Lahore. Less than 10 products in Additional Section Eye Drops (General) vide letter No. F.6-1/2013-Lic (M-232) dated 29th Aug,013.	Brex Fort 1.5 % Eye Drops Each ml of solution contains:- Tobramycin (USP)….15mg (aminoglycoside) (USP)	Rs.200/5ml	Form-5 7-11-2013(744) Rs.20,000/-	1.Required 2.Obrex Fort (Vega) 3. Grant of Additional sections recommended (17-12-2012)	Approved

7.	-do-	Cyclospor 0.05% Eye Drop Each ml contains:- Cyclosporine BP……0.5mg (calcineurin inhibitor)	Rs.200/10ml	Form-5 7-11-2013(743) Rs.20,000/-	1.Required 2.C-Spor (Opth Pharma) 3. Grant of Additional sections recommended (17-12-2012)	Deferred for Product Specific Inspection and review of Manufacturing Facility of Immunosupressants.
8.	-do-	Hydro Gel Eye Drops Each gram contains:- Hypromellose…..3mg Carbomer 980…..2mg (artificial tears)	Rs.185.00/10ml	Form-5 7-11-2013(742) Rs.20,000/-	1.Required 2.Required 3. Grant of Additional sections recommended (17-12-2012)	Deferred for (i) Confirmation of me-too status (ii)International availability (iii) Manufacturing facility.
9.	-do-	MCS Eye Drops Each ml contains:- Sodium cromoglycate…..40mg Tetrahydrozoline HCl…0.5mg (mast cell stabilizer, vasocon strictor)	Rs.200.00/10ml	Form-5 7-11-2014(741) Rs.20,000/-	1.Required. 2.Cromozil (Sante) 3. Grant of Additional sections recommended (17-12-2012)	Approved

Evaluator – III

10.	M/s Paradise Pharmaceuticals (Pvt) Ltd.23 K.M Lahore-Sheikhupura Road, P.O Kot Abdul Malik, Distt: Sheikhupura	Kaolin Poultice Poultice Composition: Heavy Kaolin…527 Boric Acid…45g Methyl Salicylate….2g Glycerin…425g Thymol…0.5gm Peppermint oil…0.5ml Manufacturer	As per SRO/pack of 100gm	Form5 Routine Dy No 940 dated 06-06-2013 06-06-2013 Rs.20,000/-	Kaolin Poultice BP of KL Pharmaceuticals Scotland UK Kayoplast of Karachi chemical industries	Approved
11.	-do-	Acriflavine Topical Solution Acriflavine…0.1%w/v Antiseptic BPC	As per SRO/Pack of 25ml	Form5 Routine Dy No 239 dated 06-06-2013 06-06-2013 Rs.20,000/-	Not provided/not found Acrflavine of Sapient Pharma	Approved
12.	-do-	Mercurochrome Lotion Solution Each 5ml contains: Mercurochrome….2%w/v Antibacterial/Antiseptic BPC	As per SRO/Pack of 25ml	Form5 Routine As per SRO 06-06-2013 Rs.20,000/-	Merbromina of Lainco SA Mercurochrome of Euro Pharma International Karachi	Approved
13.	-do-	Paralax Drops, L-Drops, Sulfolax Drops Oral liquid E ach ml contains: Sodium Pico	As per SRO/15ml in plastic bottle	Form5 Routine Dy No 938 dated 06-06-2013 06-06-2013	Dulcolax SP Drops of Boheringer Australia Conspic drops of Sami pharmaceuticals Karachi	Approved

		Sulphate…7.5mg Laxative		Rs.20,000/-		
14.	-do-	Gention Violet Solution Solution Gentian Violet….1%w/v Antiseptic BP	As per SRO/pack of 25ml	Form5 Routine Dy No 943 dated 06-06-2013 Rs.20,000/-	Gention Violet 1% topical solution of Humco Gensol of Macter Internationl Karachi	Approved
15.	M/s Novamed Pharmaceuticals, Lahore	Nimodip Injection Injection Each 50ml contains Nimodipine 10mg CCB Manufacturer	Rs 839.25/ pack of 1's	Form5 Routine 03-10-2013 Rs 20,000/-	Me too (Bredin of Medisure) Inspection of the firm was conducted on 05-01-2014 and 21-01-2014 by the panel of inspectors and was GMP compliant at th time of inspection. Moreover the firm was granted approval of section of SVP on 29-08-2013	Approved
16.	-do-	Lizorex Injection Infusion Each 100ml contains Linezolid 200mg Antibacterial Manufacturer	Rs 300/- pack of 1's	Form5 Routine 03-10-2013 Rs.20,000/-	Me too (Ecasil of Sami)	Approved
17.	-do-	Tenamed Injection/ Transamed Injection/ Tramix Injection Injection Each 5ml Ampoule contains: Tranexamic Acid …500 mg Antiplasminic	Rs.850/- for 10 ampoules	Form5 Routine 03-10-2013 Rs.20,000/-	Me too (Btrol of Bosch)	Approved

		JP				
18.	-do-	Sorbitrate Injection/ Isocardium Injection/Isonitrate Injection Liquid Injection IV Each 10ml Ampoule contains:Isosorbide dinitrate…10mg Nitrate Therapy BP	Rs-145/- Pack of 1's	Form5 Routine 03-10-2013 Rs.20,000/-	Me too (Carsodil of Accurate)	Deferred for Product Specific Inspection by (i) Director DTL Lahore (ii) Area FID
19.	-do-	Onamed Injection Liquid infusion IV Each 50ml infusion contains: Fluconazole …100 mg Antifungal Manufacturer	Rs.487.34/- 50ml infusion	Form5 Routine 03-10-2013 Rs.20,000/-	Me too (Diflucan of Pfizer)	Approved
20.	-do-	Anzole Injection, Metgyl Injection, Novadizole Injection Liquid infusion IV Each 100ml infusion contains: Metronidazole…500 mg Bactericidal, Amoebicidal and Trichomoncidal BP	Rs.78/- pack of 1's	Form5 Routine 03-10-2013 Rs.20,000/-	Me too (Anata of Medisave)	Approved

21.	-do-	Ketanov Injection/ Ketolac Injection/ Ketomed Injection Liquid Injection IV/IM Each 1ml Ampoule contains: Ketorolac Tromethamine 30mg NSAID	Rs.557/-pack of 5's	Form5 Routine Rs.557/-5Ampoules 03-10-2013 Rs.20,000/-	BP Me too (Monak of Aaraf)	Approved
22.	-do-	Supamol Injection/ Novacet Injection/ Cetamol Injection Liquid Infusion IV Each 100ml infusion contains: Paracetamol BP …1g Analgesic/Antipyretic Manufacturer	Rs.80/- Pack of 1's	Form5 Routine 08-10-2013 Rs.20,000/-	Me too (Falgan of Bosch)	Approved
23.	M/s Metro Pharmaceuticals Rawat	Metrazol 2.5mg tablets Each Tablet contains:- Letrozole……..2.5mg Nonsteroidal aromatase inhibitor BP	As per SRO/ 3x10's	Form-5 New section As Per SRO 19-12-2013 Dy.No.3051 Rs. 20,000/-	Me too (Femara of Novartis)	Deferred for review of manufacturing facility.
24.	-do-	M-Kast 5mg Dry Suspension Each 5ml when reconstituted contains:- Montelukast as sodium…5mg/5ml Bronchodialators / anti-Asthma Selective / Leukotriene Receptor Antagonist	As per SRO/Pack of 30ml	Form-5 New Section As Per SRO 19-12-2013 Dy.No.8229 Rs. 20,000/-	Me too (Lulast by Hygeia)	Deferred for review of formulation by the Review Committee.

		Manufacturer				
25.	-do-	Iromet 50mg Dry Suspension Dry Suspension Each 5ml when reconstituted contains:- Iron (III) Hydroxide Polymaltose Complex eq. to Elemental Iron……50mg Hematinic/Iron Supplement Manufacturer	As per SRO/Pack of 30ml	Form-5 New section 19-12-2013 Dy.No.3047 Rs. 20,000/-	Me too	Approved
26.	-do-	Flukazol 50mg Dry Suspension Dry Suspension Each 5ml when reconstituted contains:- Fluconazole……50mg Anti Fungal (Triazole) Manufacturer	As per SRO/Pack of 35ml	Form-5 New section 19-12-2013 Dy.No.3046 Rs. 20,000/-	Me too (Deyeast of Nenza Pharma)	Approved
27.	-do-	Leket 2.5% Gel Gel Each 30gram tube contains:- Ketoprofen (BP)……2.5% Analgesic, NSAID's Manufacturer	As per SRO/Pack of 30gm	Form-5 New section 19-12-2013 Dy.No.3050 Rs. 20,000/-	Me too (PRIFEN OF PRIME PHARMA)	Approved
28.	-do-	Dipesin Sachet Sachet Each sachet contains:- Dihydroartemisinin…….15mg	As per SRO/Pack of 16 sachet	Form-5 New section 19-12-2013 Dy.No.3052 Rs. 20,000/-	Me too (Artequine of Platinum)	Approved

		Pepraquine Phosphate….120mg Anti Malarial Manufacturer				
29.	-do-	Stronlate 2gm Sachet Each sachet contains:- Strontium Ranelate……..2gm Antiosteoporotic drug Manufacturer	As per SRO/ Pack of 7 sachet	Form-5 New section 19-12-2013 Dy.No.3049 Rs. 20,000/-	Me too (Osstium of Atco Laboratories Karachi)	Approved
30.	M/s Crystolite Pharmaceuticals Rawat.	Tazo 0.1% Cream Cream Each tube contains:- Tazarotene.....0.1 % w/w Karyolitic Agents Manufacturer	As per SRO/10gm	Form-5 New section 4. 31-10-2013 Dy.No.2064 Rs. 20,000/-	Me too Azoten of Danas Pharmaceuticals Inspection of the firm was conducted on 20-02-2013 by the panel of inspectors and recommended for the grant of license of tablet, capsule, cream and ointment section general and steroidal and lotion (general and steroidal section)	Approved
31.	-do-	Crystolov-250 Tablets Tablet Each film coated tablet contains:- Levofloxacin Hemihydrate eq. to Levofloxacin …….250mg Anti-Biotic Fluoroquinolone Manufacturer	As per SRO/pack of 10's	Form-5 New section 19-12-2013 Dy.No.3045 Rs. 20,000/-	Me too (Leflox of Getz Pharma)	Approved

32.	M/s Filix Pharmaceuticals Islamabad	Flucofix 150mg Capsules Each capsule contains:- Fluconazole (BP)……..150mg Fungicides	As per SRO/ not provided	Form-5 New section 17-05-2013 Dy.No.1459 Rs. 20,000/-		Deferred for completion of Form 5
33.	-do-	Sporafix 100mg Capsules Each capsule contains:- Itraconazole…100mg Anti-Fungal	As per SRO/ not provided	Form-5 New section 27-11-2013 Dy.No.2095 Rs. 20,000/-		Deferred for completion of Form 5

Evaluator – V

34.	M/s Arsons Pharmaceutical Industries (Pvt) Ltd. 22 Km Multan Road off 4 Km Defence Road, Lahore **Anomaly Case:** Capsule (General Antibiotic) Vide letter No. F. 1-14/95 – Lic (Vol I) (M – 227) dated 13th June, 2011	**DOXICYCLINE 100mg Capsules** Capsule Each Capsule contains:- Doxycycline as Hyclate…..100 mg Tetracycline	As Per SRO 10 x 10's	Form-5 28-09-2012 2280 R&I Rs.20,000/-	Vibramycin 100mg Capsules US FDA DOTUR 100mg Capsule Novartis	Deferred for status of lisence in light of inspection report dated 15-04-2013

e) Deferred cases of previous meeting M-242 in which codal-formalities / Form-5 has been completed (30 Applications)

Evaluator – II

S. No.	Name and Address of Manufacturer / Applicant.	Brand Name Dosage Form Composition (pharmacological Group) Finished product specification	Demanded Price / Pack size	1. Type of Form 2. Initial date, diary. 3. Date on which fee becomes complete according to type of application /or Form (total Fee)	1. International status in stringent regulatory agencies 2. Me-too status 3.GMP status as depicted in inspection report (dated)	Decision of previous meeting	Remarks
1.	M/s Venus Pharma, 23 KM Multan Road, Lahore	Chloropox-5 Tablets Each tablet contains:- Chlordiazepoxide (as HCl)…5mg (Benzodiazepine) (B.P)	Rs 160/1000's Jar	1.Form 5 2.15-07-2013, (9007) Rs. 60,000/- 5. 15-07-2013	1. **BNF 58 Chlordiazepoxide Hydrochloride** (Non-proprietary) Tablets, chlordiazepoxide hydrochloride 5 mg; 10 mg 2. Alium by AMROS PHARMACEUTICALS 3. Good, Renewal of DML recommended.(27-06-2013)	Deferred for final reminder for completion of Form 5 and confirmation of section for Controlled Drug as per CLB decision.	Deferred for completion of Form 5 and confirmation of manufacturing facility for Controlled Drugs.

Evaluator – III

i) Human

2.	M/s Barrett Hodgson Pakistan(Pvt) Ltd F/423, SITE, Karachi-75700-Pakistan	Barizold infusion 600mg/300ml Infusion Each 300ml vial contains Linezolid 600mg Synthetic antibacterial agent of oxazolidinone class USP	Rs 450/- Pack of 1's	Form 5 Fast Track 1392 dated 17/07/13 16/07/2013	Me too(Ecasil, of sami Pharmaceuticals Karachi) Inspection of the firm was carried out on 14th & 15th May 2013 by area FID and as per report the firm has good facilities for compliance of GMP guidelines.	Approved. (Confirmation of Liquid particle counter and TOC availability by area FID)
3.	-do-	Barizold infusion 200mg/100ml Infusion Each 100ml vial contains Linezolid 200mg Synthetic antibacterial agent of oxazolidinone class USP	Rs 450/- Pack of 1's	Form 5 Fast Track 1396 dated 17/07/13 16/07/2013	Me too(Zolrest, of Bosch Pharmaceuticals) Inspection of the firm was carried out on 14th & 15th May 2013 by area FID and as per report the firm has good facilities for compliance of GMP guidelines.	Approved.
4.	-do-	Barizold infusion 400mg/200ml Infusion Each 200ml vial contains Linezolid 400mg Synthetic antibacterial agent of oxazolidinone class Manufacturer	Rs 500/- Pack of 1's	Form 5 Fast Track 1391 dated 17/07/13 16/07/2013	Me too(Zolrest, of Bosch) Inspection of the firm was carried out on 14th & 15th May 2013 by area FID and as per report the firm has good facilities for compliance of GMP guidelines.	Approved. (Confirmation of Liquid particle counter and TOC availability by area FID)

5.	-do-	Baripenem for injection 500mg Injection Each Meropenem Trihydrate USP equivalent to Meropenem….500mg Carbipenem antibiotic USP	Rs 1400/- Pack of 1's	Form 5 Fast Track 1535 dated 19/08/13 16/08/2013	Mee too (Meronem, of ICI) 3. Inspection of the firm was carried out on 14th & 15th May 2013 by area FID and as per report the firm has good facilities for compliance of GMP guidelines. (Dedicated carbipenam section is not mentioned in inspection report)	Deferred for confirmation of dedicated manufacturing facility for carbapenems
6.	-do-	Baripenem for injection 1000mg Injection Each Meropenem Trihydrate USP equivalent to Meropenem….1000mg Carbipenem antibiotic USP	Rs 2300/- Pack of 1's	Form 5 Fast Track 1536 dated 19/08/13 16/08/2013	Me too (Meronem, of ICI) Inspection of the firm was carried out on 14th & 15th May 2013 by area FID and as per report the firm has good facilities for compliance of GMP guidelines. (Dedicated carbipenam section is not mentioned in inspection report)	Deferred for confirmation of dedicated manufacturing facility for carbapenems
7.	-do-	Febrol Infusion 500mg/50ml IV Infusion Each 50ml vial contains Paracetamol BP 500mg Analgesic & antipyretic Manufacturer	150/-Rs Pack of 1's	Form 5-D Fast Track 1371 dated 15/07/13 12/07/2013 Rs 60,000/- Dy No 2024 dated 30-04-2014 Rs 90,000/-	Perfalgan of BMS UK Not applicable Inspection of the firm was carried out on 10th September 2012by area FID and as per report the firm is considered to fall in good category towards compliance of GMP guidelines.	Approved

8.	-do-	Febrol Infusion 1000mg/100ml IV Infusion Each 100ml vial contains Paracetamol BP 1000mg Analgesic & antipyretic Manufacturer	Rs -150/- Pack of 1's	Form 5 Fast Track 1372 dated 15/07/13 12/07/2013	Me too(Falgan of Bosch) Inspection of the firm was carried out on 10th September 2012by area FID and as per report the firm is considered to fall in good category towards compliance of GMP guidelines.	Approved
9.	-do-	S-Gliptin Plus Tablets 50mg+850mg Tablets Each film coated tablet contains Sitagliptin phosphate monohydrate equivalent to Sitagliptin 50mg + Metformin HCl USP…..850mg Antihyperglycemic dipeptidyl peptidase-4 inhibitor + biguanide Manufacturer	Pack of 10's Rs 1100/- Pack of 14's Rs 1508/- Pack of 3140/-	Form 5-D Fast Track 1440dated 25/07/13 23/07/2013 Rs 60,000/- Dy No 2026 dated 30-04-2014 Rs 90,000/-	Janumet of Merck Inc Not applicable Inspection of the firm was carried out on 14th & 15th May 2013 by area FID and as per report the firm has good facilities for compliance of GMP guidelines.	Approved with change of brand name as other strengths of same formulation are already registered, being US FDA approved product and expert opinion.
10.	-do-	Esegrow-D Forte Suspension Suspension Each 5ml contains Cholecalciferol USP 0.01mg + Ossein microcrystalline hydroxyappatite compound 584.18 equivalent to Calcium…125 mg Phosphorous…57.9mg Residual mineral	Pack of 60ml Rs 300/- Pack of 120ml Rs 500/-	Form 5D Fast Track 1537 dated 19/08/13 12/08/2013 Rs 60,000/- Dy No 2027 dated 30-04-2014 Rs 90,000/-	Not found Not applicable Inspection of the firm was carried out on 14th & 15th May 2013 by area FID and as per report the firm has good facilities for compliance of GMP guidelines	Deferred for Expert Opinion by (i) Dr. Tabish Hazir , PIMS. (ii) Major Gen. Salman Ali, AMC, Rawalpindi. (iii) Head Department of Paediatrics , Shifa International Hospital, Islamabad.

		salts…17.5mg Collagen…157.7mg Other proteins…46.7mg Trace elements….F,Mg,Fe,Zn,Cu,Ni 4. Cholecalciferol (Vitamin D) is a group of fat soluble secosteroids responsible for enhancing the intestinal absorption of calcium and phosphate. Ossein mineral complex is a calcium preparation. Manufacturer				
11.	-do-	ChewBar-D Chewable Tablets Tablet Each tablet contains Vitamin D 3 (Cholecalciferol) 2000IU Cholecalciferol (Vitamin D) is a group of fat soluble Secosteroids responsible for enhancing the intestinal absorption of calcium and phosphate. Manufacturer	Rs 150/-Pack of 10's Rs 300/- Pack of 30's Rs 600/-Pack of 60's	Form 5D Fast Track Dy No 1614 dated 28/08/13 Rs 60,000/- Dy No 2025 dated 30-04-2014 Rs 90,000/-	Not found Not applicable Inspection of the firm was carried out on 14th & 15th May 2013 by area FID and as per report the firm has good facilities for compliance of GMP guidelines	Deferred for Expert Opinion by (i) Dr. Tabish Hazir , PIMS. (ii) Major Gen. Salman Ali, AMC, Rawalpindi. (iii) Head Department of Paediatrics , Shifa International Hospital, Islamabad.

12.	M/s. Metro Pharmaceuticals Plot #14, Street No.SS-2, National Industrial Zone, Rawat, Islamabad	Mecoxib 200mg Capsules Capsules Each Capsule contains: Celecoxib …. 200mg NSAIDS Manufacturer	As per SRO/ Blister packing of 20's capsules	Form 5 Fast Track Dy. No.6270 dated 02-10-2013 02-10-2013 Rs.60,000/-	Me too (Cele of TG Pharma Karachi)	Approved
13.	-do-	Laxicam 15mg Tablets Tablet Each film coated tablet contains: Meloxicam …. 15mg Oxicam BP	As per SRO/ Blister packing of 10's Tablets	Form 5 Fast Track Dy. No.6273 dated 02-10-2013 02-10-2013 Rs.60,000/-	Me too (Artex tablets of Pharmedic Laboratories Lahore	Approved
14.	-do-	Fexdin 120mg Capsules Capsules Each Capsule contains: Fexofenadine HCl …. 120mg Antihistamine Manufacturer	As per SRO Blister packing of 10's capsules	Form 5 Fast Track Dy. No.6274 dated 02-10-2013 02-10-2013 Rs.60,000/-	Me too (Fexicame of Caraway Pharmaceuticals Islamabad)	Approved
15.	-do-	Mekast 5mg chewable Tablets Tablet Each chewable Tablet contains: Montelukast as (Sodium) …. 5mg Bronchodilators / Anti-Asthma Selective / Leukotriene Receptor	As per SRO Blister packing of 14's Tablets	Form 5 Fast Track Dy. No.6269 dated 02-10-2013 02-10-2013 Rs.60,000/-	Me too(Montewns of Winsfield)	Approved

		Antagonist Manufacturer				
16.	-do-	1.Mekast 10mg chewable Tablets 2.Tablet 3. Each chewable Tablet contains: Montelukast as (Sodium) …. 10mg 4. Bronchodilators / Anti-Asthma Selective / Leukotriene Receptor Antagonist Manufacturer	As per SRO Blister packing of 14's Tablets	Form 5 Fast Track Dy. No.6268 dated 02-10-2013 02-10-2013 Rs.60,000/-	Me too(Kast of Semos)	Deferred for review of formulation by the Review Committee.
17.	-do-	Irocom Tablets Tablet Each Chewable Tablet contains: Iron(III) Hydroxide Polymaltose Complex eq. to Elemental Iron ..100mg Erythopoitic, Hematinic Manufacturer	As per SRO Blister packing of 10's Tablets	Form 5 Fast Track Dy. No.6272 dated 02-10-2013 02-10-2013 Rs.60,000/-	Me too (Irobrain of Winbrains)	Approved
18.	-do-	Moxi 400 Tablets Tablet Each film coated tablet contains: Moxifloxacin as HCl 400mg Antibiotic /Quinolone Manufacturer	As per SRO Blister packing of 5's Tablets	Form 5 Fast Track Dy. No.6277 dated 02-10-2013 02-10-2013 Rs.60,000/-	Me too (Avelox tablets of Bayer Healthcare Karachi)	Approved

19.	-do-	Estom 10mg Dispersible Tablets Tablet Each Dispersible Tablet contains: Escitalopram as Oxalate eq. to Escitalopram ..10mg Selective Serotonin Reptake Inhibitor (SSRI) Antidepressant Manufacturer	As per SRO Blister packing of 14's Tablets	Form 5 Fast Track Dy. No.6266 dated 02-10-2013 02-10-2013 Rs.60,000/-	Me too (Citom dispersible tablets of Winilton Pharmaceuticals Islamabad)	Approved
20.	-do-	Rapzol Tablets Tablet Each enteric coated Tablet contains: Rabeprazole Sodium...20mg Proton Pump Inhibitor Manufacturer	As per SRO Blister packing of 14's Tablets	Form 5 Fast Track Dy. No.6275 dated 02-10-2013 02-10-2013 Rs.60,000/-	Me too (Acifix of Aeries Pharma Peshawar)	Approved
21.	-do-	Catazole-V 500mg Tablets Tablet Each Tablet contains: Clotrimazole...500mg Amidazole / Antifungal BP	As per SRO Blister packing of 1 Tablet	Form 5 Fast Track Dy. No.6279 dated 02-10-2013 02-10-2013 Rs.60,000/-	Me too (Clozim of Stanley Pharmaceuticals Peshawar)	Approved

22.	-do-	Mexicam Tablets Tablet Each Dispersible Tablet contains: Piroxicam as Beta Cyclodextrin …. 20mg Anti rheumatics Systemic (NSAID) Manufacturer	As per SRO Blister packing of 2 x 10's Tablets	Form 5 Fast Track Dy. No.6267 dated 02-10-2013 02-10-2013 Rs.60,000/-	Me too (Beta-I of Wins field)	Approved
23.	-do-	Metrose-F Syrup Syrup Each 5ml contains: Iron-III-Hydroxide Polymatose Complex eq. to Elemental Iron…. 50mg Folic Acid … 0.35mg Haematinic Manufacturer	As per SRO 60ml, 120ml	Form 5 Fast Track Dy. No.6271 dated 02-10-2013 02-10-2013 Rs.60,000/-	Me too (Malcifer-F of Martin Dow Pharmaceuticals Karachi)	Deferred for Product Specific Inspection by (i) Dr. Muzammil Hasan Najmi, Member Registration Board (ii) Area FID
24.	-do-	Metapride-50 Tablets Tablet Each film tablet contains: Itopride Hydrohloride …. 50mg Gastroprokinetic Manufacturer	As per SRO/ Blister packing of 10's Tablets	Form 5 Fast Track Dy. No.6278 dated 02-10-2013 02-10-2013 Rs.60,000/-	Me too (Enteropride of Dyson Research Lab)	Deferred for review of formulation by the Review Committee.
25.	M/s Danas Pharmaceuticals (Pvt) Ltd,312 Industrial Triangle Kahuta Road Islamabad.	Danacot Injection (Ampoule) 40mg/ml Injection Each 1 ml ampoule contains triamicinlone acetonide …..40mg Glucocorticoid BP	As per policy of MOH/Pack of 1's	Form 5 Fast Track Dy No 3272 dated 21/05/2013 21/05/2013 Rs.60,000/-	Not provided Lonacort of Zafa Pharmaceuticals Karachi The inspection of the firm was conducted on 01-10-12 & 09-10-12 by panel of inspectors and firm was	Deferred for confirmation of manufacturing facility from Licensing section)

					found GMP compliant	
26.	M/s Venus Pharma 23 KM Multan Road Lahore.	VALRON-P 75 Each film coated tablet contains: Diclofenac Potassium…75mg NSAID BP	Rs 110/- pack of 2x10's	Form-5 Fast Track Dy No 1058 dated 10-12-13 Rs 60,000/-	Diclofenac Potassium of Apotex Inc Andic-K of Nova Med Pharma Lahore The Inspection of the firm was conducted on 24-06-2013 by panel of inspectors and recommended renewal of DML by the way of formulation	Approved as the Firm has rectified the shortcomings in Form 5.
27.	-do-	VALRON-100 SR TABLETS Each sustained release tablet contains: Diclofenac Sodium…100mg NSAID BP	Rs 120/- Pack of 2x10's	Form-5 Fast Track Dy No 1291 dated 19-12-13 Rs 60,000/-	Voltaren XR tablets of Novartis Inc Araam of Alliance Pharma Karachi The Inspection of the firm was conducted on 24-06-2013 by panel of inspectors and recommended renewal of DML by the way of formulation	Approved as the Firm has rectified the shortcomings in Form 5.
28.	-do-	NIMSOL-100 TABLET Each tablet contains Nimesulide…100mg NSAID	Rs-130/- pack of 2x10's	Form-5 Fast track Dy No 1093 dated 13-12-13 Rs 60,000/-	Not provided/Not found Cox-2 of Vision Pharmaceuticals Islamabad The Inspection of the firm was conducted on 24-06-2013 by panel of inspectors and recommended renewal of DML by the way of formulation	Deferred for review of formulation by the Review Committee.

29.	M/s Saffron Pharmaceticals Faisalabad.	Prostam Capsules Each capsule contains:- Tamsulosin HCl (as modified release pellets)…….....0.4mg 5-Antagonist of Alpha 1A Adrenoceptors Manufacturers Source:M/s Rachem Pharma Ltd, Plot No A-19/C Road No 18 IDA Nacharam Hyderabad 560076, Andra Paradesh, India	Rs.600/Pack of 10's	Form 5 Fast Track Dy. No 1022 dated 06-12-2013 (Rs. 100,000/-) Dy. No 1483 dated 07-04-2014 (Rs. 200,000)	Me too Tamsolin Getz Firm was inspected on 17/12/2013 by area FID along with DDG (E&M) and ADC and recommended for the grant of GMP.	Approved. Firm will provide legalized GMP certificate of Source, COA and stability data. Chairman RB will approve issuance of registration letter

ii) Veterinary

30.	M/s. Jfrin Pharmaceutical Laboratories Plot No.16, 17 & 20 Hub Industrial trading Estate, Hub Lasbela Balochistan	JF Colmine Oral Powder Powder Each 100gm contains: Enrofloxacin HCl 10gm Colistin Sulphate 4gm Amantadine HCl 4gm Antibiotic	De-controlled Plastic Jar 100gm, 500gm & 1000gm	Form 5 Fast Track Dy. No.866 dated 24-07-2013 23-07-2013	Not provided Colamen Powder of Attabak Pharma Rawalpindi Inspection of the firm was conucted on 23-08-2013 by the area FID anf the overall GMP was rated as satisfactory	Approved

f) Already considered cases in which correction is required (4 - Applications)

Following applications were considered by the Registration Board in its M-242 meeting. There are some corrections required in these cases as under.

S/N	Name and address of manufacturer/Applicant	1. Brand Name 2. Dosage Form 3. Composition 4. pharmacological group	1.Type of Form 2. Type of application 3. Demanded Price / Pack size 4. Initial date, diary. 5. Date on which fee becomes complete according to type of application /or Form (total Fee)	1. Me-too status	Decision in M-242	Decision
1.	M/s. Navegal Laboratories, 41/1-A2, Phase-1 , Industrial Estate, Hattar.	1. Azifast 500mg Capsules 2. Each capsule contains:- Azithromycin Dihydrate 524mg equivalent to Azithromycin (U.S.P)...500mg 3.A Nitrogen-Containing Marrolide	1. Form-5 2. Fast track 3. As per SRO per 1x6's. 4. 20/5/2013, 430 (R&I) 5. 20/05/2013 Rs. 60,000/-	**U.S.P** **Azorox (Caylex Pharma) R. No. 054327**	Approved	Referred to review committee for review of all registered products.

2.	M/s. Novartis Pharma (Pvt) Ltd. 15 West Wharf Road P.O Box 100 & 7247 Karachi-74000	1.Lozal Rapid 40mg Sachets 2.Sachet 3. Each sachet contains: Omeprazole 40mg Sodium bicarbonate 1680mg 4. antiulcerant	1. Form 5 2. Routine 3. 10's =Rs.200/- Carton / Sachet / Label etc, 4. Dy. No.1137 dated 29-05-2013 5. **Rs. 20,000/- dated 29-05-2013 Rs.40,000/- dated 16.07.2013**	a. Manufacturer b. Me too (Risek insta 40/1100mg) c. Inspection of the firm was conducted by the area FID on 08-02-2012 nas was considered to be working at acceptable level of GMP compliance. Latest inspection report is required	Rejected as firm does not have manufacturing facility	Registration Board approved the correction and endorsed its previous decision.
3.	s. Novartis Pharma (Pvt) Ltd. 15 West Wharf Road P.O Box 100 & 7247 Karachi-74000	1.Lozal Rapid 20mg Sachets 2.Sachet 3. Each sachet contains: Omeprazole 20mg Sodium bicarbonate 1680mg 4. antiulcerant	1. Form 5 2. Routine 3. 10's =Rs.120/- Carton / Sachet / Label etc, 4. Dy. No.1136 dated 29-05-2013 5. **Rs. 20,000/- dated 29-05-2013 Rs.40,000/- dated 16.07.2013**	a. Manufacturer b. Me tood(Risek insta 20/1100mg) c. Inspection of the firm was conducted by the area FID on 08-02-2012 was considered to be working at acceptable level of GMP compliant Latest inspection report is required. d. Sachet section is not mentioned in inspection report moreover the firm has not provided any proof that they have	Rejected as firm does not have manufacturing facile	Registration Board approved the correction and endorsed its previous decision.

				sachet section.		
4.	M/s English Pharmaceuticals Lahore	E-Flash10mg tablet Each tablet contains. Ebastine…10mg Manufacturer	As per SRO/ Pack of 10,s	Form 5 Fast Track 11-12-13 Dy no. 09-0702014 Rs.60, Aerius of Dermagem Inspection of firm was conducted on 17-12-13 and found GMP compliant	Approved	Registeration Board approved the product for M/s English Pharmaceuticals Lahore instead of M/s Jaens Pharma Lahore as the product was inadvertently considered for M/s Jaens Pharma Lahore in 242nd meeting of Registration Board which is now approved/corrected for M/s English Pharmaceuticals Lahore.

Item No: VI Products referred for expert opinion (Imported).

The Registration Board considered the following applications of new molecules and decided as mentioned against each. The approved applications are subject to inspection of manufacturer abroad as per policy, verification of storage facilities and price fixation / calculation etc where applicable.

S#	Name of Indenter/ Manufacturer	Name of drug (s)/ Composition & Therapeutic Group	Demanded Price/Pack	Shelf Life	Decsion
1.	M/s. Chiesi Pharmaceticals (Pvt) Ltd, Lahore. / M/s. Alfa Waseermann S.p.A Via Enrico Fermi 1, IT65020 Alanno (PE) Italy.	Peyona Solution for Infusion Each ml contains:- Caffeine Citrate 20mg eq to 10mg Caffeine. (Xanthine Derivatives).	Rs.4516/ Per 1's Rs.45160/ Pack of 10 Ampoules	03 years	Approved On recommendations of the following experts. a. Mr. Abdul Latif Sheikh, Director Pharmacy, Nutrition & CSSD Services, Agha Khan University Hospital, Karachi. b. Dr. Mussarat Hussain , Chief of Pediatrics, Shifa International Hospital, Islamabad. And c. Brig. (R) Prof. Dr. Muzammil Hasan Najmi, Chairman, Department of Pharmacology/Associate Dean, Basic Sciences Division, Foundation University, Medical College, Rawalpindi. Who give his recommendations during the

					meeting.
2.	M/s. Hashir Surgical Services (Pvt) Ltd Peshawar / M/s. Vigilenz Medical Devices SDN BHD Pulau Pinang, Malaysia.	Catgut Chrom Absorbable Surgical Suture (Synthetic Suture).	As per PRC	05 years	Approved On recommendations of the following experts. a. Prof. Tanwir Khaliq, Professor of Surgery, Department of General Surgery, PIMS, Islamabad. and b. Prof. Dr. Harun Majid Dar, Professor of Surgery, Department of Surgery, FPGMI & Sheikh Zayed Hospital, Lahore.
3.	M/s. Hashir Surgical Services (Pvt) Ltd Peshawar / M/s. Vigilenz Medical Devices SDN BHD Pulau Pinang, Malaysia.	ECOSORB Absorbable Surgical Suture (Synthetic Suture).	As per PRC	05 years	-do-
4.	M/s. Hashir Surgical Services (Pvt) Ltd Peshawar / M/s. Vigilenz Medical Devices SDN BHD Pulau Pinang, Malaysia.	ECOLENE Non-absorbable Surgical Sutures (Synthetic Suture).	As per PRC	05 years	-do-
5.	M/s. Hashir Surgical Services (Pvt) Ltd Peshawar / M/s. Vigilenz Medical Devices SDN BHD Pulau	Silk Non-absorbable Surgical Sutures (Synthetic Suture).	As per PRC	05 years	-do-

	Pinang, Malaysia.				
6.	M/s. Hashir Surgical Services (Pvt) Ltd Peshawar / M/s. Vigilenz Medical Devices SDN BHD Pulau Pinang, Malaysia.	Ecosorb Fast Absorbable Surgical Sutures. (Synthetic Suture).	As per PRC	05 years	-do-
7.	M/s. Hashir Surgical Services (Pvt) Ltd Peshawar / M/s. Vigilenz Medical Devices SDN BHD Pulau Pinang, Malaysia.	Steel Wire Twisted, Non-absorbable Monofilament Surgical Suture (Surgical Suture).	As per PRC	05 years	-do-
8.	M/s. Hashir Surgical Services (Pvt) Ltd Peshawar / M/s. Vigilenz Medical Devices SDN BHD Pulau Pinang, Malaysia.	Esteron Non-absorbable Surgical Suture (Surgical Suture).	As per PRC	05 years	-do-
9.	M/s. Hashir Surgical Services (Pvt) Ltd Peshawar / M/s. Vigilenz Medical Devices SDN BHD Pulau Pinang, Malaysia.	Vigimesh Non-absorbable Surgical Mesh (Surgical Mesh)	As per PRC	05 years	-do-
10.	M/s. Hashir Surgical Services (Pvt) Ltd Peshawar / M/s. Vigilenz Medical Devices SDN BHD Pulau	Vigiroll Cassette Suture (Cassette Suture)	As per PRC	05 years	-do-

	Pinang, Malaysia.				
11.	M/s. Hashir Surgical Services (Pvt) Ltd Peshawar / M/s. Biosintex, 4th Vladiceasca Street Sangov, llfov Country, Romania.	Herni Pro Plus Suture	As Per PRC	05 years	-do-
12.	M/s. Hashir Surgical Services (Pvt) Ltd Peshawar / M/s. Biosintex, 4th Vladiceasca Street Sangov, llfov Country, Romania.	Nylon Multi Non-absorbable Suture	As Per PRC	05 years	-do-
13.	M/s. Hashir Surgical Services (Pvt) Ltd Peshawar / M/s. Biosintex, 4th Vladiceasca Street Sangov, llfov Country, Romania.	Bioster Non-absorbable Surgical Suture	As Per PRC	05 years	-do-
14.	M/s. Hashir Surgical Services (Pvt) Ltd Peshawar / M/s. Biosintex, 4th Vladiceasca Street Sangov, llfov Country, Romania.	Biosilk Non-absorbable Surgical Suture	As Per PRC	05 years	-do-
15.	M/s. Hashir Surgical Services (Pvt) Ltd Peshawar / M/s. Biosintex, 4th Vladiceasca Street Sangov,	Bicril Rapid Absorbable Surgical Suture	As Per PRC	05 years	-do-

	llfov Country, Romania.				
16.	M/s. Hashir Surgical Services (Pvt) Ltd Peshawar / M/s. Biosintex, 4th Vladiceasca Street Sangov, llfov Country, Romania.	Herni Pro Surgical Suture	As Per PRC	05 years	-do-
17.	M/s. Hashir Surgical Services (Pvt) Ltd Peshawar / M/s. Biosintex, 4th Vladiceasca Street Sangov, llfov Country, Romania.	Biopro Non-absorbable Surgical Suture	As Per PRC	05 years	-do-
18.	M/s. Hashir Surgical Services (Pvt) Ltd Peshawar / M/s. Biosintex, 4th Vladiceasca Street Sangov, llfov Country, Romania.	Pdox Absorbable Surgical Suture	As Per PRC	05 years	-do-
19.	M/s. Hashir Surgical Services (Pvt) Ltd Peshawar / M/s. Biosintex, 4th Vladiceasca Street Sangov, llfov Country, Romania.	Nylon Mono Non-absorbable Surgical Suture	As Per PRC	05 years	-do-
20.	M/s. Hashir Surgical Services (Pvt) Ltd Peshawar / M/s. Biosintex, 4th Vladiceasca Street Sangov, llfov Country,	Bicril Absorbable Surgical Suture	As Per PRC	05 years	-do-

	Romania.				
21.	M/s. Reckitt Benckiser Pakistan Ltd, Karachi. / M/s. Reckitt Benckiser Texas, USA	Mucinex Tablet Contains: - Guaifenesin……....600mg (Expectorant).	Price Not mentioned	03 years	Approved On recommendations of the following experts. a. Prof. Dr. Irshad Hussain, Kind Edward Medical University/ Mayo Hospital, Lahore. b. Dr. Kaleem Ullah Toori, KRL Hospital, Islamabad. c. Brig. Dr. Aslam Khan, Professor of Medicine, Military Hospital, Rawalpindi. Who give his recommendations during the meeting
22.	M/s. Revive Health Care, Lahore. / M/s. United Biotech (P) Limited, Bagbani, Baddi, Nalagarh Road, District, Solan, India.	Egybort 3.5mg Powder for Lyophilized Injection Each vial contains:- Bortezomib…….3.5mg (ATC Class: L01XX32)	As per PRC/SRO	24 months	Approved On recommendations of the following experts. a. Brig. Dr. Naeem Naqi, Head of Oncology Department, Combined Military Hospital, Lahore. b. Head of Oncology Department, NOORI Hospital, G-8/3, Islamabad. c. Dr. Neelam Siddiqui, Head of Oncology Department, Shaukat Khanum Hospital,

					Lahore.
23.	M/s. Revive Health Care, Lahore. / M/s. United Biotech (P) Limited, Bagbani, Baddi, Nalagarh Road, District, Solan, India.	Lenid 10 Capsules 10mg Each hard gelatin capsules contains:- Lenalidomide ……10mg (ATC Class L04AX04).	As per PRC/SRO	24 months	-do-
24.	M/s. Revive Health Care, Lahore. / M/s. United Biotech (P) Limited, Bagbani, Baddi, Nalagarh Road, District, Solan, India.	Gefitec Tablets 250mg Each film coated tablet contains:- Gefitinib……250mg (ATC Class: L01XE02).	As per SRO/PRC	24 months	-do-
25.	M/s. GlaxoSmith Kline Pakistan Ltd, Karachi. / M/s. GlaxoSmith Kline, LLC, Zebulon, USA / Packed and supplied by: GlaxoSmithKline S.A., Aranda, Spain.	Trobalt Tablet 50mg Each table contains:- Retigabine……...50 mg (Antiepileptic)	Rs.2275/ Per 21's Rs.8600/ Per 84's	18 Months	Approved On recommendations of the following experts. a.Col. Dr. Waseem Wali, Combined Military Hospital, Lahore. b.Prof. Dr. Nasrullah, Neuro Clinic, 29-Block-E, Phase-I, Johar Town, Lahore. The Board also endorsed the recommandations of experts for reduction in costs of treatment to comes down to 60-

					120 Rupees/day. That means cost to Tablet of 200mg is about Rs.20-25.
26.	-do-	Trobalt Tablet 100mg Each table contains:- Retigabine……100 mg (Antiepileptic)	Rs.4100/ Per 21's Rs.17300/ Per 84's	18 Months	-do-
27.	-do-	Trobalt Tablet 200mg Each table contains:- Retigabine……..200mg (Antiepileptic)	Rs.8000/ Per 21's Rs.33500/ Per 84's	18 Months	-do-
28.	-do-	Trobalt Tablet 300mg Each table contains:- Retigabine……..300mg (Antiepileptic)	Rs.13500/ Per 21's Rs.53500/ Per 84's	18 Months	-do-
29.	-do-	Trobalt Tablet 400mg Each table contains:- Retigabine.....400 mg (Antiepileptic)	Rs.18000/ Per 21's Rs.70100/ Per 84's	18 Months	-do-
30.	M/s. Bajwa Sons, Lahore. / M/s. Yancheng Huida Medical Instruments Co.	Trugut Chromic Surgical Suture	As per PRC	05 years	Approved On recommendations of the following experts. a.Dr. Moeed. I.

	Ltd, Jiangsu, China.				Qureshi Head, Department of Surgery, Sheikh Zayed Hospital, Lahore. b. Prof. Dr. Imran Skindar, Orthopedic Surgeon, Head of Department, Pakistan Institute of Medical Sciences, Islamabad. c. Lt. Col. Dr. Farhan Ahmad Majeed, Professor of Surgery, Combined Military Hospital, Rawalpindi.
31.	-do-	Trucryl (PGA) Surgical Suture	As per PRC	05 years	-do
32.	-do-	Trulon Nylon Monofilament Surgical Suture	As per PRC	05 years	-do-
33.	-do-	TruSilk Silk Braided Surgical Suture	As per PRC	05 years	-do-

Item No: VII **Imported Human Drugs (New Drugs**).

The Registration Board considered the following applications and decided as mentioned against each. The approved applications are subject to inspection of manufacturer abroad, verification of storage facilities and price fixation / calculation etc as per policy

S.#	Name of Manufacturer / Importer.	Name of Drug (s) Composition & Therapeutic	Demanded Price &	Shelf Life	Decsion

		Group.	Pack Size.		
1.	M/s. Novartis Pharma (Pakistan) Limited, Karachi / M/s. Novartis Farmaceutica SA, Spain.	Diovan 40 Film Coated Tablets Each film coated tablet contains:- Valsartan…….40mg (Antihypertensive).	Rs.1400/- Per packs of 28's Rs. 50/Per Tablet	03 years	**Deferred** as COPP of spain is not provided.
2.	M/s. Sanofi-aventis Pakistan Limited, Karachi. / M/s. Genzyme Ireland Ltd., IDA Industrial Park, Waterford, Ireland. Responsible for: Drug Product Manufacturing, Labelling, Packaging, Batch Release, Stability, Storage and Distribution. M/s. Genzyme Ltd., Haverhill-Suffolk, United Kingdom.	Renvela ® 800mg Tablets Each film coated tablets contains:- Anhydrous Sevelamer Carbonate……800 mg (Treatment of Hyperphosphatemia).	Rs.3900/ Per 30's Tablets	03 years	**Approved**
3.	M/s. Sncura Enterprises Pakistan (Pvt) Ltd., Saddar, Rawalpindi. / M/s. Emcure Pharmaceuticals Ltd., Plot No. P-1, IT BT Park Phase-II, M.I.D.C., Hinjwadi, Pune-411 057, India.	Foseal-400 Tablets 400mg Sevelamer Hydrochloride…400 mg (Chronic Kidney Disease).	Rs.828/ Per packs of 1x10 Tablets	24 months	**Approved**
4.	M/s. Sncura Enterprises Pakistan (Pvt) Ltd., Saddar, Rawalpindi. / M/s. Emcure Pharmaceuticals Ltd., Plot No. P-1, IT BT Park Phase-II, M.I.D.C., Hinjwadi, Pune-411 057, India.	Foseal-800 Tablets 800mg Sevelamer Hydrochloride…800 mg (Chronic Kidney Disease).	Rs.1323/ Per packs of 1x10 Tablets	24 months	**Approved**

5.	M/s. Sncura Enterprises Pakistan (Pvt) Ltd., Saddar, Rawalpin di. / M/s. Emcure Pharmaceuticals Ltd., Plot No. P-1, IT BT Park Phase-II, M.I.D.C., Hinjwadi, Pune-411 057, India.	BiCNU® -100mg Injection Each vial contains:- Carmustine USP…100mg (Anticancer)	Rs.17325/ Per vial	24 months	**Deferred** for clarification of diluents as no application was submitted for the diluent.
6.	M/s. Sncura Enterprises Pakistan (Pvt) Ltd., Saddar, Rawalpindi. / M/s. Emcure Pharmaceuticals Ltd., Plot No. P-1, IT BT Park Phase-II, M.I.D.C., Hinjwadi, Pune-411 057, India.	Encifer Iron Sucrose Injection 100mg/ 5ml Each 5ml contains:- Ferric Hydroxide in complex with sucrose equivalent to elemental iron……100mg (Haematinic)	Rs.840/ Per 100mg/5ml vial	24 months	**Approved**
7.	M/s. Allmed Laboratories, Karachi. / M/s. Haupt Pharma AG Pfaffenrieder Str. Wolfratshausen, Germany. For Biolitec Pharma, Dublin, Ireland.	Foscan 1ml/ml Solution for injection 3ml vial Each ml of solution contains:- Temoporfin….1mg (Photosensitizing agent).	Rs.700,000 /Per 3ml vial	5 years	**Deferred** for clarification of indications.
8.	M/s. Allmed Laboratories, Karachi. / M/s. Haupt Pharma AG Pfaffenrieder Str. Wolfratshausen, Germany. For Biolitec Pharma, Dublin, Ireland.	Foscan 1ml/ml Solution for injection 6ml vial Each ml of solution contains:- Temoporfin…….1mg (Photosensitizing agent).	Rs.1200,000/Per 6ml vial	5 years	**Deferred** for clarification of indications.
9.	M/s. Allmed Laboratories, Karachi. / M/s. Yuria-PHarm Ltd., Amosova Str., Kyiv, Ukraine.	Paskonat 3% Solution fort injection Each 100ml solution contains:- Sodium Aminosalicylate…..3 g (Anti-tuberculosis	Rs.2795/Per 100ml	1.5 years	**Deferred** for expert opinion of following; a. Brgd. Dr. Dilawar Ahmed.

		drugs).			MH Rwp. b. Dr. Naeem Zaki
10.	M/s. Allmed Laboratories, Karachi. / M/s. Yuria-Pharm Ltd., 10, Mykoly Amosova Str., Kyiv, Ukraine.	Rifonate Concentrate for Solution for Infusion Each 1ml of concentrate contains:- Rifamycin Sodium Salt……..30mg (Anti-tuberculosis drugs Antibiotics).	Rs.2700/Per pack of 5ml	02 years	**-do-**
11.	M/s. Allmed Laboratories, Karachi. / M/s. Yuria-PHarm Ltd., Amosova Str., Kyiv, Ukraine.	Inbutol Solution for Injection Each 1ml solution for injection contains:- Ethambutol Hydrochloride….100 mg (Anti-tuberculosis drugs).	Rs.1650/Per pack 10ml	02 years	**-do-**
12.	M/s. Allmed Laboratories, Karachi. / M/s. Yuria-PHarm Ltd., Amosova Str., Kyiv, Ukraine.	Isoniazid 100mg/5ml Syrup Each 5ml of the syrup contains:- Isoniazid……100mg (Anti-tuberculosis drugs).	Rs.1650/Per pack 100ml Rs.2100/Per pack of 200ml	02 years	**-do-**
13.	M/s Otsuka Pakistan Ltd. (H.I,T,E), Distt. Lasbella, Balochistan./ M/s. Otsuka Pharmaceutical Factory Inc, 115 Kuguhara, Tateiwa, Muya-cho, Naruto, Tokushima, Japan.	MIXID/ ® H Injection 900ml Each dual chamber soft bag contains 900ml:- In upper chamber solution (fate emulsion glucose solution...600ml In low chamber solution (amino acid and electrolyte solution)…….300 ml	Rs.5748/ Per Mixed H 900ml	18 months	**Deferred** for confirmation of Free sale Status in country of origin

		(Glucose, emulsion fat, amino acids, electrolytes).			
14.	M/s Otsuka Pakistan Ltd. (H.I,T,E), Distt. Lasbella, Balochistan. / M/s. Otsuka Pharmaceutical Factory Inc, 115 Kuguhara, Tateiwa, Muya-cho, Naruto, Tokushima, Japan.	Artcereb ® 500ml Injection Each dual chamber soft bag contains 500ml:- In upper chamber solution……150 ml In low chamber solution…….350 ml (Glucose, emulsion fat, amino acids, electrolytes).	Rs.4826/ Artcereb ® 500ml	03 years	**Deferred** for confirmation of Free sale Status in country of origin
15.	M/s. Abbott Laboratories (Pakistan) Limited, Karachi. / M/s. Laboratoires SOPHARTEX 21 Rue du Pressoir Vernouillet, France.	Hidrasec 10mg Sachet Each sachet contains:- Racecadotril……10mg (Anti-Diarrheal).	Rs.1046.30 /Per 16 Sachets	24 months	**Deferred** for confirmation of approval status in FDA, EMA, TGA and Japan.
16.	M/s. Abbott Laboratories (Pakistan) Limited, Karachi. / M/s. Laboratoires SOPHARTEX 21 Rue du Pressoir Vernouillet, France.	Hidrasec 30mg Sachet Each sachet contains:- Racecadotril….30mg (Anti-Diarrheal).	Rs.1046.30 /Per 16 Sachets	24 months	**Deferred** for confirmation of approval status in FDA, EMA, TGA and Japan.
17.	M/s. Abbott Laboratories (Pakistan) Limited, Karachi. / M/s. Laboratoires SOPHARTEX 21 Rue du Pressoir Vernouillet, France.	Hidrasec 100mg Capsules Each capsule contains:- Racecadotril….100mg (Anti-Diarrheal).	Rs.654/ Per 10 Capsules	24 months	**Deferred** for confirmation of approval status in FDA, EMA, TGA and Japan.
18.	M/s. RG Pharmaceutica (Pvt) Ltd., Karachi-75400 M/s. Genewel Co.	Guardix-Sol 5.0g Injection Each 5ml contains:- Sodium	Rs.17480/ Per 5.0gm Prefilled Syringe	24 months	**Deferred** for confirmation of approval

	Ltd., Seongnam-si, Gyeonggi-do, Korea. Marketed by (Sole Exclusive Supplier: M/s. Trasen, Bisan-dong, Dongan-gu, Anyang City, Korea.	hyaluronate…12.50 mg Sodium Carboxymethyl Cellulose…...25.00 mg Water For injection……..…5.0 ml NaCI……40.0 mg KCI……1.0 mg KH_2PO_4…….1.0 mg Na_2HPO_4……..5.75 mg **(Wound Dressing).**			status in FDA
19.	M/s. RG Pharmaceutica (Pvt) Ltd., Karachi-75400 M/s. Genewel Co. Ltd., Seongnam-si, Gyeonggi-do, Korea. Marketed by (Sole Exclusive Supplier: M/s. Trasen, Bisan-dong, Dongan-gu, Anyang City, Korea.	Guardix-Sol 1.5g Injection Each 1.5ml contains:- Sodium hyaluronate…..3.75 mg Sodium Carboxymethyl Cellulose……..7.50 mg Water For injection……1.50 ml NaCI……12.0 mg KCI……..0.30 mg KH_2PO_4……...1.73 mg Na_2HPO_4……..5.75 mg (Wound Dressing).	Rs.8740/ Per 1.5gm Prefilled Syringe	24 months	**Deferred** for confirmation of approval status in FDA
20.	M/s. Bayer Pakistan (Private) Limited, Karachi./	Xarelto 2.5mg Tablets Each tablet contains:- Rivaroxaban…….2.5	Rs.13230/ Per packs of 14’s	36 months	**Approved**

	M/s. Bayer Pharma AG, Germany.	mg (Factor Xa inhibitor).	Rs.26460/ Per packs of 28's		
21.	M/s. 3 M Surgicals, Sarwar Road, Rawalpindi. / M/s. Peters Surgical Z.I. Les Vignes 42, rue Benoit Frachon Bobigny Cedex, France.	Premio ® Non-absorbable Surgical Sutures, P.V.D.F Monofilament (Surgical Sutures).	As per SRO	05 years	**Deferred** for expert opion by the following; a. Dr. Moeed. I. Qureshi Head, Department of Surgery, Sheikh Zayed Hospital, Lahore. b. Prof. Dr. Imran Skindar, Orthopedic Surgeon, Head of Department, Pakistan Institute of Medical Sciences, Islamabad. c. Lt. Col. Dr. Farhan Ahmad Majeed, Professor of Surgery, Combined Military Hospital, Rawalpindi.
22.	M/s. 3 M Surgicals, Sarwar Road, Rawalpindi. /	Black Silk ® Non-absorbable Surgical Sutures, Black	As per SRO	05 years	**-do-**

	M/s. Peters Surgical Z.I. Les Vignes 42, rue Benoit Frachon Bobigny Cedex, France.	Braided Silk Waxed, Ophthalmic Sutures (Surgical Sutures).			
23.	M/s. 3 M Surgicals, Sarwar Road, Rawalpindi. / M/s. Peters Surgical Z.I. Les Vignes 42, rue Benoit Frachon Bobigny Cedex, France.	Cardioxyl ® Non-absorbable Surgical Sutures, Coated Polyester Braid (Surgical Sutures).	As per SRO	05 years	**-do-**
24.	M/s. 3 M Surgicals, Sarwar Road, Rawalpindi. / M/s. Peters Surgical Z.I. Les Vignes 42, rue Benoit Frachon Bobigny Cedex, France.	Soie/Silk ® Non-absorbable Surgical Sutures Waxed Silk Braid. (Surgical Sutures).	As per SRO	05 years	**-do-**
25.	M/s. 3 M Surgicals, Sarwar Road, Rawalpindi. / M/s. Peters Surgical Z.I. Les Vignes 42, rue Benoit Frachon Bobigny Cedex, France.	Optime ® Absorbable Surgical Sutures, Coated Polyglycolic Acid Braid (Surgical Sutures).	As per SRO	05 years	**-do-**
26.	M/s. 3 M Surgicals, Sarwar Road, Rawalpindi. / M/s. Peters Surgical Z.I. Les Vignes 42, rue Benoit Frachon Bobigny Cedex, France.	Optime-R ® Absorbable Surgical Sutures, Coated Polyglycolic Acid Braid with Fast Resorption. (Surgical Sutures).	As per SRO	05 years	**-do-**
27.	M/s. 3 M Surgicals, Sarwar Road, Rawalpindi. / M/s. Peters Surgical Z.I. Les Vignes 42, rue Benoit Frachon Bobigny Cedex, France.	Cardioflon ® Non-absorbable Surgical Sutures Coated Polyester Braid. (Surgical Sutures).	As per SRO	05 years	**-do-**

28.	M/s. 3 M Surgicals, Sarwar Road, Rawalpindi. / M/s. Peters Surgical Z.I. Les Vignes 42, rue Benoit Frachon Bobigny Cedex, France.	Acier ® Non-absorbable Surgical Sutures, Stainless Steel Monofilament. (Surgical Sutures).	As per SRO	05 years	**-do-**
29.	M/s. 3 M Surgicals, Sarwar Road, Rawalpindi. / M/s. Peters Surgical Z.I. Les Vignes 42, rue Benoit Frachon Bobigny Cedex, France.	Corolene ® Non-absorbable Surgical Sutures, Polyproplene Monofilament (Surgical Sutures).	As per SRO	05 years	**-do-**
30.	M/s. Zenith International, Karachi. / M/s. Sutures India (Pvt) Ltd. Bangalore, India.	"Trusilk" Black Silk Braided (Nonabsorbable Surgical Suture U.S.P) (Without Needle) (All sizes). (Surgical Suture).	As per PRC	05 years	**Deferred** for expert opion by the following; d. Dr. Moeed. I. Qureshi Head, Department of Surgery, Sheikh Zayed Hospital, Lahore. e. Prof. Dr. Imran Skindar, Orthopedic Surgeon, Head of Department, Pakistan Institute of Medical Sciences,

					Islamabad. f. Lt. Col. Dr. Farhan Ahmad Majeed, Professor of Surgery, Combined Military Hospital, Rawalpindi. The firm also directed to submit valid CE Certificate.
31.	M/s. Zenith International, Karachi. / M/s. Sutures India (Pvt) Ltd. Bangalore, India.	"Trulene Mesh" Nonabsorbable Polypropylene Surgical Mesh (All sizes) (Surgical Suture).	As per PRC	05 years	**-do-**
32.	M/s. Zenith International, Karachi. / M/s. Sutures India (Pvt) Ltd. Bangalore, India.	"Trugut" Chromic Catgut (Absorbable Surgical Suture U.S.P) (With or Without Needle) (All sizes) (Surgical Suture).	As per PRC	05 years	**-do-**
33.	M/s. Zenith International, Karachi. / M/s. Sutures India (Pvt) Ltd. Bangalore, India.	"Trulene" Monofilament Polypropylene (Nonabsorbable Surgical Suture U.S.P) (With or Without Needle) (All Size)	As per market leader price	05 years	**-do-**
34.	M/s. Zenith International, Karachi. / M/s. Sutures India	"Trusynth" Polyglactin 910 (Absorbable Surgical Suture U.S.P,	As per market leader price	05 years	**-do-**

	(Pvt) Ltd. Bangalore, India.	Synthetic) (With or Without Needle) (All Size)			
35.	M/s. Zenith International, Karachi. / M/s. Sutures India (Pvt) Ltd. Bangalore, India.	"Truglyde" Polyglycolic Acid (Absorbable Surgical Suture U.S.P Synthetic) (With or Without Needle) (All Size)	As per market leader price	05 years	**-do-**

Item No: VIII Anticancer Adjuvants & Immunosuppressent Drugs (Imported)

The Registration Board considered the following applications and decided as mentioned against each. The approved applications are subject to inspection of manufacturer abroad, verification of storage facilities and price fixation / calculation etc as per policy

S. #	Name of applicant / Manufacturer	Name of Drug (s)/ Composition & Therapeutic Group	DMRP/ Pack Size	Shelf Life	Decsion
1.	M/s. CCL Pharmaceuticals (Pvt) Ltd., Lahore. / M/s. Glenmark Generics S.A. Calle 9 Ing Meyer Oks Nº593 Parque Industrial Pilar, Buenos Aires, Argentina.	Gemmin 1gm Lyophilized Powder for Injection Each vial contains:- Gemcitabine hydrochloride U.S.P equivalent to Gemcitabine……1g (Antineoplastic agent).	As per brand leader	02 years	**Approved**
2.	M/s. CCL Pharmaceuticals (Pvt) Ltd., Lahore. / M/s. Glenmark Generics S.A. Calle 9 Ing Meyer Oks Nº593 Parque Industrial Pilar, Buenos Aires, Argentina.	Gemmin 200mg Lyophilized Powder for Injection Each vial contains:- Gemcitabine hydrochloride U.S.P equivalent to Gemcitabine……200mg (Antineoplastic agent).	As per brand leader	02 years	**Approved**

3.	M/s. Merixil Pharma, I-8 Markaz, Islamabad. / M/s. Biolyse Pharma Corporation, 59 Welland Vale Road, ST Catharines Ontario L2S3Y2, Canada.	Biopac 100mg Injection Each vial contains:- Paclitaxel...100mg/ 16.67ml (Anticancer).	Already fixed by PRC	30 months	**Approved**
4.	M/s. Merixil Pharma, I-8 Markaz, Islamabad. / M/s. Biolyse Pharma Corporation, 59 Welland Vale Road, ST Catharines Ontario L2S3Y2, Canada.	Biopac 300mg Injection Each vial contains:- Paclitaxel…300mg/ 50ml (Anticancer).	Already fixed by PRC	30 months	**Approved**
5.	M/s. Revive Health Care, Lahore. / M/s. United Biotech (P) Limited, Bagbani, Baddi, Nalagarh Road, District, Solan, India.	Citabin 500mg Tablets Each film coated tablets contains:- Capecitabine USP……500mg (ATC Class : L01BC06).	As per PRC	02 years	**Approved**
6.	M/s. Revive Health Care, Lahore. / M/s. United Biotech (P) Limited, Bagbani, Baddi, Nalagarh Road, District, Solan, India.	Uniphos-500 Injection Each vial contains:- Cyclophosphamide eq. to anhydrous Cyclophosphamide..500mg (ATC Class : L01AA01).	As per PRC	02 years	**Approved**
7.	M/s. Revive Health Care, Lahore. / M/s. United Biotech (P) Limited, Bagbani, Baddi, Nalagarh Road, District, Solan, India.	Erlotec 150mg Tablets Each film coated tablet contains:- Erlotinib Hydrochloride eq. to Erlotinib……150mg (ATC Class : L01XE03).	As per PRC	02 years	**Approved**
8.	M/s. Revive Health Care, Lahore. / M/s. United Biotech (P) Limited, Bagbani, Baddi, Nalagarh Road, District, Solan, India.	Ifomid-M 1gm Injection Each vial contains:- Ifosfamide…….1gm Sodium 2-Sulphanylethansulphonate BP……..……100mg (ATC Class: L01AA06).	As per SRO/PRC	02 years	**Approved**

9.	M/s. Sncura Enterprises Pakistan (Pvt) Ltd., Saddar, Rawalpindi. / M/s. Emcure Pharmaceuticals Ltd., Plot No. P-1, IT BT Park Phase-II, M.I.D.C., Hinjwadi, Pune-411 057, India.	Mofilet-500 Tablets 500mg Each film coated tablets contains:- Mycophenolate Mofetil……..…500mg (Immunosuppressant)	Rs.2100/ Per packs of 1x10 Tablets	24 months	**Approved**
10.	M/s. Sncura Enterprises Pakistan (Pvt) Ltd., Saddar, Rawalpindi. / M/s. Emcure Pharmaceuticals Ltd., Plot No. P-2, IT BT Park Phase-II, M.I.D.C., Hinjwadi, Pune-411 057, India.	Citafine 1g Injection Each vial contains:- Gemcitabine Hydrochloride Equivalent to Gemcitabine……..…1g (Anticancer).	Rs.16275/Per vial	24 months	**Approved**
11.	M/s. Sncura Enterprises Pakistan (Pvt) Ltd., Saddar, Rawalpindi. / M/s. Emcure Pharmaceuticals Ltd., Plot No. P-2, IT BT Park Phase-II, M.I.D.C., Hinjwadi, Pune-411 057, India.	Oxaliplatin Injection USP 50mg/10ml Each ml contains:- Oxaliplatin USP……5mg Water for injection USP…….q.s. (Anticancer).	Rs.15062/Per vial	24 months	**Approved**
12.	M/s. Sncura Enterprises Pakistan (Pvt) Ltd., Saddar, Rawalpindi. / M/s. Emcure Pharmaceuticals Ltd., Plot No. P-2, IT BT Park Phase-II, M.I.D.C., Hinjwadi, Pune-411 057, India.	Oxaliplatin Injection USP 100mg/20ml Each ml contains:- Oxaliplatin USP…….5mg Water for injection USP…….q.s. (Anticancer).	Rs.30123/Per vial	24 months	**Approved**
13.	M/s. Sncura Enterprises Pakistan (Pvt) Ltd., Saddar, Rawalpindi. / M/s. Emcure Pharmaceuticals Ltd., Plot No. P-2, IT BT Park Phase-II, M.I.D.C., Hinjwadi, Pune-411 057, India.	Vingraf 1 Capsules 1mg Each hard gelatin capsule contains:- Tacroliums…….1mg (Immunosuppressant)	Rs.1097/ Per packs of 1x10 Capsules	24 months	**Approved**

14.	M/s. GlaxoSmithKline Pakistan Limited, Karachi. / M/s. Onco Therapies Ltd, Bangalore, India.	Dovestac Injection 20mg Each vial contains:- Docetaxel Anhydrous…….20mg (Anti Cancer Product).	Rs.8,000/ Per 1's	24 months	**Approved**
15.	M/s. GlaxoSmithKline Pakistan Limited, Karachi. / M/s. Onco Therapies Ltd, Bangalore, India.	Diluent for Dovestac (Docetaxel) Injection 20mg Each vial contains:- 13% w/v ethanol in water for injection (Diluent for Anticancer product).	Free of cost.	24 months	**Approved**
16.	M/s. GlaxoSmithKline Pakistan Limited, Karachi. / M/s. Onco Therapies Ltd, Bangalore, India.	Dovestac Injection 80mg Each vial contains:- Docetaxel Anhydrous……80mg (Anti Cancer Product).	Rs.20,000/ Per 1's	24 months	**Approved**
17.	M/s. GlaxoSmithKline Pakistan Limited, Karachi. / M/s. Onco Therapies Ltd, Bangalore, India.	Diluent for Dovestac (Docetaxel) Injection 80mg Each vial contains:- 13% w/v ethanol in water for injection (Diluent for Anticancer product).	Free of cost.	24 months	**Approved**
18.	M/s. GlaxoSmithKline Pakistan Limited, Karachi. / M/s. Onco Therapies Ltd, Bangalore, India.	Gercizar Injection 200mg Each vial contains:- Gemcitabine Hydrochloride equivalent to Gemcitabine……200mg (Anti Cancer Product).	Rs.2,050/ Per 1's	24 months	**Approved**
19.	M/s. GlaxoSmithKline Pakistan Limited, Karachi. / M/s. Onco Therapies Ltd, Bangalore, India.	Gercizar Injection 1g Each vial contains:- Gemcitabine Hydrochloride equivalent to Gemcitabine……1000mg (Anti Cancer Product).	Rs.10,100/ Per 1's	24 months	**Approved**

Item No: IX Imported Veterinary Drugs.

The Board referred all of the following applications except Application at S.No.13 (Containg Metamizole) to committee comprises of Dr. Muhammad Arshad, Member Registration Board, Dr. Muhammad Ashraf, UVAS, Lahore and Head of Pharmacology Department Arid Universtiy Rawalping for expert opinion. Recommendations of expert will be broght before the Board for further decision on the matter.

S. No.	Name of Importer/ Manufacturer.	Name of Drug (s)/Composition.	Price / Pak Size.	Shelf Life.	Decsion
1.	M/s. Ghazi Brothers, Karachi-75350 / **Product License Holder:-** M/s. Agrovet Market S.A., San Luis, Lima, Perua. **Manufacturer Under Product License Holder:-** M/s. Pharmadix Corp. S.A.C. Urbanizacion La Aurora-Ate Lima 3-Peru.	Metri-CEF 3 Intrauterine Suspension Each 30ml contains:- Cephalexin monohydrate (Base)…….600mg Neomycin sulfate (Base)…….1.02gm Cloxacillin benzathine……..…1.50gm Vitamin A……30.000 IU	Decontrolled 30ml Pre-filled syringe	03 years	Referred for expert opinion
2.	M/s. Ghazi Brothers, Karachi-75350 / **Product License Holder:-** M/s. Agrovet Market S.A., San Luis, Lima, Perua. **Manufacturer Under Product License Holder:-** M/s. Pharmadix Corp. S.A.C. Urbanizacion La Aurora-Ate Lima 3-Peru.	Catofos B9 + B12 Injectable Solution Each ml contains:- Butaphosphan…….100mg Vitamin B9 (Folic Acid)…….…..15mg Vitamin B12 (Cyanocobalamin)..0.05mg (Vitamin and Mineral).	Decontrolled 10ml 20ml 50ml 100ml 250ml 500ml	03 years	-do-
3.	M/s. Ghazi Brothers, Karachi. / M/s. Vetanco S.A. Buenos Aires, Argentina.	Ketoxilen Injection Each 100ml contains:- Oxytetracycline…….20gm Ketoprofen……3gm (Antibiotic/Anti-inflammatory).	Decontrolled 40ml 50ml 100ml 250ml 500ml	2 years	-do-

4.	M/s. Ghazi Brothers, Karachi. / M/s. Cheilbio Co. Ltd., Moknae-Dong, Ansan-Si, Gyeonggi-Do, Korea.	Geslong Injection Each ml of solution contains:- MetoclopramideHCI…5mg (Antiemetic/ Gastroprokinetic).	Decontrolled 2ml 10ml 20ml 50ml 100ml vials	02 years	-do-
5.	M/s. Ghazi Brothers, Karachi. / M/s. Cheilbio Co. Ltd., Moknae-Dong, Ansan-Si, Gyeonggi-Do, Korea.	Cheil Tonocomp Injection Each ml of solution contains:- Toldimfos sodium……200mg	Decontrolled 50ml 100ml 200ml 250ml 500ml vials	02 years	-do-
6.	M/s. Ghazi Brothers, Karachi. / M/s. Cheilbio Co. Ltd., Moknae-Dong, Ansan-Si, Gyeonggi-Do, Korea.	Seletoco Injection Each ml of solution contains:- Vitamin E acetate…….100mg Sodium Selenite……1mg (Nutritional additive).	Decontrolled 10ml 20ml 50ml 100ml vials	02 years	-do-
7.	M/s. Ghazi Brothers, Karachi. / M/s. Cheilbio Co. Ltd., Moknae-Dong, Ansan-Si, Gyeonggi-Do, Korea.	Procillin-LA Injection Each ml contains:- Pencillin G Benzathine ……..1,00,000 IU Penicillin G Procaine……1,00,000 IU Dihydrostreptomycin sulfate…200mg (Antibacterial).	Decontrolled 20ml 50ml 100ml vials	02 years	-do-
8.	M/s. Ghazi Brothers, Karachi. / M/s. Cheilbio Co. Ltd.Gyeonggi-Do, Korea.	Oxyneo Powder Each 1 Kg contains:- Oxytetracycline Quaternary Ammonium Salts…..110gm Neomycin sulfate….110gm (Antibiotic).	Decontrolled 1Kg 5Kg 10Kg 15Kg 20Kg 25Kg	02 years	-do-
9.	M/s. Ghazi Brothers, Karachi. / M/s. Cheilbio Co. Ltd.Gyeonggi-Do, Korea.	Oxyone Powder Each 1 Kg contains:- Oxytetracycline Quaternary Ammonium Salts….200g (Antibiotic).	Decontrolled 1Kg 5Kg 10Kg 15Kg 20Kg	02 years	-do-

			25Kg		
10.	M/s. Ghazi Brothers, Karachi. / M/s. Hebei Yuanzheng Pharmaceutical Co. Ltd., Shijiazhuang City, Hebei Province, China.	Cefquin Suspension for Injection Each ml contains:- Cefquinome (as sulfate)……..25mg (Antibiotic).	Decontrolled 50ml 100ml	03years	-do-
11.	M/s. Ghazi Brothers, Karachi. / M/s. Hebei Yuanzheng Pharmaceutical Co. Ltd., Shijiazhuang City, Hebei Province, China.	Isomedium Powder for parental administration Each sachet contains:- Isometamedium chloride hydrochloride……1g (Antiprotozoal).	Decontrolled 1 gm sachet	03years	-do-
12.	M/s. Ghazi Brothers, Karachi. / M/s. Hebei Yuanzheng Pharmaceutical Co. Ltd., Shijiazhuang City, Hebei Province, China.	Oxybiotic LA 30% Solution for Injection Each ml contains:- Oxytetracycline (as dihydrate)….300mg (Antibiotic).	Decontrolled 50ml 100ml	03years	-do-
13.	M/s. Ghazi Brothers, Karachi. / M/s. Hebei Yuanzheng Pharmaceutical Co. Ltd., Shijiazhuang City, Hebei Province, China.	Analgin Solution for Injection Each ml contains:- Metamizole……..300mg (Analgesic and Antipyretic).	Decontrolled 50ml 100ml	03years	**Metamizole has been withdrawn from Pakistan in 192nd meeting of Registration Board. Therefore Board reject this application.**
14.	M/s. Ghazi Brothers, Karachi. / M/s. Hebei Yuanzheng Pharmaceutical Co. Ltd., Shijiazhuang City, Hebei Province, China.	Bupaquone Solution for Injection Each ml contains:- Buparvaqone…….50mg (Antiprotozoal).	Decontrolled 50ml 100ml 500ml	03 years	
15.	M/s. Orient Animal Health (Pvt) Ltd., Karachi. / M/s. Univet Ireland Ltd. Tullyvin, Cootehill, Co. Cavan, Ireland.	Unimox LA Injection Each ml contains:- Amoxicillin (as Amoxicillin Trihydrate) Ph. Eur…150mg (Antibacterial).	Decontrolled 10ml 30ml 50ml 100ml 250ml	03 years	Referred for expert opinion

			500ml		
16.	M/s. Orient Animal Health (Pvt) Ltd., Karachi. / M/s. Univet Ireland Ltd. Tullyvin, Cootehill, Co. Cavan, Ireland.	Unicycline LA Injection Each ml contains:- Oxytetracycline (as Oxytetracycline Dihydrate Ph. Eur)……..200mg (Antibacterial).	Decontrolled 10ml 30ml 50ml 100ml 250ml 500ml	03 years	-do-
17.	M/s. Orient Animal Health (Pvt) Ltd., Karachi. / M/s. Univet Ireland Ltd. Tullyvin, Cootehill, Co. Cavan, Ireland.	Multivit Injection Each 1 ml contains:- Vitamin B1……..…10mg Vitamin B2……..…5mg Vitamin B6……..…3mg Vitamin B12…….0.05mg Nicotinamide…..….35mg D-Panthenol……...25mg Vitamin A……..…15,000 IU Vitamin D3……...1,000 IU Vitamin E……..10mg (Multivitamins).	Decontrolled 10ml 50ml 100ml 250ml 500ml	03 years	-do-
18.	M/s. Orient Animal Health (Pvt) Ltd. Karachi. / M/s. V.M.D. N.V, Hoge Mauw, Arendonk-Belgium.	Promycin-1000 Injectable Solution Each ml contains:- Colistin Sulphate……..1,000,000 IU (Polypeptide Antibiotic).	Decontrolled 10ml 40ml 100ml 250ml 500ml	36 months	-do-
19.	M/s. Orient Animal Health (Pvt) Ltd., Karachi. / M/s. V.M.D. N.V, Hoge Mauw, Arendonk-Belgium.	Promycin-4800 Water Soluble Powder Each gram contains:- Colistin Sulphate…….4,800,000 IU (Polypeptide Antibiotic).	Decontrolled 100gm 500gm 1 Kg 2.5 Kg 5 Kg 25 Kg	36 months	-do-
20.	M/s. Marush (Pvt) Ltd., Lahore. / M/s. Univet Ltd. Tullyvin, Cootehill, Co. Cavan, Ireland.	Ubroloxin ® Intramammary Suspension Each 1 injector with 10g (12ml) contains:- Cefalexin monohydrate……..200mg	Decontrolled 10 x 10g	12 months	-do-

		Kanamycin monosulfate……133mg (Corresponds to 100,000 I.U). (Pharmaceuticals).			
21.	M/s. U.M. Enterprises, Karachi-74900/ M/s. Qilu Animal Health Products Co. Ltd., Jinan, Shandong, China.	Flumeglu 5gm Injection Each 100ml contains:- Flunixin Meglumine equivalent to 5.0g of Flunixin. (Non-steriod, Ant-inflammatory drug).	Decontrolled 50ml 100ml	24 months	-do-
22.	M/s. U.M. Enterprises, Karachi-74900/ M/s. Qilu Animal Health Products Co. Ltd., Jinan, Shandong, China.	Cefent 1gm Injection Each 25ml vial contains:- Ceftiofur Sodium equivalent to 1.0g Ceftiofur. (B.Lactum Antibiotics).	Decontrolled 1gm/25ml	24 months	-do-
23.	M/s. U.M. Enterprises, Karachi-74900/ M/s. Qilu Animal Health Products Co. Ltd., Jinan, Shandong, China.	Cefent 4gm Injection Each 100ml vial contains:- Ceftiofur Sodium equivalent to 4.0g Ceftiofur. (B.Lactum Antibiotics).	Decontrolled 4gm/100ml	24 months	-do-
24.	M/s. U.M. Enterprises, Karachi-74900/ M/s. Qilu Animal Health Products Co. Ltd., Jinan, Shandong, China.	Ceftihyde 5gm Injection Each 100ml contains:- Ceftiofur Hydrochloride equivalent to 5.0g Ceftiofur. (B.Lactum Antibiotics).	Decontrolled 50ml 100ml	24 months	-do-

Item No: X Imported Human Drugs (Mee-Too & Other Drugs)

The Registration Board considered the following applications and decided as mentioned against each. The approved applications are subject to inspection of manufacturer abroad, verification of storage facilities and price fixation / calculation etc as per policy

S.#	Name of Manufacturer / Importer.	Name of Drug (s) Composition & Therapeutic Group.	Demanded Price & Pack Size.	Shelf Life	Decsion
1.	M/s. Matrix Pharma (Pvt) Ltd., Karachi. / M/s. Dong-A Pharm	Zydena 100mg Tablet Each tablet contains: -	Rs.2210/ per pack of 2's	03 years	**Deferred** for safety and clinical data of

	Co Ltd Yongdu-Dong, Dongdaemun-Ku, Seoul Korea.	Udenafil…….100mg PDE5-Inhibitor (Erectile Dysfunction)			the drug along with complete clinical trial data.
2.	M/s. Matrix Pharma (Pvt) Ltd., Karachi. / M/s. Dong-A Pharm Co Ltd Yongdu-Dong, Dongdaemun-Ku, Seoul Korea.	Zydena 200mg Tablet Each tablet contains: - Udenafil….200mg (Erectile Dysfunction)	Rs.3788/ per pack of 2's	03 years	-do-
3.	M/s. Biomedics Medical System Rawalpindi. / M/s. Ain Medicare SDN BHD Kota Bharu Kelantan, Malaysia.	Infusol NS Infusion Contains: - Sodium Chloride BP….0.9% W/V (Parenteral)	Rs.45/	5 years	**Deferred** as COPP is expired
4.	M/s. Network Marketing Services, Lahore / M/s. Shanghai Xudong Haipu Pharmaceutical Co, Ltd jinhu Road, Jinqiao, Pudong, Shanghai, China.	Megluvision Injection Each 20ml ampoule contains: - Diatrizoate…..12.64g Meglumine……3.20g (Contrast Media)	Rs.168/20 ml Rs.840/ 5 x 20ml	03 years	**Deferred** as COPP of Countrty of origin is not provided on WHO Format.
5.	M/s. A&Z Health Services Rawalpindi. / M/s. Guerbet Roissy CdG cedex France.	Dotarem Solution for Injection Each 100ml contains: -Gadoteric Acid 27.932mg corresponding to Dota……..20.246g m Gadolinium Oxide……..9.062g m	11 Euro / 10ml 15 Euros / 15ml 19Euros / 20ml	3 years	Approved
6.	M/s. Atlantic Pharmaceuticals, Karachi. / M/s.NCPC North Best Co, LTD, East Heping Road, Shijiazhuang, Hebei Province China.	Nicozat Injection Each vial contains: - Piperacillin……..4g m Tazobactam…..0.5g m	Rs.915/1's Rs.9100/ 10's	2 years	**Approved**

7.	M/s. BN Pharmaceuticals Lahore. / M/s. Laboratories Chaix et Du Marais Lavoisier Head Quarter Paris France.	Sulphate De Magnesium Lavoisier (1.5G/10ML) 15% (I.V) Injectable Each ampoule contains: - Magnesium as Sulphate. 1.5g/10ml (15%) (Adjuvant analgesic in cancer / Electrolytes).	Rs.450/Per ampoule Rs.4500/Per 10 ampoules	02 years	**Approved**
8.	M/s. Barrett Hodgson Pakistan (Pvt) Ltd, Karachi. / M/s. Allergan Pharmaceuticals, West Port, Co Mayo Ireland.	Ganfort Eye Drops Each ml contains: - Bimatoprost…0.3mg Timolol (as Timolol Maleate)….5.0mg (Beta Blocker)	Rs.1550/3 ml	24 Months	**Approved**
9.	M/s. Getz Pharma (Private) Limited, Karachi. / M/s. Jewim Pharmaceutical (Shandong) Co. Ltd., Shandong, China.	Ipra Inhaler 20mcg Each metered dose contains:- Ipratropium Bromide Monohydrate equivalent to Ipratropium Bromide…….20mcg (Anticholinergic Bronchodilator).	Rs. 450/ Per pack size of 1 canister	3 years	**Approved**
10.	M/s. Chiesi Pharmaceuticals (Private) Ltd., Lahore. / M/s. Chiesi Farmaceutici S.p.A., Italy.	Curosurf Sterile Suspension in vials for Intratracheal Instillation. Each 3ml contains:- Pulmonary surfactant of natural Origin……80.0mg (corresponding to approx. 74.0 of total phospholipids). (Pulmonary Surfactant).	Rs.45,000/ Per 3ml vial	18 months	**Approved**
11.	M/s. Atlantic Pharmaceuticals, Karachi. / M/s. Hebei New	Xoproc 1.2gm Powder for Solution for Injection Each vial contains:-	Rs.183.42/ Per Vial Rs.1834.20/Per pack	02 years	**Deferred** as Copp is expied

	Zhangjiakou Pharmaceuticals Co. Ltd., Hebei Province, China.	Amoxicillin Sodium…1g Clavulanate Potassium……0.2g (Broad- Spectrum Semi-synthetic Antibiotic).	of 10 vials		
12.	M/s. Atlantic Pharmaceuticals, Karachi. / M/s. Hebei New Zhangjiakou Pharmaceuticals Co. Ltd., Hebei Province, China.	Xoproc 600mg Powder for Solution for Injection Each vial contains:- Amoxicillin Sodium……0.5g Clavulanate Potassium……0.1g (Broad- Spectrum Semi-synthetic Antibiotic).	Rs.91.77/ Per Vial Rs.917.70/ Per pack of 10 vials	02 years	**Deferred** as COPP is expied
13.	M/s. Atlantic Pharmaceuticals, Karachi. / M/s. Hebei New Zhangjiakou Pharmaceuticals Co. Ltd., Hebei Province, China.	Atcef 1.0g Injection Each vial contains:- Cefoperazone Sodium……..0.5g Sulbactam……0.5g (Semi-synthetic broad- spectrum cephalosporin).	Rs.290/Per vial	02 years	**Deferred** as COPP is expied
14.	M/s. Atlantic Pharmaceuticals, Karachi. / M/s. Hebei New Zhangjiakou Pharmaceuticals Co. Ltd., Hebei Province, China.	Atcef 2.0g Injection Each vial contains:- Cefoperazone Sodium……..1.0g Sulbactam…..1.0g (Semi-synthetic broad- spectrum cephalosporin).	Rs.412/Per vial	02 years	**Deferred** as COPP is expied
15.	M/s. Hospital Services & Sales, Karachi. / **Manufactured by:** M/s. Nanjing Chiatai-Tianqing Pharmaceutical Co. Ltd., Nanjing,	Hestra Injection Each 100ml of the solution contains:- Hydroxyethyl Starch 130/0.4….6g Sodium Chloride…0.9g	Rs.1445/ Per 500ml bag	24 months	**Approved**

	People's Republic of China. **Exported by :** M/s. Shenzhen Mellow Hope Pharma Industrial Co., Ltd., Shenzhen, P.R. China.	(Plasma Substitute Solution).			
16.	M/s. Novartis Pharma (Pakistan) Limited, Karachi-74000. / M/s. Novartis Pharmaceutical, USA.	Tobi Podhaler 28mg Hard Capsules Each Inhalation powder hard capsule contains:- Tobramycin……28mg (Management of Pulmonary Pseudomonus infection in Cystic Fibrosis (CF)	Rs.98000/Per 56 Capsules + 1 Inhaler Rs.1750/Per Capsule	36 months	**Approved**
17.	M/s. Highnoon Laboratories Limited, Lahore. / M/s. JW Pharmaceutical Corporation, Seoul, Republic of Korea.	Pospenem Injection 500mg Each vial contains:- Meropenem……500 mg (Carabapenem Antibiotic).	Rs.1350/ Per 1's Rs.13500/ Per 10's	36 months	**Approved**
18.	M/s. OBS Pharma (Pvt) Ltd.,Karachi-75600./ M/s. Myungmoon Pharmaceutical Co. Ltd., Hwaseong-Si, Gyeonggi-Do, Korea.	Tipem Injection Each vial contains:- Imipenem (monohydrate), U.S.P……500mg Cilastatin Sodium, U.S.P.., equivalent to Cilastatin……500mg (Carbapenem Antibiotics).	Rs.1500/ Per vial Rs.15000/ Per packs of 10 vials	24 months	**Approved**
19.	M/s. Pharmatec Pakistan (Pvt) Limited, Karachi. / M/s. Laboratorio Aldo-Union, S.A. Baronesa de Malda, Barcelona-Spain.	Venex Plus Inhaler Each actuation contains: - Salbutamol Sulphate……100mcg Beclometasone dipropionate…..50mcg	Rs.156.40/ Per 1'	03 years	**Approved**

		(Anti-asthmatic).			
20.	M/s. Pak China International, Karachi. / M/s. Zheijing Chimin Pharmaceutical Co. Ltd, 888 Beiyuan Road, Huangyan, Zhejiang, P.R. China. Exported by:- M/s. Ningbo Tisun Biochemi Company Ltd. Ningbo, China.	Sodium Ringer Lactate Injection Each 500ml bottle contains:- Sodium Chloride…3.0g Sodium Lactate, Anhydrous……1.55g Potassium Chloride ..0.15g Calcium Chloride...0.1g Water for injection……..add to q.s (Electrolyte Supplement).	Rs.56/ Per 500ml bottle Rs.77/Per 1000ml bottle	3 years	**Deferred** for confirmation of pack size.
21.	M/s. Mehran International, Karachi / **Manufactured by:** M/s. Zhejiang Tianrui Pharmaceutical Co. Ltd., Ruain, P.R, China. **Exported by:** M/s. Ningbo Tisun Biochemi Co.Ltd. Ningbo, China.	Potassium Chloride Injection 7.45% 20ml. Each 20ml plastic bottle contains:- Potassium Chloride 1.49gm. (Electrolyte Supplement).	As per leader price.	03 years	**Approved**
22.	M/s. CCL Pharmaceuticals (Pvt) Ltd., Lahore. / **Product Licence Holder :-** M/s. EUSA Pharma (Europe) Limited, Oxford Science Park, United Kingdom. **Manufacturing Site:-** M/s. Syntacoll	Collatamp EG Implantable Collagen Sponge Each cm^2 sponge contains:- Collagen……..2.8mg Gentamicin sulphate……....2.0mg (Antibacterial).	As per brand leader Pack Sizes 5 x 5cm 10 x 10cm 20 x 20cm	04 years	**Deferred as** GMP of the source is not verified by any regulatory authority

	GmbH Donausstrasse, Saal/Donau, Germany.				
23.	M/s. Biocare Pharmaceutica, Lahore. / M/s. Xiangbei Welman Pharmaceutical Co. Ltd., Hunan Province, China.	Penitrax for Injection Each vial contains:- Piperacillin Sodium equivalent to Piperacillin…….2gm Tazobactam sodium equivalent to Tazobactam…...0.25 gm (Anti-infective Beta Lactamase Inhibitor).	Rs.495/ Per vial	02 years	**Approved**
24.	M/s. Biocare Pharmaceutica, Lahore. / M/s. Xiangbei Welman Pharmaceutical Co. Ltd., Hunan Province, China.	Penitrax for Injection Each vial contains:- Piperacillin Sodium equivalent to Piperacillin……3.0gm Tazobactam sodium equivalent to Tazobactam…0.375gm (Anti-infective Beta Lactamase Inhibitor).	Rs.720/ Per vial	02 years	**Approved**
25.	M/s. Biocare Pharmaceutica, Lahore. / M/s. Xiangbei Welman Pharmaceutical Co. Ltd., Hunan Province, China.	Penitrax for Injection Each vial contains:- Piperacillin Sodium equivalent to Piperacillin…….4.0gm Tazobactam sodium equivalent to Tazobactam……0.5gm (Anti-infective Beta Lactamase Inhibitor).	Rs.875/ Per vial	02 years	**Approved**
26.	M/s. Novartis Pharma (Pakistan) Limited, 15 West Wharf, Karachi./ M/s. LTS Lohmann	Exelon Transdermal Patch Each patch of 15 cm^2 contains:-	Rs.18,105/ Per 30 Patches Rs.603.50/	24 months	**Approved**

	Therapie-Systeme AG, Germany.	27mg rivastigmine base, in vivo release rate of 13.3mg/24 hours. (Brain selective cholinesterase inhibitor).	Per Patch		
27.	M/s. Novartis Pharma (Pakistan) Limited, Karachi./ M/s. Ever Pharma Jena GmbH, Otto-Schott-StraBe, Jena, Germany. **License Holder:-** M/s. Hexal AG, Holzkirchen, Germany.	Zumatram 100mg/2ml Solution for Injection Each 2ml ampoule contains:- Tramadol HCI…100mg (Non-Narcotic Analgesic).	Rs.258.61/ Per pack of 5's	05 years	**Approved**
28.	M/s. Ghani Brothers, Karachi. / M/s. Laboratorios Haymann S.A. Gianelli 1489, Montevideo Uruguay.	Estravent 20mcg Aerosol Solution HFA Each dose contains:- Ipratropium Bromide……..20mcg Citric Acid Anhydride…2.2625mcg (Anticholinergic Agent)	As per brand leader	02 years	**Approved**
29.	M/s. Ghani Brothers, Karachi. / M/s. Laboratorios Haymann S.A. Gianelli 1489, Montevideo Uruguay.	Ventoxiplus Aerosol 50mcg/100mcg Inhaler HFA Each inhaled dose contains:- Beclomethasone Dipropionate…..0.05 mg Salbutamol (*)...0.10mg (Glucocorticoid & Adrenergic Agent)	As per brand leader	02 years	**Approved**
30.	M/s. Ghani Brothers, Karachi. / M/s. Laboratorios	Ventiplus (Suspension) 100mcg Inhaler HFA	As per brand leader	02 years	**Deferred** for confirmation of **Status of**

	Haymann S.A. Gianelli 1489, Montevideo Uruguay.	Each inhaled dose contains:- Salbutamol (as sulfate)…….0.100 mg (Beta-2, Adrenergic Agonist).			**Market Authorization**
31.	M/s. Ghani Brothers, Karachi. / M/s. Laboratorios Haymann S.A. Gianelli 1489, Montevideo Uruguay.	Serflu 50 Aerosol Inhaler HFA Each inhaled dose contains:- Fluticasona Propionate……0.050 mg Salmeterol Xinafoate (*)……..0.0363 mg (Adrenergic Agonist).	As per brand leader	02 years	**Approved**
32.	M/s. Ghani Brothers, Karachi. / M/s. Laboratorios Haymann S.A. Gianelli 1489, Montevideo Uruguay.	Serflu 125 Aerosol Inhaler HFA Each inhaled dose contains:- Fluticasona Propionate……0.125 mg Salmeterol Xinafoate (*)……..0.0363 mg (Adrenergic Agonist).	As per brand leader	02 years	**Approved**
33.	M/s. Ghani Brothers, Karachi. / M/s. Laboratorios Haymann S.A. Gianelli 1489, Montevideo Uruguay.	Serflu 250 Aerosol Inhaler HFA Each inhaled dose contains:- Fluticasona Propionate……0.250 mg Salmeterol Xinafoate (*)……..0.0363 mg (Adrenergic Agonist).	As per brand leader	02 years	**Approved**
34.	M/s Otsuka Pakistan Ltd., Distt. Lasbella./ M/s. Otsuka Pharmaceutical Co. Ltd., Kanda-Tsukasamachi,	Samsca Tablets 15mg Each tablets contains:- Tolvaptan……15mg (Diuretic,	Price not mentioned.	04 years	**Rejected** as not registred in country of origin

	Chiyoda-ku, Tokyo, Japan. Import of finished product from Otsuka America Pharmaceutical Inc. (USA) and market in Pakistan.	Vasopressin Antagonist/Cardiovascular drug for hyponatremia).			
35.	M/s Otsuka Pakistan Ltd., Distt. Lasbella./ M/s. Otsuka Pharmaceutical Co. Ltd., Kanda-Tsukasamachi, Chiyoda-ku, Tokyo, Japan. Import of finished product from Otsuka America Pharmaceutical Inc. (USA) and market in Pakistan.	Samsca Tablets 30mg Each tablets contains:- Tolvaptan…….30 mg (Diuretic, Vasopressin Antagonist/Cardiovascular drug for hyponatremia).	Price not mentioned.	04 years	**Rejected** as not registred in country of origin
36.	M/s. Allmed Laboratories, Karachi. / M/s. NCPC International Corp. East Heping Road, Shijiazhuang, Hebei, P.R. China.	Piptaz Powder for Injection Each vial contains:- Piperacillin Sodium equivalent to Piperacillin……..….4.0g Tazobactam Sodium equivalent to Tazobactam……0.5g (Combination of Penicillins, including beta-lactamase inhibitors).	Rs.728/ Per vial of 4.5gm	03 years	**Approved**
37.	M/s. Allmed Laboratories, Karachi. / M/s. Yangzhou No.3 Pharmaceutical Co. Ltd. Guotai Road, Yiling Town, Jiangdu Distrcit, Yangzhou	Salbusol Inhalation Aerosol 100mcg/dose, 200 doses Each dose contains:- Salbutamol BP..100mcg Excipients……q	Rs. 200/ for 1's inhaler	03 years	**Approved**

	City, Jiangsu, P.R. China.	.s.			
38.	M/s. Highnoon Laboratories Limited, Lahore. / M/s. Acino AG Miesbach, Germany.	Fentavera 25 µg/h Transdermal Patch Each Transdermal patch contains:- Fentanyl…….5.1mg (Opioid Analgesic).	Rs. 2400/ Per 5's	24 Months	**Approved**
39.	M/s. Highnoon Laboratories Limited, Lahore. / M/s. Acino AG Miesbach, Germany.	Fentavera 50 µg/h Transdermal Patch Each Transdermal patch contains:- Fentanyl…….10.2 mg (Opioid Analgesic).	Rs.4400/ Per 5's	24 Months	**Approved**
40.	M/s. Hashir Surgical Services (Pvt) Ltd. Peshawar-Pakistan. / M/s. Zhejiang Bangli Medical Products Co. Ltd., Yuegui South Road City West New District Yongkang City, Zhejiang Province, China.	Bio Shield First Aid Bandages 76X19mm 76X19mm 56x19mm 40x10mm DIA22mm 76X19mm 56x19mm 40x10mm DIA22mm 72X19mm 72X19mm 72X19mm 56x19mm 40x10mm Dia22mm 76x19mm 76x19mm 38x38mm 76X19mm 76X19mm 72x19mm 72x19mm 70x18mm (Disposable Bandages).	As per PRC	05 years	**Deferred** for confirmation of registration status in FDA, EMA, TGA or Japan.
41.	M/s. Hashir Surgical	Bio Shield Cooling	As per	05	**Deferred** for

	Services (Pvt) Ltd. Peshawar-Pakistan. / M/s. Zhejiang Bangli Medical Products Co. Ltd., Yuegui South Road City West New District Yongkang City, Zhejiang Province, China.	Gel Patch 4 x 10cm 5 x 12cm 10 x 14cm (Disposable Medical).	PRC	years	confirmation of registration status in FDA
42.	M/s. Hashir Surgical Services (Pvt) Ltd. Peshawar-Pakistan. / M/s. Zhejiang Bangli Medical Products Co. Ltd., Yuegui South Road City West New District Yongkang City, Zhejiang Province, China.	Bio Shield Medicated Plaster (Zinc Oxide). 1.25cm x 5m 2.5cm x 5m 5cm x 5m 7.5cm x 5m 10cm x 5m 1.25cm x 10m 2.5cm x 10m 5cm x 10m 7.5cm x 10m 10cm x 10m (Disposable Medical).	As per PRC	05 years	**Deferred** for confirmation of registration status in FDA
43.	M/s. Hashir Surgical Services (Pvt) Ltd. Peshawar-Pakistan. / M/s. Zhejiang Bangli Medical Products Co. Ltd., Yuegui South Road City West New District Yongkang City, Zhejiang Province, China.	Bio Shield Surgical Tape (Non Woven). All sizes 1.25cmx5m 2.5cmx5m 5cmx5m 7.5cmx5m 10cmx5m 1.25cmx10m 2.5cmx10m 5cmx10m 7.5cmx10m 10cmx10m (Disposable Medical Devices/Surgical Tape).	As per PRC	05 years	**Deferred** for confirmation of registration status in FDA
44.	M/s. Hashir Surgical Services (Pvt) Ltd. Peshawar-Pakistan. / M/s. Zhejiang Bangli Medical Products Co. Ltd., Yuegui South Road City West New	Bio Shield Wound Dressing 5x7cm 8x10cm 10x10cm 15x10cm 20x10cm	As per PRC	05 years	**Deferred** for confirmation of registration status in FDA, EMA, TGA or Japan.

	District Yongkang City, Zhejiang Province, China.	25x10cm 30x10cm 35x10cm 5x7cm 6x8cm 74X20cm 60X50cm (Disposable Medical).			
45.	M/s. Hashir Surgical Services (Pvt) Ltd. Peshawar-Pakistan. / M/s. Zhejiang Bangli Medical Products Co. Ltd., Yuegui South Road City West New District Yongkang City, Zhejiang Province, China.	Bio Shield Surgical Tape PE 1.25cmx5m 2.5cmx5m 5cmx5m 7.5cmx5m 10cmx5m 1.25cmx10m 2.5cmx10m 5cmx10m 7.5cmx10m 10cmx10m (Surgical Tape).	As per PRC	05 years	**Deferred** for confirmation of registration status in FDA
46.	M/s. Hashir Surgical Services (Pvt) Ltd. Peshawar-Pakistan. / M/s. Yafho Bio-technology Co. Ltd., Plant, Hengsheng Ind. Zone, West Yicun Ind. Road, Luopu Street, Panyu District, Guangzhou, China.	Biopore Surgical Tape 5cm x 1000cm 10cm x 1000cm 15cm x 1000cm 20cm x 1000cm (Fix Roll)	As per PRC	05 years	**Deferred** for confirmation of registration status in FDA
47.	M/s. Hashir Surgical Services (Pvt) Ltd. Peshawar-Pakistan. / M/s. Yafho Bio-technology Co. Ltd., Plant, Hengsheng Ind. Zone, West Yicun Ind. Road, Luopu Street, Panyu District, Guangzhou, China.	Biopore Wound Dressing Non-woven 4.5cm x 7cm 6cm x 7cm 6cm x 10cm 9cm x 10cm 10cm x 12cm 9cm x 15cm 9cm x 20cm 9cm x 25cm 9cm x 30cm (Disposable Wound Dressing).	As per PRC	05 years	**Deferred** for confirmation of registration status in FDA
48.	M/s. Hashir Surgical	Biopore Surgical	As per	05	**Deferred** for

	Services (Pvt) Ltd. Peshawar-Pakistan. / M/s. Yafho Bio-technology Co. Ltd., Plant, Hengsheng Ind. Zone, West Yicun Ind. Road, Luopu Street, Panyu District, Guangzhou, China.	Drapes 45cm x 45cm 30cm x 45cm 30cm x 50cm 40cm x 50cm 40cm x 60cm 30cm x 40cm 35cm x 35cm 20cm x 30cm 15cm x 20cm 14cm x 35cm 14cm x 20cm 10cm x 15cm (Surgical Drapes)	PRC	years	confirmation of registration status in FDA, EMA, TGA or Japan.
49.	M/s. Novartis Pharma (Pakistan) Limited, Karachi / M/s. Mipharm S.p.A., Milan, Italy.	Caflam 50mg Sachets Each sachet contains:- Diclofenac potassium……50mg (Non-steroidal anti-inflammatory drug (NSAID) Analgesic.	Rs.198/ Per packs of 9's Rs.22/Per Sachet	02 years	**Deferred** for submission of COPP from regulatory authority of Itlay

Item No. XI Miscellaneous cases.

Registration-I

Case No.01 Deferred cases importeed veterinary and locally manufactured veterinary drugs (M-236, M-237 & M-239) for therapeutic justification.

(A) Imported Veterinary Drugs.

The Board referred all of the following applications to committed comprises of Dr. Muhammad Arshad, Member Registration Board, Dr. Muhammad Ashraf, UVAS, Lahore and Head of Pharmacology Department Aried Universtiy Rawalping for expert opinion. Recommendations of expert will be broght before the Board for further decision on the matter.

S#	Name of Manufacturer.	Name of Drug (s)/Composition.	Decontrolled Packs Size	Shelf Life	Reasons.
1.	M/s. Siddiqui Pharma (Pvt) Ltd., Multan. / M/s. KBNP, INC, Dugok-ri, Sinam, Yesan, Chungnam, Korea.	Ciroxin 10% Oral Solution Each Liter contains:- Ciprofloxacin…100g (Antibiotics).	Decontrolled 100ml 250ml 500ml 1 Liter	02 years	Justification of formulation for food producing animals, food safety and human health **Rs.15000+ Rs.85000 = Rs.100000/-** **(Reply Received).**
2.	M/s. Siddiqui Pharma (Pvt) Ltd., Multan. / M/s. KBNP, INC, Dugok-ri, Sinam, Yesan, Chungnam, Korea.	Kenoxin 10% Oral Solution Each Liter contains:- Enrofloxacin…100g (Antibiotics).	Decontrolled 50ml 100ml 250ml 500ml 1 Liter	02 years	Justification of formulation for food producing animals, food safety and human health **Rs.15000+ Rs.85000 = Rs.100000/-** **(Reply Received).**
3.	M/s. Siddiqui Pharma (Pvt) Ltd., Multan. / M/s. KBNP, INC, Dugok-ri, Sinam, Yesan, Chungnam, Korea.	Noroxin 200 Oral Solution Each Liter contains:- Norfloxacin…200g (Antibiotics).	Decontrolled 100ml 500ml 1 Liter 5 Liter	02 years	Justification of formulation for food producing animals, food safety and human health. **Rs.15000+ Rs.85000 = Rs.100000/-** **(Reply Received).**

4.	M/s. Mustafa Brothers Faisalabad. / M/s. Laboratorio Centrovet Santiago, Chile.	Cefalexine Injectable Suspension 15% Each 10ml contains: - Cefalexine ….150/ml (Beta lactam Antibiotic)	Decontrolled 20ml 50ml 100ml 250ml	02 years	Justification of formulation for food producing animals, food safety and human health **Rs.15000+ Rs.85000 = Rs.100000/-** **(Reply Received).**
5.	M/s. Mustafa Brothers Faisalabad. / M/s. Laboratorio Centrovet Santiago, Chile.	Ceftiofur Hydrochloride Injectable Suspension 5% Contains: Ceftiofur Hydrochloride…..50mg (Antibiotic)	Decontrolled 20ml 50ml 100ml 250ml	02 years	Justification of formulation for food producing animals, food safety and human health **Rs.15000+ Rs.85000 = Rs.100000/-** **(Reply Received).**
6.	M/s. Ghazi Brothers, Karachi. / M/s. CEVASA S.A. Buenos Aires, Argentina.	Sulfyvit Water Soluble Powder Each 100gm contains:- Sodium sulfaquinoxaline…..15 gm Sodium sulfamethazine……14gm Sodium sulfadimethoxine…2gm Trimethoprim …..…6gm Prednisolone…0.004gm Vitamin A……..…300,000IU Vitamin E……...200 IU Vitamin D3…60.000IU Vitamin C…….…2gm Vitamin K3……..….1gm Excipients……..…..q.s (Antibiotic, steroids Vitamin).	Decontrolled 100gm 1 Kg 5 Kg 10 Kg	24 months	Deferred, Therapeutic Justification. **(Reply Received).**

7.	M/s. Fartal Pharmaceuticals, Karachi. / M/s. Laboratorios Microsules Uruguay S.A. Canelones, Uruguay.	Ivermic M.O. Injectable Suspension Each ml contains:- Ivermectin……..1,000 g Zinc Sulphate 7H20……0,043 g Magnesum Chloride 6H20……..…….0,650 g Copper Chloride 2H20……..0,004g Magnesium Hypophosphite 6H20…….2,67 0g Potassium Iodide..0.030g Vitamin B12…….0,010g Histidine HCI……...…0,42 0g Valine…….….0,420 g Arginine HCI……0,510g Methionine……0,42 0g Threonine…….0,50 0g Sodium monobasic glutamate……..0,84 0g (Endectocide, organic	Decontrolled 500ml	02 years	Deferred, Therapeutic Justification for formulation. **(Reply Received).**
8.	M/s. International Chempharma (Pakistan) Lahore. / M/s. Biopharmachemie Co Ltd TangNhon Phu Vietnam.	CTC Plus Water Soluble Powder Contains:- Chlortetracycline5500 mg Vitamin A……2400IU Potassium Chloride……760mg Vitamin B12……...280mc	Decontrolled 100gm	02 years	Therapeutic Justification of formulation. (**Reply Received).**

		g Lysine…….60mg (Antibiotic)			
9.	M/s. Better Traders International, Faisalabad. / M/s. Kepro B.V. Maagdenburgstraat, Holland.	Thiacol 10% Oral Solution Each ml contains:- Thiamphenicol….100 mg (Broad Spectrum Antimicrobial Agent).	Decontrolled 1000ml	O3 years	Deferred, Therapeutic Justification and specimen of label. **(Reply Received).**
10.	M/s. Ani Cure Veterinary Services, Rawalpindi. / M/s. Interchemie Werken ”De Adelaar” B.V. Metaalweg, CG Venray, Holland.	Nemovit Water Soluble Powder Each gm contains: - Neomycin Sulpahte….40mg Oxytetracycline HCl….60mg Vitamin A…7500IU Vitamin D3, Cholecalciferol…1500 IU Vitamin E, a-tocopherol acetate….5mg Vitamin B1….thiamine hydrochloride….1mg Vitamin B2, riboflavine….2mg Vitamin B6, pyridoxine hydrochloride….2mg Vitamin B12, cyanocobalamin….7.5 µ Vitamin C, Ascorbic acid…25mg Ca-pantothenate…7.5mg Vitamin K3, menadione sodium bisulfite….5mg Nicotinamide…15mg Folic Acid….300µg DL-	Decontrolled 100gm 500gm 1000gm	03 years	Justification of formulation. **(Reply Received).**

		Methionine….30mg L-Lysine hydrochloride...50mg			
11.	M/s. Ani Cure Veterinary Services, Rawalpindi. / M/s. Interchemie Werken ”De Adelaar” B.V. Metaalweg, CG Venray, Holland.	Aliseryl Water Soluble Powder Each gm contains: - Erythromycin thiocyanate…35mg Oxytetracycline HCl…50mg Streptomycin Sulphate…35mg Colistin Sulphate..200,000IU Vitamin A, retinol acetate….3000IU Vitamin D3, cholecalciferol…1500IU Vitamin E, a-tocopherol acetate….2mg Vitamin B1, thiamine hydrochloride…2mg Vitamin B2, riboflavine…4mg Vitamin B6, pyridoxine hydrochloride…2mg Vitamin B12, cyanocobalamin…10µg Vitamin C, Ascorbic Acid….20mg Ca-pantothenate…10mg Vitamin K3, menadione sodium bisulfite…2mg Nicotinamide…20mg Inositol…1mg	Decontrolled 100gm 500gm 1000gm	03 years	Justification of formulation. **(Reply Received).**
12.	M/s. Seignior Pharma Karachi./ M/s. Instituto	Ceftiofur LPU Injectable Each 100ml vial contains: -	Decontrolled 100ml vial	2 years	Justification of formulation for food producing animals, food safety and human health.

	Rosenbusch S.A. de Biologia Experimental Agropecuaria, San Jose 1469 (1136) Buenos Aires, Argentina.	Ceftiofur HCL……50mg Excipients……..…100 ml (Antibiotic)			**Rs.15000+ Rs.85000 = Rs.100000/- (Reply Received).**
13.	M/s. Seignior Pharma, Karachi. / M/s. Instituto Rosenbusch S.A. de Biologia Experimental Agropecuaria, San Jose 1469 (1136) Buenos Aires, Argentina.	Florfenicol 30% Rosenbusch Injectable Each 100ml vial contains:- Florfenicol…….30gm Excipients q.s……100ml (Antibiotic)	Decontrolled 100ml vial	2 years	Justification of formulation for food producing animals, food safety and human health. **Rs.15000+ Rs.85000 = Rs.100000/- (Reply Received).**
(B) LOCALLY MANUFACTURED VETERINARY DRUGS					
14.	M/s. Bio-Labs (Pvt) Ltd., Islamabad.	Bio-Enrocol-A Liquid Each 100ml contains:- Enrofloxacin…….10 % Colistin Sulphate….3.5% Amantadine……...4 % (Antibiotic, Anti-viral).	Decontrolled 100ml 150ml 250ml 500ml 1 Liter	02 years	Justification of formulation for food producing animals and food safety. **Rs.8000 + Rs.12000 = Rs.20000/- (Reply Received).**
15.	M/s. Bio-Labs (Pvt) Ltd., Islamabad.	Coliflox 20% Liquid Each 100ml contains:- Enrofloxacin…20gm Colistin Sulphate..50,000,000 i.u. (Quinolones).	Decontrolled 100ml 200ml 250ml 450ml 500ml 1000ml	02 years	Justification of formulation for food producing animals, food safety and human health. **Rs.8000 + Rs.12000 = Rs.20000/- (Reply Received).**
16.	M/s. Leads Pharma (Pvt)	Virex CRD Powder Contains:-	Decontrolled 100 gm	02 years	Therapeutic Justification of formulation

	Ltd., Islamabad.	Tylosin Tartrate……10% Doxycycline HCI….22% Colistin Sulphate…...4% Amantadine HCI……3% (Antibiotic).	250 gm 500 gm 1 Kg 5 Kg 25 Kg		**(Reply Received).**
17.	M/s. Elko Organization (Pvt) Ltd., Karachi.	Fe-Zole SC 5% Oral Suspension Each ml contains:- Fenbendazole……50mg Elemental Selenium……...1.6 mg Elemental Cobalt...10mg (Anthelmintic).	Decontrolled 100ml 250ml 500ml 1000ml	02 years	Deferred, Therapeutic Justification for formulation. **(Reply Received).**
18.	Noble Pharma Mirpur Azad Kashmir.	ENTRO-5 Powder Each 1000gm contains:- Tylosin Tartrate BP……10% Doxycycline Hyclate USP..20% Colistin Sulphate……450 MIU Bromhexine HCI…0.5% Neomycin SO4…...3.6% (Antibacterial).	Decontrolled 100gm 200gm 500gm 1 Kg 2.5Kg	02 years	Deferred for justification of formulation. **(Reply Received).**
19.	M/s. Mallard Pharmaceuticals (Pvt) Ltd., Multan.	Centrum Liquid Each 100ml contains:- Enrofloxacin HCI……7500mg Sulphamethoxypyridazine……7500 mg Sulphamethazine…….5000 mg	Decontrolled 100ml 250ml 500ml 1000ml 2.5 Liter 5 Liter	02 years	Deferred, Therapeutic Justification for formulation. **(Reply Received).**

		Trimethoprim…2500mg (Antibiotic).			
20.	M/s. Intervac (Pvt) Ltd, Sheikhupura Road, Sheikhpura.	Tilmodox Liquid Each 100ml contains:- Tilmicosin Phosphate……...15gm Doxycycline HCl...15gm (Antibiotic).	Decontrolled 100ml 200ml 500ml 1 Liter 2 Liter	02 years	Justification of formulation. **(Reply Received).**
21.	M/s. Intervac (Pvt) Limited, Lahore.	Amprobit Liquid Each liter contains:- Amprolium HCl..250gm Ethopabate……16gm (Anticoccidial).	Decontrolled 100ml 250ml 500ml 1 Liter 2.5 Liter	02 years	Deferred, Therapeutic Justification for quantity Ethopabate in formulation. **(Reply Received).**
22.	M/s. Attabak Pharmaceutical, Islamabad.	Tylothrodox Powder Each 1000gm contains:- Doxycycline HCl…100g Tylosin tartrate ……50g Amantadine HCl ….40g Erythromycin thiocyanate ……..…60g (Antibacterial, Antiviral).	Decontrolled 100gm 250gm 500gm 1Kg 5Kg,10Kg 25Kg	02 years	Deferred, Therapeutic Justification for formulation **(Reply Received).**
23.	M/s. Attabak Pharmaceutical, Islamabad.	Spiralinc-B Powder Each 100gm powder contains:- Lincomycin HCl…….5g Spectinomycin HCl..7.5g Spiramycin adipate...2.5g Bromhexine HCl….0.5g (Antibacterials).	Decontrolled 100g 250g 500g 1 Kg 5 Kg 10 Kg 25 Kg	02 years	Deferred, Therapeutic Justification for formulation **(Reply Received).**
24.	M/s. D-	CRD-555 Water	Decontrolled	02	Therapeutic Justification of

	Maarson Pharmaceuticals, Rawat, Islamabad.	Soluble Powder Each 1000g contains:- Doxycycline HCl ...200g Tylosin tartrate …...100g Colistin sulphate…….500MIU Amantadine HCl …..40g	100gm 250gm 500gm 1Kg 5Kg 10Kg 25KG	years	formulation **(Reply Received).**
25.	M/s. Symans Pharmaceuticals (Pvt) Ltd. Lahore.	SPZ-Plus Feed Additive Oral Each 100gm contains:- Procaine Penicillin B.P……1200mg Streptomycine Sulphate B.P…3600mg Zinc Bacitracin B.P…….5200mg Colistin Sulphate B.P……..500 MIU (Antimicobial).	Decontrolled 500gm 1Kg 2.5Kg 5Kg 25Kg	02 years	Justification of formulation. **(Reply Received).**
26.	M/s. Symans Pharmaceuticals (Pvt) Ltd. Lahore.	Cipro Plus Solution Each Liter Contains:- Ciprofloxacin…..200gm Colistin Sulphate…….400MIU Amantadine……40gm (Antibiotics).	Decontrolled 100ml 500ml 1 Liter 10 Liter 25 Liter	02 years	Deferred, Therapeutic Justification for formulation **(Reply Received).**
27.	M/s. Jfrin Pharmaceutical Laboratories, Hub, Balochistan.	Jfpidox Oral Powder Each Kg contains:- Tylosin Tartrate…100gm Doxycycline Hcl..200gm Phyenylbutazone…12gm Bromhexine	Decontrolled 100gm 500gm 1000gm	02 years	Deferred, Therapeutic Justification for formulation **(Reply Received).**

		Hcl…...5gm Colistine Sulphate……500 MIU (Antibacterial/Antibiotic).			
28.	M/s. Biogen Pharma. 8th Km Rawat Chak Beli Road, Rawat.	Amcocin Liquid Each 100ml contains:- Enrofloxacin……10% Colistin Sulphate……3% Amantadine HCI…4% (Antibiotic)	Decontrolled 100ml 250ml 500ml 1 Lit 5 Lit	02 years	Justification of formulation. **(Reply Received).**
29.	M/s. Biogen Pharma. 8th Km Rawat Chak Beli Road, Rawat.	Doxytylodine Powder Each 1000gm contains:- Tylosin Tartrate BP……..200gm Doxycycline HCI BP…….100gm Amantadine HCI…….40gm	Decontrolled 100gm 250gm 500gm 1Kg 5Kg	02 years	Justification of formulation. **(Reply Received).**
30.	M/s. Biogen Pharma, Rawat.	Advantage Water Soluble Powder Each 1000gm contains:- Tylosin Tartrate BP……..200gm Doxycycline HCI BP…….40gm Amantadine HCI……...100gm Colistin Sulphate…5000 MIU (Antibiotic/ Antibacterial/Antiviral).	Decontrolled 100gm 200gm 500gm 1 Kg 5 Kg	02 years	Therapeutic Justification of formulation **(Reply Received).**

Case No: 02. Deferred cases (M-240) meeting for change of formulation of their already approved veterinary drugs.

Following cases were deferred (M-240) meeting for change of formulation of their already approved veterinary drugs by the Drug Registration Board.The registration letters of the drugs have not been issued so far due to new formulation. Now the firm has requested for change of formulation as per already approved drugs. The Board after detailed discussion and deliberations from the veterinary expert and member Law decided that the firm has changed the composition of their products i.e generics are changed therefore it will be treated as new application and did not acceded the request of the firm. Letter issued to M/s. Attabak Pharmaceuticals, Islamabad to deposited the differential. Now M/s. Attabak Pharmaceuticals, Islamabad has deposited the differential fee Rs. 20,000 x 11 = 220,000/-

S.No.	Existing Formulation.	New Formulation.	Price/Pack Size	Shelf Life
1.	Lorfen Oral Liquid Each ml contains:- Florfenicol ….101mg	Lorfen Oral Liquid Each ml contains:- Florfenicol……10mg Colistin Sulphate…..50 MIU **(Me-Too Drug)**	Decontrolled 100ml 150ml 250ml 450ml 1Lit. 2.5 Lit.	02 years
2.	IVO-JS Injection Each ml contains:- Ivermectin …11mg	IVO-JS Injection Each ml contains:- Ivermectin ……20mg Vitamin –A……80,000 I.U Vitamin-D3……40,000 I.U Vitamin-E……..20mg **(Me-Too Drug)**	Decontrolled 10ml 20ml 30ml 50ml 100ml 250ml 450ml 500ml	02 years
3.	IVO-Super Injection Each ml contains:- Ivermectin …15mg	IVO-Super Injection Each 100ml contains:- Ivermectin ……1gm Vitamin A ……..2500,000 I.U Vitamin D3 ……...375000 I.U Vitamin E ……. 2.5gm **(Me-Too Drug)**	Decontrolled 10ml 20ml 30ml 50ml 100ml 250ml 450ml 500ml	02 years
4.	Sulfatrim Powder	Sulfatrim Powder	Decontrolled	02

	Each 100g contains:- Sulfadiazine Sodium...42g Trimethoprim……8g	Each 1000gm contains:- Florfenicol…….150gm Oxytetracycline…….150gm **(Me-Too Drug)**	100g 250g 500g 1 Kg 5 Kg 10 Kg 25 Kg	years
5.	Sulfabak Injection Each 100ml contains:- Sulphadimidine Sodium.(B.P vet)...33.34%	Sulfabak Injection Each 100ml contains:- Enrofloxacin……100mg **(Me-Too Drug)**	Decontrolled 50ml 100ml 500ml 1000ml	02 years
6.	FNO Mix Water Soluble Powder Each gm contains:- Neomycin sulphate….150mg Oxytetracycline HCl ..150mg Florfenicol …….100mg	FNO Mix Water Soluble Powder Each gm contains: - Neomycin Sulfate…….150mg Oxytetracycline Hcl…..300mg Florfenicol…….300mg **(Me-Too Drug)**	Decontrolled 30gm 50gm 100gm 125g 250gm 500gm 1Kg 5Kg	02 years
7.	Doxylo-S Powder Each 1000gm contain Doxycycline HCl …...200g Tylosin tartrate ……100g Dihydrostreptomycin ...35g Bromhexine HCl ……...5g	Doxylo-S Powder Each 1000g contains:- Doxycycline HCl ….200g Tylosin Tartrate …...100g Colistin Sulphate…..500MIU Amantadine HCl …..40g Bromhexine HCl …..5g **(Me-Too Drug)**	Decontrolled 100gm 250gm 500gm 1Kg 5Kg 10Kg 25Kg	02 years
8.	Tylobrom-S Powder Each 1000gm contains:- Doxycyclinse HCl …..200g Tylosin tartrate ……100g Dihydrostreptomycin …25g Bromhexine HCl …… 5g	Tylobrom-S Powder Each 1000gm contains:- Doxycline Hydrochloride.....200gm Tylosin Tartrate……100gm Colistin Sulphate…500 MIU **(Me-Too Drug)**	Decontrolled 100gm 250gm 500gm 1Kg 5Kg 10Kg 25Kg	02 years
9.	Doxytil-S Powder Each 1000gm contain Doxycycline HCl	Doxytil-S Powder Each 1000gm contains:- Doxycyline Hcl ……200gm	Decontrolled 100gm 250gm	02 years

	……200g Tylosin tartrate ……100g Dihydrostreptomycin …30g Bromhexine HCl ……5g	Tylosin Tartrate ……100gm Colistin Slphate …..480 MIU Bromohexine Hcl …..3gm **(Me-Too Drug)**	500gm 1Kg 5Kg 10Kg 25Kg	
10.	Spiradox-T Water Soluble Powder Each 1000g contains:- Doxycycline HCI……200g Tylosin Tartrate……..100g Spiramycin adipate……25g Bromhexine HCI……5g	Spiradox-T Water Soluble Powder Each 100gm contains:- Oxytetracycline Hcl…6000mg Spiramycin Adipate……8,000,000 IU Bromhexine Hcl……..150mg **(Me-Too Drug)**	Decontrolled 100g 250g 500g 1 Kg 5 Kg 10 Kg	02 years
11.	Lincosol Powder Each 100gm powder contains:- Lincomycin HCI……..5g Spectinomycin HCI…....5g Amoxicillin trihydrate…10g Bromhexine HCI……...1.0g	Lincosol Powder Each 100gm contains:- Lincomycin as Hcl …..... 5gm Spectinomycin as Hcl ...10gm Amantadine Hcl……..3gm **(Me-Too Drug)**	Decontrolled 100g 250g 500g 1 Kg 5 Kg 10 Kg 25 Kg	02 years

Decision: Request of the firm was not approved by the Board.

Case No.03 Change of formulation of already approved veterinary drugs.

M/s. Attabak Pharmaceuticals, Islamabad have requested for change of formulation discussed (M-240) meeting but it was over looked by the Board. The same composition are already registered by M/s. D-Maarson Pharmaceuticals, Islamabad.. The registration letters of the drugs have not been issued so far due to new formulation. Now the firm has requested for change of formulation as per already approved drugs:-

S.No.	Existing Formulation.	New Formulation.	Price/Pack Size	Shelf Life
1.	OXY Plus Injection Each ml contains:- Oxytetracycline HCI.51mg	OXY Plus Injection Each ml contains:- Oxytetracycline (as Hcl)…… 200mg **(Me-Too Drug)**	Decontrolled 10ml 20ml 50ml 100ml	02 years

Decision: Request of the firm was not approved by the Board.

Case No.04 Products not recommended by Veterinary Expert Committee.

The following registration applications of veterinary drugs for locally manufacture were considered by the veterinary expert committee in its 76th meeting held on 16th march, 2010 and not recommended as per reasons as mentioned against each. Later on, Registration Board in its 237th meeting held on 26-02-2013 defer the under mentioned recommendations for its forthcoming meeting and under mentioned firms has deposited the differential fee.

S#	Name of Manufacturer.	Name of Drug (s)/Composition.	Decontrolled / Packs Size	Shelf Life	Reasons.
1.	M/s. Venus Pharma, Lahore.	Gentadine Injection Each ml contains: - Gentamicin (As Sulphate)……....30 mg Trimethoprim…….25 mg Sulphadimidine…125 mg	Decontrolled 50ml 100ml	02 years	The firm was served final notice requesting to provide within 15 days the scientific information for rationality of composition, compatibility of ingredients and evidence of registration of same composition by Japan, EU member countries and USA. The firm could not respond even after three months hence the VEC decided to drop the product from the agenda. **Rs.8000 + Rs.12000 = Rs.20000/-**
2.	M/s. Leads	LAS Powder	Decontrolled	02	The firm was served final

	Pharma (Pvt) Ltd Islamabad.	Each gm contains: - Spectinomycin…..88mg Lincomycin HCl……88 mg Amoxycilline…...200 mg	100gm 250gm 500gm 1kg 5kg 25kg	years	notice requesting to provide within 15 days the scientific information for rationality of composition, compatibility of ingredients and evidence of registration of same composition by Japan, EU member countries and USA. The firm could not respond even after three months hence the VEC decided to drop the product from the agenda. **Rs.8000 + Rs.12000 = Rs.20000/-**
3.	M/s. Biogen Pharma Rawat	Fresh All Oral Liquid Each 100ml contains :- Furosemide……..2gm Extract Belladonna……....0.2gm Sodium Chloride……....3.5gm Sodium Citrate….2.9gm Potassium Chloride……....1.5gm	Decontrolled 50ml 100ml 150ml 200ml 250ml 450ml 500ml 1 liter 5 liter	02 years	The firm was served final notice requesting to provide within 15 days the scientific information for rationality of composition, compatibility of ingredients and evidence of registration of same composition by Japan, EU member countries and USA. The firm could not respond even after three months hence the VEC decided to drop the product from the agenda. **Rs.8000 + Rs.12000 = Rs.20000/-**
4.	M/s. Vetcon Pharmaceuticals (PTE) Ltd., AJK.	Methacon Injection Each ml contains: Sodium methyl ammino methane, Sulphonate hydrate…….500 mg Caffein and Sodium benzoate…….10 mg	Decontrolled 5ml 10ml 20ml 50ml 100ml	02 years	The firm was served final notice requesting to provide within 15 days the scientific information for rationality of composition, compatibility of ingredients and evidence of registration of same composition by Japan, EU member countries and USA. The firm could not respond even after three months hence the VEC decided to

		Benzyl alcohol…...20mg Sodium theosuphate……..Q.S D.W……..Q.S			drop the product from the agenda. **Rs.8000 + Rs. 12000 = Rs.20000/-**
5.	M/s. Vetcon Pharmaceuticals (PTE) Ltd., AJK.	Ampicon-Plus Injection Each 100 ml contains: Ampicillin Trihydrate…….10 gm Colistin Sulphate…2,500,000 I.U T. Butylhydroxyanisol……..18 mg Benzyl Alcohol….0.9 ml	Decontrolled 5ml 10ml 20ml 50ml 100ml	02 years	The firm was served final notice requesting to provide within 15 days the scientific information for rationality of composition, compatibility of ingredients and evidence of registration of same composition by Japan, EU member countries and USA. The firm could not respond even after three months hence the VEC decided to drop the product from the agenda. **Rs.8000 + Rs. 12000 = Rs.20000/-**
6.	M/s. Cherished Pharmaceuticals (Pvt) Ltd., Lahore.	Gentel Plus Injection Each ml contains:- Gentamycin Sulphate equivalent to 30 mg gentamycin base. Sulphadimidine…125 mg Trimethoprim……25mg	Decontrolled 5ml 10ml 20ml 50ml 100ml	02 years	The firm was served final notice requesting to provide within 15 days the scientific information for rationality of composition, compatibility of ingredients and evidence of registration of same composition by Japan, EU member countries and USA. The firm could not respond even after three months hence the VEC decided to drop the product from the agenda.

					Rs.8000 + Rs. 12000 = Rs.20000/-
7.	M/s. Cherished Pharmaceuticals (Pvt) Ltd., Lahore.	Sulphagold Oral Suspension Each ml contains: - Sulphadiazine……......35.500mg Sulphadiamidine……28.400mg Neomycine Sulpahte……....1.800 mg Hyoscin Methylbromide…0.04 mg Pectin……7.100 mg Kaolin……103.300 mg Vitamin B1..….0.150mg Vitamin B2……0.220mg	Decontrolled 10ml 100ml 200ml 450ml 1000ml	02 years	The firm was served final notice requesting to provide within 15 days the scientific information for rationality of composition, compatibility of ingredients and evidence of registration of same composition by Japan, EU member countries and USA. The firm could not respond even after three months hence the VEC decided to drop the product from the agenda. **Rs.8000 + Rs. 12000 = Rs.20000/-**
8.	M/s. Cherished Pharmaceuticals (Pvt) Ltd., Lahore.	Raoactive Injection Each 100 ml contains: Ampicillin trihydrate……...….10gm Collistin Sulphate….2,500,000 IU T.Butylhydroxyanisol……...18mg Benzyl alcohol…..0.9ml	Decontrolled 5ml 10ml 20ml 50ml 100ml	02 years	The firm was served final notice requesting to provide within 15 days the scientific information for rationality of composition, compatibility of ingredients and evidence of registration of same composition by Japan, EU member countries and USA. The firm could not respond even after three months hence the VEC decided to drop the product from the agenda. **Rs.8000 + Rs. 12000 = Rs.20000/-**

9.	M/s. Cherished Pharmaceuticals (Pvt) Ltd., Lahore.	ST NOR + Oral Solution Each 100 gm contains: 1 ethyl-6 flouro-1,4-oxo 71 piperaziny-3 quinoline Carboxylic acid…..50mg Sulphamethoxypyridazine……..50mg Trimethoprim…….10 mg Phenylbutazone…..12 mg Bromhexine……..5 mg	Decontrolled 100ml 200ml 500ml 1000ml	02 years	The firm was served final notice requesting to provide within 15 days the scientific information for rationality of composition, compatibility of ingredients and evidence of registration of same composition by Japan, EU member countries and USA. The firm could not respond even after three months hence the VEC decided to drop the product from the agenda. **Rs.8000 + Rs. 12000 = Rs.20000/-**

Decision: The Board after discussion approved the recomandations of the Veterinary Expert Committee and rejected these applications.

Case No.05 Drugs deferred by Registration Board in 238th meeting.

Drug Registration Board in its 238th meeting held on 05th & 06th August, 2013 considered and deferred the following products for clarification regarding free availability in country of origin and approval status of these combinations from EMA, US-FDA or regulatory body of Australia or Japan. The replies of the firm are mentioned against each:-

S.#	Name of Importer/ Manufacturer.	Name of Drug (s) Composition & Therapeutic Group.	Decision	Reply of the firm.
1.	M/s. CSH Pharmaceuticals North (Pvt) Ltd Lahore / M/s. Joint Stock Company AVVA RUS, Russian Federation.	Lactofiltrum Tablets. Each tablet contains: - Lactulose…120mg. Lignin Hydrolyzed 355mg. (Enterosorbent Agent)	Deferred as these combinations are not approved by stringent regulatory authority. The Board after detailed deliberations deferred these products for clarification from the firm for submission of	Firm have provided registration approval in Cyprus but the documents is not legalized and shows it is available their as food supplement. Not approved by

			detail of approval of these combinations from EMA, US-FDA or regulatory body of Australia or Japan.	EMA, US-FDA or regulatory body of Australia or Japan as asked by the board.
2.	M/s. CSH Pharmaceuticals North (Pvt) Ltd Lahore / M/s. Joint Stock Company AVVA RUS, Russian Federation.	Filtrum Tablets. Each tablet contains: - Lignin Hydrolyzed 400mg. (Enterosorbent Agent)	-do-	-do-
3.	M/s. Ali Gohar & Co. (Pvt) Ltd., Karachi. / M/s. S.A. Alcon-Couvreur N.V. Puurs, Belgium.	Cellugel Ophthalmic Viscosurgical Device 1.0ml. Each ml contains:- Hydroxypropyl Methylcellulosea 15.3mg. Hydroxypropyl Methylcelluloseb 7.7mg. Calcium Chloride dihydrate……0.48mg. Sodium Chloride…5.25mg. Potassium Chloride….0.75mg. Magnesium Chloride hexahydrate……0.3mg. Sodium Citrate…1.7mg. Sodium Acetate……3.9mg. (Ophthalmologicals-Surgical aids-Viscoelastastic substances-Hypromellose).	Deferred for clarification from the firm for confirmation of freely availability in country of origin and submission of approval of the product from EMA, US-FDA or regulatory body of Australia or Japan.	Firm have provided Certificate of Medical Device and FDA approval duly attested by Pakistan Embassy.
4.	M/s. Grace Health Care (Pvt) Ltd. Karachi / M/s. Dihon Pharmaceutical Group Co., Ltd. Keyi Road, Hi-Tech Development Zone, Kunming City, China.	Skineal Cream. Each gram contains:- Ketoconazole …..10mg. Clobetasol Propionate ..... 0.25mg. Neomycin Sulfate 5000IU. (Anti Fungal)	Deferred for clarification from the firm for confirmation of freely availability in country of origin and submission of approval of the product from EMA, US-FDA or regulatory body of Australia or Japan.	Firm have submitted the free availability in country of origin is already submitted and it is not available in EMA, US-FDA or regulatory body of Australia or Japan.
5.		Haicneal Lotion. Each gram contains:- Ketoconazole……15mg.		

		Clobetasol Propionate……..0.25mg. (Anti Fungal, Anti Inflammatory, Anti Puritic).		
6.	M/s. Biocare Pharmaceutica, Lahore. / M/s. Xiangbei Welman Pharmaceutical Co. Ltd., Hunan Province, China.	Ceflet 0.75gm for injection Each 0.75gm vial contains:- Cefotaxime……0.5gm Sulbactam……0.25gm	Deferred as these combinations are not approved by stringent regulatory authority. The Board after detailed deliberations deferred these products for clarification from the firm for submission of of approval of these combinations from EMA, US-FDA or regulatory body of Australia or Japan.	Firm have submitted the research papers of different countries also free availability in country of origin. ***It is not approved by EMA, US-FDA or regulatory body of Australia or Japan.***
7.		Ceflet 1.5gm for injection Each 1.5gm vial contains:- Cefotaxime……1.0gm Sulbactam……..….0.5gm		
8.		Ceflet 3.0gm for injection Each 3.0gm vial contains:- Cefotaxime……2.0gm Sulbactam……..…1.0gm		
9.		Xtrax 1.5gm for Injection Each 1.5gm vial contains:- Ceftriaxone……..1.0gm Sulbactam……0.5gm		
10.		Xtrax 3.0gm for Injection Each 3.0gm vial contains:- Ceftriaxone……..2.0gm Sulbactam……1.0gm		

Decision: **The Board after thorugh discussion deferred above mentioned cases for submission of safety and clinical data of the drug along with complete clinical trial data.**

Case No.06 Extension in exemption from Drugs (Labelling & Packing) Rules, 1986.

M/s. Atco Laboratories Limited, Karachi have submitted that they are importing the following products from M/s. Ferring Pharmaceuticals since 1994 that are in the process of shifting their manufacturing facility and it would not be possible for them during this period to incorporate all requirements according to the local labeling rules on the packaging material. As these products are niche and patient need them, therefore M/s. Atco Laboratories Limited,

Karachi have requested to extend the following exemptions on the below mentioned products for further 20 months:-

S.#	Reg. No.	Name of drug (s).	Exemption requested	Quantity
1.	016110	Decapeptyl 0.1mg Injection.	i) Generic name not in bracket. ii) Drug registration number to be printed locally. iii) MRP to be printed locally. iv) Urdu instruction to be printed locally. v) Pharmaceutical specifications i.e. B.P/U.S.P.	924 units.
2.	016111	Decapeptyl 3.75mg Injection.	-do-	2638 units.
3.	016112	Minirin Nasal Spray 10mcg/dose.	-do-	6000 units.
4.	016114	Minirin 0.1mg Tables.	-do-	5460 units.
5.	016115	Minirin 0.2mg Tablets.	-do-	2550 units.
6.	016116	Minirin Injection 4ug/ml.	-do-	200 units.
7.	031333	Pentasa 500mg Tablets.	-do-	4040 units.
8.	032143	Menogon Injection.	-do-	6106 units.
9.	016153	Glypressin 1mg Injection.	-do-	3438 units.

M/s. Atco Laboratories Limited, Karachi have deposited the required fee Rs.5000x9=45000/-.

Decision: The Board after thorugh discussion defered above mentioned cases for confirmation of pharmacological group.

Case No. 08 Registration of Drugs under the Drugs Act, 1976 – Change of authorized agent.

The Drug Registration Board in its 226th meeting held on 21st & 22nd July, 2010 approved registration of the under-mentioned drugs applied M/s. Wasay Health Care (Pvt) Ltd., Karachi subject to inspection of facilities of manufacturer abroad M/s. Shenzhen Main Luck

Pharmaceuticals Inc., Main Luck Building Bagua Road 4, Futain District, Shenzhen, PRC China by the nominated panel:-

S. No.	Name of Drugs.
1.	Vinobine Injection 10mg. Each vial contains: - Vinorelbine Tartrate…10mg.
2.	Aclitax 30mg Injection. Each 5ml contains: - Paclitaxel ……30mg.
3.	Aclitax 60mg Injection. Each 10ml contains: - Paclitaxel ……60mg.
4.	Docetal 20mg Injection. Each 0.5ml contains: - Docetaxel……20mg.
5.	Docetal 40mg Injection. Each 1ml contains: - Docetaxel…….40mg.

The schedule for inspection of the said foreign manufacturer is not yet approved. Meanwhile, M/s. Aster Life Sciences, Lahore have informed that the manufacturer abroad M/s. Shenzhen Main Luck Pharmaceuticals Inc., China has terminated the agreement with M/s. Wasay Health Care (Private) Ltd., Karachi and appointed them as their authorized sole agent in Pakistan.

They have therefore requested to change the name of sole agent of M/s. Shenzhen Main Luck Pharmaceuticals Inc., China from M/s. Wasay Health Care (Pvt) Ltd., Karachi to M/s. Aster Life Sciences, Lahore. They have also requested that the registration process of the products of M/s. Shenzhen Main Luck Pharmaceuticals Inc., China be expedited and further correspondence regarding registration process of the above said products be done with them.

M/s. Aster Life Sciences, Lahore have submitted the following supporting documents:-

i) Registration fee Rs.15000/each product. (Fee deposited on 24th July, 2012).

ii) Copy of termination letter of agent-ship with M/s. Wasay Health Care (Pvt) Ltd., Karachi issued by M/s. Shenzhen Main Luck Pharmaceuticals Inc., China.
iii) Copy of authorization letter in the favour of M/s. Aster Life Sciences, Lahore issued by M/s. Shenzhen Main Luck Pharmaceuticals Inc., China.

Keeping in view the above situation M/s. Wasay Health Care (Pvt) Ltd., Karachi we ask to provide fresh agreement with the manufacturer abroad M/s. Shenzhen Main Luck Pharmaceuticals Inc., China before taking any decision.

In response, to DRAP's letter M/s. Wasay Health Care (Pvt) Ltd., Karachi have informed that their agreement with M/s. Shenzhen Main Luck Pharmaceuticals Inc., China is an exclusive and sole distribution agreement for the entire territory of Pakistan and is valid for at least 5 years, technically the time period of validity extends to at least 5 years after the date of registration of the products. The termination notice period of a minimum of 12 months. They have also submitted that the M/s. Shenzhen Main Luck Pharmaceuticals Inc., China cannot terminate the agreement at their will before first going into medication.

M/s. Wasay Health Care (Pvt) Ltd., Karachi have further informed that they have already invested in this entire matter, and they intend to pursue any & all avenues of recourse available to them. The firm is called for personal hearing too.

Decision: The Board after thorugh discussion deferred above mentioned case for submission of balance fee by the applicant.

Case No. 09 Registration of Surgical Sutures.

Drug Registration Board in its 237th meeting held on 26-02-2013 approved the registration of the following Surgical Sutures applied M/s. Medicamp Distributors, Rawalpindi subject to inspection of facilities of manufacturer abroad M/s. Shanghai Pudong Jinhuan Medical Products Co. Ltd., China:-

S. No.	Name of Products.
1.	Milene Polypropylene Surgical Suture.
2.	Micryl PGLA Surgical Suture.

3.	Plain Catgut Surgical Suture.
4.	Misilk Silk Surgical Suture.
5.	Chromic Catgut Surgical Suture.

Meanwhile, M/s. A. Feroz & Co., Karachi have also applied for registration of following Surgical Sutures from the same source / manufacturer M/s. Shanghai Pudong Jinhuan Medical Products Co. Ltd., China and informed that the manufacturer abroad M/s. Shanghai Pudong Jinhuan Medical Products Co. Ltd., China has appointed them their new sole distributor for Pakistan for their all products and terminated the agreement with M/s. Medicamp Distributors, Rawalpindi:-

S. No.	**Name of Products.**
1.	Star PGA Suture (PGLA Suture- Poly (glycolide-co lactide) (90/10).
2.	Star PGA Suture (PGA (Polyglycolicacid) Suture.
3.	Star Polyester Suture (Polyester Suture).
4.	Star Silk Suture (Silk Suture).
5.	Star Nylon Suture (Nylon Suture).
6.	Star Polypropylene Suture (Polypropylene Suture).
7.	Star Plain Catgut Suture (Plain Catgut Suture).
8.	Star Chromic Catgut Suture (Chromic Catgut Suture).

M/s. A. Feroz & Co., Karachi has therefore requested to consider their application for registration of the above said Surgical Sutures. The firm has also submitted attested letter of sole agency and termination letter for other agent, attested by Embassy of Pakistan.

M/s. Medicamp Distributors, Rawalpindi was advised to deposit the remaining fee as per revised fee Schedule F and submit fresh agency agreement with the manufacturer i.e. M/s. Shanghai Pudong Jinhuan Medical Products Co. Ltd., China legalized by the Pakistan Embassy in China. M/s. Medicamp Distributors, Rawalpindi have not deposit the remaining fee as per

revised fee Schedule F and also not submitted fresh agency agreement with the manufacturer abroad till date.

M/s. A. Feroz & Co., Karachi was also advised to deposit the remaining fee as per revised fee Schedule F. In response, M/s. A. Feroz & Co., Karachi have deposited the remaining fee for the following 07 products out of 08 products and requested to drop dossier for the registration of **Star Plain Catgut Suture**:-

S. No.	**Name of Products.**
1.	Star PGLA Suture (Polyglycolide-co lactide).
2.	Star PGA Suture (Polyglycolicacid).
3.	Star Polyester Suture.
4.	Star Silk Suture.
5.	Star Nylon Suture.
6.	Star Polypropylene Suture.
7.	Star Catgut Chromic Suture.

M/s. Medicamp Distributors, Rawalpindi was again advised to deposit the remaining fee as per revised fee Schedule F and submit fresh agency agreement with the manufacturer i.e. M/s. Shanghai Pudong Jinhuan Medical Products Co. Ltd., China legalized by the Pakistan Embassy in China. M/s. Medicamp Distributors, Rawalpindi have not deposit the remaining fee as per revised fee Schedule F and also not submitted fresh agency agreement with the manufacturer abroad despite reminder.

Decision: The Board after thorugh discussion deferred above mentioned case for personal hearing to M/s. Medicamp Distributors Rawalpindi.

Case No. 10 Transfer of Registration of Veterinary Drugs.

M/s. Huzaifa International, Sargodha have applied for transfer of registration of the following registered imported veterinary drugs in their name from the name of previous importer M/s. Atzan Pharmaceutical, Sargodha as the manufacturer abroad M/s. Komipharm International

Co., Ltd, Korea have appointed them as their new sole distributor for Pakistan and terminated distribution agreement with M/s. Atzan Pharmaceutical, Sargodha:-

S.No.	Reg. No.	Name of Drug (s).
1.	049533	Dexa-SP Injection. Each ml contains:- Procaine Penicillin G 200,000 IU. Dihydrostreptomycin Sulfate 250mg (Potency). Dexamethasone ....1mg.
2.	049534	Combicillin-L.A Injection. Each ml contains:- Procaine Penicillin G 150,000 IU. Benzathine Penicillin G 100,000 IU. Dihydrostreptomycin Sulfate 200mg (Potency).
3.	049535	Amcicoli-D Injection. Each ml contains:- Ampicillin Trihydrate (KP VIII) 100mg (Potency). Colistin Sulfate (KP VIII) 250,000 IU. Dexamethasone acetate (USP) ....0.5mg.

The applicant M/s. Huzaifa International, Sargodha have deposited required fee Rs.100000x3=300000/- and submitted following supporting documents:-

i) Original NOC from previous agent M/s. Atzan Pharmaceutical, Sargodha.
ii) Copy of appointment letter of M/s. Huzaifa International, Sargodha.
iii) Copy of termination letter of M/s. Atzan Pharmaceutical, Sargodha.
iv) Copy of registration letter.
v) Copy of Drug Sale Licence of M/s. Huzaifa International, Sargodha.

Keeping in view the submitted documents request of the firm for transfer of registration of the drugs from M/s. Atzan Pharmaceutical, Sargodha to M/s. Huzaifa International, Sargodha is submitted for consideration.

Decision: Request of the firm was approved by the Board.

Case No. 11 Grant of Additional Pack of already Registered Veterinary Drug.

M/s. ICI Pakistan Limited, Karachi have applied for approval of additional packs of their following already registered imported veterinary drug as mentioned below:-

S. No.	Reg. No.	Name of Drug/Composition	Existing Pack	Demanded Additional packs
1	020133	Cepravin TM Dry Cow Intra-Mammary. (Cefalonium (as dihydrate) 250mg).	20x3gm syringes.	4x3gm syringes. 24x3gm syringes. 72x3gm syringes.

M/s. ICI Pakistan Limited, Karachi have deposited the required fee Rs.5000x3=15000/- and submitted following clinical justification for demand of additional packs:-

1. Smaller pack will be affordable to the customers.
2. Larger packs are easier to port.
3. Variety of pack sizes for customer convenience.
4. For supplies to corporate dairy farms/Institutions.

M/s. ICI Pakistan Limited, Karachi was advised to submit approval of these packs from country of origin and whether these packing are already available with some other manufacturer or importer.

In response, M/s. ICI Pakistan Limited, Karachi have submitted copy of legalized Certificate of origin and free sale of Cepravin as evidence that these packs are already approved in the country of origin. Original certificate was submitted along with the change of manufacturing site request. M/s. ICI Pakistan Limited, Karachi have further informed that no other product with the exact formulation is available in Pakistan market.

Registration of the drug is valid as change of manufacturing site was approved on 24th June, 2011. Prices of veterinary drugs are de-controlled.

Decision: The Board approved the request of the firm for additional packs.

Case No. 12. Application for Registration of Veterinary Drug Ketsat Injection for Export.

M/s. Noble Pharma, B-1, Old Industrial Area, Mirpur, Azad Kashmir have applied for

registration of the following veterinary drug for export to Afghanistan:-

S. No.	Name of Drug /Composition.	Pack Sizes.
1.	Ketsat Injection.	10ml vial,
	Each ml solution contains:-	50ml vial,
	Ketamine Hydrochloride ..... 100mg.	100ml vial & 200ml vial.

M/s. Noble Pharma, Mirpur, Azad Kashmir have deposited required fee Rs.20000/- and submitted following supporting documents:-

i) Registration applications on prescribed Form-5.
ii) Copy of the confirm order.
iii) Copy of last inspection report.
iv) Copy of NOC for CRF.

The firm has applied for the registration of "Ketsat Injection (Ketamine HCl)" for veterinary use. The molecule is not already registered for veterinary use in Pakistan. However the US FDA has granted approval for this molecule in veterinary medicine. The brand name is similar in the USA.

Decision: The Board after approved the request of the firm for grant of registration for export purpose only.

Case No. 13. Exemption for udru / special labeling.

M/s. Ghazi Brothers, Karachi have requested to grant them exemption of Urdu / Special Labeling conditions for their registered imported veterinary drug "KILTIX Collar for Large Dogs (Reg. No. 063879)". M/s. Ghazi Brothers, Karachi have submitted the required fee Rs.5000/-.

The firm has further submitted that Kiltix Collars will be used for their topical effects. Kiltix Collars Large will be fixed around necks of dogs for their topical anti-parasitic effect (ticks and fleas infections). While considering smaller market size in Pakistan, it is not possible for their principal to prepare special labels and print MRP on labels for Pakistan. Most of the conditions of labeling rules have already been met in standard labels. They have therefore, requested to issue them an exemption letter for Urdu / Special Labeling conditions for "KILTIX Collar for Large Dogs (Reg. No. 063879)".

The firm applied for the placement of stickers on their drug as referred above, which is not permissible under the Drugs (Labeling & Packaging) Rules, 1986. They are also not involved in manufacture of drugs and can not use jet printer in their premises.

Decision: The Board decided that M/s Ghazi Brothers, Karachi may be permitted for inject printing of urdu version on KILTIX Collar for Large Dogs (Reg. No. 063879) in any licensed manufacturing unit having facility for this purpose. The firm will provide NOC of any licensed manufacturing unit and case will be processed for approval for issuance of letter.

Case No. 14. Correction in composition of registered veterinary drugs.

M/s. Myrtle Pharma, Karachi have requested for correction in composition of their registered veterinary drugs as these were erroneously registered against their request in the product dossier submitted to DRAP. They have requested that following correction may kindly be made in their registration letter:-

S#	Reg. No.	Name of Drug.	Incorrect (written in the registration letter).	Correct (submitted in the product dossier).
1	072603	Myovit Oral Powder.	**Myovit Oral Powder.** Each 1000gm contains:- Vitamin A …. 20000000 IU. Vitamin D …. 40,00000 IU. Vitamin E ….. 1600 IU. Vitamin K …. 9000mg. Vitamin B1 … 1250mg. Vitamin B2 … 20000mg. Vitamin B6 … 6800mg. Vitamin B12 … 30000mcg. **Vitamin C …… 10,000mcg.** Folic Acid …… 2000mcg. **Nicotinamide … 100000mcg.** Calcium D Pantothenate 3000mg. **Biotin ……. 20,000mg.**	**Myovit Plus** Each 1000gm contains:- Vitamin A …. 20000000 IU. Vitamin D …. 40,00000 IU. Vitamin E ….. 1600 IU. Vitamin K …. 9000mg. Vitamin B1 … 1250mg. Vitamin B2 … 20000mg. Vitamin B6 … 6800mg. Vitamin B12 … 30000mcg. **Vitamin C …… 10,000mg**. Folic Acid …… 2000mcg. **Nicotinamide … 30,000mg.** Calcium D Pantothenate 3000mg. **Biotin ……. 20,000mcg.**
2	072613	Myo-Sel Premix	Each 1000gm contains:- Vitamin E ……. 150gm. **Selenium ……150gm.**	Each 1000gm contains:- Vitamin E ……. 150gm. **Selenium ……150mg.**
3	073957	MYO CTC Oral	Each 1000gm contains:- **Chlortetracycline 250gm.** **Neomycin Sulphate 100gm.**	Each 1000gm contains:- **Chlortetracycline 75gm.** **Neomycin Sulphate 40gm.**

		Powder.	**Furltadone ..... 250gm.**	**Furltadone ..... 30gm.**
4	072607	Myrobac Oral Liquid.	**50ml** **100ml**	**500ml** **1000ml**
5	072608	Myrtleflox Oral Liquid.	Each 100ml contains:- Enrofloxacin ……. 20gm. **Colistin Sulphate 2,00,000 IU.**	Each 100ml contains:- Enrofloxacin ……. 20gm. **Colistin Sulphate 50000000 IU.**
6	072610	Myrtrovit Oral Liquid.	Each ml contains:- Vitamin A …….. 100,000 IU. Vitamin D3……. 20,000 IU. Vitamin E …… 20mg.	Each ml contains:- Vitamin A …….. 100,000 IU. Vitamin D3……. 20,000 IU. Vitamin E …… 20mg. **Vitamin K ..... 20mg.**

M/s. Myrtle Pharma, Karachi have deposited fee Rs.5000/each. The aforesaid mistake/omission has not been verified from the registration applications submitted by the firm at the time of registration.

The drugs mentioned in above were registered in 2011 & 2012, now firm has applied for the correction of formulation after the lapse of about 3 years, which means they have not manufacture these products which is violation of the condition of registration

The record of these product is scrutinized from dossier submitted by the firm and found the letter were issued according to the dossier submitted by the firm and no lacking at the part of the Drug Regulatory Authority of Pakistan.

Decision: The Board after thorugh discussion deferred above mentioned case for presentation of case by the firm in next meeting.

Case No.15. Approval for Additional Pack Sizes of "Kenflox 10% Oral (Reg. No.048133).

M/s. Better Traders International, Faisalabad have applied for approval of additional packs of their following already registered imported veterinary drug as mentioned below:-

Reg. No.	Name of Drug/Composition.	Existing Pack.	Demanded Additional packs.
048133	Kenflox 10% Oral. Each ml contains:- Enrofloxacin ……. 100mg.	100ml 500ml 1000ml	2.5 Liter 5 Liter 10 Liter 25 Liter 200 Liter

M/s. Better Traders International, Faisalabad have deposited the required fee

Rs.5000x5=25000/- and submitted following supporting documents: -

i) Copy of registration letter.
ii). Copy of renewal of registration.

M/s. Better Traders International, Faisalabad have further submitted that poultry has expanded a lot in the last few years. Lot of controlled houses have been established with each about thirty thousand (30000) chicks capacity and now there are number of big poultry farmers who demand large pack size of 2.5 liter, 5 liter, 10, liter, 25 liter & 200 liter of this product so that it becomes economical. They have therefore requested to allow the import of 2.5 liter, 5 liter, 10, liter, 25 liter & 200 liter packs.

M/s. Better Traders International, Faisalabad was advised to submit approval of these packs from country of origin and whether these packing are already available with some other manufacturer or importer.

In response, firm has submitted demand letters of some poultry farmers in large pack sizes and copy of commercial invoice and bill of lading of Kenflox 10% Oral in 200 liter packing to export to Egypt. The firm has also submitted a letter from principal abroad M/s. Kepro B.V., Holland that they have in packing several Kepro products in larger packing volumes. The nature of the poultry industry is changing and they notice a shift in demand from their standard 1L packing size to large pack-sizes as the 2.5L, 5L, 10L, 25L even 200L.

The pack sizes demanded by the firm are very large i.e. 200Lit, which are not generally used in medicines, it may lead to local repacking at "Retail Site".

Decision: Request of the firm was not acceded to by Registration Board.

Case No.16. Change of manufacturer name from M/s. Bayer Schering Pharma AG, Germany to M/s. Bayer Pharma AG, Germany.

M/s. Medipharm (Private) Limited, Lahore have informed that due to a Bayer Group-wide initiative to change the name of the pharmaceutical company, they have requested to approved the change of the manufacturer name of their following registered imported drug as follows:-

S#	Reg. No.	Name of Drug (s)	Current Name of Manufacturing Site.	Proposed Name of Manufacturing Site.
1.	010221	Androcur Tablets	**Manufactured by:**	**Bulk Manufactured by:**

		50mg.	M/s. Delpharm lille SAS France. **Pack and Final release:** M/s. Bayer Schering Pharma AG, Germany.	M/s. Delpharm Lille S.A.S., France. **Packaging and Final release:** M/s. Bayer Weimar GmbH und Co. KG, 99427 Weimar, Germany. **Product License Holder:-** M/s. Bayer Vital GmbH, 51368 Leverkusen, Germany.

M/s. Medipharm (Private) Limited, Lahore have deposited fee Rs.50000/- and submitted following supporting documents:-

i) Copies of Registration letters.
ii) Notarized Declaration from their Princiapl regarding the Name Change from Bayer Schering Pharma AG to Bayer Pharma AG.
iii) Original legalized CoPP's of Androcur 50mg Tablets.
iv) Copy of name change of company.
v) Copy of NOC for CRF.

M/s. Meipharm (Private) Limited, Lahore was advised to Provide fresh legalized CoPP from France as manufacturing facility is located in France and status of license holders:-

In response, M/s. Meipharm (Private) Limited, Lahore have submitted fresh original legalized CoPP of Androcur Tablets 50mg from Germany as there is a change in Pack & Final release site located in Germany. They have further submitted that CoPP from France cannot be issued as there is no change in manufacturing facility located in France.

The firm has not provided CoPP of French authority as the "Androcur, is manufactured in France and German authorities can not verify its GMP status.

Decision: Registration board deferred case for submission of legalized COPP of the product from French regulatory authority.

Case No. 17. Change of packaging site.

M/s. GlaxoSmithKline Pakistan Limited, Karachi have requested to approve the change of packaging site of their following registered imported drugs as follows:-

S#	Reg. No.	Name of Product (s).	Existing Manufacturing & Packaging Site.	Future Manufacturing & Packaging Site.
1.	069534	Votrient Tablets 200mg.	M/s. Glaxo Operations UK Limited, Ware, UK.	**Manufactured Site:** M/s. Glaxo Operations UK Limited, Ware, UK. **Packaging Site:**

				M/s. Glaxo Wellcome S.A., Aranda, Spain.
2.	069535	Votrient Tablets 400mg.	-do-	-do-

M/s. GlaxoSmithKline Pakistan Limited, Karachi have deposited fee Rs.50000x2=100000/- and submitted following supporting documents:-

i) Copy of registration letter of the products.
ii) Original legalized CPP from new packaging site.
iii) Supporting letters from new source (Spain) and existing source (UK).
iv) Copy of NOC for CRF.
v) Applications on Form 5(A).
vi) Site Master File.

Decision: Request of the firm was acceded to by Registration Board.

Case No. 18. Rectification of manufacturing site.

The Drug Registration Board in its 237th meeting held on 26-02-2013 approved the registration of following imported veterinary drug in the name of M/s. ICI Pakistan Limited, Karachi, manufactured by M/s. Intervet International GmbH, Unterschleissheim, Germany subject to inspection of manufacturer abroad and verification of storage facilities as per policy:-

Name of Drug (s) / Composition & Therapeutic Group.	Pack Size.	Shelf Life
Metricure white, oily,homogenous intra-uterine suspension Each 19gm syringe contains:- Cefapirin….....500mg. (First Generation Cephalosporins).	Box of 10 Syringe	03 years

M/s. ICI Pakistan Limited, Karachi has requested for issuance of registration letter of the above said drug. During evaluation of the registration dossier it is pointed out that the manufacturer name of the product is M/s. Intervet International B.V., Wim de Korverstraat 35, Boxmeer, The Netherland instead of M/s. Intervet International GmbH, Unterschleissheim, Germany. Therefore, approval of the Board is solicited for rectification of the error.

Decision: Registration Board approved M/s. Intervet International B.V., Wim de Korverstraat 35, Boxmeer, The Netherland as manufacturer of the product.

Case No.19. Correction in composition of Ventolin Evohaler (Reg. No. 041195).

M/s. GlaxoSmithKline Pakistan Limited, Karachi have requested for correction of composition of their registered imported drug "Ventolin Evohaler (Reg. No.041195)" (previous brand name of the product Aerolin Evohaler), as per the submitted composition / formulation of the product as follows:-

Reg. No.	Name of Drug.	Existing composition	Corrected composition
041195	Ventolin Evohaler.	Per unit dose contains- Salbutamol Sulphate 120.5mcg.	Each actuation contains:- Salbutamol Sulphate 120.5mcg equivalent to Salbutamol 100mcg.

The firm have deposited fee Rs.50000/= and submitted following supporting documents:-

i) Copy of registration letter of the product.
ii) Copy of change of brand name letter of the product.
iii) Copy of last renewal letter of the product.
iv) Copy of NOC for CRF clearance.
v) Copy of legalized CoPP of the product.
vi) Copies of carton & label of the product.

As per label the composition is wrote as "Salbutamol (as sulphate) 100mcg" which is supported by CoPP issued by TGA.

Decision: Request of the firm for correction in composition was acceded to by Registration Board.

Case No. 20. Drugs deferred by Registration Board.

Drug Registration Board in its 238th meeting held on 05th & 06th August, 2013 considered and deferred the following products applied by M/s. Merck (Private) Limited, Quetta for clarification regarding free availability in country of origin and approval status of these combinations from EMA, US-FDA or regulatory body of Australia or Japan:-

S.#	Name of Manufacturer / Importer.	Name of Drug (s) Composition & Therapeutic	Demanded Price & Pack	Shelf Life

		Group.	**Size.**	
1.	M/s. Merck (Private) Limited, Quetta / M/s. Egis Pharmaceuticals PLC, Budapest, Hungary.	Concor ® AM Tablets 5mg/5mg Each tablet contains:- Bisoprolol Fumarate……5mg Amlodipine Besylate 6.95mg equivalent to Amlodipine Base……..5mg (Anti-Hypertensive Agent).	Rs.307/ Per 20's Tablets Rs.15.35/ Per Tablet	02 years
2.	-do-	Concor ® AM Tablets 10mg/10mg Each tablet contains:- Bisoprolol Fumarate…….10mg Amlodipine Besylate 6.93mg equivalent to Amlodipine Base……..10mg (Anti-Hypertensive Agent).	Rs.506/ Per 20's Tablets Rs.25.30/ Per Tablet	02 years
3.	-do-	Concor ® AM Tablets 10mg/5mg Each tablet contains:- Bisoprolol Fumarate…….10mg Amlodipine Besylate 6.95mg equivalent to Amlodipine Base……..5mg (Anti-Hypertensive Agent).	Rs.477/ Per 20's Tablets Rs.23.85/ Per Tablet	02 years
4.	-do-	Concor ® AM Tablets 5mg/10mg Each tablet contains:- Bisoprolol Fumarate...5mg Amlodipine Besylate 13.90mg equivalent to Amlodipine Base……10mg (Anti-Hypertensive Agent).	Rs.337/ Per 20's Tablets Rs.16.86/ Per Tablet	02 years

Accordingly, M/s. Merck (Private) Limited, Quetta was advised to provide the same. In response, M/s. Merck (Private) Limited, Quetta have informed that they have already provide the free availability (Certificate of Pharmaceutical Product) certificates of the products. But as per their information and record they are sending it again. They have also clarified that the above mentioned products are currently registered in European countries like Hungary (which is country of origin), Bulgaria, Latvia, Poland and Romania.

M/s. Merck (Private) Limited, Quetta was again advised to confirm the approval status of these combinations from EMA, US-FDA or regulatory body of Australia or Japan.

In response, M/s. Merck (Private) Limited, Quetta have submitted that the above said products are approved by the regulatory bodies of European Union States (like Bulgaria, Hungary, Latvia, Poland and Romania) whose credibility is recognized by the DRAP as per the new Import Policy.

Decision: The Board defered above mentioned cases for submission of safety and clinical data of the drug along with complete clinical trial data.

Case No. 21. Registration of Imported Veterinary Drugs.

Drug Registration Board in its 237th meeting held on 26-02-2013 approved the registration of following imported veterinary drugs in the name of M/s. Better Traders International, Faisalabad, manufactured by M/s. Kepro B.V. Maagdenburgstraat, Deventer, Holland, subject to inspection of manufacturer abroad, verification of storage facilities as per policy. The firm has deposited the differential fee Rs.85000x5=Rs.425000/- (Pages.2-8/Cor):-

S.#.	Name of Drug (s) /Composition.	Decontrolled / Pack Size.	Shelf Life
1.	Tilmi 25% Oral Liquid. Each ml contains:- Tilmicosin (as tilmicosin phosphate) ..... 250mg.	100ml 250ml 500ml 1 Liter 2.5 Liter 5 Liter	02years
2.	L.S. Water Soluble Powder. Each gm contains:- Lincomycin HCI…….222mg. Spectinomycin HCI……444mg.	100gm. 150gm. 1000gm.	02years
3.	L.S. Injection. Each ml contains:- Lincomycin (as HCI H_2O) 50mg. Spectinomycin (as HCI 5 H_2O) 100mg.	100ml.	02years
4.	Florum 10% Oral Solution. Each ml contains:- Florfenicol…….100mg.	1000ml.	02years

Storage facility of the importer has already been verified by the Area FID.

The applicant M/s. Better Traders International, Faisalabad have requested for issuance of registration letters of the above said drug.

As the above said products are not on free sale in Netherlands and are registered for export purpose only. Therefore, M/s. Better Traders International, Faisalabad was advised to clarify the same.

In response, M/s. Better Traders International, Faisalabad have submitted the detailed information reply on the registration of veterinary medicines in Netherlands from their principal M/s. Kepro B.V, Holland (Pages 11-12/Corr). Furthermore, firm have submitted that similar products are already registered for local and import by the DRAP, even the imported products are not registered in the country of origin. The disease challenges (threshold) are very high in the country and good quality medicines are the need of the formers to meet these challenges. Kepro products are result oriented and demand of the formers. M/s. Kepro B.V, Holland is a European GMP company.

The firm M/s. Kepro B.V, Holland has accepted that these products referred above are not registered in Netherlands due to less demands of antibiotics use in their country. The GMP certificate provided by them also indicate they only have approval for batch certification of products & not production, which is a questionable.

Decision: The Board discussed matter of non-availability of finished drug in country of origin. It was deliberated that finished drug should be permitted for import only if it is free for sale in country of origin. Thus the Board decided to call firm,s representatives for presentation of their case in next meeting.

Case No. 22. Transfer of Registration of Elidel Cream 1% (Reg. No.041165).

M/s. Martin Dow Pharmaceuticals Limited, Karachi have applied for transfer of registration of registered imported drug **"Elidel Cream 1% (Reg. No.041165)"** from the name of M/s. Novartis Pharma (Pakistan) Limited, Karachi to their name under License from M/s. MEDA Pharma GmbH & Co. KG, Germany.

M/s. Martin Dow Pharmaceuticals Limited, Karachi have deposited the fee Rs.50000/- and submitted following supporting documents:-

i) Copy of registration letter.
ii) Coy of renewal letter.
iii) No Objection Certificate (NOC) from M/s. Novartis Pharma (Pakistan) Limited, Karachi.
iv) Original Sole Agency Agreement between M/s. MEDA Pharma GmbH & Co. KG, Germany and M/s. Martin Dow Pharmaceuticals Limited, Karachi.
v) Original legalized CoPP of Elidel Cream 1%.
vi) Application on Form 5-A.

M/s. Martin Dow Pharmaceuticals Limited, Karachi was advised to provide the following documents:-

i) Status of the product approval from EMA, US FDA, TGA, Japan or WHO.
ii) CRF, NOC up-to 2012.
iii) Report on clinical trials in local condition, as advised in registration letter.

In response, M/s. Martin Dow Pharmaceuticals Limited, Karachi have submitted that "Elidel Cream 1%" is registered in 112 countries including US FDA, Canada & TGA and provided copy of approval from US-FDA, Germany & TGA. Firm have also provided copy of CRF, NOC up-to 2012.

The previous importer M/s. Novartis Pharma (Pakistan) Limited, Karachi have submitted the clinical trials conducted global and regional Clinical / Phase-IV Studies.

As Registration of Elidel Cream 1% (Reg. No.041165) was granted subject to clinical trial within one year of registration and local contract manufacturing after two years. The firm has not complied these conditions. Therefore, M/s. Martin Dow Pharmaceuticals Limited, Karachi was advised to clarify their position why they have not complied the conditions of registration.

In response, M/s. Martin Dow Pharmaceuticals Limited, Karachi have requested to withdraw their application for transfer of registration of Elidel Cream 1% (Reg. No.041165) from M/s. Novartis Pharma (Pakistan) Limited, Karachi to their name.

Registration of Elidel Cream 1% (Reg. No.041165) was granted subject to clinical trial within one year of registration and local contract manufacturing after two years. M/s. Novartis Pharma (Pakistan) Limited, Karachi have not complied these conditions. Therefore, M/s.

Novartis Pharma (Pakistan) Limited, Karachi was advised to clarify their position why you have not comply the conditions of registration.

In response, M/s. Novartis Pharma (Pakistan) Limited, Karachi have submitted that in continuation to a request from M/s. Martin Dow Pharmaceuticals Limited, Karachi dated 13th March, 2013 to transfer this product from M/s. Novartis Pharma (Pakistan) Limited, Karachi following a mutual agreement between their principals. Unfortunately, this transfer could not be granted by Drug Regulatory Authority of Pakistan during last one year despite of its worldwide transfer. Consequently, the principal offices have to cancel their agreement and revert their decision in Pakistan only.

M/s. Martin Dow Pharmaceuticals Limited, Karachi has now informed DRAP about their decision to withdrawal of this request. Therefore, they have now request to kindly condone this request for the transfer of registration and also consider this as withdrawal of their registration.

M/s. Novartis Pharma (Pakistan) Limited, Karachi has not fulfill the condition of registration of Elidel Cream 1% as recorded above and now they have informed to this office that they want to withdraw their registration. This is a lacking on the part of the firm for not honoring the local regulatory authorities.

There is no alternate of the "Elidel Cream (Pimecrolimus) is available in Pakistan. Therefore, it is propose that firm may be directed to make arrangement for local manufacturing of the product or given this brand name to any other company for marketing in Pakistan.

Decision: Registration Board discussed the case in detail and decided to call firm (M/s. Novartis) for personal hearing / presentation for not fulfilling the condition of registration i.e. conduction of clinical trials in local population.

Case No. 23. Registration of Imported Drugs under the Drugs Act, 1976.

Registration Board in its 226th meeting held on 20th -21st July, 2010 approved the registration of following drugs for import in the name of M/s. Genesis Pharmaceuticals (Pvt) Ltd., Lahore subject to inspection of facilities of manufacturer abroad M/s. Chong Kun Dang Pharmaceutical Corp., Seoul Korea:-

S#	Name of Drug (s) & Composition.	Fee deposited.	Price approved by the Price Advisory Committee.
1.	Calutami Tablet 50mg. Each tablet contains: - Bicalutamide (HIS)……..50mg.	Rs.100,000	Rs.3094.00/28's.
2.	Gemtan Injection 200mg. Each vial contains:- Gemcitabine as HCl……200mg.	Rs.100,000	Rs.1675.00/Per vial.
3.	Gemtan Injection 1gm. Each vial contains:- Gemcitabine as HCl…….1gm.	Rs.100,000	Rs.8330.00/Per vial.
4.	Belloxa Injection 50mg. Each vial contains:- Oxaliplatin……50mg.	Rs.100,000	Rs.10000.00/Per vial.
5.	Belloxa Injection 100mg. Each vial contains:- Oxaliplatin….100mg.	Rs.100,000	Rs.20000.00/Per vial.

In compliance, inspection of the manufacturer aboard M/s. Chong Kun Dang Pharmaceutical Corp., Seoul Korea has been carried out by the nominated panel comprised Dr. Obaid Ali, Deputy Drugs Controller, CDL, Karachi & Dr. Kifayat Ullah Khan, Chief Inspector of Drugs / Secretary Quality Control & Drugs, Gilgit.

The panel has recommended the registration of above said drugs. The storage facility of the importer has also already been verified by the Area FID.

The applicant M/s. Genesis Pharmaceuticals (Pvt) Ltd., Lahore have requested for issuance of registration letter of the above said drugs.

The inspection of the manufacturer was conducted by the nominated panel in November 2011 i.e. more than two years back. The panel also wrote that the firm involved in manufacture of immunosuppressant drugs in the same premises and commuted to change manufacturing facilities (site).

Therefore, it is propose before issuance of "Registration Certificate" we may ask the firm to clarify whether they have shift the immunosuppressant product's manufacturing to new site or otherwise.

Decision: The Board deliberated the case and advised the applicant to submit confirmation of proof of sparation of both manufacturing facilities by Korean regulatory authorities.

Case No. 24. **Change of Manufacturer Name.**

M/s. Akhai Agencies, Karachi have requested to approve the change of manufacturer name of their registered imported drug namely **"Halothane Inhalation (Reg. No.001217)**" from M/s. Piramal Healthcare Limited, India to M/s. Piramal Enterprises Limited, India. They have deposited required fee Rs.100, 000/- and submitted following supporting documents:-

i) Original request letter from M/s. Piramal Healthcare Limited, India regarding change of company name.
ii) Last change of manufacturer name letter.
iii) Original copy of Certificate of In-corporation legalized by Pakistan Embassy.
iv) Original Certificate of Pharmaceutical Product legalized by Pakistan Embassy.
v) Original copy of Manufacturing License legalized by Pakistan Embassy.
vi) Original copy of WHO GMP Certificate legalized by Pakistan Embassy.
vii) Copy of approval of Halothane Inhalation from UK MHRA.
viii) Site Master File.

Registration of the drug is valid as change of manufacturer name of Halothane Inhalation (Reg. No.001217) was approved on 21st November, 2012.

Drug Registration Board in its 242nd meeting held on 24-25th February, 2014 considered and approved the request of firm for change of manufacturer's name for "Halothane Inhalation (Reg. No.001217)" from M/s. Piramal Healthcare Limited, India to M/s. Piramal Enterprises Limited, India.

The firm is located in India, therefore, it is mandatory to visit the manufacturing facility for production of **"Halothane Liquid".** It is propose we may brought the facts before Drug Registration Board for policy decision whether when change of name of firm is applied it is need to inspect the unit or otherwise.

Decision: Request of the firm was approved by the Board.

Case No. 25. T**ransfer of registration of drug from local manufacturing to finished import.**

Drug Registration Board in its 237th meeting held on 26-02-2013 have approved the request of M/s. CCL Pharmaceuticals (Pvt.) Ltd, Lahore for registration of **"Stresam Capsule 50mg"** subject to submission of dossier for drug registration on prescribed Performa, fee as per revised fee schedule and completion of all codal formalities. The Board also authorized Chairman, Drug Registration Board for taking decision.

M/s. CCL Pharmaceuticals (Pvt.) Ltd, Lahore have deposited the balance fee i.e. Rs.35000/- and also provided registration application on prescribed Form 5-A and fresh CPP and GMP Certificate of the manufacturer legalized by the Pakistan Embassy.

Firm has also provided the copy of NOC for CRF.

M/s. CCL Pharmaceuticals (Pvt.) Ltd, Lahore have requested for issuance of registration letter as the drug is imported from M/s. Biocodex, France.

Decision: The Board approved request of the firm.

Case No. 26. Termination of agreement.

M/s. Genome Pharmaceuticals (Pvt) Ltd., Rawalpindi have requested for transfer of registration of the following registered imported **Blood Bags** from the name of previous agent M/s. 3H Hoffmann Human Health Pakistan Ltd., Lahore to their name as the manufacturer abroad M/s. Shandong Weigao Group Medical Polymer Co. Ltd., China has terminated the agency agreement of the previous agent and appointed them as new agent in Pakistan for these products:-

S. No.	Reg. No.	Name of Products
1.	033123	Single Disposable Blood Bag (CPDA Solution) with Transfusion Set.
2.	033124	Double Disposable Blood Bag (CPDA Solution) with Transfusion Set.
3.	033125	Triple Disposable Blood Bag (CPDA Solution) with Transfusion Set.

The applicant M/s. Genome Pharmaceuticals (Pvt) Ltd., Rawalpindi have deposited fee Rs.50000x3=150000/= and submitted following supporting documents:-

i) Termination of Agreement of Previous Agent.
ii) Authorization of New Sole Distribution of the New Agent

M/s. Genome Pharmaceuticals (Pvt) Ltd., Rawalpindi was advised to provide NOC of the former agent M/s. 3H Hoffmann Human Health Pakistan Limited, Lahore regarding transfer of registration of the above said products. In response, M/s. Genome Pharmaceuticals (Pvt) Ltd., Rawalpindi have not provided NOC of the former agent.

The previous agent M/s. 3H Hoffmann Human Health Pakistan Ltd., Lahore was advised to clarify that as the manufacturer abroad M/s. Shandong Weigao Group Medical Polymer Co. Ltd., China has terminated the agency agreement with you for the products.

In response, M/s. 3H Hoffmann Human Health Pakistan Ltd., Lahore intimated that they have serious reservation on the decision by the M/s. Shandong Weigao Group Medical Polymer Co. Ltd., China. The matter "Termination of Agreement" is under discussion with M/s. Shandong Weigao Group Medical Polymer Co. Ltd., China and it is hoped that the matter will be resolved very soon and business relation will be continued further after getting satisfactory response from M/s. Shandong Weigao Group Medical Polymer Co. Ltd., China. Therefore they have requested to wait for further processing in the matter and oblige.

Decision: The Board after thorugh discussion deferred above mentioned case and called M/s. 3H Hoffmann Health Pakistan Ltd., Lahore for personal hearing in the matter.

Case No. 27. Transfer of registration of drugs.

M/s. Ali Gohar & Company (Private) Limited, Karachi have applied for transfer of registration of the following registered imported drugs in their name from the name of previous importer M/s. Novartis Pharma (Pakistan) Limited, Karachi due to merger between M/s. Novartis AG, Switzerland and M/s. Alcon, Inc., Switzerland:-

S. No.	Reg. No.	Name of Drug (s).	Name of Manufacturer.

1.	045693	Genteal Eye Drops.	M/s. Excelvision, France.
2.	045694	Genteal Gel.	M/s. Excelvision AG, Switzerland.

The applicant M/s. Ali Gohar & Company (Private) Limited, Karachi have deposited fee Rs.50000x2=100000/- and submitted following supporting documents:-

i) Original NOC from previous agent M/s. Novartis Pharma (Pakistan) Limited, Karachi.
ii) Copies of Registration Letters.
iii) Artworks of the products.
iv) Copy of Merger Agreement.
v) Copies of the acknowledgement of last renewal of registration of the products applied by the previous importer M/s. Novartis Pharma (Pakistan) Limited, Karachi.
vi) Copy of complete merger agreement.
vii) Justification of using Alcon Logo.

M/s. Ali Gohar & Company (Private) Limited, Karachi was advised to submit CoPP country of origin & evidence of approval from US-FDA, EMA, TGA or Japan for the above said drugs.

In response, the firm has submitted following documents:-

1) Original Certificate of Medical Device duly attested by Pakistan Embassy for Genetal Gel.
2) Original Free Sales Certificate duly attested by Pakistan Embassy for Genetal Gel.
3) Original Free Sales Certificate duly attested by Pakistan Embassy for Genteal Eye Drops.

M/s. Ali Gohar & Company (Private) Limited, Karachi was again advised to submit CoPP of "Genteal Gel" from Switzerland which is the country of origin and also clarify about approval of "Genteal Eye Drops" by TGA, Australia indicating USA as manufacturing site instead of France.

In response, the firm has submitted following documents:-

i) Original Free Sale Certificate of "Genteal Eye Gel" from Switzerland duly attested by Pakistan Embassy.

ii) Original letter regarding change of exporting country of origin from Switzerland to Belgium.

iii) Applications on Form 5A.

Decision: Request of the firm was approved by the Board.

Case No. 28. Change of manufacturing site of Galvus Met 50/500mg Tablets (Reg. No.078106).

M/s. Novartis Pharma (Pakistan) Limited, Karachi have requested to approve the change of manufacturing site of their registered imported drug "Galvus Met 50/500mg Tablets (Reg. No.078106)" as follows:-

Reg. No.	Name of Product.	Existing Manufacturing Site / Product Licence holder.	New Manufacturing Site / Product Licence holder.
078106	Galvus Met 50/500mg Tablets. Each tablets contains:- Vildagliptin 50mg. Metformin hydrochloride 500mg.	Manufactured by:- M/s. Novartis Pharma Stein AG, Schaffhauserstrasse 4332 Stein AG, Switzerland / Product licence holder:- M/s. Novartis Pharma Schweiz AG, Monbijoustrasse 118, 3007 Bern, Switzerland.	Manufactured by: M/s. Norartis Pharma Produktions GmbH, Oflinger Str. 44, 79664 Wehr, Baden-Wurttemberg, Germany. Product licence holder:- M/s. Novartis Pharma GmbH, Roonstrasse 25, 90429 Nurnberg, Germany.

M/s. Novartis Pharma (Pakistan) Limited, Karachi have deposited required fee Rs.100000/- and submitted following supporting documents:-

i) Original legalized GMP Certificate of new manufacturing site.
ii) Copy of product registration letter.
iii) Original legalized German CPP mentioning new manufacturing site.
iv) Application on Form-5 (A).
v) Site Master File.
vi) Copy of NOC for CRF.

Registration of the drug is valid.

The CoPP provided by the firm issued by German authorities indicates that the product is neither authorized to be placed on German market nor on free sale in country of origin i.e. Germany.

There are other similar pending cases with same status of product. This required across the board decision by Registration Board.

Decision: The Board discussed matter of non-availability of finished drug in country of origin. It was deliberated that finished drug should be permitted for import only if it is for free sale in country of origin. Thus the Board decided to call firm's representatives for presentation of their case in next meeting.

Case No. 29. Registration of more than one formulation for a manufacturer.

Patron in Chief of Pakistan Veterinary Pharmaceuticals Association, Rawalpindi have forwarded copies of registration letters granted to M/s. Attabak Pharmaceuticals, Islamabad and informed that he received complaints from various Veterinary Manufacturers regarding one Special Manufacturer i.e. M/s. Attabak Pharmaceuticals, Islamabad, which after details investigation forwarded to the DRAP.

According to Drug Act, 1976, the manufacturer has undertaken that they don't have any registration in same formulation before. Is the manufacturer is kidding with DRAP, or he is using his political influence.

Patron in Chief of Pakistan Veterinary Pharmaceuticals Association, Rawalpindi has further requested to de-register all the same formulations which were granted to M/s. Attabak Pharmaceuticals, Islamabad.

Decision: Registration Board decided to call firm for personal hearing in next meeting and also advised to review the registration data for such other cases.

Case No. 30. Change of manufacturing site of "Jevtana 60mg/1.5ml Concentrate for Solution for Infusion (Cabazitaxel)" & Registration of Solvent for JEVTANA.

Drug Registration Board in its 236th meeting held on November 20, 2012 approved the registration of "Jevtana 60mg/1.5ml Concentrate for Solution for Infusion (Cabazitaxel)" subject

to inspection of manufacturer abroad, verification of storage facilities and price fixation / calculation etc as per policy.

The applicant M/s. Sanofi-Aventis Pakistan Limited, Karachi have requested to approve the change of manufacturing site of "Jevtana 60mg/1.5ml Concentrate for Solution for Infusion (Cabazitaxel)" from M/s. Aventis Pharma, Dagenham, United Kingdom to M/s. Sanofi-Aventis Deutschland GmbH, Bruningstrasse 50, D-65926 Frankfurt am Main, Germany.

The firm have deposited fee Rs.100000/- and submitted following supporting documents:-

i) Original Legalized Certificate of Pharmaceutical Product.
ii) Original Legalized GMP Certificate.
iii) Attested copy of Site Master File.
iv) Pharmaceutical Information – Drug Product (CTD Module 3).
v) Pharmaceutical Information – Solvent for Dilution (CTD Module 3).
vi) Copy of NOC for CRF.
vii) Application of Form 5-A.

M/s. Sanofi-Aventis Pakistan Limited, Karachi have also submitted separate registration application on Form 5-A along-with required fee Rs.100, 000/- for "Solvent for dilution 4.5ml" free of cost for approval for "Jevtana 60mg/1.5ml Concentrate for Solution for Infusion (Cabazitaxel)".

The Drugs Pricing Committee in its 8th meeting held on 18-11-2013 also approved the price of drug for "Jevtana 60mg/1.5ml Concentrate for Solution for Infusion (Cabazitaxel)".

M/s. Sanofi-Aventis Pakistan Limited, Karachi have requested to issue registration letter of the product with new manufacturing site i.e. M/s. Sanofi-Aventis Deutschland GmbH, Bruningstrasse 50, D-65926 Frankfurt am Main, Germany.

Application for registration of Solvent for Jevtana was evaluated. In registration application, manufacturing site has been mentioned as M/s. Sanofi- Aventis Deutschland GmbH, Bruningstrasse 50, D-65926 Frankfurt am Main, Germany but stability data provided was from M/s. Dagenham, UK. M/s. Sanofi-Aventis Pakistan Limited, Karachi. Accordingly, M/s. Sanofi-Aventis Pakistan Limited, Karachi was advised to clarify the ambiguity for further necessary action in the matter.

In response, M/s. Sanofi-Aventis Pakistan Limited, Karachi have submitted stability report from M/s. Sanofi- Aventis Deutschland GmbH, Bruningstrasse 50, D-65926 Frankfurt am Main, Germany.

The firm was advised to submit the revised stability data for new site. The firm have again provided the copy of stability data already submitted. The firm have further clarify that as per the EU Guidelines, the manufacturing site transfer approval does not require the site-specific stability studies. This is the reason why the stability studies submitted in the dossier were related to the Dagnham, UK and not Frankfurt, Germany. M/s. Sanofi-Aventis Pakistan Limited, Karachi was advised to submit copy of EU guidelines.

In response, M/s. Sanofi-Aventis Pakistan Limited, Karachi have submitted copy of EU guidelines.As per EU guideline submitted by the firm "stability data" is required for such changes.

M/s. Sanofi-Aventis Pakistan Limited, Karachi have also requested to have an opportunity to present their case via personal hearing before the Registration Board.

Decision: Dr. Shuja ud Din and Ms. Aisha appeared befor the Board and presented their case about shelf life of drug. Firm presented stability data of new manufacturing site, thus the Board approved firm's request for registration of solvent for Jevtana with shelf life of 24 months. The Board also approved new manufacturing site for these products.

Case No 31: Products deferred for expert opinions

a. Kalimate 5gm Sachet-Maple Pharmaceuticals, Karachi.

Registration Board in 218th meeting deferred following registration application of M/s Maple Pharmaceuticals (Pvt.) Ltd, Karachi for expert opinion and inspection of manufacturing abroad.

S. No	Name of drug(s) & Composition	Proposed Pack size	Demanded Price
1	Kalimate 5gm Sachet Each 1gm sachet contains:- Calcium Polystyrene Sulfonate…… 1gm (Agent for circulatory organs) (Import in bulk from M/s Kowa Company Ltd, Japan and repacked locally)	7's	Rs.453

Registration Board in 228th meeting considered views of following experts and after detailed discussion advised firm to conduct local clinical trials for the product. Accordingly firm was advised to coordinate with R&D section for clinical trials.

Abdul Latif Sheikh, Consultant, Department of Pharmacy Services, AKUH, Karachi	**Syed Ather Hussain,** Head of Nephrology, Agha Khan University Hospital, Karachi	**Prof.Dr. S.M.Abbass**, Department of Nephrology, Abbasi Shaheed Hospital, Nazimabad No.5, Karachi
Ca-Polystyrene Sulfonate is an ion exchange resin that is primarily prescribed in the treatment of hyperkalemia. It removes the potassium by exchanging calcium ions in the intestine and is requally effective in hyperkalemia associated with pathological conditions such as renal failure and that in drug induced hyperkalemia. It is utilized in a form of cocktail with the Regualr insulin and Ca-Gluconate for life threatening hyperkalemia.	Kalimate is calcium based cationic resin to be used for hyperkalemia. The mode of action is to have calcium absorption in exchange of potassium within the gastrointestinal tract. The study included about 75 patients with 63 being on dialysis and 12 non-dialysis CKD patients, out of these only 47 dialysis and 12 non-dialysis CKD patients actually participated in the study. Among the non-dialysis patients several of the patients had inconsistencies in the study. Among the non-dialysis	Not received

The usual adult dose is 15g 1-4 times a day PO and 30-50 g q6h rectally. While in pediatrics, the oral dose is 1 g/kg q6h either PO or rectal. This generally well tolerated with main side effects related to electrolyte abnormality, constipation, nausea/vomiting are seen. The products launch in Pakistan is a much needed step as currently there is no registered product in the local market till date which can be used in the serious conditions listed above. The registration of this product in Pakistani market is endorsed, moreover it is highly suggested that it to be registered on fast track for the benefit of the patients.	patients several of the patients has inconsistencies in collecting data on blood pressures and weights, so they were not included in final analysis. Only about 30 of total were included in the final analysis. In the statistical analysis the study does not mention about what was the proposed sample size and how it was designed, what was the objective of the study. This makes it difficult to evaluate the results of the study. The results of the study show a drop in serum potassium levels with no significant rise in serum calcium. There was a drop in serum phosphate level also which could be due to calcium binding phosphate in the intestine but same drop also was seen when sodium resin was used. The dose of the Kalimate was also very variable. There is no mentioned about constipation/ increased GI motility which is another concern with these resins. Even though the mechanism of the proposed drug looks promising and efficacy from the provided data shows comparable efficacy, safety and quality to currently available sodium resin but the number to treat (patients/subjects) in the study are very small to asses all these parameters. The provided study seems more applicable to assess efficacy of Kalimate. To evaluate safety and quality/ effectiveness compared to currently used sodium resin, we need to include more patients and properly divide in different study proups (ESRD on dialysis and or CKD).	

The firm conducted clinical trails at The Kidney Centre under supervision of Dr. Asim Ahmed, Dean & Chief Nephrologist and assisted by Dr. Kiran Nasir, Consultant Nephrologist in Kidney Center. Report of trial was also submitted to Assistant Drugs Controller (CT), Ministry of Health. Firm has also submitted that trials about Kalimate has also been published in medical journal published in Indonesia. This product has already been acknowledged in Korea, Philippines, Japan, Thailand, Taiwan, Malaysia and Indonesia.

Registration Board in 237 meeting discussed clinical trial data submitted by the firm and decided that Prof. Dr. Zafar Iqbal and Prof. Dr. Maqsood Ahmad, member, Registration Board will evaluate clinical trial data and authorized its Chairman to decide the case in light of recommendation of experts. Both experts presented their reports as follows:

Prof. Dr. Zafar Iqbal	**Prof. Dr. Maqsood Ahmad**
• Clinical trial conducted shows good results and trials have been conducted in Pakistan that shows the efficacy and safety of drug. Therefore, according to the data provided, drug is beneficial for patients and may be registered in Pakistan. **Conclusion:** • The drug is registered in Japan and some other Asian countries and also found in B P 2012. The registration of drug may please be allowed with strict labeling conditions and warning for patients. The clinical trial (provided) in Pakistan showed the safety and efficacy of drug and will be beneficial to patients.	• This study was conducted on hypothesis that sodium resin can worsen the volume overload in patients of chronic kidney disease where as calcium polystyrene is devoid of this effect. These results were unable to prove this hypothesis because both drugs were unable to show any significant effect on serum electrolyte levels of calcium, phosphorus, and sodium and no significant change was observed on weight of patients who were under clinical investigation. • On basis of above results, it was wrongly concluded that calcium polystyrene can be preferred over polystyrene sodium. • These results reported that calcium polystyrene when administered in a dosage 3 to 5 gm daily can cause hypomagnesaemia indicating the decrease of serum magnesium concentration which is required for the activity of a number of important enzymes, where as such effect was not observed with sodium polystyrene. • The study was conducted without getting any approval from ethical committee which is one of the basic requirements to conduct clinical trials. **Recommendation:** Kalimate 5gm cannot be registered on the basis of results presented in this clinical trial. It is further recommended that multicentered clinical trial may be conducted after the fulfillment of all basic requirements for such studies.

Prof. Dr. Ghias Butt, Pakistan Institute of Medical Sciences, Islamabad.	**Brig (R) Hakeem Khan, Quaide-e-Azam International Hospital, Islamabad.**	**Chairman, Departemt of Pharmacy, University of Balcohistan, Quetta**
I have studied and assessed the documents related to trials that were conducted in Pakistan, shows satisfactory result regarding the safety and efficacy of product. Hyperkalemia is a known complication of chronic kidney disease. As kidneys are responsible for the excretion of 90% of potassium while rest of the 10% was removed by the gut. Kalimate is orally administrated 15-30g a day dividing into 2-3 times. The study shows that by giving this product to the subjects, lower side effects were faced with kalimate as compared to sodium polystyrene. This makes the drug safe and efficacious. This product can be used safely in patients with volume overload., cardiac failure, edema, hypertension and chronic kidney diseases due to the absence of sodium. In light of the above, I strongly recommend to register the drug and allowing it to come into the market immediately.	Awaited	After detailed study of the literature and clinical trails of Kalimate, my opinion and evaluation is that the drug Kalimate if registered here will be a good addition in the drugs list in Pakistan with more bnefits to the patients with hyperkalemia. Thus the request submitted by the M/s Maple Pharmaceuticals for the registration of kalimate sachet may be acceded to and the registration may be granted.

Decision: Registration Board referred case to Sahbizada Abdul Haleem, Quaide-e-Azam International Hospital, Islamabad for his exert views on the product at the earliest.

b. Xyquil DR Tablet - Sami Pharmaceuticals, Karachi

Registration Board in 240th meeting deferred following product for expert opinion. Accordingly product was referred to expert for view. Comments are as under.

S. No	Name of drug(s) & Composition	Proposed Pack size	Demanded Price
1	Xyquil DR Tablet Each delayed release tablet contains: Doxylamine Succinate …10 mg Pyridoxine HCl …….....10 mg (Anti-Emetic)	As per PRC	As per PRC

Prof. Dr. Zafar Iqbal, Department of Pharmacy, Peshawar.	**Prof. Dr. Mehmood Ahmad, Department of Pharmacy, Bahawalpur.**	**Prof. Dr. Ghulam Sarwar, Women University, Karachi**
The data provided was evaluated and following are comments. **Dissolution Profile:** Dissolution study was conducted in comparing with the Diclegis DR 10mg Tablet used as reference drug. **Stability Profile:** Stability studies was carried out on 03 batches (using long term (30ºC /65% RH for 12 months and 30ºC /75% RH for 6 months. According to the data provided the Xyquil DR Tablets are stable. The product also qualifies various physical and chemical tests performed during the study period. **Raw Material** The raw material is purchased	Fixed dose combination is indicated for the treatment of nausea and vomiting during pregnancy. It is the only FDA approved Category A medicine to treat medical condition known as nausea and vomiting of pregnancy (NVP), commonly referred to as morning sickness. This combination is already registered in Canada and also in Pakistan. The data provided is complete and comprehensive regarding raw materials specifications along with detailed references of	I have reviewed the file and our findings are as follow:- 1. Data for dissolution is comparable and satisfactory with that of innovator. 2. The method of analysis of the finished drug is satisfactory. 3. Photocopies for the purchase of raw material are available. However the photocopies are not authenticated (Documents is not certified by their Health Authority) 4. Though the certificate of analysis of raw material is attached by this document is authenticated.

from the India. The analytical report is attached that showed material is according to USP specifications. The certificate of the analysis of the from the manufacturer is hereby attached. **Method of Analysis** The method of analysis is HPLC based and record of the method validation is provided that shows the method is validated. The product is available in other countries and also manufactured by other manufacturers in Pakistan. In the light of the data provided, the product is recommended for the registration.	official compendia's analytical procedures and finished product specifications. The data regarding labeling, prescribing information and type of container and packaging is sufficient to meet the Drugs Registration Requirements. Stability studies conducted at 40° for 6 months meet the specifications in all respects of appearance, mean weight, assay and disintegration time. The comparative dissolution studies conducted in acidic and basic media meet the required quality specifications. Therefore, keeping the above mentioned facts in view, the requested registration of drug may be granted.	Therefore, it is recommended that approval may kindly be granted for the registration.

Decision: Registration Board approved the Xyquil DR Tablet for registration.

c. Maltofer Fol Syrup – M/s Pharmatec Pakistan (Pvt.) Ltd, Karachi.

Registration Board in 239th meeting deferred following product for expert opinion. Accordingly product was referred to expert for view. Comments are as under.

S. No	Name of drug(s) & Composition	Proposed Pack size	Demanded Price
1	Maltofer Fol Syrup Each 5ml contains: Iron as iron (III) hydro oxide ploymaltose100 mg Folic acid……400 mcg (Supplementation and treatment of ID and IDA)	150ml	As per PRC

Prof. Dr. Riffat Shaheen, **Head, Department of Gynecology,** **Federal Government Services Hospital,** **Islamabad**	**Prof. Dr. Ghazala Mehmood,** **Head, Department of Gynecology,** **Pakistan Institute of Medical Sciences,** **Islamabad**	**Prof. Dr. Asma Tanveer Usman** **Head, Department of Gynecology,** **Benazir Hospital, (Rawalpindi General Hospital)** **Rawalpindi**
Need assessment: Nutrition deficiency is a common occurrence in woken before conception. They should ideally take iron and multivitamin supplementation in the periconceptional period. Folic Acid is an essential vitamin required throughout pregnancy which helps in prevention of congenital malformations like neural tube defects and megaloblastic anemia. However, compliance for oral tablets containing iron and folic acid is poor and a large number of pregnant woken have gastric symptoms and prefer to take syrup. Therefore, the syrup should ideally contain iron and folic acid.\ **Efficacy & Safety:** Combination of Iron Polymaltose 50mg and 100mg with Folic acid 0.35mg /5ml is safe and effective. **Quality:** The above combination can be easily tolerated with minimum side effects. **Recommendation:-** This combination of iron and folic acid in the form of syrup is beneficial for pregnant women due to good tolerance and patient compliance.	Global prevalence of anemia has the highest burden of disease especially in women and children. Under the National Health Policy, prenatal care should include provision of iron supplements, folic acid supplements, two doses of tetanus vaccine, blood pressure measurement, and identification and treatment of reproductive tract and sexually transmitted infections. The most recent reports showed an increase in its frequency among low income group and more in underdeveloped countries. Pakistan nutrition survey found that 65% of population between the ages of 7-60 years had IDA. In young children incidence of anemia is 43%, but children between 1-2 years are at greatest risk. Deficiency of folate and B12 constitutes one of major nutritional deficiency after iron deficiency. Nutritional deficiency is far more common in vegetarian. B12 deficiency seen in infants and young children have been particularly related to maternal deficiency which results in poor body stores at the time of birth.	Expert informed that she has been retired

	Any product with iron alone does not address the problem of Nutritional Anemia in Pakistan. All oral products, tablets or syrups should include folic acid in its formulation. Studies have shown that folic acid has a pivotal role in preventing neural tube defects. Pregnancy, Iron and folate supplementation improves the maternal and new newborn outcome and hence decreases pregnancy related anemia and newborn problems. I recommend the availability of Iron Polymaltose Complex syrup with folic acid. It can offer ease for those patients who cannot take iron and folic acid tablet separately. The compliance would also be enhanced.	

Decision: Registration Board referred Maltofer Fol Syrup for expert opinion of Dr.Riffat Najeeb, Fauji Foundation Medical College, Rawalpindi.

d. Dispermox 250mg Tablet and Dispermox 500mg Tablet - M/s Zafa Pharmaceutical Laboratories (Pvt.) Ltd, (DML No.000558), Karachi.

Registration Board in 240th meeting deferred following product for expert opinion. Accordingly product was referred to expert for view. Comments are as under.

S. No	Name of drug(s) & Composition	Proposed Pack size	Demanded Price
1	Dispermox 250mg Tablet Each dispersable tablet contains: Amoxicillin USP …….250 mg (Semisynthetic penicillins)	As per DPC	As per DPC
2	Dispermox 500mg Tablet	As per DPC	As per

	Each dispersable tablet contains: Amoxicillin USP …….500 mg (Semisynthetic penicillins)		DPC

Prof. Dr. Tabish Hazir, Pakistan Institute of Medical Sciences, Islamabad.	**Maj. Gen. Salman Ali, Principal, Army Medical College, Rawalpindi.**	**Prof. Dr. Muhammad Jamshed, Dean, Faculty of Pharmacy, University of Central Punjab, 1-khayaban-e-Jinnah, Johar Town, Lahore.**
The latest revisions to the WHO / UNICEF, IMNCI guidelines 2013 highlight the issue of Dispersible amoxicillin tablets vs liquid formulation for the treatment of childhood pneumonia in community and outpatient department settings. 17th meeting of expert committee on selection and use of essential medicine in children held in Geneva in December, 2008 concluded "In general, there was greater acceptance of the benefits of solid dosage form over liquid dosage forms for stability, dosing and administration issues". In addition it was also concluded that Dispersible tablets are easily produced, stable in variety of climates better transportable due to low bulk / weight. In addition they are affordable and commercially viable. Based on these advantages the meeting recommended the following:	Dispermox dispersible tablets would be a useful addition to the preparations of amoxicillin in our country in view of its ease of transport and clinical use. It would be cost effective and safe to use this preparation. Dispersible, preparations of amoxicillin are also in use in developed countries. Therefore, this preparation can be safely standards and maintains the quality of the product.	This dosage form is already registered in the Netherlands, Europe, to Sandoz B.V and it has also been registered in France to Zydusfrance. It has also been verified that Amoxicillin dispersible tablets 250mg and 500mg have been indicated for the treatment of pneumonia in WHO's list for the priority Medicines for Mothers and Children 2011. It is observed that this dosage form is marketed in the European countries for various indications. I have gone through the technical manufacturing aspects of this dosage form and they comply with the existing standards. The manufacturing equipment, facilities and the competent professionals to look after the quality of the product are adequate and may be verified physically expert personnel. The stability study data provided by M/s Zafa demonstrated that the products comply with the official specifications during the

" In general, the dosage form of medicine that are likely to prove most suitable particularly for developing countries are flexible solid dosage form" such as Oro-Dispersible tablets" Based on the WHO recommendation oral Dispersible Amoxicillin tablets should be made available as part of the essential drug list for treatment of childhood pneumonia in Pakistan.		study period i.e two years. It has generally been observed that dispersible dosage forms offer better bioavailability compared to conventional products. **Conclusion:** Based on the data / material provided by the firm and need for the said dosage form, it is recommended that Dispermox 250mg Tablet and Dispermox 500mg Tablet --- M/s Zafa Pharmaceutical Laboratories (Pvt.) Ltd, (DML No.000558), Karachi should be registered under the drug act, 1976.

Decision:Registration Board approved Dispermox 250mg and 500mg Tablet for registration.

e. Palip XR 1.5mg Tablet and Palip XR 3mg Tablet – M/S Pharmatec Pakisatn, Karachi.

Registration Board in 240th meeting deferred following product for expert opinion. Accordingly product was referred to expert for view. Comments are as under.

S. No	Name of drug(s) & Composition	Proposed Pack size	Demanded Price
1	Palip XR 1.5mg Tablet Each film coated tablet contains: Paliperidone ……. 1.5 mg (Anti-Psychotic)	14's	Rs.8600/-
2	Palip XR 3mg Tablet Each film coated tablet contains: Paliperidone ……. 3 mg (Anti-Psychotic)	14's	Rs.8700/-

Prof. Dr. Rizwan Taj, Department of Psychiatry, Pakistan Institute of Medical	Prof. Dr. Mazhar Malik, Rawal Medical College, Rawalpindi.	Head, Department of Psychiatry, Aga Khan Univeristy & Hospital,

Sciences, Islamabad.		Karachi.
This now is a well established and safe antipsychotic available in the USA and European countries. I have no hesitation to recommend it for use in Pakistan. I understand it is already registered by Jansseen. Company may be requested to reduce price at a level that it can be given to a large population in Pakistan.	The detail review of clinical trials (efficacy) and related documents on this atypical anti-psychotic medication, Paliperidone indicated for patients suffering from schizophrenia and schizoaffective disorder is quite convincing. The safety profile of the drug is comparable with the standard atypical anti-psychotics currently available in the market. On the basis of overall review I recommend registration of Paliperidone (Palip XR 1.5mg and 3mg) Tablets for the patients suffering from schizophrenia and schizoaffective disorder.	

Decision:Registration Board approved Palip XR 1.5mg and 3 mg Tablet for registration.

Case No.32 Deferred Drugs

a. Semos Pharmaceuticals, Karachi

Registration Board in its 241st meeting deferred following products (on fast track basis) of M/s Semos Pharmaceuticals, Karachi for reason as per mentioned in last column.

Name of Drug & Composition	Pack	Demanded MRP	Date of application, Diary No. & Form	Decision
Asen Tablet Each tablet contains: Asenapine……..5 mg (Antipsychotic)	As per PRC	As per PRC	02-05-2012 Dy.No.795 Form-5 Rs.8000/- Rs.52,000/- 28-1-2013	Registration Board deferred the registration application as USFDA approved the drug as sublingual preparation and M/s Semos applied as

			Rs.90,000/-	plain tablet. The Board advised concerned Registration section to check the registration dossier and submit before Registration Board in its next meeting.
Asen Tablet Each tablet contains: Asenapine……..10 mg (Antipsychotic)	As per PRC	As per PRC	02-05-2012 Dy.No.794 Form-5 Rs.8000/- Rs.52,000/- 28-1-2013 Rs.90,000/-	-do-

Above registration applications are checked and confirm that firm applied Asenapine Tablet as sublingual tablet as mentioned the same in composition of drug. It is submitted that due to typographical mistake it was not mentioned in agenda.

Decision: Registration Board deferred products till expert opinion as in case of M/s Amarant Pharma, Karachi.

b. Kaizen Pharmaceuticals, Karachi

Registration Board in its 239th meeting deferred following product of M/s Kaizen Pharmaceuticals, Karachi for reason as per mentioned in last column.

Name of Drug & Composition	Pack	Demanded MRP	Date of application, Diary No. & Form	Decision
Proart Dry Suspension Each 5ml contains: Dihydroartemisinin..15mg Piperaquine phosphate……..…120 mg (Anti malarial)	30ml 40ml 60ml 80ml	As per PRC	08-11-2012 Dy.No.1766-A Form-5 Rs.20,000/-	Deferred for me too status & confirmation of WHO approved formulation

Later on scrutiny of registration data reveals that the above formulation is already registered for M/s Hilton Pharma, Karachi under the brand name Dipip 15/120 Dry Suspension, Reg. No.076167 which is approved in 241st meeting of Registration Board.

As regard confirmation of WHO approved formulation it is submitted that this combination is recommended in WHO 2nd edition of Guidelines (2010) for treatment of Malaria for treating uncomplicated P.Falciparum Malaria as a 1st line treatment worldwide.

Decision: Registration Board approved Proart Dry Suspension for registration.

c. Atco Laboratories, Karachi

Registration Board in its 237th meeting deferred following product of M/s Atco Labs, Karachi for reason as per mentioned in last column.

Name of Drug & Composition	Pack	Demanded MRP	Date of application, Diary No. & Form	Decision
Viglip-M 50/500mg Tablet Each tablet contains: Vildagliptin ……50 mg Metformin HCl…500 mg (Antidiabetic)	14's 20's 30's	Rs. 35/- Per tablet	24-06-2011 Dy.No.1679 Form-5 Rs.8000/- Rs.52,000/- 24-1-2013	Deferred for submission of application on Form5D with balance fee

M/s Atco Labs, Karachi has claimed that the above formulation is approved by the Registraton Board in its 241st meeting in favour of M/s Hilton Pharma, Karachi. It is submitted that above formulation is approved by the Registration Board in its 241st meeting but registration letter not yet issued due to non availability of MRP fixed by the the Pricing Section.

Decision: Registration Board approved Viglip-M 50/500mg Tablet for registration.

d. Helix Pharmaceuticals, Karachi

Registration Board in its 238th meeting held on 5th & 6th August, 2013 deferred following registration applications of M/s Helix Pharmaceuticals, Karachi for reason mentioned in last column.

S. No.	Name of drug(s) & Composition	Proposed Pack size	Demanded Price	Decision
1.	Dipros Tablet Each tablet contains: Diclofenac Sodium…..50mg Misoprostol……200mcg	20's	Rs.230.00	Deferred for product specific inspection by area FID Karachi and Director DTL, Karachi
2.	Dipros Tab. Each tablet contains: Diclofenac Sodium…..75mg Misoprostol……200mcg	20's	Rs.230.00	Deferred for product specific inspection by area FID Karachi and Director DTL, Karachi
3.	Osmin-D Tab. Each Film Coated tablet contains:- Vitamin D ……..400 iu Ossein Mineral Complex 830mg corresponding to : Calcium ……..177.6mg Phosphorous ……82.2mg Residual Mineral Salts.…24.9mg Collagen ……..224mg Other Proteins…..66.4mg Trace elements F, Mg, Fe, Zn, Cu, Ni Corresponding to approx. 440mg Hydroxyaptite	30's	Rs.247.00	Deferred for product specific inspection by area FID Karachi and Director DTL, Karachi

Now FID, DRAP, Karachi has furnished inspection report dated 6th December, 2013 conducted by panel comprising Mr. Abdul Razaq Javindha, Director DTL, Karachi, and Ms. Muneeza Khan, concerned FID, DRAP, Karachi. Recommendations of panel are as under:-

> " Keeping in view the good faculties under schedule –BII & under the rule 20 of the Drugs (Licensing, Registering & Advertising) Rules, 1976 and DRAP Act, 2012 there upon are made available for the manufacturing & quality control of the products to be registered in the name of firm, the panel is of the opinion to recommend for registration of drugs (Dipros Tablet-50mg & 75mg, Osmin-D tablet) instructed vide letter No.F.3-2/2013-Reg.II (M-238)."

Decision: Registration Board approved Dipros Tablets (50+200; 75+200) and Osmin-D Tablets for registration.

e. Helix Pharmaceuticals, Karachi

Registration Board in its 237th meeting held on 8th March, 2013 deferred following registration applications of M/s Helix Pharmaceuticals, Karachi for reason mentioned in last column.

S. No.	Name of drug(s) & Composition	Proposed Pack size	Demanded Price	Date of application, Diary No. & Form	Decision
1.	Raspro 500mcg Tablet Each tablet contains: Roflumilast……...500 mcg (Anti-Inflammatory)	10's	As per PRC	16-06-2011 Dy.No.1609 Form-5 Rs.8000/- Rs.52,000/- 31-12-2012	Deferred for submission of application on Form5D with balance fee
2.	Noger Total Capsules Each capsule contains: Pantoprazole sodium sesquihydrate eq. to Pantoprazole…..….40 mg Itopride HCl …….150 mg (proton pump inhibitors)	10's	As per PRC	01-11-2011 Dy.No.296 Form-5 Rs.8000/- Rs.40,000/- 31-12-2012	Deferred for submission of application on Form5D with balance fee
3.	Nap-X Tab. Each tablet contains: Naproxen USP enteric coated 500mg and Esomeprazole as magnesium ……..20 mg (NSAID)	10's	As per PAC	31-08-2010 1636 Form-5 Rs.8000/- Rs.35,000/- Rs.10,000/- 31-12-2012	Deferred for submission of application on Form5D with balance fee & bilayered tablet facility

Now firm has provided applications on Form 5-D and remaining fee Rs.90,000/- for each product.

Decision: Registration Board referred these dossiers to Pharmaceutical Evaluation Cell for scrutinization in light of check list approved by Registration Board.

f. Pharmatec Pakistan (Pvt.) Ltd, Karachi

Registration Board in its 236th meeting deferred following registration applications of M/s Pharmatec Pakistan (Pvt.) Ltd, Karachi for reason mentioned in last column.

Name of drug(s) & Composition	Proposed Pack size	Demanded Price	Decision
Morease OD Tablet Each tablet contains: Doxylamine succinate ….20 mg Vitamin B6 ……..20 mg (Anti-allergic (Antihistamines)	10's	Rs. 395/-	Deferred being new formulation& application on Form5D

Now firm has provided applications on Form 5-D and remaining fee Rs.90,000/- for the purpose.

Decision: Registration Board referred Morease OD Tablet to Pharmaceutical Evaluation Cell for scrutinization in light of check list approved by Registration Board.

g. Atco Laboratories , Karachi

Registration Board in its 238th meeting deferred following registration application of M/s Atco Labs, Karachi for reason mentioned in last column.

Name of drug(s) & Composition	Proposed Pack size	Demanded Price	Decision
Ascard Plus Forte Tablets Each film coated tablet contains:- Acetylsalicylic Acid (Aspirin) BP ….162mg Clopidogrel Bisulphate USP eq. to Clopidogrel …….75mg	10's	Rs.217.50	Deferred for confirmation of availability of Bi-layered tablets machine

Now firm has submitted that above mentioned product is not a ' **bi-layered tablet**' but, is a '**tablet in tablet**' formulation and will be prepared like there presently registered product **Ascard Plus Tablet.** The only difference between two products is the quantity of Aspirin.

Decision: Registration Board approved Ascard Plus Forte Tablets for registration.

h. Sante (Pvt.) Ltd , Karachi

Registration Board in its 237th meeting deferred following registration application of M/s Sante (Pvt.) Ltd, Karachi for reason mentioned in last column.

S.No.	Name of drug(s) & Composition	Proposed Pack size	Demanded Price	Date of application,	Remarks

				Diary No. & Form	
1	Travost 0.004% Eye Drops Each ml contains: Travoprost …….40 mcg (Prostaglandin Analogues/ anti glaucoma)	2.5ml	Rs.855/-	31-1-2013 Dy.No.86 Form-5 Rs.20,000/-	Deferred for Confirmation of manufacturing facilities.
2	Co-Travost Eye Drops Each ml contain: Travoprost…….0.004% Timolol……..0.5% (Anti Glaucoma)	2.5ml	Rs.950/-	31-1-2013 Dy.No.93 Form-5 Rs.20,000/-	Deferred for Confirmation of manufacturing facilities.

Now firm has submitted that Travoprost is a prostaglandin F2a analogue and is used to decrease the elevated intraocular pressure. This product is also registered in the name of Novartis / Alcon Brand name Travatan Eye Drops, Reg. No.028401 under the pharmacological group of Miotics and Antiglaucoma, topical preparation.

Decision: Registration Board approved Travost 0.004% Eye Drops and Co-Travost Eye Drops for registration.

i. Hilton (Pvt.) Ltd, Karachi

Registration Board in its 241st meeting held on 23-12-2013 deferred following registration applications of M/s Hilton Pharma, Karachi for reason mentioned in last column.

Name of drug(s) & Composition		**Decision**
1. Lacolep 2. Syrup 3.Each ml contains: Lacosamide…10mg 4.Antiepileptic	1. Form-5 2.Fast Track 3.60ml,120ml Rs.1800/-, Rs.3,600/- 4.17-05-2013/989 5. 09-12-2013/7787 **Rs.150,000/-**	Deferred for submission of Form 5-D.

Now firm has provided applications on Form 5-D.

Decision: Registration Board referred the case for expert opinion of Prof.Rizwan Taj, PIMS; Prof. Fareed Minhas and Prof.Aftab Asif

j. Kaizen Pharmaceuticals, Karachi

Registration Board in its 235th meeting deferred following product of M/s Kaizen Pharmaceuticals, Karachi for reason as per mentioned in last column.

Name of Drug & Composition	Pack	Demanded MRP	Date of application, Diary No. & Form	Decision
Vitoss-D 400mg Syrup Each 5ml contains: Ossein Mineral Complex……..400 mg Corresponding to: Calsium……85.59mg Phosphorus ……39.61 mg Residual Mineral Salt.12 mg Collagen……107.95 mg Other Proteins……..32 mg Trace Elements……..(F1,Mg, Fe, Zn, Cu & Ni) Vitamin D……400 I.U (Calcium Phosphorus supplement+Vitamin-D analogue)	60ml 120ml	As per PRC	29-08-2012 1462 Form-5 Rs.8000/- 26-03-2013 Rs.12000/-	Deferred for confirmation of atomic absorption spectrometer

Federal Inspector of Drugs, DRAP, Karachi has verified that Atomic Absorption Spectrophotometer is available in the Quality Control Laboratory of M/s Kaizen Phamacetuical, Karachi.

Decision: Registration Board approved Vitoss-D 400mg Syrup for registration.

k. Lisko Pakistan Ltd, Karachi

Registration Board in its 181-A meeting held on 3rd & 4th November, 2003 deferred following registration applications of M/s Lisko Pakistan Ltd, Karachi for reason mentioned in last column.

S. No.	Name of drug(s) & Composition	Proposed Pack size	Demanded Price	Decision
1.	Wintol Syrup Each 5ml contains:-	60ml	Rs.23.00	Deferred for inspection

	Salbutamol (as Sulphate)….2mg (B2 Andrenergic receptors)			

Now M/s Lisko Pakistan Ltd, Karachi have submitted their current inspection report dated 02-12-2013 conducted by Mr. Abdul Rasool Shaikh, FID, DRAP, Karachi. Firm has also deposited remaining fee Rs.12,000/- for the purpose.

Decision: Registration Board referred Wintol Syrup to Pharmaceutical Evaluation Cell for scrutinization in light of check list approved by Registration Board.

l. GlaxoSmithKline Pakistan Ltd, F-268, SITE, Karachi

Registration Board in its 239th meeting held on 12th September, 2013 deferred following registration application of M/s GlaxoSmithKline Pakistan Ltd, Karachi for reason mentioned in last column.

Name of drug(s) & Composition	Proposed Pack size	Demanded Price	Date of application, Diary No. & Form	Decision
Panadol sinus Caplets Each Caplet contains:- Paracetamol……. 500 mg Phenylephrine HCl. 5.00mg (Cold Preparation)	100's	Rs.300/-	24-07-2013 Dy.No.1047 Form-5 Rs,60,000/-	Deferred for submission of application on Form5D & remaining fee.

Now firm has provided applications on Form 5-D and deposited remaining fee Rs.90,000/- (8000/- + 82000/-) for the purpose.

Decision: Registration Board referred Panadol sinus Caplets to Pharmaceutical Evaluation Cell for scrutinization in light of check list approved by Registration Board.

m. Reign Pharmaceuticals PCSIR KLC, Karachi

Registration Board in its 240th meeting deferred following product of M/s Reign Pharmaceuticals PCSIR KLC, Karachi for reason as per mentioned in last column.

Name of Drug & Composition	Pack	Demanded MRP	Remarks / Decision
Dirolyte Syrup	300 ml	Rs.11/-	Registration

Each 100ml contains: Sodium Chloride ……0.26g Trisodium Citrate Dihydrate…….. 0.29g Potassium Chloride……....0.15g Glucose ……1.35g (Electrolytes/ORS Liquid)	500 ml 600 ml	Per 100ml	Board advised to confirm the facility by area FID.

Now firm has submitted inspection report dated 28-11-2013 inspected by Mr. Qaiser Muhammad, Member Central Licensing Board, Dr. Shahid Hussain, FID-I, DRAP, Karachi & Mr. Abdul Rasool Shaikh, Area FID-III, DRAP, Karachi. In inspection report panel has mentioned that Autoclav for terminal sterilization for liquid ORS has also been purchased and found installed.

Decision: Registration Board approved Dirolyte Syrup for registration subject to change in brand name.

n. Reign Pharmaceuticals PCSIR KLC, Karachi

Registration Board in its 239th meeting deferred following product of M/s Reign Pharmaceuticals PCSIR KLC, Karachi for reason as per mentioned in last column.

Name of Drug & Composition	Pack	Demanded MRP	Remarks / Decision
Lotrol Low Osmolarity Sachet Each sachet contains: Sodium chloride…….1.3g Potassium Chloride……..0.75g Trisodium Citrate Dihydrate…1.45 g Glucose anhydrous……6.75g Eq. to sodium 37.5mmol, Potassium10.00mmol, chloride 32.5mmol, citrate 5.00mmol, Glucose 37.5mmol. (Low-Osmolarity electrolytes/ORS)	As per PRC	As per PRC	Deferred for confirmation of WHO approved formula

Now firm has submitted that they have already applied above formulation in accordance with WHO approval formula for 500ml (02 glass) and also mentioned in their registration dossier as per WHO recommendation. Firm has further stated that above formulation is also registered in favour of M/s Atco Labs, Karachi with the brand name of Osmolar under Reg. No.045416.

Decision: Registration Board approved Lotrol Low Osmolarity sachet for registration

o. Merck (Pvt.) Ltd, Quetta

Registration Board in its 237th meeting deferred following products of M/s Merck (Pvt.) Ltd, Quetta for reason as per mentioned in last column.

Name of Drug & Composition	Pack	Demanded MRP	Date of application, Diary No. & Form	Decision
Glucovance 1gm/5mg Tablet Each tablet contains: Metformin Hydrochloride……1gm Glibenclamide…..5 mg (Antidiabetic)	30's	Rs.170/-	21-01-2011 Dy.No.345 Form-5 Rs.8000/- Rs.52,000/- 4-2-2013	Deferred for submission of application on Form 5D and balance fee
Concor 5 plus Tablet Each film coated tablet contains: Bisoprolol Hemifumerate…….5 mg Hydrochlorothiazide12.5mg (Anti Hypertensive Agent)	14's	Rs.165/-	28-07-2011 Dy.No.28 Form-5 Rs.8000/- Rs.52,000/- 4-2-2013	Deferred for submission of application on Form 5D and balance fee

Now firm has provided applications on Form 5-D for above mentioned products alongwith balance fee (Rs.150000/- for Glucovance 1gm/5mg Tablet and Rs.300000/- for Concor 5 plus Tablet). As per Form 5D, Concor 5 plus Tablet will be imported in bulk from Merck KGaA, Frankfurter strasse 250, Germany and will be repacked locally. Firm has not provided COPP of the product.

Decision: Registration Board referred above products to Pharmaceutical Evaluation Cell for scrutinization in light of check list approved by Registration Board.

p. Merck (Pvt.) Ltd, Karachi.

Registration Board in its 237th meeting deferred following products of M/s Merck (Pvt.) Ltd, Quetta for reason as per mentioned in last column.

Name of Drug & Composition	Pack	Demanded MRP	Date of application, Diary No. & Form	Decision

Vitabone 1000IU Capsule Each soft gelatin capsule contains: Cholecalciferol (Vitamin D3)…….1000 IU (Vitamins)	30's	Rs.450/-	22-10-2012 1672 Form-5 Rs.20,000/- Rs.40,000/- 4-2-2013	Deferred for submission of application on Form 5D and balance fee
Vitabone 400IU Capsule Each soft gelatin capsule contains: Cholecalciferol (Vitamin D3)……400 IU (Vitamins)	30's	Rs.360/-	22-10-2012 1673 Form-5 Rs.20,000/- Rs.40,000/- 4-2-2013	Deferred for submission of application on Form 5D and balance fee

Now firm has provided applications on Form 5-D for above mentioned products alongwith balance fee (Rs.150000/- each).

Decision: Registration Board referred above products to Pharmaceutical Evaluation Cell for scrutinization in light of check list approved by Registration Board.

q. M/s PharmEvo (Pvt.) Ltd, Karachi

Registration Board in its 241st meeting held on 23-12-2013 deferred following products of M/s PharmEvo (Pvt.) Ltd, Karachi for reason as per mentioned in last column.

Name of Drug & Composition	Pack	Demanded MRP	Date of application, Diary No. & Form	Decision
Infixa Tablet Each tablet contains: Rivaroxaban……...15mg (Antithrombotic)			1. Form-5 2. Fast Track 3.7's,10's,14's Rs.5,670/- Rs.8,100/- Rs.11,340/- 4.25-04-2013/719 5. 16-05-2013/439 Rs.60,000/-	Deferred being new drug. The firm has to apply on Form 5-D with differential fee of Rs.90,000/-
Infixa Tablet Each tablet contains: Rivaroxaban……....20mg (Antithrombotic)			1. Form-5 2. Fast Track 3.7's,10's,1	Deferred for application on Form 5-D with differential fee of Rs.90,000/-

			4's Rs.7,560/- Rs.10,800/- Rs.15,120/- 4.25-04-2013/719 5. 16-05-2013/445 Rs.60,000/-	

Now the firm has submitted that the above formulations are already registered for M/s Bayer Health Care, Karachi under the brand name Xarelto 15mg Tablet, Reg. No.072540 and Xarelto 20mg Tablet, Reg. No.072550.

Decision: Registration Board approved Infixa Tablet (15mg, 20mg) for registration.

r. **M/s PharmEvo (Pvt.) Ltd, Karachi**

Registration Board in its 214th meeting deferred following products of M/s PharmEvo (Pvt.) Ltd, Karachi for reason as per mentioned in last column.

Name of Drug & Composition	Pack	Demanded MRP	Decision
Osmin Tablets Each tablet contains:- Ossien Mineral Complex 830mg Corresponding to Calcium * …….177.60mg Phosphorus * ….. 82.20mg Residual Mineral Salt 24.90mg Collagen……..224.00mg Other Proteins …66.10mg Trace Elements F1,Mg,Fe,Zn,Cu,Ni * Corresponding to approximate 440mg of Hydroxyapatite (anti Arthritic)	3x10's	Rs.300.00	Deferred for confirmation of atomic absorption

Now the firm has submitted inspection report dated 20-03-2013 conducted by Mr. S. Hakim Masood, Federal Inspector of Drugs, DRAP, Karachi wherein FID has confirmed that Atocmic Absorption Spectrophotomerter is installed in the Q.C Labs of firm.

Decision: Registration Board approved Osmin Tablets for registration.

s. Megaklar DS Suspension - Barrett Hodgson Pakistan (Pvt.) Ltd, Karachi.

Following product of M/s Barrett Hodgson Pakistan (Pvt.) Ltd, Karachi was deferred for confirmation whether powder or granules by the Registration Board in its 239th meeting.

Name of Drug & Composition	Pack size	Demanded MRP
Megaklar DS Suspension 250mg/ml Each 5ml contains: Clarithromycin*…250mg (Antibacterial and Antibiotic)	60ml	Rs.450/-

Now the firm has submitted that raw material i.e Clarithromycin granules will be used in formulation and furnished requisite information as under:-

i) Clarithromycin Granules will be purchased locally from M/s Surge Laboratories (Pvt.) Ltd, Sheikhupura
ii) GMP Certificate of Granules source
iii) Certificate of Analysis
iv) Stability study data
v)

Decision: Registration Board approved Megaklar DS Suspension 250mg/ml for registration.

t. ToproZok Injection – M/s Barrett Hodgson (Pvt.) Ltd, Karachi

Registration Board in its 228th meeting deferred following product of M/s Barrett Hodgson, Karachi for me too status.

S. No	Name of drug(s) & Composition	Proposed Pack size	Demanded Price	Decision
1	Toprozok Injection Each 5ml contains: Metoprolol Tartrate…….5 mg (Beta- Adrenergic Receptor Blocking Agent)	5 Ampoule	Rs.275/-	Deferred for me too status

Now the firm has submitted that the above formulation is already registered for M/s Novartis Pharma, Jamshoro under the brand name “Lopressor Injection” Reg. No. 012846 containing Metoprolol Tartrate…..5mg.

Decision: Registration Board approved Toprozok Injection for registration.

Case No.33: Cases of registration of Nalbuphine and Tramadol.

Registration Board in its 236th meeting held on 20th November, 2012 had decided that since Nalbuphine and Tramadol are not controlled drugs as per INCB regulation. So the Board will not consider these cases in light of controlled drug guidelines. However to avoid misuse potential, their procurement and manufacturing record shall be strictly maintained and submitted in quadruplicate under Rule 30 (6) of Drugs (Licensing, Registering and Advertising) Rules, 1976 to the E&M (Evaluation of Monitoring) Department of DRAP.

In light of above decision for registration of Nalbuphine and Tramadol containing products of various manufacturers was pending for decision. Following firms deposit the remaining fee (Rs.12000/- each product) as per revised schedule for fees. Details are as under:-

S. No.	Name of firm	Name of Drug(s)	Pack	MRP	Decision
1.	M/s Tabros Pharma, Karachi (M-225)	Allay 50mg Tablets Each tablet contains:- Tramadol HCl ……50mg (Non Narcotic Analgesic)	10's	Rs.180.00	**225th RB** Deferred for confirmation of manufacturing facility
2.	-do- (M-226)	Allay SR 100mg Tablets Each tablet contains:- Tramadol HCl ……100mg (Non Narcotic Analgesic)	10's	Rs.280.00	**226th RB** Approved subject to segregated area
3	-do- (M-226)	Allay 100mg Injection Each 2 ml contains:- Tramadol HCl ……100mg (Non Narcotic Analgesic)	5's x2ml	Rs.300.00	**225th RB** Approved subject to segregated area
4	M/s Searle Pakistan, Karachi	Nubin Injection 10mg/ml Each ml contains:- Nalbuphine HCl (Searle	1's	Rs.49.00	**214th RB** Approved

		Speci.)……10mg (Opioid Analgesics)			subject to confirmation of narcotic policy
5	-do-	Nubin Injection 20mg/ml Each ml contains:- Nalbuphine HCl (Searle Speci.)……20mg (Opioid Analgesics)	1's	Rs.64.00	**214th RB** -do-
6	M/s Indus Pharma, Karachi	Exnal 10mg / ml Injection Each ml contains:- Nalbuphine HCl…..10mg (Opioid analgesic)	10's	Rs. 51.00 / per ampoule	**213th RB** Approval is subject to the fulfillment of all conditions of Narcotic/ Psychotropic policy.
7	-do-	Exnal 20mg / ml Injection Each ml contains:- Nalbuphine HCl…..20mg (Opioid analgesic)	10's	Rs. 63.00 / per ampoule	**213th RB** -do-
8	M/s Ray Pharma, Karachi	Raytram Injection 100mg Each 2ml contains:- Tramadol HCl (B.P)100mg (Non Narcotic Analgesic)	5's	Rs.195.00	**214th RB** Approved subject to fulfillment of narcotic policy
9	-do-	Raytram Capsule 50mg Each capsule contains:- Tramadol HCl …….50mg	10's	As per SRO	**218th RB** Approved subject to confirmation of Narcotic / Psychotropic / Controlled drugs policy.

M/s Tabros, Karachi has requested that in place of Allay SR 100mg Tablets (Tramadol HCl 100mg), following formulation may be substituted as (Paracetamol 325mg + Tramadol 37.5mg).

Decision: Registration Board referred above products (S.No.1-9) to Pharmaceutical Evaluation Cell for scrutinization in light of check list approved by Registration Board on priority.

Case No.34 Correction cases.

a. M/s Noa Hemis Pharmaceuticals, Karachi

The Registration Board in its 241st meeting approved following registration in favor of M/s Noa Hemis Pharmaceuticals, Karachi. At the time of issuance of registration letter following typographical error are found in working paper & minutes. Details are as under:-

Existing Composition	**Correct Composition**
Arteka Tablet Each co-blister contains:- 3 tablets, each containing Sulfadoxine …….500mg Pyrimethamine……...25mg **3** tablets, each containing Artesunate ……100mg (Anti Malarial)	Arteka Tablet Each co-blister contains:- 3 Tablets: Each tablet contains:- Sulfadoxine …….500mg Pyrimethamine……...25mg **6** Tablets: Each tablet contains:- Artesunate ……100mg (Anti Malarial)

Decision: Registration Board approved Arteka Tablet for registration.

b. M/s PharmEvo (Pvt.) Ltd, Karachi

M/s PharmEvo (Pvt.) Ltd, Karachi has informed that they have been granted registration of Xcept 10mg Tablet, Reg. No.076157 by the Registration Board in 239th meeting but due to typographical error of applied price they have submitted subsequent corrected price. Firm has submitted that they were granted registration letter with MRP below than Price Advisory Committee approved price, so they cannot be rational for their commercial activity. Details are as under:-

S. No.	**Existing MRP & Pack size**	**Reg. No.**	**Correct MRP & Pack size**

(I)	(II)	(III)	(IV)
(i)	Xcept 10mg Tablet Each tablet contains:- Rivaroxaban ……10mg (Manufacturer's Specification) **Pack Size : 10's** **MRP : Rs.1714.00** **Pack Size : 30's** **MRP : Rs.5142.00**	076157	Xcept 10mg Tablet Each tablet contains:- Rivaroxaban ……10mg (Manufacturer's Specification) **Pack Size : 10's** **MRP : Rs. 5023.00** **Pack Size : 30's** **MRP : Rs.13864.00**

Firm has requested that they may be granted MRP as fixed by the DAC.

Decision: Registration Board deferred the case for personal hearing / presentation by the firm in its next meeting.

Case No 35: Products Approved by Registration Board in 239th Meeting subject to Evaluation of Dossiers.

The Registration Board in 239th meeting had considered the following registrations of M/s Reign Pharmaceuticals PCSIR KLC, Karachi and approved subject to condition mentioned against each:-

S. No.	Name of drug(s) & Composition	Proposed Pack size	Demanded Price	Date of application, Diary No. & Form	Remarks
1	Montikol 10mg Tablet Each tablet contains: Montelukast Sodium…….10 mg (Is oral leukotriene receptor antagonist)	As per PRC	As per PRC	21-05-2013 Dy.No.528 Form-5 Rs.20,000/-	Approved However the Registration Board advised the registration sections to again review the Registration Dossiers before issuance of Registration letters

2	Fluben 100mg Capsule Each capsule contains: Flurbiprofen……100 mg (NSAID)	As per PRC	As per PRC	21-05-2013 Dy.No.531 Form-5 Rs.20,000/-	Approved However the Registration Board advised the registration sections to again review the Registration Dossiers before issuance of Registration letters
3	Omzol 40mg Capsule Each capsule contains: Omeprazole……..40 mg (Proton pump inhibitor)	As per PRC	As per PRC	21-05-2013 Dy.No.532 Form-5 Rs.20,000/-	-Do-
4	Omzol 20mg Capsule Each capsule contains: Omeprazole……..20 mg (Proton pump inhibitor)	As per PRC	As per PRC	21-05-2013 Dy.No.530 Form-5 Rs.20,000/-	-Do-
5	Fosfon 250mg/5ml oral Suspension Each 5ml contains: Fosfomycin Sodium…….250 mg (Broad Spectrum Antibiotic of macrolide group)	As per PRC	As per PRC	21-05-2013 Dy.No.533 Form-5 Rs.20,000/-	Approved However the Registration Board advised the registration sections to again review the Registration Dossiers before issuance of Registration

					letters
6	Renflox 250mg/5ml Dry Powder Suspension Each 5ml contains: Ciprofloxacin ….250 mg (Antibiotic)	As per PRC	As per PRC	21-05-2013 Dy.No.535 Form-5 Rs.20,000/-	-Do-
7	Zinkid 20mg/5ml Susp. Each 5ml contains: Zinc Sulphate ……20 mg (Astringent (for zinc deficiency)	As per PRC	As per PRC	21-05-2013 Dy.No.534 Form-5 Rs.20,000/-	-Do-
8	DuMol Syrup Each 5ml contains: Paracetamol…….120 mg (Analgesic and antipyretic)	As per PRC	As per PRC	21-05-2013 Dy.No.536 Form-5 Rs.20,000/-	Approved. The Board advised to change brand name. The Registration Board also advised the registration sections to again review the Registration Dossiers before issuance of Registration letters
9	Nuprin 100mg Suspension Each 5ml contains: Ibuprofen……100 mg (Analgesic and antipyretic NSAID)	As per PRC	As per PRC	21-05-2013 Dy.No.537 Form-5 Rs.20,000/-	Approved

Shortcomings were communicated to the firm which has now been rectified.

Decision: Registration Board approved above products (S.No.1-9) for registration.

Case No.36 Grant of Registration for Export Purpose - Contract Manufacturing.

Following firms have requested for registration of drug for export purpose only, on basis of contract manufacturing.

Contract giver	Contract manufacturer	Name of drug(s) & Composition	Date of application, Diary No. & Form
M/s Nabiqasim Industries, Karachi	M/s Surge Labs, Sheikhupura	Transic Injection 250mg Each ampoule contains:- Tranexamic Acid ……250mg	20-08-2013 548 Form-5 Rs.20,000/-
-do-	-do-	Transic Injection 500mg Each ampoule contains:- Tranexamic Acid ……500mg	20-08-2013 549 Form-5 Rs.20,000/-
M/s Getz Pharma, Karachi	M/s Opal Labs, Karachi	Loraget Syrup 5mg/5ml Each 5ml contains:- Loratadine …….5mg	31-07-2013 514 Form-5 Rs.20,000/-

Decision: Registration Board approved above products for contract manufacturing exclusicely for export purpose.

Case No.37 Registration of Drugs for export purpose-Not me too Drugs.

a. M/s Getz Pharma, Karachi:

Registration Board in its 241st meeting held on 23rd December, 2013 considered request of M/s Getz Pharma, Karachi for registration of following drugs for export purpose which are not registered in Pakistan. After thorough discussion Registration Board decided to advise the firm for provision of import order from the importing country duly approved by the regulatory authority of importing country.

S. No.	Name of drug(s)
1.	Montizal Tablets 10mg + 5mg Each tablet contains:- Montelukast Sodium eq. to Montelukast…..10mg Levocetirizine Dihydrochloride…….5mg
2.	Montigetzine Tablets 10mg + 5mg Each tablet contains:- Montelukast Sodium eq. to Montelukast…..10mg Levocetirizine Dihydrochloride……..…5mg

Now M/s Getz Pharma, Karachi has informed that after getting registration for export purpose from DRAP then registration process in exporting countries will be initiated and it is mandatory requirement for a product to be registered in the country of origin. Due to this reason the import order cannot be furnished at this point of time as they do not have marketing authorization from importing countries. However, they will submit the import order once they get registration approval / marketing authorization from the importing countries.

Decision: Registration Board advised firm to provide original import order.

b. M/s Pharmatec Pakistan (Pvt.) Ltd, Karachi:

M/s Pharmatec Pakistan (Pvt.) Ltd, Karachi has informed that they have granted registration of following drugs for export purpose which are not me too but registered for export purpose only with different brand name. Now they intend to export these formulations to Combodia & Afghanistan with different brand name. Details are as under:-

S. No.	Existing brand name for export purpose & Reg. No.	Proposed Brand name and formulation
1.	Fludol DM Syrup Each 5ml contains:- Dextromethorphan HBr 10mg Phenylephrine HCl BP….5mg Chlorpheniramine Maleate 2mg Reg. No.004019-EX	Reltus DM Syrup Each 5ml contains:- Dextromethorphan HBr …10mg Phenylephrine HCl BP…..5mg Chlorpheniramine Maleate. 2mg
2.	Fludol P + Syrup Each 5ml contains:- Paracetamol……120mg Phenylephrine HCl …5mg Chlorpheniramine Maleate 1mg Reg. No.004099-EX	Reltus C&F Syrup Each 5ml contains:- Paracetamol ……..120mg Phenylephrine HCl BP…..5mg Chlorpheniramine Maleate. 1mg

Decision: Registration Board advised firm to provide original import order.

Case No.38: Change in quantity of activated carbon (filter aid) in infusions-M/s Otsuka Pakistan Ltd, Baluchistan

M/s Otsuka Pakistan Ltd, Baluchistan has informed that they use activated carbon during manufacturing of their following IV solution and it is filtered out by making a filter bed in Neo Filter during the process. It is not a part of formula or label claim and it is not used by any other IV manufacturer in Pakistan.

S. No.	Reg. No.	Name of drug(s)
1.	018360	Pladex-5 I.V Infusion
2.	003031	Plasaline I.V Infusion
3.	007782	Ringolact Injection
4.	011224	Ringolact-D Injection
5.	011225	Plabolyte-M Injection
6.	018800	Pan-Amin G Injection
7.	018361	Pladex-10 I.V Infusion
8.	003028	Pladexsal Injection
9.	018362	Pladexsal ½ Injection
10.	005120	Aminovel 600 Injection
11.	027215	Aminoleban Injection
12.	048516	Sodium Chloride Ampoule
13.	048514	Potassium Chloride Ampoule
14.	048515	25% Dextrose Ampoule

They have further informed that as per suggestion of their principal (M/s Otsuka Pharmaceutical Factory Japan), they have revised percentage 0.025% (0.25gm/l) for filter aid during process of above mentioned drugs. Firm was asked to provide the related stability study data and justification for reduction in quantity of activated carbon on scientific grounds which

were referred for expert opinion to 03 experts. Details of recommendations of the experts as follows.

Prof. Dr. Rafi-uz-Zaman Saed-ul-Haq, Dean University of Lahore, Islamabad.	**Dr. Amanullah Khan,** **Director, Drug Testing Laboratory, Government of Baluchistan, Quetta.**	**Mr. Abdul Razzak Jawinda, Director, Drug Testing Laboratory, Government of Sindh, Karachi.**
The accelerated study of the above mentioned products passed all the required tests. Therefore the accelerated study of Otsuka Pakistan Ltd. in reference to the reduction of the activated carbon is recommended for acceptance.	Through the stability data provided by M/s Otsuka Pakistan Ltd, in respect of their products. Ringolcat Injection, Pan-Amin G Injection and Pladex-10 IV Infusion it has been observed that the real time stability studies have been conducted for only two years (24 months). Since the expiration dating is based on the real time stability studies therefore, only two years (24 months) shelf-life for the above mentioned products may be recommended.	The firm has introduced modern system including new GMP Compliance HVAC system alongwith its controls, new advanced filling sealing plant for infusion and up graded the whole plant from Raw material handling to filling/sealing with new prefabricated clean room panels. Reduction of active carbon is based on the environmental aspects. Therefore, he recommends the reduction of the active carbon from 0.07% to 0.025% based on the stability data by the firm.

Comments of experts are placed before Registration Board for deciding the firm's request. Firm has requested to give presentation on their request.

Decision: Dr.Muhammad Aslam, Director M/s otsuka appeared before the Board and explained their point of view about stability data provided by the firm. Members of the Board deliberated that as activated carbon is not the part of composition of all products, thus Board acceded firm's request for reduction of active carbon from 0.07% to 0.025% in 14 formulations of M/s Otsuka, Hub as per their existing expiry date.

Case No. 39: Change of bulk import source – Telfast –D Tablets – M/s Sanofi – Aventis Pakistan Ltd, Karachi

Registration Board in 239th meeting permitted M/s Sanofi Aventis, Karachi for import of Telfast-D tablet from M/s Sanofi Aventis, Kansas, USA in tablet form and then further processing to finished form in M/s Sanofi-Aventis, Karachi for 02 years time. However, the Board advised firm to provide legalized COPP of the source and authorized its chairman to accord approval for issuance of regsirtation letter. The Board further advised the firm to apprise them about future strategy for transfer of technology to Pakistan in 02 months time.

During meeting Mr.Muhammad Idress incharge QA and Mr.Jaffar Zaida, Regulatory Officer, SITE appeared before the Board and presented that they have tried to make arrangements for local manufacturing of the product but their principal did not agree to the proposal as M/s Sanofi Aventis, Arkansas, USA is the only site of M/s Sanofi Aventis for providing Telfast-D tablets across the globe.

Now M/s Sanofi – Aventis Pakistan Ltd, Karachi has requested for change of bulk import source for their already registered drug Telfast - D Tablet, Reg. No. 023617. Existing and proposed bulk import sources are as under:-

Existing Bulk import source	**Proposed Bulk import source**
M/s Sanofi Aventis U.S LLC, 10236 Marion Parke Drive, Missouri, Kansas City 64134-0708, USA	Sanofi Winthrop Industries, 56 route de choisy-au-Bac Compiegne 60205, France

Firm has submitted following documents to support their request.

i) Form-5
ii) Copy of registration letters along with renewal status
iii) Original legalized Certificate of Pharmaceutical Product from Australian TGA.
iv) Original leglalizd GMP Certificate
v) Fee Rs.100,000/- for the purpose

Scrutiny of documents revealed that COPP of the product is from australin TGA and firm confirmed that product of new site is not available in country of manufacture i.e. France.

Decision: Registration Board discussed in detail matter of non-availability of drug of the manufacturer in France and decided to call firm's representatives for presentation of their case in next meeting.

Case No.40: Extension in reduction of shelf life of Thyroxin Tablet, Reg. No.000374.

Registration Board in its 234th held on 23rd & 24th July, 2012 had reduced shelf life of one year (previously shelf life of two years have been assigned to the product). This permission of one year shelf life was for six months only. The Board also directed to resolve the issue of stability during six months under intimation to this Board.

Now M/s GlaxoSmithKline Pakistan Ltd, Karahci have requested for extension in permission for six (06) months to continue production of Thyroxine Tablet, Reg. No.000374 with 1 (one) year shelf life. They further submitted that schedule for upgradation of manufacturing facility, project plan and stated that they anticipate completing manufacturing facility updradaton and commencement of commercial supplies of Thyroxine Tablet, Reg. No.000374 with 18-24 months shelf life 3rd / 4th quarter, 2014 subject to successful stblity result.

Decision: Registration Board showed its deep concern about non-availability of Thyroxine Tablet despite of reduction in shelf life as per demand of the firm. However, the Board again acceded firm's request for manufacturing of Thyroxine Tablet, Reg. No.000374 with one year shelf life for further six months with strong advise to ensure free availability of the drug across the country.

Case No.41: Transfer from temporary import to local manufacturing - M/s OBS Pakistan (Pvt.) Ltd, Karachi

Following products of M/s OBS Pakistan (Pvt.) Ltd, Karachi were initially registered for local manufacturing. Later on, firm was granted permission for temporary import of these drugs on 01.04.2000 and then extended. Last extension was granted on 13.12.2012 for a period of 18 months with the direction to firm to develop facility for manufacturing of these products. Details are as under:-

S. No.	Reg. No.	Name of Drug(s)	Existing source
1.	012094	Orgametril Tablets Each tablet contains:- Lynostrenol……5mg	NV Organon, Kloosterstraat, 6,5349 AB OSS, Netherlnds
2.	020050	Livial 2.5mg Tablet Each tablet contains:-	-do-

		Tibolone …….2.5mg	
3.	026397	Remeron 30mg Tablet Each tablet contains:- Mirtazapine …….30mg	-do-

Now as per direction of Registration Board firm has develop their own facility i.e. Tablet hormone for manufacturing of these drugs and requested for change of status from temporary import to complete local manufacturing at their own plant i.e. C/14, Mangopir Road, Karachi. Firm has also submitted undertaking for conduction of stability studies for above mentioned products before sale of drug.

Decision: Registration Board acceded firm's request for local manufacturing of above drugs in their designated areas. The Board advised the manufacturer to perform pharmaceutical development, stability studies, validation of manufacturing process and method of analysis as per its commitment before sale of drug. The Board also decided to follow same principal in cases in which manufacturing site will be changed.

Case No. 42: Contract Manufacturing of Drugs.

DRAP's Policy Board in its 1st meeting on 21-01-2013 approved contract manufacturing policy. Later on, Policy Board considered concerns of stakeholders (Pharma Bureau and PPMA) in its 04th meeting on 23-10-2013 and resultantly approved the amendments in Contract Manufacturing Policy. Draft notification was published vide SRO.1086 (I)/2013 dated 02-01-2014 for comments / suggestions. Various stakeholders submitted suggestion / objection on the draft notification. These suggestions were then considered by DRAP's Policy Board in 05th meeting on 16-01-2014 and the Board amended the Rule 20-A and Schedule-H of the Drugs (Licensing, Registering and Advertising) Rules, 1976. The amended rules have been vetted by Ministry of Law, Justice and Human Rights and has been issued vide SRO 152(I)/2014 dated 04-03-2014. Copy of policy is as under:

TO BE PUBLISHED IN PART-II OF THE GAZETTE OF PAKISTAN

Government of Pakistan
Drug Regulatory Authority of Pakistan
Ministry of National Health Regulation Services and Coordination
****

Islamabad, the 05th March, 2014.

NOTIFICATION

S.R.O.152(I)/2014: In exercise of the powers conferred by section 23 of the Drug Regulatory Authority of Pakistan Act, 2012 (XXI of 2012), read with clause (a) of section 7 thereof and section 43 of the Drug Act, 1976 (XXXI of 1976), the Drug Regulatory Authority of Pakistan, with the approval of the Federal Government is pleased to direct that the following further amendments shall be made in the Drugs (Licensing, Registering and Advertising) Rules, 1976. The same having been previously published vide Notification No.SRO1086 (I)/2013 dated 02nd January, 2014 as required by sub-section (3) of the section 43, namely:-

In the aforesaid Rules,-

(1) for rule 20 A, the following shall be substituted, namely:-

"20A. Contract manufacture.- (1) Manufacture or analysis on contract is permissible on behalf of a licensee or of a licensed pharmaceutical company whose products are registered for sale in Pakistan or as may be registered by the Registration Board and for the purposes including the following categories, namely:-

(a) for encouraging local production of imported drugs;

(b) for meeting export requirements of a local manufacturer or a foreign pharmaceutical company, provided that a drug manufactured under this arrangement shall not be sold in Pakistan; and

(c) as a special case and for genuine reasons, including break down, renovation, up-gradation, as may be determined by the Registration Board, provided that the contract manufacturing under this clause shall be for a period not exceeding thirty months;

(2) The provisions of sub-rule (1) shall be subject to the following conditions, namely:-

(a) The Provisions of rule 29 *mutatis mutandis* apply;

(b) Contract manufacturing shall be allowed only on the basis of similar category of drugs including human to human, veterinary to veterinary, cotton to cotton, medical devices to medical devices or as the case may be, etc;

(c) Contract manufacturing of controlled drugs (narcotic drug or psychotropic substances or precursor chemicals) shall not be allowed;

(d) Contract manufacturing shall also be subject to the conditions laid down in Schedule-H."; and

(2) for Schedule-G, the following shall be substituted, namely:-

"SCHEDULE H

1. Contract production and analysis.-

1.1. Contract of manufacture or analysis shall be undertaken only by a manufacturer that holds a valid drug manufacturing licence and the contract acceptor shall have adequate facilities, knowledge, experience and competent personnel to satisfactorily carry out the work ordered by the contract giver.

1.2. General- contract production and analysis shall be correctly defined, agreed and controlled in order to avoid misunderstandings that could result in a product or work or analysis of unsatisfactory quality.

1.3. All arrangements for contract manufacture and analysis, including any proposed changes in technical or other arrangements, shall be in accordance with the regulation in force and condition of registration of the drug concerned if it is for sale in Pakistan. In case of a foreign pharmaceutical company getting its products manufactured in Pakistan the manufacturing specification shall be the responsibility of the contract giver however a copy of such specifications shall be provided to the Registration Board for the purpose of information.

1.4. There must be a written contract (drawn by the people having suitable knowledge in pharmaceutical technology, analysis and cGMP requirements) between the contract giver and the contract acceptor that shall clearly establish the duties of each party. The quality management system of contract giver must clearly state responsibilities and the way in which the authorized person of each party shall exercise his full responsibility in releasing each batch of product for sale or issuing the certificate of analysis and a copy of such a contract shall be supplied to the Registration Board.

1.5. The contract shall have explicit provision for auditing the facilities of the contract acceptor and contract giver at any time to ensure that manufacturing or analysis of contracted products are being done as per specifications and the contract.

1.6. In the case of contract analysis, final approval for release must be given by the authorized persons.

2. Contract giver.-

2.1 The contract giver before submission of application for contract manufacturing permission shall be responsible for assessing the legality, suitability and competence of the contract acceptor in successfully carrying out the work or tests required and for ensuring that the principles of good manufacturing practices are followed. This assessment report shall be a part of contract manufacturing or analysis application submitted to the Registration Board.

2.2 Upon receiving of contract manufacturing or analysis application, the Registration Board may cause to inspect the manufacturing or analysis facility of contract acceptor by

a panel of experts as determined by the Board to verify the report submitted by contract giver, evaluation of cGMP compliance for manufacturing, quality control, validation, stability and storage facilities of both contract giver and contract acceptor etc.

2.3 The contract giver shall provide the contract acceptor with all the information necessary to carry out the contracted operations correctly in accordance with the registration and any other legal requirements and the contract giver shall ensure that the contract acceptor is fully aware of any problem associated with the product, work or tests that might pose a hazard to premises, equipment, personnel, other materials or other products. Contract giver shall ultimately be responsible to ensure that processes are in place and complied with during contract manufacturing period and will inform Registration Board in case of any breach of any facility of the contract.

2.4 The contract giver shall ensure that all processed products and materials delivered by the contract acceptor comply with their specifications or that the product has been released by the authorized persons.

2.5 Contract manufacturing shall be allowed for five registered products per section as approved by the Central Licensing Board only up to maximum thirty products, on part of contract giver, excluding drugs registered for export purpose.

3 Contract acceptor.-

3.1 The contract acceptor must have adequate premises, equipment, knowledge, facilities, experience and competent personnel to carry out satisfactorily the work ordered by the contract giver.

3.2 The contract acceptor shall not pass to a third party any of the work entrusted to him under the contract without the written consent of the contract giver and arrangements made between the contract acceptor and any third party shall ensure that the manufacturing and analytical information is made available in the same way as between the original contract giver and contract acceptor.

3.3 The contract acceptor shall refrain from making any change outside the terms of the contract or any activity that may adversely affect the quality of the product manufactured, packed and analyzed for the contract giver.

3.4 Any change required in manufacturing process, raw or packaging material by the contract acceptor shall be made through a change control mechanism approved by both

contract giver and acceptor and properly validated through required processes like stability testing, validation etc. before the product is produced after change and is released for sale.

3.5 Contract acceptor is responsible for keeping the record of production and analysis. Both the contract giver and the contract acceptor shall retain sufficient number of samples of each batch to allow double testing of product, till the expiry of the product for reference. The record shall be made accessible to the contract giver or Registration Board or any other investigating agency etc. at all times for the purpose of compliance to law.

3.6 Contract manufacturer shall submit details of production of each batch of drug manufactured under contract on Form-7 to the Registration Board quarterly, as required by Drugs (Licensing, Registering and Advertising) Rules, 1976.

3.7 In case of change of source of raw material and machinery by the contract manufacturer, proper validation and stability study shall be conducted and recorded for cGMP compliance.

4 The contract.-

4.1 A contract shall be drawn up between the contract giver and contract acceptor that specify their respective responsibilities relating to the manufacture and control of the product and technical aspects of the contract shall be drawn up by competent persons having suitable knowledge in pharmaceutical technology, analysis and good manufacturing practices. All arrangements for production and analysis must be in accordance with the registration or marketing authorization in country of origin in case of foreign pharmaceutical company and agreed by both parties.

4.2 The contract shall specify the way in which the authorized person releasing the batch for sale ensures that each batch has been manufactured in, and checked for, compliance with the requirements of the marketing authorization.

4.3 The contract shall clearly describe the person responsible for knowledge management, technology transfer, quality, supply chain, purchasing, testing and releasing of materials (active and inactive) and for undertaking production and quality controls, including in-process controls, and the person responsibile for sampling and analysis and in the case of contract analysis, the contract shall state whether or not the contract

acceptor shall take samples at the premises of the manufacturer. Contract shall also clearly describe the mechanism for any change in all of the above responsibilities.

4.4 The contract shall clearly specify the mechanism for keeping of record pertaining to manufacturing, analytical, sale and reference samples by contract acceptor. It shall also specify the availability of the aforementioned record and samples to the contract giver (the samples if required shall be other than the retention samples). All records pertaining to the contract manufactured product will be accessible for assessing the quality of a product in the event of a complaint or a suspected defect. Recall procedure must be clearly mentioned, if required.

4.5 The contract shall describe the handling of starting materials, intermediate and bulk products and finished products if they are rejected and it shall also describe the processing of information if the contract analysis shows that the tested product must be rejected.

4.6 The contract shall include an SOP for pharmacovigilance and the responsibilities of both parties in case of any Adverse Drug Reaction (ADR) and reporting of the same to the Drug Regulatory Authority of Pakistan.

4.7 The SOP for recall of defective products shall also be part of the contract that clearly defines the responsibilities of both parties and a comprehensive recall procedure.

5 Miscellaneous.-

5.1 The specifications for drugs shall be in accordance with the Drugs (Specification) Rules, 1978.

5.2 Fee for contract manufacturing permission will be fifty thousand rupees per product. However, in order to promote export, fee will be twenty thousand rupees per product for grant of registration for export purpose.

5.3 Contravention to any provision of the Drug Regulatory Authority of Pakistan Act, 2012, Drugs Act, 1976 and rules made there under including Schedule-H, or any condition of registration by the contract giver or contract acceptor shall be liable to the cancellation of contract manufacturing registration by the Registration Board.

5.4 If any drug manufactured on contract basis is found or reported in contravention of any of the provisions of Drugs Act, 1976 and rules made thereunder, then both the contract giver and acceptor shall be liable to any action under the said Act and rules.

5.5 Apart from the labeling requirements as per Drug (Labeling and Packaging) Rules 1986, name, address, and DML number of contract giver (if manufacturer), in case of contract manufactured drugs registered for import, pharmaceutical company name and address of contract giver will also appear on all labels and packaging materials.

5.6 Contract manufactured products registered for export purpose will not be permitted for sale in Pakistan. In case of violation contract manufacturing permission will be withdrawn in addition to other legal proceedings. Moreover exporter will also furnish confirmation about receiving of stock in importing country after export.

5.7 Change of contract manufacturer shall be allowed during contract period only on genuine reasons including *Force Majeure*, the fee for this will be fifty thousand rupees per product. New contract manufacturer shall ensure the stability and validation of the product and all other quality assurance specifications. If the previous contract manufacturer is still manufacturing the drug after change of its status, then it would be treated as spurious drug and would be dealt with under relevant provision of the Drugs Act, 1976 or the Drug Regulatory Authority of Pakistan Act, 2012.".

F.No.1-13/2013-DDG (Reg-I)

Case No. 43: Extension in Contract Manufacturing Permission:

Following products were deferred by Registration Board in 238th and 240th meeting, as these products were not convered in then contract manufacturing policy. As the policy has been amended, thus these are submitted before Registration Board.

S. No.	Applicant	Contract manufacturer	Reg. No.	Name of drug(s) & Composition	Date of application, Diary No. & Form	Category
1.	M/s Novartis Pharma, Karachi 238th meeting	M/s Indus Pharma, Kar.	000175	CacC-1000 Vitamin C Injection Each 10ml contains: Calcium Glucono galacto gluconate (Calcium glubionate)…….1375 mg Vitamin C (Ampoule grade)……550 mg	01-04-2013 Dy.No. 1148 Form-5 Rs.50,000/-	
2.	-do-	-do-	001584	Hydergine Injection Each ml contains: Co-dergocrine Mesylate…….0.3 mg	01-04-2013 Dy.No. 1148 Form-5 Rs.50,000/-	
3.	-do-	-do-	001954	Methergin Injeciton Each 1ml contains: Methylergometrine maleate……..0.2 mg	01-04-2013 Dy.No. 1148 Form-5 Rs.50,000/-	
4.	-do-	-do-	001582	Syntocinon Injection Each ml contains: Synthetic Oxytocin……..5 IU	01-04-2013 Dy.No. 1148 Form-5 Rs.50,000/-	
5.	-do-	-do-	004791	Tandegyl Injection Each 2ml contains: Clemastine (As hydrogen fumarate) ……..2 mg Ethanol……8.2% v/v	01-04-2013 Dy.No. 1148 Form-5 Rs.50,000/-	
6.	-do-	-do-	004311	Voltral Injection Each 3ml ampoule contains:	01-04-2013 Dy.No.	

				Diclofenac sodium…75mg	1148 Form-5 Rs.50,000/ -	
7.	M/s GSK, Karachi 238th meeting	M/s Pharmatec, Karachi	000817	Panadol 500mg Tablet Each tablet contains: Paracetamol BP……500 mg (NSAID)	05-04-2010 Form5 Rs.8000/- 15-04-2013 Dy.No. 224 Rs.42,000/ -	
8.	-do-	-do-	012473	Panadol Extra Tablet Each tablet contains: Paracetamol BP…….500.00mg Caffeine BP……..65.00mg (NSAID + Anti migraine)	15-04-2013 Form5 Rs.8000/- 15-04-2013 Dy.No. 224 Rs.42,000/ -	
9.	-do-	-do-	008492	Children's Panadol Liquid Each 5ml contains: Paracetamol BP …….160.00 mg (NSAID)	15-04-2013 Form5 Rs.8000/- 15-04-2013 Dy.No. 224 Rs.42,000/ -	
10.	-do-	-do-	008556	Children's Panadol Drops Each 0.8ml contains: Paracetamol BP…….80.00mg	17-3-2010 Form5 Rs.8000/- 15-04-2013 Dy.No. 224 Rs.42,000/ -	
11.	-do-	-do-	013113	Panadol CF Tablets Each tablet contains: Paracetamol……500.00 mg Pseudoephedrine HCl…..60.00 mg Chlorpheniramine maleate……..4.00 mg (cough & cold preparation)	15-04-2013 Form5 Rs.8000/- 15-04-2013 Dy.No. 224 Rs.42,000/ -	Controlle d Drug

12.	-do-	-do-	000813	Philips Milk of Magnesia Magnesium hydroxide……..…7.9% w/w	15-04-2013 Form5 Rs.8000/- 15-04-2013 Dy.No. 224 Rs.42,000/-	
13.	M/OBS Pharm, Karachi	M/s Highnoon Lab. Lahore	019173	Ovafin 50mg Tablet Each tablet contains: Clomifene Citrate …50 mg	12-04-2013 Dy.No.63 Form-05 Rs.42,000/- 06-05-2010 Rs.8000/-	
14.	M/s Bayer Pharmaceuticals, Karachi	M/s Macter Int. F-216, Kar.	001040	Benerva 100mg Dragees Each sugar coated tablet contains: Thiamine hydrochloride….100 mg	12-04-2013 Dy.No.67 Form-05 Rs.42,000/-	
15.	-do-	-do-	001042	Ephynal 100mg Dragees Each tablet contains: Vitamin E……100 mg (100IU)	12-04-2013 Dy.No.68 Form-05 Rs.42,000/-	
16.	-do-	-do-	010102	Supradyn N Dragees Vitamin A……..3333 I.U Vitamin D2…..500 I.U Vitamin B1…….20 mg Vitamin B2…….5 mg Vitamin B6 ……..10 mg Vitamin B12…….5 mcg Niacinamide…….50 mg Calcium D-Pantothenate……..11.6 mg Ascorbic Acid……150 mg Biotin ……..0.25 mg Folic Acid……..1 mg Vitamin E……10 mg Calcium……..50 mg Magnesium……..18.1 mg Iron Sulphate……..50 mg Phosphorous…….25.5 mg Copper ……1 mg	12-04-2013 Dy.No.69 Form-05 Rs.42,000/-	

				Manganese……..0.5 mg Zinc …….0.5 mg Molybdenum…….0.1 mg		
17.	-do-	-do-	001050	Rovigon Dragees Each tablet contains: Vitamin A…….30,000 IU Vitamin E……70 mg	12-04-2013 Dy.No.66 Form-05 Rs.42,000/ -	
18.	-do-	-do-	014726	Berocca Tablet Each tablet contains: Vitamin B1……..15 mg Vitamin B2……15 mg Vitamin B6……10 mg Vitamin B12…….10 mcg Vitamin C…….500 mg Biotin ……..150 mcg Niacinamide……50 mg Pantothenic Acid….23 mg Calcium……100 mg Magnesium…….100 mg	12-04-2013 Dy.No.70 Form-05 Rs.42,000/ -	
19.	-do-	-do-	009776	Benical Syrup Each ml contains: Dextromethorphan hyrrobromide……2 mg Pseudoephedrine HCl..4mg Chlorpheniramine maleate……..0.40 mg	12-04-2013 Dy.No.65 Form-05 Rs.42,000/ -	
20.	-do-	-do-	017880	Supradyn Effervescent Tablet Each tablet contains: Vitamin A……..25000 IU In form of vitamin Apalmitate powder, type…….250 mg In form of vitamin A palmitate power, type500……..66 mg Vitamin D……..500 IU In form of vitamin D2 powder type 50 CWS……12,000mg Vitamin B1……..20 mg Form of thiamine	12-04-2013 Dy.No.64 Form-05 Rs.42,000/ -	

				mononitrate vitamin B2……5.0 mg In form of riboflavin Vitamin B6…….10.0 In form of pyridoxine hydrochloride vitamin B12…….5.0 mg In form of vitamin B12 0.1% type SD Necotinamide……50.0mg Calcium-D-Panthothenate……11.6 mg In form of a mg0/PVP granulate 67% Consisting of: Calcium-D-Panthothenate Magnesium oxide Polyvinylyrrolidone Ascorbic acid…….150.0 mg D-Biotin……..0.25 mg Folic acid 100% ….1.0 mg Vitamin D (dl-a-tocopherol acetate)……10.0 mg		
21.	M/s OBS, Karachi	M/s Pharmatec, Pak. Kar.	017789	Orgesic Injection Each ml contains: Buprenorphine HCl…0.33 mg	15-04-2013 Dy.No.55 Form-05 Rs.42,000/-	Controlled Drugs
22.	M/s Nabiqasim kar.	M/s Surge Lab. Sheikhupura. Kar.	030288	Mecobal Injection Each ml ampoule contains: Mecobalamin …..500mcg	15-04-2013 Dy.No.131 Form-05 Rs.42,000/- Rs.8000/- 28-9-2010	Associated company
23.	-do-	-do-	055633	Zucloact 100mg/2ml Inj. Each 2ml ampoule contains: Zuclopenthixol acetate……..100 mg	15-04-2013 Dy.No.129 Form-05 Rs.42,000/- Rs.8000/- 28-9-2010	Associated company

24.	-do-	-do-	055634	Zuclodept 200mg Inj Each ml contains: Zuclopenthixol decanoate……200 mg	15-04-2013 Dy.No.128 Form-05 Rs.42,000/- Rs.8000/- 28-9-2010	Associated company
25.	-do-	-do-	055630	Erabact 200mg Injection Each 100ml contains: Ciprofloxacin HCl eq. to Ciprofloxacin ….200 mg	15-04-2013 Dy.No.125 Form-05 Rs.42,000/- Rs.8000/- 28-9-2010	Associated company
26.	-do-	-do-	055629	Hifer 100mg/5ml Inj. Each 5ml ampoule contains: Iron Sucrose…100 mg	15-04-2013 Dy.No.120 Form-05 Rs.42,000/- Rs.8000/- 28-9-2010	Associated company
27.	-do-	-do-	055628	Warior 500mg Infusion Each 100ml contains: Levofloxacin hemihydrates eq. to Levofloxacin..500mg	15-04-2013 Dy.No.116 Form-05 Rs.42,000/- Rs.8000/- 28-9-2010	Associated company
28.	M/s Bayer Pak. Pvt. Ltd. Kar.	M/s Zafa Pharma, Kar.	023008	Baydal Syrup Each 5ml contains: Cetirizine dihydrochloride……5mg	15-04-2013 Dy.No.222 Form-05 Rs.42,000/-	Line extension
29.	M/s Getz, Karachi	M/s Opal Lab. Kar.	027212	Allerget 5mg Syrup Each 5ml contains: Loratadine…….5 mg	12-04-2013 Dy.No.11 Form-05 Rs.42,000/- Rs.8000/- 16-4-2010	
30.	-do-	-do-	050646	Ferotein 800mg Syrup Each 15ml contains: Iron Protein Succinylate……..800 mg	12-04-2013 Dy.No.16 Form-05 Rs.42,000/-	

					Rs.8000/- 24-5-2010	
31.	-do-	-do-	020590	Lilac Syrup 67g/100ml Each 5ml contains: Lactulose……3.35g	12-04-2013 Dy.No.17 Form-05 Rs.42,000/- Rs.8000/- 16-4-2010	
32.	M/s Merck Pvt. Ltd, Kar.	M/s Bosch Pharmaceuticals, Kar.	028625	Mercip INV Infusion 200mg Each vial contains: Ciprofloxacin lactate eq. to Ciprofloxacin …200 mg	15-04-2013 Dy.No.110 Form-05 Rs.42,000/-	
33.	M/s Merck Pvt. 7, Jail Road, Quetta	M/s Merck Pharma, F-126, Kar.	020244	Multibionta M Capsule Each soft Gelatin Capsule contains: Vitamin B1 (thiamine mononitrate)…..10 mg Vitmain B2 (riboflavin)……..10 mg Vitmain B6 (Pyridoxine Hydrochloride)…5 mg Vitmain B12(Cyanocobalamin)…….8 mcg Vitmain C(Ascorbic acid)……100mg Folic acid…….200 mcg Nicotinamide…..30 mg Calcium D-Pantothenate……20 mg Vitmain E (DL- Alpha Tocopheryl Acetate)……10 mg Vitmain A (Palmitate)…….5500 IU Vitmain D (Cholecalciferol)..500 IU Iron As ferrous Gluconate dehydrate…..10 mg Manganese as manganese sulfate……500 mcg Magnesium as mangnesium Oxide..5mg	15-04-2013 Dy.No.115 Form-05 Rs.42,000/- Rs.8000/- 01.06.2010	

				Potassium as potassium sulphate……1 mg Copper as copper sulphate…….200 mcg Calcium as calcium carbonate……..20 mg Zinc as zinc sulphate heptahydrate……..1.5 mg Iodine as potassium iodide……150 mcg		
34.	-do-	-do-	039495	Polybion Z Capsule Each soft gelatin capsule contains: Zinc as zinc sulfate…….22.5mg Vitamin E Dl-Alpha tocopheryl acetate…30 IU Vitamin C Ascorbic acid…….500 mg Folic acid……150 mcg Vitamin B1 (thiamin mononitrate)…..15 mg Vitamin B2 (Riboflavin)……15 mg Nicotinamide …….100 mg Vitamin B6 pyridoxine Hydrochloride…….20 mg Vitamin B12 Pyridoxine hydrochloride…….20 mg Vitamin B12 (Cyanocobalamin)…12 mg Pantothenic acid (Calcium d-Pantothenate)…….20 mg	15-04-2013 Dy.No.114 Form-05 Rs.42,000/- Rs.8000/- 01.06.2010	
35.	-do-	-do-	008754	Evion 400mg Capsule Each soft gelatin capsule contains: DL-Alpha Tocopheryl acetate……..400 mg	15-04-2013 Dy.No.113 Form-05 Rs.42,000/- Rs.8000/- 01.06.2010	
36.	-do-	-do-	001493	Sangobion Capsule Each soft capsule contains: Ferrous gluconate	15-04-2013 Dy.No.112 Form-05	

				dehydrate…..250 mg Manganese Sulfate monohydrate…….0.2mg Copper sulphate….0.2mg Vitamin C Ascorbic acid……..50 mg Folic acid……..1 mg Vitamin B12 Cyanocobalamin….7.5mcg	Rs.42,000/- Rs.8000/- 01.06.2010	
37.	-do-	-do-	008509	Supramycin Capsule Each soft gelatin capsule contains: Doxycycline hydrochloride eq.to doxycycline.100mg	15-04-2013 Dy.No.111 Form-05 Rs.42,000/- Rs.8000/- 01.06.2010	
38.	-do-	-do-	008753	Evion 200mg Capsule Each soft gelatin capsule contains: DL-Alpha tocopheryl acetate…….200 mg	15-04-2013 Dy.No.88 Form-05 Rs.42,000/- Rs.8000/- 01.06.2010	
39.	-do-	-do-	016099	Evion 600mg Capsule Each soft gelatin Capsule contains: DL-Alpha Tocopheryl Acetate,……600 mg	15-04-2013 Dy.No. 87 Form-5 Rs.42,000/- Rs.8000/- 01.06.2010	
40.	-do-	-do-	020243	Multibionta Capsule Each soft gelatin capsule contains: Vitamin A (palmitate)…….5500 iu Vitamin D (Cholecalciferol)…500 iu Vitamin B1 (thiamine mononitrate) …10 mg Vitamin 2	15-04-2013 Dy.No. 86 Form-5 Rs.42,000/- Rs.8000/- 01.06.2010	

				(Riboflavin),……..10 mg Vitamin B1((Py7ridoxine hydrochloride)…5 mg Vitamin B12 (Cyanocobalamin)..8 mcg Vitamin C (Ascorbic acid)……100 mg Folic Acid…….200 mcg Nicotinamide….30 mg Calcium D-Pantothenate…….20 mg Vitamin E (DL-Alpha Tocopheryl Acetate)…….10mg		
41.	M/s Sanofi Kar.	M/s Merck Pharmaceuticals, F-126, Kar.	004520	Essentiale Capsule Each capsule contains: Vitamin B1……3 mg Vitamin B2…….3 mg Vitamin B6…….3mg Vitamin B12…..3 mg Nicotinamide……15 mg Vitamin E-acet. ….3.3 mg	15-04-2013 DyNo.201 Form-05 Rs.50,000/-	
42.	M/s GSK, Karachi	M/s Akhai Pharmaceuticals, Baluchistan.	035411	Betonil N 0.1% Cream Each gm contains: Betamethasone 17 Valarete…….0.10 % Neomycin sulphate…….0.50%	15-04-2013 Dy No.298 Form-05 Rs.50,000/-	
43.	-do-	-do	019464	Brevoxyl Cream Each gm contains: Benzoyl peroxide…..4 %	15-04-2013 Dy No.298 Form-05 Rs.50,000/-	
44.	-do-	-do	029331	Betonil Lotion Each gm contains: Betamethasone 17 Valerate……1 mg	15-04-2013 Dy No.298 Form-05 Rs.50,000/-	
45.	-do-	-do	043657	Clinagel Each gm contains: Clindamycin	15-04-2013 Dy No.298 Form-05	

				phosphate……..10 mg	Rs.50,000/-	
46.	-do-	-do	019738	Lacticare 1% Lotion Each gm contains: Hydrocortisone….1.06 %	15-04-2013 Dy No.298 Form-05 Rs.50,000/-	
47.	-do-	-do	019739	Lacticare 2.5% Lotion Each gm contains: Hydrocortisone……2.5 %	15-04-2013 Dy No.298 Form-05 Rs.50,000/-	
48.	-do-	-do	005039	Lacticare Lotion Each gm contains: Sodium pyrrolidone, Carboxylate……..2.75 % Lactic acid……..5.70 %	15-04-2013 Dy No.298 Form-05 Rs.50,000/-	
49.	-do-	-do	024308	Minoderm Tablet Each tablet contains: Minocycline…..100 mg	15-04-2013 Dy No.298 Form-05 Rs.50,000/-	
50.	-do-	-do	024757	Stiemazole Lotion Each gm contains: Clotrimazole……..1 %	15-04-2013 Dy No.298 Form-05 Rs.50,000/-	
51.	-do-	-do	048074	Stieproxal Liquid Each gm contains: Ciclopiroxolamine…15 mg Salicylic acid……30 mg	15-04-2013 Dy No.298 Form-05 Rs.50,000/-	
52.	-do-	-do	026392	Stieprox Liquid Each gm contains: Cyclopirox Olamine……..1.500 %	15-04-2013 Dy No.298 Form-05 Rs.50,000/-	
53.	-do-	-do	042951	Zemagis Lotion	15-04-2013	

				Each gm contains: Prednicarbate …0.25 w/w	Dy No.298 Form-05 Rs.50,000/ -	
54.	-do-	-do-	024307	Zolanix Capsule Each capsule contains: Fluconazole……150 mg	15-04-2013 Dy No.298 Form-05 Rs.50,000/ -	
55.	M/s Novartis Pharma, West Wharf, Karachi	M/s Saffron Pharma, Faisalabad	032638	Elgin 500mcg Tablets Each tablet contain:- Mecobalamin ……0.5mg	28-03-2013 Form-5 Rs.42,000/ -	
56.	-do-	-do-	033047	Elgin 500mcg Injection Each ampoule contains:- Mecobalamin ….500mcg	28-03-2013 Form-5 Rs.42,000/ - 24-05-2010 Rs.8000/-	
57.	-do-	M/s Noa Hemis Pharmaceuticals, Karachi	044389	Sanlac Syrup Each 100ml contains:- Lactulose ……67gm Galactose ……..11gm Lactose …… 6gm	28-03-2013 Form-5 Rs.42,000/ - 24-05-2010 Rs.8000/-	
58.	M/s Pfizer, Pakistan Karachi	-do-	031265	Bacteriostatic Water for Injection	15-05-2013 Dy.No. 327 Form-5 Rs.50,000/ -	
59.	-do-	-do-	002420	Water for Injection	15-05-2013 Dy.No. 327 Form-5 Rs.50,000/ -	
60.	M/s Wyeth Pakistan	M/s Spencer Pharma, Karachi	000083	Ativan 1mg Tablet Each tablet contains Lorazepam…….1mg	15-05-2013 Rs.50,000/ -	Controlled Drug

	Ltd, Karachi					
61.	-do-	-do-	000084	Ativan 2mg Tablet Each tablet contains Lorazepam…….1mg	15-05-2013 Rs.50,000/-	Controlled Drug
62.	M/s Novartis Pharma, West Wharf, Karachi 240th RB	M/s Global Pharmaceuticals, Islamabad	030510	Levofin 250mg Tablets (Levofloxacin)	28-03-2013 Rs.42,000/- Rs.8000/- 14.06.2010	General products
63.	-do-	-do-	030511	Levofin 500mg Tablets (Levofloxacin)	28-03-2013 Rs.42,000/- Rs.8000/- 14.06.2010	-Do-
64.	-do-	-do-	023992	Claramed Dry Suspension (Clarithromycin)	28-03-2013 Rs.42,000/- Rs.8000/- 14.06.2010	-Do-
65.	-do-	-do-	023993	Claramed 250mg Tablets (Clarithromycin)	28-03-2013 Rs.42,000/- Rs.8000/- 14.06.2010	-Do-
66.	-do-	-do-	023994	Claramed 500mg Tablets (Clarithromycin)	28-03-2013 Rs.42,000/- Rs.8000/- 14.06.2010	-Do-
67.	-do-	-do-	054727	Acemed 100 mg Tablets (Aceclefenac)	28-03-2013 Rs.42,000/- Rs.8000/- 14.06.2010	-Do-
68.	-do-	-do-	032153	Montelo 5 mg Tablet (Montelukast)	28-03-2013 Rs.42,000/	-Do-

					- Rs.8000/- 14.06.2010	
69.	-do-	-do-	032154	Montelo 10 mg Tablet (Montelukast)	28-03-2013 Rs.42,000/ - Rs.8000/- 14.06.2010	-Do-

Decision: Registration Board discussed above products in light of contract manufacturing policy and decided as follows:

- **Products at S.No.13, 22-27, 32-41,58,59 extended till 30.6.2015 subject to provision of agreement between contract manufacturer and contract giver as required by contract manufacturing policy. The Board authorized its Chairman to accord approval for issuance of permission letter.**
- **Products at S.No.1-12, 29-31, 42-54 deferred as matter is subjudice in Sind High Court, Karachi.**
- **Products at S.No.21,60,61 rejected as it is not covered under contract manufacturing policy.**
- **Products at S.No.14-20,28, 55-57,62-69 deferred due to non provision of details as required in the policy.**
- **Product at S.No. 11 already transferred to M/s GSK, Karachi for local manufacturing**

Case No.44: Transfer of registration from bulk import to local contract manufacturing by M/s CSH Pharma, Lahore – M/s Novartis Pharma (Pakistan) Ltd, West Wharf, Karachi

Following products of M/s Novartis Pharma (Pakistan) Ltd, West Wharf, Karachi were initially registered for import in bulk form from M/s Sandoz, Austria and repacked locally at M/s Novartis Pharma (Pakistan) Ltd, Karachi. Later on, site of repacking was changed to M/s CSH Pharma, Lahore. Details are as under:-

S. No.	Reg. No.	Name of Drug(s)	Formulation(s)
1	031355	Amoxi-Clav 375mg Tablets	Each film coated tablet contains:- Amoxicillin …….250mg Clavulanic Acid …….125mg
2	031356	Amoxi-Clav 625mg Tablets	Each film coated tablet contains:- Amoxicillin …….500mg Clavulanic Acid …….125mg

3	031357	Amoxi-Clav 1gm Tablets	Each tablet contains:- Amoxicillin …….875mg Clavulanic Acid …….125mg
4	031358	Amoxi-Clav 156.25mg Dry Suspension	Each tablet contains:- Amoxicillin …….875mg Clavulanic Acid …….125mg
5	031359	Amoxi-Clav 312.5mg Dry	Suspension Each 5ml contains:- Amoxicillin …….250mg Clavulanic Acid …….62.5mg

M/s Novartis has submitted that they intend to manufacture above products at M/s CSH Pharmaceuticals, Lahore on contract manufacturing basis, for which Drug Regulatory Authority of Pakistan has already granted permission for stability studies. Firm has furnished stability studies and requested that they may be allowed contract manufacturing of above products at M/s CSH Pharmaceuticals, Lahore.

Decision: Registration Board acceded request of M/s Novartis Pharma, Karachi for contract manufacturing of above products (S.No.1-5) from M/s CSH Pharmaceuticals, Lahore till 30.06.2015. However, this permission is subject to provision of agreement between contract manufacturer and contract giver as required by contract manufacturing policy. The Board authorized its Chairman to accord approval for issuance of permission letter.

Case No.45: Transfer of registration from import to local toll manufacturing

Following products of M/s High-Q International, Karachi are registered for import in finished form. Now they intend to transfer the registration from import to local manufacturing under contract manufacturing arrangements as mentioned against each. Details are as under:-

S. No.	Reg. No.	Name of Drug(s)	Existing Import Manufacturer(s)	Proposed Contract Manufacturer (s)
1	045616	Ruling Injection 40mg Each vial contains:- Omeprazole (as Sodium) ….40mg	M/s Hainan Lingkang Pharmaceutical Co., Ltd., China (Bulk Import and Local repacking)	M/s Nabiqasim Industries, Karachi

2	018501	Remethan Injection 75mg Each 3ml contains:- Diclofenac Sodium…….75mg	M/s Shin Poong Pharmaceutical Co Ltd, Seoul Korea	M/s Surge Labs, Sheikhupura
3	019467	Cycin 100mg / 50ml Injection I.V/ I.M Each vial contains:- Ciprofloxacin ..100mg	M/s Shin Poong Pharmaceutical Co Ltd, Seoul Korea	M/s Surge Labs, Sheikhupura
4	019468	Cycin 200mg/100ml Injection I.V/ I.M Each vial contains:- Ciprofloxacin ..200mg	M/s Shin Poong Pharmaceutical Co Ltd, Seoul Korea	M/s Surge Labs, Sheikhupura
5	022645	Hizone Injection 250mg IM Each vial contains:- Ceftriaxone as Sodium……250mg	M/s Shin Poong Pharmaceutical Co Ltd, Seoul Korea (Bulk import and local repacking)	M/s Surge Labs, Sheikhupura
6	018300	Hizone Injection 1gm IV Each vial contains:- Ceftriaxone as Sodium……1gm	M/s Shin Poong Pharmaceutical Co Ltd, Seoul Korea (Bulk import and local repacking)	M/s Surge Labs, Sheikhupura
7	014947	Cefapezone Injection 1gm Each vial contains:- Cefoperazone Sodium……..1gm	M/s Shin Poong Pharmaceutical Co Ltd, Seoul Korea (Bulk import and local repacking)	M/s Surge Labs, Sheikhupura
8	015589	Fugacin Tablets Each film coated tablet contains:- Ofloxacin ……..200mg	M/s Shin Poong Pharmaceutical Co Ltd, Seoul Korea	M/s High-Q Pharmaceuticals, Karachi
9	019522	Cycin 500mg Tablets Each tablet contains:- Ciprofloxacin HCl…… 500mg	M/s IL Dong Pharmaceutical Co. Ltd, Korea	M/s High-Q Pharmaceuticals, Karachi
10	019523	Cycin 250mg Tablets Each tablet contains:-	M/s IL Dong Pharmaceutical Co.	M/s High-Q Pharmaceuticals,

		Ciprofloxacin HCl…… 250mg	Ltd, Korea	Karachi

Firm has furnished following information to support their request.

- Registration dossier on Form -5.
- Original consent of M/s Nabiqasim Industries (Pvt.) Ltd, Karachi and M/s Surge Laboratories, Sheikhupura & M/s High-Q Pharmaceuticals, Karachi
- Contract manufacturing agreement with M/s Nabiqasim Industries (Pvt.) Ltd, Karachi and M/s Surge Laboratories, Sheikhupura & M/s High-Q Pharmaceuticals, Karachi
- Copy of Registration letters & Renewal
- Fee of Rs.50,000/- for each product.
- Firm has requested to change name of Remethan injection to Qufen injection. Proposed name is already registered for M/s High-Q Pharmaceutical, Karachi and firm has granted NOC for change of name.

Decision: Registration Board acceded request of M/s High-Q International, Karachi for contract manufacturing of above products (S.No.1-10) from manufacturers as mentioned against each till 30.06.2015. However, this permission is subject to provision of agreement between contract manufacturer and contract giver as required by contract manufacturing policy. The Board authorized its Chairman to accord approval for issuance of permission letter.

Case No.46: Extension in contract manufacturing permissions – Meezab International, Karachi.

Following products of M/s Meezab International, Karachi were initially registered for import and then permitted for local contract manufacturing. Registration Board in 238th meeting considered case for extension in contract manufacturing of these products (import to local contract) and deferred for submission of data about grant of registration, transfer to contract manufacturing, subsequent renewal and copy of DSL. Lateron, firm provided the documents including copy of DSL and remaining fee and the Board in 241st meeting extended contract manufacturing permission of following products till 30.06.2015. As per DSL No450 dated 24.12.2013, address is F1-A/3-A, SITE, Karachi.

Now Mr.Mukhtiar Ahmad, Assistant General Manager of M/s Meezab International, Karachi has sent a reference alongwith a set of documents (advertisement in news papers, memorandum of agreement of business acquisition, copy of Drug sale License) stating and claiming that Mr.Rajesh is owner of the business. As per Drug sale License No.650 dated

17.03.2014; Mr.Rajesh is proprietor of the firm and address is Office No.8, 5th floor, Namco centre, Campbel street, near city court, Karachi.

S. No.	Applicant	Contract manufacturer	Reg. No.	Name of drug(s) & Composition	Date of application, Diary No. & Form	Category
1.	M/s Meezab Intr. Kar.	M/s Farmaceutics Intl. Karachi	021906	Diclovat 75mg Injection Each 3ml contains: Diclofenac Sodium..75mg	15-04-2013 Dy.No.188 Form-05 Rs.42,000/ Rs.8000/- dated 27-8-2013	Import to local contract
2.	-do-	-do-	015730	Labentrol 250mg Tablet Each film coated tablet contains: Ciprofloxacin HCl eq. to Ciprofloxacin…250 mg	15-04-2013 Dy.No.187 Form-05 Rs.42,000/ Rs.8000/- dated 27-8-2013	Import to local contract
3.	-do-	-do-	021907	Diclovat 50mg Tablet Each enteric coated tablet contains: Diclofenac sodium ..50 mg	15-04-2013 Dy.No.186 Form-05 Rs.42,000/ Rs.8000/- dated 27-8-2013	Import to local contract
4.	-do-	-do-	014638	Lomadryl 150mg Tablet Each tablet contains: Ranitidine HCl eq. to Ranitidine…….150 mg	15-04-2013 Dy.No.185 Form-05 Rs.42,000/ Rs.8000/- dated 27-8-2013	Import to local contract
5.	-do-	-do-	021905	Alenstran 10mg Tablet Each tablet contains: Cetirizine dihydrochloride.10 mg	15-04-2013 Dy.No.184 Form-05 Rs.42,000/ Rs.8000/-	Import to local contract

					dated 27-8-2013	
6.	-do-	-do-	021908	Tradolint 100mg Injection Each 2ml ampoule contains: Tramadol HCl….100 mg	15-04-2013 Dy.No.183 Form-05 Rs.42,000/ Rs.8000/- dated 27-8-2013	Import to local contract
7.	-do-	-do-	021904	Lomadryl 50mg Injection Each 2ml ampoule contains: Ranitidine HCl eq. to Ranitidine……50 mg	15-04-2013 Dy.No.182 Form-05 Rs.42,000/ Rs.8000/- dated 27-8-2013	Import to local contract
8.	-do-	-do-	014671	Labentrol 500mg Tablet Each film coated tablet contains: Ciprofloxacin HCl eq. to Ciprofloxacin…..500 mg	15-04-2013 Dy.No.181 Form-05 Rs.42,000/ Rs.8000/- dated 27-8-2013	Import to local contract
9.	M/s Meezab Intr. Kar.	M/s Farmaceutics Intl. Karachi	014675	Molelant 1gm Injection Each vial contains: Cefotaxime Sodium eq. to Cefotaxime……1 gm	15-04-2013 Dy.No.178 Form-05 Rs.42,000/ Rs.8000/- dated 27-8-2013	Import to local contract
10.	-do-	-do-	021903	Molelant 250mg Injection Each vial contains: Cefotaxime Sodium eq. to Cefotaxime……250mg	15-04-2013 Dy.No.179 Form-05 Rs.42,000/ Rs.8000/- dated 27-8-2013	Import to local contract
11.	-do-	-do-	014672	Labentrol 750mg Tablet Each tablet contains: Ciprofloxacin HCl eq. to Ciprofloxacin……750mg	15-04-2013 Dy.No.180 Form-05	Import to local contract

					Rs.42,000/ Rs.8000/- dated 27-8-2013	
12.	-do-	-do-	014639	Alenbit 400mg Tablet Each tablet contains: Norfloxacin …….400 mg	15-04-2013 Dy.No.175 Form-05 Rs.42,000/ Rs.8000/- dated 27-8-2013	Import to local contract
13.	-do-	-do-	023694	Katinol 250mg Capsule Each capsule contains: Cefaclor……250 mg	15-04-2013 Dy.No.176 Form-05 Rs.42,000/ Rs.8000/- dated 27-8-2013	Import to local contract
14.	-do-	-do-	014677	Molelant 500mg Injection Each vial contains: Cefotaxime Sodium eq. to Cefotaxime……500mg	15-04-2013 Dy.No.177 Form-05 Rs.42,000/ Rs.8000/- dated 27-8-2013	Import to local contract
15.	-do-	-do-	021909	Tradolint 50mg Capsule Each capsule contains: Tramadol HCl……50 mg	15-04-2013 Dy.No.189 Form-05 Rs.42,000/ Rs.8000/- dated 27-8-2013	Import to local contract
16.	-do-	-do-	014637	Lamadryl 300mg Tablet Each tablet contains: Ranitidine HCl…..300mg	15-04-2013 Dy.No.190 Form-05 Rs.42,000 dated 27-8-2013	Import to local contract
17.	-do-	-do-	021902	Suprin Suspension	15-04-	Import to

				Each 5ml contains: Cefixime…….100 mg	2013 Dy.No.191 Form-05 Rs.42,000 dated 27-8-2013	local contract
18.	-do-	-do-	021901	Bifin 10mg Injection Each vial contains: Nalbuphine HCl……10 mg	15-04- 2013 Dy.No.192 Form-05 Rs.42,000 dated 27-8-2013	Import to local contract

Decision: Registration Board discussed the case in detail and constituted a committee comprising of DDG (E&M), DRAP, Karachi and Chief Drug Inspector, Sind to investigate the matter in detail and submit report in 30 days time.

Registration-III

Case No.47

The Registration Board in its 241st meeting deferred the following product firm M/s Bio Labs Islamabad for the reasons mentioned in the last column as below:-

S/N	Name and address of Manufacturer / Applicant	1. Brand Name 2. Dosage Form 3. Composition 4. Pharmacological group	1.Type of Form 2. Type of application 3. Demanded Price / Pack size 4. Initial date, diary. 5. Date on which fee becomes complete according to type of application / or Form	Previous Decision M-214
1.	M/s Bio-Labs Pvt. Ltd. Plot No.145, Industrial Triangle Islamabad	E-Cital 10mg Tablets Each Dispersible tablet contains:- Escitalopram (as Oxalate)….10mg (Antidepressant Reuptake Inhibitors (SSRIs)	1.Form5 2.Fast Tack 3.14's As per SRO 4.21-05-2013 Dy.No.1606 Fee Rs.60,000 (Original)	Deferred as the formulation in dispersible dosage form is not me-too. The firm has to apply on form 5-D alongwith differential fee of

Now the firm has rectified / addressed all the above deficiencies and submitted complete documents in this regard.

Decision: Registration Board deferred product for confirmation of international availability, me too status and expert opinion.

Case No.48.

The following drugs were initially applied by M/s Wilson, Islamabad for contract manufacturing by M/s. Scotmann Pharmaceutical, Islamabad and then deferred because the policy of manufacturing on toll basis was not finalized. The products were again considered in 237th meeting in view of the development of the relevant facilities by the firm and were approved subject to the provision of fundamental requirements regarding the imported pellets. The firm has submitted the remaining fee amounting Rs.92,000/- for each of the strength alongwith GMP certificate, COA (certificate of analysis) and stability study with the request to grant the

registration for manufacturing of the said products in the premises of M/s. Wilson Pharmaceuticals, Islamabad.

The firm has now applied to import Duloxetine enteric coated pellets 25.0% w/w from the Hetero Labs Ltd as mentioned below:

S.No.	Name of Products	Addresses of Pellets
1.	King 30mg Capsules Each delayed release capsules contains:- Duloxetine enteric coated pellets 25.0% w/w ≡ Duloxetine……30 mg	**Hetero Labs Limited – Unit VII Plot No.14, sy.No.50, Phase-III, IDA Jeedimetla, Qutubullapur Mandal, Ranga Reddy Dist, Hyderabad-500 055**
2.	King 40mg Capsules Each delayed release capsules contains:- Duloxetine enteric coated pellets 25.0% w/w ≡ Duloxetine……40 mg	
3.	King 60mg Capsules Each delayed release capsules contains:- Duloxetine enteric coated pellets 25.0% w/w ≡ Duloxetine……60 mg	
4.	King 90mg Capsules Each delayed release capsules contains:- Duloxetine enteric coated pellets 25.0% w/w ≡ Duloxetine……90 mg	

Decision: Registration Board approved King (30mg, 40mg, 60mg and 90mg) for registration

Case No.49

The Registration Board in its 231st meeting approved the following product of M/s Hygeia Pharmaceuticals, Islamabad with following formulation & pack size:-

S. No	Name of the Firm.	Brand Name / Label Claim	Demanded Pack Size	Demanded Price	Decision Registration Board in its 231st Meeting
1.	M/s Hygeia Pharmaceutica	Moxan 400 Infusion Each vial (250 ml) contains:-	250 ml	As Per SRO	Approved

	ls Islamabad	Moxifloxacin ……400 mg			

But inadvertently, the Registration letter was issued on 20th August, 2011 with following pack size / price:-

S. No	Reg. No.	Name of drug (s) & Composition	Packing	M R P
1.	072794	Moxan 400 Infusion Each 100 ml contains:- Moxifloxacin (as HCl) ……400 mg (Hygeia's Specs.)	100 ml	Rs.950.00

Since, the firm applied the above formulation with the accounting unit of 250 ml but inadvertently it was mentioned as 100 ml in the certificate of registration of even number dated 20.08.2011. The firm has pointed out that they have manufactured the said formulation in 100ml for one time but they have to recall all of the stock of the said batch due to the problem of crystallization in the vial. The management has been now requested to issue the registration certificate of above formulation for 250 ml as per their original application approved by the Registration Board in 231st Meeting. It is pointed out that Medisure has been granted the pack of Moxifloxacin (as HCl) 400 mg/100 ml.

Decision: Registration Board approved firm,s request for changing pack size of moxifloxacin infusion to 250ml with MRP as approved by Drug pricing Committee. Moreover, the Board advised that all other manufacturers will be advised to change the existing 100 ml pack size with 250ml and authorized its Chairman to grant this approval.

Case No.50 Grant of Registratio for export purpose-Contract manufacturing

M/s Focus & Rulz Pharmaceuticals, Islamabad has applied for Contract Manufacturing of following of the products from M/s Bio-Labs (Pvt) Ltd, Islamabad **for export purpose only.** M/s Bio-Labs possess approval for both sections i.e. General Injections and Cephalosporin Injections.

S. No	Name of the Firm.	Brand Name / Label Claim	Demanded Pack Size	Demanded Price	Date of Submission
1.	M/s Focus & Rulz Pharmaceuticals (Pvt) Ltd, Islamabad.	Omper 40 mg Injection IV Each vial contains:- Omeprazole (as Sodium) Powder……40 mg (Proton Pump Inhibitor)	1's vial	As Per SRO	02-01-2014 Dy.No.02 **Fee Rs.20,000/=**

	Contract manufacturing by M/s M/s Bio-Labs (Pvt) Ltd, Islamabad.				
2.	-do-	Esro 40mg Injection Each vial contains:- Esomeprazole (as Sodium)……..40mg (Proton Pump Inhibitor)	1's vial	As Per SRO	02-01-2014 Dy.No.04 **Fee Rs.20,000/=**
3.	-do-	M-Fer 100mg Injection Each ampoule contains:- Iron (as iron sucrose)……..…100 mg (Replenishes Hgb and depleted iron stores)	5mlx1's	As Per SRO	02-01-2014 Dy.No.06 **Fee Rs.20,000/=**
4.	-do-	Arther 80mg Injection Each ampoule contains:- Artemether……..80 mg (Antimalarial)	1's vial	As Per SRO	02-01-2014 Dy.No.03 **Fee Rs.20,000/=**
5.	-do-	Alcal Injection Each ml contains:- Alfacalcidol…….2ug (Vitamin-D)	5mlx1's	As Per SRO	02-01-2014 Dy.No.05 **Fee Rs.20,000/=**

Decision: Registration Board approved above products for contract manufacturing exclusicely for export purpose.

Case No.51 Grant of Registration of export purpose.

M/s Caraway Pharmaceutical, Rawat have applied for registration of following drugs exclusively for the purpose of export:-

S. No.	Brand Name	Composition
3.	**Cara-Lina 5mg Tablets**	**Each film coated tablet contains:- Linagliptin ……. 5 mg**

		(Caraway's Specs.)

Product is not registered in Pakistan.

Decision: Registration Board registered Cara-Lina 5mg Tablets for export purpose only.

Case No.52

The Registration Board in its 241st meeting deferred the following product firm M/s Caraway Pharmaceuticals, Rawat for the reasons mentioned in the last column as below:-

S/N	Name and address of Manufacturer / Applicant	1. Brand Name 2. Dosage Form 3. Composition 4. Pharmacological group	1.Type of Form 2. Type of application 3. Demanded Price / Pack size 4. Initial date, diary. 5. Date on which fee becomes complete according to type of application / or Form	1. Finished Product Specification	Previous Decision M-241
1.	M/s Caraway Pharmaceuticals, Rawat,	1.Dulox 2. Capsule 3. Each Capsule contain: Duloxetine HCl..30 mg 4.Antidepressants	1. Form-5 2. Routine 3. 14's As per SRO 4.16-07-2010/6641 5.20-05-2013/3153 Rs. 20,000/-		1. Form-5 2. Routine 3. 14's As per SRO 4.16-07-2010/6641 5.20-05-2013/3153 Rs. 20,000/-

The firm is now intended to purchase Duloxetine HCl EC Pellets 17.0% from local source from M/s Vision Pharmaceuticals, Plot No.224, Street No.1, I-10/3, Industrial Area, Islamabad. the firm has submitted the following documents:-

1. Certificate of analysis.
2. specifications of the Duloxetine HCl EC Pellets 17.0%
3. Standard analytic procedure.
4. Stability Data.
5. cGMP Certificate of M/s Vision Pharmaceuticals.
6. Drug Manufacturing license of M/s vision Pharmaceuticals.

Decisioon: Registration Board registered Dulox capsules 30mg.

Registration-IV

Case No. 53

M/s. Medicraft Pharmaceuticals, Peshawar has applied for registration of Neurocam Injection (Vitamin B Complex) for export purpose only.

S.No	Name of drugs with composition
1	Neurocam Injection I.M. Each 3ml contains Thiamine HCl (B1)……..……..100 mg Pyridoxine HCl (B6)…….100 mg Riboflavin phosphate sodium (B2)……..5 mg Cyanocobalamine (B12)……..1000 mcg D-Panthenol…….……..50 mg Niacinamide……..100 mg Benzyl Alcohol……..1.50 %v/v Lidocaine HCl…….20 mg Water for injection ……q.s

It is submitted that the exactly similar formulation is not available in Pakistan. However for the promotion of the export, generally a leniency has been opted. The management has submitted that this formulation is registered in India manufactured by M/s. Zee Laboratories, India. Now the management of the firm has requested for issuance of registration letter.

Decision: Registration Board registered Neurocam Injection I.M. for export purpose only.

Case No.54

The following drug of M/s. Shaheen Pharmaceuticals, Swat was approved in 235th and 239th meetings of Registration Board:-

1	Iro-Plus Tablets Each tablet contains:- Iron protein Succinylate 800mg ≡ Iron (element)……..……40 mg Folic Acid……..……5 mg (Anti Aneamic)	3x10's	As Per SRO

2	Paroxet 10 mg Tablets Each tablet contains:- Paroxetine (as HCl)…….10 mg (Antidepressant)	3x10's	As Per SRO

The product at S.No. 1 could not be traced successfully in the form of tablet having the above mentioned strength of the relevant ingredients so it could not be referred to the pricing section because it also was not supported with the available literature on the internet. Hence does not comply with the status of being me too products.

It is submitted that the Paroxetine (as HCl) has been formulated by GSK, (brand leader) in the strength of 10, 12.5, 20 & 30 mg controlled release whereas extended release and prolonged release are also used for describing the said formulation and dosage form. M/s. Shaheen has applied for Paroxetine (as HCL) in the form of uncoated plain tablet which could not be supported with the available literature on the relevant website and in comparison of Seroxat and Paroxil Tablets. While referring the case to department of Pricing for determination of price it was observed that the product does not fall under the category of me too product.

Decision: Registration Board advised firm to apply on Form 5D along with requisite fee.

Case No. 55

The following applications of M/s. CSH Pharmaceuticals, Peshawar for grant of extension in manufacturing on the basis of toll as well as for changing the manufacturer from M/s. Surge Laboratories, Sheikhupura to M/s. Medisave Pharmaceuticals, Lahore. The firm has recently deposited the fee amounting Rs.50,000/- per each products in two installments on various dates. The management has provided the proof of previously deposited fee for grant of extension which was valid up to June, 2010 and requested for approval of the products.

1.	044092	M/s. CSH Pharmaceuticals, Peshawar	Toll manufactured by M/s. Surg Laboratories, Sheikhupura	Cealth 250mg Injection Each vial contains:- Cefuroxime Sodium ≡ Cefuroxime..250mg	Dy. No.1385 Form-5 Rs.20000/- Rs.30,000/- dated 23-12-2013	Cephalosporin

2.	044093	-do-	-do-	Cealth 750mg Injection Each vial contains:- Cefuroxime Sodium ≡ Cefuroxime..750mg	-do-	Cephalosporin
3.	044094	-do-	-do-	Cealth 1.5gm Injection Each vial contains:- Cefuroxime Sodium ≡ Cefuroxime..1.5gm	-do-	Cephalosporin
4.	044098	-do-	-do-	Injectazone Plus 1gm Injection Each vial contains:- Cefoperazone Sodium ≡ Cefoperazon....500mg Sulbactam Sodium ≡ Sulbactam...500mg (USP Specification)	-do-	Cephalosporin
5.	044099	-do-	-do-	Injectazone Plus 2 gm Injection Each vial contains:- Cefoperazone Sodium ≡ Cefoperazon.....1 gm Sulbactam Sodium ≡ Sulbactam.....1 gm (USP Specification)	-do-	Cephalosporin
6.	044100	-do-	-do-	Injectacef 250 mg Injection Each vial contains:- Ceftriaxone Sodium ≡Ceftriaxone…250 mg	-do-	Cephalosporin
7.	044101	-do-	-do-	Injectacef 1gm Injection Each vial contains:- Ceftriaxone Sodium ≡Ceftriaxone…1gm	-do-	Cephalosporin
8.	044102	-do-	-do-	Cefgram 500mg Injection Each vial contains:- Cefepime HCl & L-arginine ≡ Cefepime…500mg	-do-	Cephalosporin

9.	044103	-do-	-do-	Cefgram 1gm Injection Each vial contains:- Cefepime HCl & L-arginine ≡ Cefepime…1 gm	-do-	Cephalosporin

Decision: Registration Board extended above products for contract manufacturing till 30.06.2015 subject to provision of agreement between contract manufacturer and contract giver. Contract manufacturer will be M/s. Medisave Pharmaceuticals, Lahore.

Case No.56

The Drug Registration Board in 237th meeting approved the following drugs and referred to Pricing Section for fixation of price. The pricing Section referred back the case with the remarks:-

1.	M/s Cirin Pharmaceuticals, Hattar	Brufam Tablets Each film coated tablet contains:- Ibuprofen…….800 mg Famotidine…….26.6 mg NSAID/H2 receptor antagonist)	10's Or HDPE bottle of 100's tablets	Rs.30.00 Per tablet

It is submitted that above mentioned drugs is available in the international market and approved by USA was referred to the committee of expert for their technical opinion which was positive regarding the availability of this product in Pakistan and efficacy of the said combination available in the abroad. It is included in FDA approved drug products. URL www.accessdata.fda.gov/scripts.cder.drugsatfda/index.cfm.

Decision: As Brufam Tablets (Ibuprofen 800 mg and Famotidine 26.6 mg) is USFDA approved formulation and experts have also recommended it. Thus Registration Board endorsed its previous decision for grant of registration.

Case No.57

The Drug Registration Board 218th and 235th meeting had deferred the following drugs of M/s. Genome Pharmaceuticals, Hattar for expert opinion due to new molecules:-

1.	M/s. Genome Pharmaceuticals, Hattar	Perilone Tablets Each tablet contains:- Paliperidone…….3 mg	10's	As Per SRO	Deferred for expert opinion being a new

		(Ant-psychotropic) (Genome Spec)			chemical entities.
2.	-do-	Perilone Tablets Each tablet contains:- Paliperidone…….6 mg (Ant-psychotropic) (Genome Spec)	10's	As Per SRO	-do-
3.	M/s. Genome Pharmaceutical, Hattar.	Genozal Tablets Each tablet contains:- Balsalazide Disodium Dihydrate……750mg (Genome Sapec) (Anti-inflammatory drug)	10's	As Per SRO	Deferred for expert opinion.
4.	-do-	Rebon-X Tablets Each film coated tablet contains:- Strontium citrate……680mg (Bone stabilizer)	10's	As Per SRO	• **Deferred due to Methylene Chloride.** • **Inspection report nil** • **Form 5/ file partially signed.**

Item at S. No. 1 & 2 was deferred for the opinion of expert committee for being a new chemical entities in 228th meeting of Registration Board. The management has informed that the same formulation has already been registered with the brand name of Invega 3mg Tablets (Paliperidone) (Reg. No.072599) & Invega 6mg Tablets (Paliperidone) (Reg. No.072600) in the name of M/s. Johnson & Johnson Pakistan hence may please be considered for registration.

The management has submitted the remaining fee of Rs.42,000/- for each formulation at S.No. 3 & 4 and requested to refer to the committee of expert for opinion. The dossiers have been rectified and resubmitted on Form-5D as per requirement.

Decision: Registration Board approved product at S.No 1and 2 and referred products at S.No3 and 4 for expert opinion.

Case No.58

The Drugs Registration Board in 239th meeting deferred the following drugs of M/s. Shazeb Pharmaceuticals, Distt Haripur for PSI by Director DTL, Peshawar and area FID. For product at S.No.9, firm will rectify shortcomings as mentioned above.

1.	Zee Hesta 3% Each 1000 ml contains:- Hydroxyethyl Starch…30 gm Sodium Chloride…….……9 gm (Plasma Substitute)	500 ml	As Per SRO	Check Hydroxyethyl Standards **Not recommended.** ***Shortcoming rectified***
2.	Zee Haemagel I.V Infusion Each 1000ml contains:- Degraded gelatin (Polygeline of average molecular weight)….35 g Sodium Chloride…..…..8.5 g Potassium Chloride……0.7 g Calcium chloride…....0.38 g (Plasma Substitute)	500 ml	As Per SRO	**Not recommended.** ***The firm has informed that they can't rectify immediately therefore they requested to postpone till next DRB meeting.***

The panel of inspectors had conducted the inspection on 01-01-2014 and recommended as under:-

> "After checking all the required facilities to manufacture the 02 products Zee Hesta 3% and Zee Haemagel IV Infusion and testing and storage facilities, the panel recommends the grant of registration by way of formulation."

Decision: Registration Board approved above products for registration.

Case No.59

The Drugs Registration Board in 238th meeting deferred the following drugs of M/s. Hizat Pharmaceuticals, Peshawar for PSI by Director DTL, Peshawar, DDCR-IV and area FID.

1.	Cefanix 500 mg Capsules Each capsule contains:- Cefaclor Monohydrate ≡ Cefaclor…….500 mg (Cephalosporin)	10's	Rs.375.00	1-6-2010	Deferred for P.S.I. by Director DTL, FID, DDC R-IV.
2.	Polymal Tablets Each tablet contains:- Iron (III) Hydroxide Polymaltose Complex eq.	10's	Rs.87.50	-do-	Deferred for P.S.I. by Director DTL, FID, DDC R-IV.

	to Elemental Iron..100 mg Folic Acid……..0.35 mg (Haematinic)				
3.	Polymal Syrup Each 5 ml contains:- Iron (III) Hydroxide Polymaltose Complex ≡ Iron (Element)…50 mg (Haematinic)	60 ml 120 ml	Rs.95.00 Rs.172.00	-do-	Deferred for P.S.I. by Director DTL, FID, DDC R-IV.
4.	Lubric Suspension Each 5 ml contains:- Lactulose…….3.35gm (Laxative)	120 ml	Rs.148.63	-do-	Deferred for P.S.I. by Director DTL, FID, DDCR-IV.
5.	Droxcef 500 mg Capsules Each capsule contains:- Cefadroxil monohydrate ≡ Cefadroxil …..500 mg (Cephalosporin)	10's	154.40	-do-	Deferred for P.S.I. by Director DTL, FID, DDCR-IV.
6.	Scabinil Cream Each gm contains:- Permethrin……..50 mg (Pediculicide, Scabicide)	30 gm	Rs.53.81	-do-	Deferred for P.S.I. by Director DTL, FID, DDCR-IV.

The panel of inspectors inspected the unit on 26th & 27th November, 2013 gave the following recommendations:

i. The registration for the applied products is not recommended.
ii. The registration of Yanil Suspension (Paracetamol 120mg/5ml) may please be cancelled.
iii. The production of the whole unit may be stopped till the above mentioned shortcoming are rectified.
iv. The unit may be re-inspected subsequently to examine the improvement in this aspect.

Decision:- The Board in view of the report of the panel took the following decisions in 242nd meeting :-

a. Cancel the registration of Yanil Suspension.

b. Forwarded report to the Secretary Central Licensing Board for taking appropriate action on issues relating to GMP.

c. The Board advised concerned registration section to present cases for which panel has not recommended the grant of registration.

The cases are detailed in above mentioned table. The action regarding the compliance of GMP yet to be carried out by the Department of Quality Assurance in view of the recommendations of the Registration Board.

Decision: Based on recommendation of panel of inspectors, the Board rejected above applications of M/s. Hizat Pharmaceuticals, Peshawar for grant of registration.

Case No.60

The following drugs of M/s. Zaynon Pharmaceuticals, Peshawar toll manufactured by M/s. Synchro Pharmaceuticals, Lahore and M/s. Aries Pharmaceuticals, Peshawar were deferred for submission of permission letter.

1.	053371	Zynoxim Dry Suspension 100mg Each 5ml contains:- Cefixime trihydrate ≡ Cefixime…….100mg	16-4-2013 Dy. No.2983 Form-5 Rs.50000/- Rs.8000/- dated 01-10-2010	Cephalosporin	Deferred for submission of permission Letter.
2.	050741	Zynoxim Capsules 400mg Each capsule contains:- Cefixime trihydrate ≡ Cefixime……400mg	16-4-2013 Dy. No.2984 Form-5 Rs.50000/- Rs.8000/- dated 01-10-2010	Cephalosporin	-do-
3.	053371	Zynoxim Dry Suspension 100mg Each 5ml contains:- Cefixime trihydrate ≡ Cefixime…….100mg	16-4-2013 Dy. No.2936 Form-5 Rs.50000/-	Cephalosporin	Deferred for submission of permission Letter.
4.	050741	Zynoxim Capsules 400mg Each capsule contains:- Cefixime trihydrate ≡ Cefixime..……400mg	16-4-2013 Dy. No.2937 Form-5 Rs.42000/- **-ive 8000/-**	Cephalosporin	Deferred for submission of permission Letter.

Initially these drugs were toll manufactured by M/s. Aries, Pharmaceuticals, Peshawar of M/s. Zaynoon Pharmaceuticals, Peshawar who has now applied for extension in permission of

contract manufacturing from M/s. Aries Pharmaceuticals, Peshawar. Simultaneously, Zaynoon applied for transfer of registration from M/s. Aries to M/s. Synchro Pharma, Lahore on contract basis. Total fee amounting Rs:200000/- was equally shared by both of Aries and Synchro Pharmaceuticals for the said purpose.

The Registration Board had deferred the case for submission of permission letter. The record reveals that these products were initially manufactured by m/s Winsfield for Zaynoon and were transferred on 06.07.2009 to Aries Pharma for toll manufacturing (F.11.13/2007-Reg-II-North). Now, the firm has requested on 15.03.2014 for grant of extension of toll manufacturing in favour of M/s. Aries, Pharmaceuticals, Peshawar.

Decision: Registration Board extended above products of M/s Zaynonn Pharma, Peshawar for contract manufacturing till 30.06.2015 subject to provision of agreement between contract giver and manufacturer as per contract manufacturing policy.

Case No.61

The following drugs of M/s. Genome Pharmaceuticals, Hattar was considered in 218th meeting of Registration Board decided as mentioned against each:-

1	M/s. Genome Pharmaceutical, Hattar.	Parawomen Tablets. Each Tablet contains;- Paracetamol…..500mg. Pamabron…….25mg.	10's	As per SRO	Approved ten molecules per section as per policy subject to the availability of similar formulation.
2	-do-	Calalfa Tablets Each tablet contains:- Alfacalcidol……..0.5mcg Calcium Carbonate….500mg (Genome Spec)(Vit.D analogue, Calcium supplement)	10's	As Per SRO	Deferred for expert opinion.

Now the firm has submitted that the item at S.No.1 is already registered with the brand name of Febrol C Tablets (Reg.No.061445) manufactured by M/s. Barrett Hodgson , Karachi and item at S.No.2 is already registered with the brand name Bone-Care C Tablets manufactured by M/s.

Schazoo Zaka (Pvt) Ltd., Lahore. The firm has also requested for correction in formulation Calcium Carbonate 500mg to Calcium Carbonate 1000mg which is equivalent to elemental calcium 400mg due to typographic mistake. The management of the firm has deposited the revised fee for this purpose and requested for early registration.

Decision: Registration Board referred products to Pharmaceutical evaluation Cell for scrutinization as per check list.

Case No.62 Cases of registration Tramadol.

Registration Board in its 236th meeting held on 20th November, 2012 had decided that since Nalbuphine and Tramadol are not controlled drugs as per INCB regulation. So the Board will not consider these cases in light of controlled drug guidelines. However, to avoid misuse potential, their procurement and manufacturing record shall be strictly maintained and submitted in quadruplicate under Rule 30 (6) of Drugs (Licensing, Registering and Advertising) Rules, 1976 to the E&M (Evaluation of Monitoring) Department of DRAP.

In light of above decision for registration of Nalbuphine and Tramadol containing products of various manufacturers was pending for decision which was recently given in favour of the manufacturers who paid the differential fee vide decision of G-Cases of registration of Nalbuphine and Tramadol. M/s. Wellborn Pharmachem & Biological, Hattar has also deposited the remaining fee (Rs.12000/- as per revised schedule. Details are as under and requested for grant of registration:-

1.	Borodol 100 mg Injection Each ampoule contains:- Tramadol (as HCl)…….100 mg (Opiate Analogue)	1x5's	As Per SRO	**215th meeting DRB** Deferred for the next meeting for detailed discussion along with all already deferred cases in different meetings.

Decision: Registration Board referred above product to Pharmaceutical Evaluation Cell for scrutinization in light of check list approved by Registration Board on priority.

Supplementary agenda of 243rd meeting Registration Board

Item No.XII: Quality Control Cases

Case No.01 Manufacture and supply of substandard Hepaferon Injection by M/s Pharmadic Laboratories (Pvt) Ltd Lahore

FID Peshawar has informed that the Provincial DG(HS) KPK vide his letter No. 4210/PHCP-dated 08-04-2014 requested to de-seal the stock of interferon Batch No. 87 & 88 for use in patients before its expiry.

The test reports received from the NCL Islamabad declared the Hepaferon batch No. 87, 88 as of standard quality vide reports No. FS2013/31 & FS2013/32 dated 22-02-2014. The Director NCL has declared the sample standard "*subject to the condition that being biological product this samples report is not applicable to whole lot or some other portion of same lot stored else where under different storage conditions*".

The samples of one of same batch No. 87 taken from Leady Reading Hospital (LRH)has been declared substandard. The FID himself admitted the fact that storage facilities in LRH do not have monitoring system.

The FID Peshawar was requested on 21-03-2014 that investigation may kindly be completed; covering details of findings, conclusion fixation of responsibility and recommendations etc, The report of the FID is awaited.

The Honorable Peshawar High Court Peshawar while disposing of the Suo Moto W.P No. 3129/2010 in the said case transferred the case to the NAB, KPK with the direction to submit progress report fortnightly to the Registrar of the Court which shall contain the position and progress in the course of enquiry and investigation till the date, the final charge sheet/reference is filed in the Court. Petition is disposed of.

The request of the FID is submitted for perusal/ consideration of the Board to allow de-sealing of standard Hepaferon Injection present at DHQ Hospital Mardan.

Decsion: The Board discussed the case at length and decided as under:-

1) **The Federal Inspector of Drugs Peshawar is advised to get the case completed by covering details of findings, conclusion, fixation of responsibilities with his recommendations.**

2) **The Board further decided to get update regarding Suo Moto notice taken by Honourable Peshawar High Court Peshawar and fate of case referred to NAB Khyber Pakhtoon Khawa.**

Case No.2 Deaths of persons allegedly due to consumption of cough syrup manufactured by M/s Ethical laboratories Pvt Ltd and M/s Reko Pharmecal Laboratories

Drug Registration Board in its 237th meeting held on 26-02-2013 considered the case of M/s Ethical laboratories Pvt Ltd and M/s Reko Pharmecal Laboratories in the light of recommendation of the Secretary, Provincial Quality Control Board (PQCB), Punjab and Central Licensing Board. It had been reported that Dextromethorphan Active Pharmaceutical Ingredients, Batch No.DMR-02-12-030, Manufactured by M/s Konduskar Laboratories (Pvt) Ltd. MIDC-India and drawn by Drug Inspector, Allama Iqbal Town, Lahore from the premises of M/s Ethical Laboratories Lahore, has been declared sub-standard by the Government Analyst. Accordingly the products were suspended by the Drug Registration Board in its 237th meeting and following decisions were taken by the August Board.

- While endorsing the ban on import from M/s Konduskar India, the Board recommended for also involving trade bodies and diplomatic channels for taking up the matter with the Indian authorities.
- Ministry of Commerce may be approached with the recommendation that a cautious approach made may be adopted for granting Most Favored Nation (MFN) status to the India in view of the substandard imports.
- A committee with following composition is constituted to thoroughly investigate the matter and submit its finding and recommendations to the Board on priority basis.
    a. Representative from DRAP
    b. Representative from the Government of Punjab
    c. Two Experts in Pharmaceutical Sciences
    d. Any other co-optive member the committee may require

ii. Suspension of registration of Tyno SF Cough Syrup of M/s Reko Pharmacal till completion of investigation and decision by the competent forum.

iii. Suspension of registration of Dextromethorphan Cough Syrup and Cocil Syrup of M/s Ethical Labs till completion of investigation and decision by the competent forum.

A complete investigation report has been received from the committee the report of CDL test report No.R.508/2012 had declared sample of Dextromethorphan as standard quality by CDL, Federal Government Analyst. A committee comprising of following members has sent the report.

S.No	Name	Designation
1.	Syed Shaid Nasir	Member Appellate Board Chairman Committee
2.	Professor Dr. Bashir Ahmed	Member
3.	Professor Muhmmad S. Iqbal	Member
4.	Mr. Asim Rauf	DDG, Secretary/ Coordinator of the Committee
5.	Dr. Saif ur Rehman Kahttak	Member

A Committee concluded as under:.

The committee in its report based on to the facts, findings, review of documents, analysis of different reports and discussions based on scientific facts the committee has reached the conclusion that suspected batches of the products i.e. Tyno SF cough syrup and Dextromethorphan cough syrup manufactured by M/s. Reko Pharmacal, Lahore and M/s Ethical laboratories Lahore respectively meet the Pharmacopoeal requirements, hence, these firms cannot be held responsible for the loss of precious lives which occurred in two incidents. The deaths are attributed to overdosing of Dextromethorphan and combining of other narcotic CNS depressants/noxious substances with the Tyno SF syrup and Dextromethorphan syrup.

Decision: The Board discussed the case at length and decided as under:-

In the light of report of committee, the case was briefed to the Board, Mr. Jamil Anwar highlighted that the facts have not been disclosed in the report and he informed the Board that report is incomplete and responsibility lie on both the firms. Sheikh Abdul Waheed and Khalid Saleem Mian, Directors / owners of M/s. Ethical Laboratories (Pvt) Ltd and M/s. Reko Pharmacal (Pvt) Ltd respectively appeared before the Board for personal hearing. The Board after heard the owners / Directors in person decided that the case is lying before the Honourable Islamabad High Court Islamabad and it being sub-judice, can not be discussed further till the decision of the Honourable Court.

Item No.XIII: Biological Drugs.

Case No. 1: Quarantined Minutes of 242nd Meeting Registration Board

The following cases were discussed in the 242nd Meeting of the Registration Board. However, the Minutes were quarantined due to observation of members on column 6 and foot note decision below. The detailed proceedings are as follows;

Product Specific Inspection of local manufacturers

The Drug Registration Board in its 240th meeting considered application of three local manufacturers in Karachi:

i. M/s Getz, Karachi
ii. M/s Hilton, Karachi
iii. M/s Macter, Karachi

The said Board after thorough discussion and scrutiny deferred the applications for Product Specific Inspection by the following panel who conducted the inspection from Jan 20 to 22, 2014:

1. Dr Khalid Khan, Director DTL Peshawar
2. Dr Ammanullah Khan, Director DTL Quetta
3. Area FIDs Karachi of the relevant territory
4. Mr. Abdul Samad Khan, Director, NCLB, Islamabad (could not attend the PSI due to some urgent official work in Islamabad).

First three members of the Panel conducted the inspection as per prescribed procedures adopted for PSI in all other cases as referred by the DRB in its various meeting.

Registration Board also constituted a committee comprising of its following members for evaluation of these inspection reports. This committee framed its recommendations keeping in view inspection reports and evaluation of ECBD for consideration of Registration Board.

1. Gen (R) Karamat A Karamat
2. Brig (R) Muzammil H Najmi
3. Dr. Muhammad Arshad
4. Mr. A.Q. Javid Iqbal
5. Director, DBER.

Following were the conclusion of the PSI team for each factory and its products:

i. **M/s Getz, Karachi**: "the panel observed in detail their entire GMP system during 2 days of inspection, respective dossier of under registered products are already been evaluated for clinical and non-clinical aspects by the ECBD and

Board itself. The panel inspected their facility and documents to ascertain their manufacturing and testing capabilities for biotech products and overall GMP compliance level. Based on the above observations and contents of the attached report the Panel is of the opinion that their GMP system supports to manufacture all their under reference biotech products locally including Unipeg injection in vials and PFS 20kDa and 40kDa which is locally pegylated and manufacturing of PEG-Interferon alfa 2a".

ii. **The recommendation of PSI committee for Unipeg also discussed and the board approved as criteria as indicated in clause (i) above.**

The Registration Board Decisions are shown in column 6:

	Applicant	**Product Specifications**	**Recommendations of the PSI Panel**	**Decision of DRB Subcommittee**	**Decision of the Board in its 242nd Meeting.**	**Decision of the Board in its 243rd Meeting.**
	2.	**3.**	**4.**	**5.**	**6.**	**7.**
1.	**Getz Pharma, Karachi** API in LDPE bags further packed in Al.foil packs (Drug substance) (in lyophilized powder form) will be imported from M/s Hybio Pharmaceutical Co. Ltd, No.37, Keji C. Str. 2nd, Shenzhen Hi-Tech Industrial Park China for local formulation.	**Eptifib** Solution for Infusion 75mg/100ml Each ml contains: Eptifibatide…. 0.75 mg (Anti-thrombotic agent) **(Local manufacture)**	**Recommended Pack size 100ml in vial in unit carton.**	**Recommended**	Product Approved, however, cGMP / COPP is required of the finished Drug manufactured using this particular drug substance in the country of origin. Biosimilarity data of locally manufactured drug needs to be disclosed by the local manufacturer.	**Decision recorded in 242nd Meeting upheld. Further, all firms will submit Bio-comparability data followed by regular Pharmaco-vigilance report.**

2.	**Getz Pharma, Karachi** API in LDPE bags further packed in Al.foil packs (Drug substance) (in lyophilized powder form) will be imported from M/s Hybio Pharmaceutical Co. Ltd, No.37, Keji C. Str. 2nd, Shenzhen Hi-Tech Industrial Park China for local formulation.	**Eptifib** Solution for Injection 20mg/10ml Each ml contains: Eptifibatide.… 2mg/ml (Anti-thrombotic agent) **(Local manufacture)**	**Recommended** **Pack size 10ml in vial in unit carton.**	**Recommended**	Product Approved, however, cGMP / COPP is required of the finished Drug manufactured using this particular drug substance in the country of origin. Biosimilarity data of locally manufactured drug needs to be disclosed by the local manufacturer.	**Decision recorded in 242nd Meeting upheld. Further, all firms will submit Bio-comparability data followed by regular Pharmaco-vigilance report.**

3.	**Getz Pharma, Karachi** API in LDPE bags further packed in Al.foil packs (Drug substance) (in powder form) will be imported from M/s Hebei Changshan Biochemical Pharmaceutical Co., Ltd., Shijiazhuang China for local formulation.	**Enoxa Injection** 20mg/0.2ml Injection Each **Pre-filled syringe** contains:- Enoxaparin sodium…..20 mg/0.2ml USP (Antithrombotic agent) **(Local manufacture)**	**Recommended** **Pack Size 2-Prefilled syringes in unit carton.**	**Recommended**	Product approved, however, cGMP / COPP is required of the finished Drug manufactured using this particular drug substance in the country of origin. Biosimilarity data of locally manufactured drug needs to be disclosed by the local manufacturer.	**Decision recorded in 242nd Meeting upheld. Further, all firms will submit Bio-comparability data followed by regular Pharmaco-vigilance report.**

4.	Getz Pharma, Karachi API in LDPE bags further packed in Al.foil packs (Drug substance) (in powder form) will be imported from M/s Hebei Changshan Biochemical Pharmaceutical Co., Ltd., Shijiazhuang China for local formulation. Biosimilar of Clexane of Sanofi.	**Enoxa** 40mg/0.4ml Injection Each **Pre-filled syringe** contains:- Enoxaparin sodium…..40mg/ 0.4ml USP (Antithrombotic agent) **(Local manufacture)**	**Recommended Pack Size 2-Prefilled syringes in unit carton.**	**Recommended**	Product approved, however,cGMP / COPP is required of the finished Drug manufactured using this particular drug substance in the country of origin. Biosimilarity data of locally manufactured drug needs to be disclosed by the local manufacturer.	**Decision recorded in 242nd Meeting upheld. Further, all firms will submit Bio-comparability data followed by regular Pharmaco-vigilance report.**

5.	**Getz Pharma, Karachi** API (in powder form) will be imported fr API in LDPE bags further packed in Al.foil packs (Drug substance) (in powder form) will be imported from M/s Hebei Changshan Biochemical Pharmaceutical Co., Ltd., Shijiazhuang China for local formulation. Biosimilar of Clexane of Sanofi.	**Enoxa** 60mg/0.6ml Injection Each **Pre-filled syringe** contains:- Enoxaparin sodium…..60 mg/ 0.6ml USP **(Local manufacture)**	**Recommended Pack Size 2-Prefilled syringes in unit carton.**	**Recommended**	Product approved, however, cGMP / COPP is required of the finished Drug manufactured using this particular drug substance in the country of origin. Biosimilarity data of locally manufactured drug needs to be disclosed by the local manufacturer.	**Decision recorded in 242nd Meeting upheld. Further, all firms will submit Bio-comparability data followed by regular Pharmaco-vigilance report.**

6.	**Getz Pharma, Karachi** API in LDPE bags further packed in Al.foil packs (Drug substance) (in powder form) will be imported from M/s Hebei Changshan Biochemical Pharmaceutical Co., Ltd., Shijiazhuang China for local formulation. Biosimilar of Clexane of Sanofi.	**Enoxa** 80mg/0.8ml Injection Each Pre-filled syringe contains:- Enoxaparin sodium....80mg / 0.8ml **(Local manufacture)**	**Recommended** **Pack Size 2-Prefilled syringes in unit carton.**	**Recommended**	Product approved, however, cGMP / COPP is required of the finished Drug manufactured using this particular drug substance in the country of origin. Biosimilarity data of locally manufactured drug needs to be disclosed by the local manufacturer.	**Decision recorded in 242nd Meeting upheld. Further, all firms will submit Bio-comparability data followed by regular Pharmaco-vigilance report.**

7.	**Getz Pharma, Karachi** API in LDPE bags further packed in Al.foil packs (Drug substance) (in lyophilized powder form) will be imported from M/s Hybio Pharmaceutical Co. Ltd, No.37, Keji C. Str. 2nd, Shenzhen Hi-Tech Industrial Park China for local formulation.	**Gilia solution for injection** Glatiramer acetate 20mg/ml Each ml contains: Glatiramer acetate 20mg **(Local Manufacture)**	**Recommended** **Pack Size 1ml pre-filled syringe in Pack of 1x1 and 1x3 cartridges in unit pack.**	**Recommended**	Approved, however, cGMP / COPP is required of the finished Drug manufactured using this particular drug substance in the country of origin. Biosimilarity data of locally manufactured drug needs to be disclosed by the local manufacturer.	**Decision recorded in 242nd Meeting upheld. Further, all firms will submit Bio-comparability data followed by regular Pharmaco-vigilance report.**

8.	Getz Pharma, Karachi API in LDPE bags further packed in Al.foil packs (Drug substance) (in lyophilized powder form) will be imported from M/s Hybio Pharmaceutical Co. Ltd, No.37, Keji C. Str. 2nd, Shenzhen Hi-Tech Industrial Park for local formulation.	**Lira Solution for injection** 6mg/ml Solution for Injection in Cartridge Each 1ml contains:- Liraglutide (free-base anhydrous)……...6mg (Anti Diabetic) **(Local manufacture)**	**Recommended** **Pack Size 3ml pre-filled syringe in Pack of 1x1 and 1x3 cartridges in unit pack.**	**Recommended**	Approved, however, cGMP / COPP is required of the finished Drug manufactured using this particular drug substance in the country of origin. Biosimilarity data of locally manufactured drug needs to be disclosed by the local manufacturer.	**Decision recorded in 242nd Meeting upheld. Further, all firms will submit Bio-comparability data followed by regular Pharmaco-vigilance report.**

9.	**Getz Pharma, Karachi** Naked filled glass vials containing lyophilized powder for injection will be imported from M/s Shanghai Livzon Pharmaceutical Co. Ltd, No.1150, Guiqiao Road, Jinqiao Export Processing Zone, Pudong, Shanghai, China and will be repacked locally.	**Menocon** Lyophilized Powders for Injection 1000 IU USP Each vial contains:- Human Chorionic Gonadotropin USP…..10 00 IU **(Bulk import local repack)**	**Recommended Pack size 2ml in vial along with 2ml of 0.9% Sod.Chloride injection(diluent) packed in 1x1's unit carton 1x5's unit carton 1x10's unit carton**	**Recommended**	Product approved, however, cGMP / COPP is required of the finished Drug manufactured using this particular drug substance in the country of origin. Biosimilarity data of locally manufactured drug needs to be disclosed by the local manufacturer.	**Decision recorded in 242nd Meeting upheld. Further, all firms will submit Bio-comparability data followed by regular Pharmaco-vigilance report.**

10.	**Getz Pharma, Karachi** Naked filled glass vials containing lyophilized powder for injection will be imported from M/s Shanghai Livzon Pharmaceutical Co. Ltd, No.1150, Guiqiao Road, Jinqiao Export Processing Zone, Pudong, Shanghai, China and will be repacked locally.	**Menocon** Lyophilized Powders for Injection 5000 IU USP Each vial contains:- Human Chorionic Gonadotropin USP…….....5000 IU (Gonadotropins and ovulation stimulants) **(Bulk import local repack)**	**Recommended Pack size 2ml in vial along with 2ml of 0.9% Sod.Chloride injection(diluent) packed in 1x1's unit carton 1x5's unit carton 1x10's unit carton**	**Recommended**	Product approved, however, cGMP / COPP is required of the finished Drug manufactured using this particular drug substance in the country of origin. Biosimilarity data of locally manufactured drug needs to be disclosed by the local manufacturer.	**Decision recorded in 242nd Meeting upheld. Further, all firms will submit Bio-comparability data followed by regular Pharmaco-vigilance report.**

11.	**Getz Pharma, Karachi** Naked filled glass vials containing lyophilized powder for injection will be imported from M/s Shanghai Livzon Pharmaceutical Co. Ltd, No.1150, Guiqiao Road, Jinqiao Export Processing Zone, Pudong, Shanghai, China and will be repacked locally.	**Menoget** Menotropins 75IU /2ml vial Each vial contains: Menotropins USP 75IU (Human menopausal gonadotrophin) (Gonadotropins and Ovulation stimulants) **(Bulk import local repack)**	**Recommended** Pack size 2ml in vial along with 2ml of 0.9% Sod. Chloride injection(diluents) packed in 1x1's unit carton 1x5's unit carton 1x10's unit carton	**Recommended**	Product approved, however, cGMP / COPP is required of the finished Drug manufactured using this particular drug substance in the country of origin. Biosimilarity data of locally manufactured drug needs to be disclosed by the local manufacturer.	**Decision recorded in 242nd Meeting upheld. Further, all firms will submit Bio-comparability data followed by regular Pharmaco-vigilance report.**

12.	**Getz Pharma, Karachi** Naked filled glass vials containing lyophilized powder for injection will be imported from M/s Shanghai Livzon Pharmaceutical Co. Ltd, No.1150, Guiqiao Road, Jinqiao Export Processing Zone, Pudong, Shanghai, China and will be repacked locally.	**Menoget** Menotropins 150IU / 2ml vial Each vial contains: Menotropins USP 150IU (Human menopausal gonadotrophin) (Gonadotropins and Ovulation stimulants) **(Bulk import local repack)**	**Recommended** Pack size 2ml in vial along with 2ml of 0.9% Sod. Chloride injection(diluents) packed in 1x1's unit carton 1x5's unit carton 1x10's unit carton	**Recommended**	Product approved, cGMP / COPP is required of the finished Drug manufactured using this particular drug substance in the country of origin. Biosimilarity data of locally manufactured drug needs to be disclosed by the local manufacturer.	**Decision recorded in 242nd Meeting upheld. Further, all firms will submit Bio-comparability data followed by regular Pharmaco-vigilance report.**

13.	**Getz Pharma, Karachi** Pegylated filgrastim will be imported in liquid form(as bulk processed intermediate) (in plastic bottle made of PETG material) from M/s Beijing Kawin Technology Share-Holding Co., Ltd, No.6 Rongjing East Street, BDA, Beijing, China for further formulation locally.	**Neupeg injection** Each Pre-Filled syringe contains:- Pegfilgrastim…..6mg/ 0.6ml (GCSF) **(Local manufacture)**	**Recommended** Pack size 6mg/0.6ml in prefilled syringe 1x1's in unit carton.	**Recommended**	Product approved, however, cGMP / COPP is required of the finished Drug manufactured using this particular drug substance in the country of origin. Biosimilarity data of locally manufactured drug needs to be disclosed by the local manufacturer.	**Decision recorded in 242nd Meeting upheld. Further, all firms will submit Bio-comparability data followed by regular Pharmaco-vigilance report.**

14.	**Getz Pharma, Karachi** API (in concentrated solution form) will be imported (in plastic bottle made of PETG material) from M/s Beijing Kawin Technology Share-Holding Co., Ltd, No.6 Rongjing East Street, BDA, Beijing, China for local formulation.	**Getiferon Solution for Injection 3 MIU in Vials** Each vial contains:- Recombinant Human **Interferon Alfa 2a** …….$3x10^6$ IU EP. **(Local manufacture)**	**Recommended** Pack size 3MIU/ 1ml vial 1x1s'in unit carton 1x5's in unit carton	**Recommended**	Product approved, however,cGMP / COPP is required of the finished Drug manufactured using this particular drug substance in the country of origin. Biosimilarity data of locally manufactured drug needs to be disclosed by the local manufacturer.	**Decision recorded in 242nd Meeting upheld. Further, all firms will submit Bio-comparability data followed by regular Pharmaco-vigilance report.**

15.	**Getz Pharma, Karachi** API (in concentrated solution form) will be imported (in plastic bottle made of PETG material) from M/s Beijing Kawin Technology Share-Holding Co., Ltd, No.6 Rongjing East Street, BDA, Beijing, China for local formulation.	**Getiferon** Solution for Injection **5MIU** in **Vials** Each vial contains:- Recombinant Human **Interferon Alfa 2a** …$5x10^6$ IU EP **(Local manufacture)**	**Recommended** Pack size 5MIU/ 1ml vial 1x1s'in unit carton 1x5's in unit carton	**Recommended**	Product approved, however, cGMP / COPP is required of the finished Drug manufactured using this particular drug substance in the country of origin. Biosimilarity data of locally manufactured drug needs to be disclosed by the local manufacturer.	**Decision recorded in 242nd Meeting upheld. Further, all firms will submit Bio-comparability data followed by regular Pharmaco-vigilance report.**

16.	**Getz Pharma, Karachi** API (in concentrated solution form) will be imported (in plastic bottle made of PETG material) from M/s Beijing Kawin Technology Share-Holding Co., Ltd, No.6 Rongjing East Street, BDA, Beijing, China for local formulation.	**Getiferon Solution for Injection 3 MIU** in **Pre-Filled Syringes** Each Pre-Filled Syringe contains:- Recombinant Human **Interferon Alfa 2a** …….$3x10^6$ IU EP **(Local manufacture)**	**Recommended** Pack size 3MIU/ 1ml in pre-filled syringe in 1x1s'in unit carton 1x5's in unit carton	**Recommended**	Product approved, however,cGMP / COPP is required of the finished Drug manufactured using this particular drug substance in the country of origin. Biosimilarity data of locally manufactured drug needs to be disclosed by the local manufacturer.	**Decision recorded in 242nd Meeting upheld. Further, all firms will submit Bio-comparability data followed by regular Pharmaco-vigilance report.**

17.	**Getz Pharma, Karachi** API (in concentrated solution form) will be imported (in plastic bottle made of PETG material) from M/s Beijing Kawin Technology Share-Holding Co., Ltd, No.6 Rongjing East Street, BDA, Beijing, China for local formulation.	**Getiferon Solution for Injection 5 MIU** in **Pre-Filled Syringes** Each Pre-Filled Syringe contains:- Recombinant Human **Interferon Alfa 2a** …….$5x10^6$ IU EP **(Local manufacture)**	**Recommended** Pack size 5 MIU/ 1ml in pre-filled syringe in 1x1s'in unit carton 1x5's in unit carton	**Recommended**	Product approved, however, cGMP / COPP is required of the finished Drug manufactured using this particular drug substance in the country of origin. Biosimilarity data of locally manufactured drug needs to be disclosed by the local manufacturer.	**Decision recorded in 242nd Meeting upheld. Further, all firms will submit Bio-comparability data followed by regular Pharmaco-vigilance report.**

18.	**Getz Pharma, Karachi** API (in concentrated solution form) will be imported (in plastic bottle made of PETG material) from M/s Beijing Kawin Technology Share-Holding Co., Ltd, No.6 Rongjing East Street, BDA, Beijing, China for local formulation.	**Uniferon Solution for Injection 3 MIU in Vials** Each vial contains:- Recombinant Human **Interferon Alfa 2b**…….$3x10^6$ IU EP **(Local Manufacture)**	**Recommended** **Pack size** **Each vial of 3MIU/ ml** **1x1's in unit carton** **1x5's in unit carton**	**Recommended**	Product approved, however, cGMP / COPP is required of the finished Drug manufactured using this particular drug substance in the country of origin. Biosimilarity data of locally manufactured drug needs to be disclosed by the local manufacturer.	**Decision recorded in 242nd Meeting upheld. Further, all firms will submit Bio-comparability data followed by regular Pharmaco-vigilance report.**

19.	**Getz Pharma, Karachi** API (in concentrated solution form) will be imported (in plastic bottle made of PETG material) from M/s Beijing Kawin Technology Share-Holding Co., Ltd, No.6 Rongjing East Street, BDA, Beijing, China for local formulation.	**Uniferon Solution for Injection 5 MIU in Vials** Each vial contains:- Recombinant Human **Interferon Alfa 2b**…….$5x10^6$ IU EP **Local manufacture**	**Recommended** **Pack size** **Each vial of 5MIU/ ml** **1x1's in unit carton** **1x5's in unit carton**	**Recommended**	Approved, however, cGMP / COPP is required of the finished Drug manufactured using this particular drug substance in the country of origin. Biosimilarity data of locally manufactured drug needs to be disclosed by the local manufacturer.	**Decision recorded in 242nd Meeting upheld. Further, all firms will submit Bio-comparability data followed by regular Pharmaco-vigilance report.**

20.	**Getz Pharma, Karachi** API (in concentrated solution form) will be imported (in plastic bottle made of PETG material) from M/s Beijing Kawin Technology Share-Holding Co., Ltd, No.6 Rongjing East Street, BDA, Beijing, China for local formulation.	**Uniferon Solution for Injection 3MIU** in **Pre-Filled Syringe** Each Pre-Filled Syringe contains:- Recombinant Human Interferon Alfa 2b ……..$3x10^6$ IU **(Local manufacture)**	**Recommended** **Pack size Each prefilled syringe of 3MIU/ ml 1x1's in unit carton**	**Recommended**	Product approved, however, cGMP / COPP is required of the finished Drug manufactured using this particular drug substance in the country of origin. Biosimilarity data of locally manufactured drug needs to be disclosed by the local manufacturer.	**Decision recorded in 242nd Meeting upheld. Further, all firms will submit Bio-comparability data followed by regular Pharmaco-vigilance report.**

21.	**Getz Pharma, Karachi** API (in concentrated solution form) will be imported (in plastic bottle made of PETG material) from M/s Beijing Kawin Technology Share-Holding Co., Ltd, No.6 Rongjing East Street, BDA, Beijing, China for local formulation.	**Uniferon** Solution for Injection **5MIU** in **Pre-Filled Syringes** Each Pre-Filled Syringe contains:- Recombinant Human **Interferon Alfa 2b** …….5x 10^6 IU **(Local manufacture)**	**Recommended Pack size Each prefilled syringe of 5MIU/ ml 1x1's in unit carton**	**Recommended**	Product approved, however,cGMP / COPP is required of the finished Drug manufactured using this particular drug substance in the country of origin. Biosimilarity data of locally manufactured drug needs to be disclosed by the local manufacturer.	**Decision recorded in 242nd Meeting upheld. Further, all firms will submit Bio-comparability data followed by regular Pharmaco-vigilance report.**

iii. **M/s Macter, Karachi:** "Keeping in view the facilities and quality control of the above listed products, the panel recommends the registration of these products to the firm. The panel also recommends the registration of Prance (imported labeled vials) under the condition that the firm will establish their own facilities for biological activity test of the same product within six months period."

	Applicant	**Product Specifications**	**Recommendations of the PSI Panel**	**Decision of DRB Subcommittee**	**Decision of the Board in its 242nd Meeting**	**Decision of the Board in its 243rd Meeting**

22.	**Macter International Limited, Karachi** (API Import in concentrated bulk from M/s Beijing Shuanglu Pharmaceutical Company Ltd, China and local formulation at M/s Macter International, F-216, SITE, Karachi)	**Heberon 2a Injection** 3MIU/0.3ml. (Liquid Solution) Each vial contains:- rh-Interferon alpha 2a ……...3MIU/ 0.3ml **(Local manufacture)**	**Recommended Pack Size 1x1's vial**	**Recommended**	Approved, however, cGMP / COPP is required of the finished Drug manufactured using this particular drug substance in the country of origin. Biosimilarity data of locally manufactured drug needs to be disclosed by the local manufacturer.	**Decision recorded in 242nd Meeting upheld. Further, all firms will submit Bio-comparability data followed by regular Pharmaco-vigilance report.**

23.	Macter International Limited, Karachi (API Import in concentrated bulk from M/s Beijing Shuanglu Pharmaceutical Company Ltd, China and local formulation at M/s Macter International, F-216, SITE, Karachi)	**Heberon 2a Injection** 5MIU/0.5ml. (Liquid Solution) Each vial contains:- rh-Interferon alpha 2a ……5MIU/ 0.5ml **(Local manufacture)**	**Recommended Pack Size 1x1's vial**	**Recommended**	Approved, however,cGMP / COPP is required of the finished Drug manufactured using this particular drug substance in the country of origin. Biosimilarity data of locally manufactured drug needs to be disclosed by the local manufacturer.	**Decision recorded in 242nd Meeting upheld. Further, all firms will submit Bio-comparability data followed by regular Pharmaco-vigilance report.**

24.	Macter International Limited, Karachi (API Import in concentrated bulk from M/s Beijing Shuanglu Pharmaceutical Company Ltd, China and local formulation and freeze-drying at M/s Macter International, F-216, SITE, Karachi)	**Heberon 2a Injection** 3MIU/ml (Lyophilized Powder) Each vial contains:- rh-Interferon alpha 2a ……3MIU/ ml **(Local manufacture)**	**Recommended Pack Size 1x1's vial**	**Recommended**	Product approved, however, cGMP / COPP is required of the finished Drug manufactured using this particular drug substance in the country of origin. Biosimilarity data of locally manufactured drug needs to be disclosed by the local manufacturer.	**Decision recorded in 242nd Meeting upheld. Further, all firms will submit Bio-comparability data followed by regular Pharmaco-vigilance report.**

25.	Macter International Limited, Karachi (API Import in concentrated bulk from M/s Beijing Shuanglu Pharmaceutical Company Ltd, China and local formulation and freeze-drying at M/s Macter International, F-216, SITE, Karachi)	**Heberon 2a Injection** 5MIU/ml (Lyophilized Powder) Each vial contains:- rh-Interferon alpha 2a ……5 MIU/ml **(Local manufacture)**	**Recommended Pack Size 1x1's vial**	**Recommended**	Product approved, however, cGMP / COPP is required of the finished Drug manufactured using this particular drug substance in the country of origin. Biosimilarity data of locally manufactured drug needs to be disclosed by the local manufacturer.	**Decision recorded in 242nd Meeting upheld. Further, all firms will submit Bio-comparability data followed by regular Pharmaco-vigilance report.**

26.	**Macter International Limited, Karachi** (API Import in concentrated bulk from M/s Intas Pharmaceuticals Ltd, India and local formulation and freeze-drying at M/s Macter International, F-216, SITE, Karachi)	**Peg-In Injection** 50mcg /0.5ml (Lyophilized Powder) Each vial contains:- Pegylated rh-Interferon alfa 2b…….50 mcg) **(Local manufacture)**	**Recommended Pack Size 1x1's vial**	**Recommended**	Product approved, however cGMP / COPP is required of the finished Drug manufactured using this particular drug substance in the country of origin. Biosimilarity data of locally manufactured drug needs to be disclosed by the local manufacturer.	**Decision recorded in 242nd Meeting upheld. Further, all firms will submit Bio-comparability data followed by regular Pharmaco-vigilance report.**

27.	Macter International Limited, Karachi (API Import in concentrated bulk from M/s Intas Pharmaceuticals Ltd, India and local formulation and freeze-drying at M/s Macter International, F-216, SITE, Karachi)	**Peg-In Injection** 80mcg /0.5ml Each vial contains:- Pegylated rh-Interferon Alfa 2b……..80mcg (Lyophilized powder for injection) **(Local manufacture)**	**Recommended Pack Size 1x1's vial**	**Recommended**	Product approved, however cGMP / COPP is required of the finished Drug manufactured using this particular drug substance in the country of origin. Biosimilarity data of locally manufactured drug needs to be disclosed by the local manufacturer.	**Decision recorded in 242nd Meeting upheld. Further, all firms will submit Bio-comparability data followed by regular Pharmaco-vigilance report.**

28.	Macter International Limited, Karachi (API Import in concentrated bulk from M/s Intas Pharmaceuticals Ltd, India and local formulation and freeze-drying at M/s Macter International, F-216, SITE, Karachi)	**Peg-In Injection** 100mcg /0.5ml (Lyophilized Powder) Each vial contains:- Pegylated rh-Interferon alfa 2b……..100 mcg/0.5ml **(Local manufacture)**	**Recommended Pack Size 1x1's vial**	**Recommended**	Product approved, however cGMP / COPP is required of the finished Drug manufactured using this particular drug substance in the country of origin. Biosimilarity data of locally manufactured drug needs to be disclosed by the local manufacturer.	**Decision recorded in 242nd Meeting upheld. Further, all firms will submit Bio-comparability data followed by regular Pharmaco-vigilance report.**

29.	Macter International Limited, Karachi (API Import in concentrated bulk from M/s Intas Pharmaceuticals Ltd, India and local formulation and freeze-drying at M/s Macter International, F-216, SITE, Karachi)	**Peg-In Injection** 120mcg /0.5ml (Lyophilized Powder) Each vial contains:- Pegylated rh-Interferon alfa 2b……....120 mcg/0.5ml **(Local manufacture)**	**Recommended Pack Size 1x1's vial**	**Recommended**	Product approved, however cGMP / COPP is required of the finished Drug manufactured using this particular drug substance in the country of origin. Biosimilarity data of locally manufactured drug needs to be disclosed by the local manufacturer.	**Decision recorded in 242nd Meeting upheld. Further, all firms will submit Bio-comparability data followed by regular Pharmaco-vigilance report.**

30.	Macter International Limited, Karachi (API Import in concentrated bulk from M/s Intas Pharmaceuticals Ltd, India and local formulation and freeze-drying at M/s Macter International, F-216, SITE, Karachi)	**Peg-In Injection** 150mcg /0.5ml (Lyophilized Powder) Each vial contains:- Pegylated rh-Interferon alfa 2b……150 mcg/0.5ml **(Local manufacture)**	**Recommended Pack Size 1x1's vial**	**Recommended**	Product approved, however cGMP / COPP is required of the finished Drug manufactured using this particular drug substance in the country of origin. Biosimilarity data of locally manufactured drug needs to be disclosed by the local manufacturer.	**Decision recorded in 242nd Meeting upheld. Further, all firms will submit Bio-comparability data followed by regular Pharmaco-vigilance report.**

31.	Macter International Limited, Karachi (API Import in concentrated bulk from M/s Intas Pharmaceuticals Ltd, India and local formulation at M/s Macter International, F-216, SITE, Karachi)	**Neupeg** 6mg/ml Injection Each vial contains:- Pegfilgrastim ……..6mg/ 0.5ml **(Local manufacture)**	**Recommended Pack Size 1x1's vial**	**Recommended**	Product approved, however cGMP / COPP is required of the finished Drug manufactured using this particular drug substance in the country of origin. Biosimilarity data of locally manufactured drug needs to be disclosed by the local manufacturer.	**Decision recorded in 242nd Meeting upheld. Further, all firms will submit Bio-comparability data followed by regular Pharmaco-vigilance report.**

32.	Macter International, Karachi. Labeled Vials imported from M/s. Beijing Shuanglu Pharmaceutical Co., China and local re-packing at M/s. Macter International, Karachi. (Import of labelled vials and local repacking)	**Prance Injection** Each vial contains: Recombinant Human Basic Fibroblast Growth Factor…… 35000IU (Growth Factor).	**Recommended** **Pack Size 1x1's vial**	**Recommended**	Product approved, however cGMP / COPP is required of the finished Drug manufactured using this particular drug substance in the country of origin. Biosimilarity data of locally manufactured drug needs to be disclosed by the local manufacturer.	**Decision recorded in 242nd Meeting upheld. Further, all firms will submit Bio-comparability data followed by regular Pharmaco-vigilance report.**

33.	Macter International, Karachi. Import of labeled PFS from M/s. Beijing Shuanglu pharmaceutical Co., China and local re-packing at M/s. Macter International, Karachi.	**Macgrastim Injection** Pre-filled Syringe Each ml contains:- Filgrastim (rhG-CSF)…….300ug (Immunomodulator).	**Recommended Pack Size 1x1's vial**	**Recommended**	Product approved, however cGMP / COPP is required of the finished Drug manufactured using this particular drug substance in the country of origin. Biosimilarity data of locally manufactured drug needs to be disclosed by the local manufacturer.	**Decision recorded in 242nd Meeting upheld. Further, all firms will submit Bio-comparability data followed by regular Pharmaco-vigilance report.**

M/s Hilton, Karachi: "Based on the above observations the Panel recommends the grant of registration of Injection Filgrastim only. For the rest of the products the firm is asking for more time till the installation of freeze drying facilities."

	Applicant	**Product specifications**	**Recommendations of the PSI Panel**	**Decision of DRB Subcommittee**	**Decision of the Board in its 242nd Meeting**	**Decision of the Board in its 243rd Meeting**
34.	**Hilton Pharma (Pvt) Ltd., Karachi.** Concentrate import from: M/s Nanogen Pharmaceutical Biotechnology Co., Ltd. Vietnam and local formulation and filling at Hilton Pharma (Pvt) Ltd., Karachi.	**Lameo** Injection 3 MIU Each vial contains:- Interferon alfa-2b…3 MIU (Lyophilized). **(Local manufacture)**	**Deferred for lyophilizer installation and verification.**	**Deferred for lyophilizer installation and verification.**	Deferred. cGMP / COPP is required of the finished Drug manufactured using this particular drug substance in the country of origin. Biosimilarity data of locally manufactured drug needs to be disclosed by the local manufacturer.	**Decision recorded in 242nd Meeting upheld.**

35.	**Hilton Pharma (Pvt) Ltd., Karachi.** Concentrate import from: M/s Nanogen Pharmaceutical Biotechnology Co., Ltd. Vietnam and local formulation and filling at Hilton Pharma (Pvt) Ltd., Karachi.	**Lameo** Injection 5 MIU Each vial contains:- Interferon alfa-2b…5 MIU (Lyophilized). **(Local manufacture)**	**Deferred for lyophilizer installation and verification.**	**Deferred for lyophilizer installation and verification.**	Deferred. cGMP / COPP is required of the finished Drug manufactured using this particular drug substance in the country of origin. Biosimilarity data of locally manufactured drug needs to be disclosed by the local manufacturer.	**Decision recorded in 242nd Meeting upheld.**
36.	**Hilton Pharma (Pvt) Ltd., Karachi.** Concentrate import from: M/s Biocon, Banglore. India formulation and filling at Hilton Pharma (Pvt) Ltd., Karachi.	**Xiro** Injection Each ml contains:- Filgrastim ……..…….. 300ug **(Local manufacture)**	**Recommended**	**Recommended**	Approved, however, cGMP / COPP is required of the finished Drug manufactured using this particular drug substance in the country of origin. Biosimilarity data of locally manufactured drug needs to be disclosed by the local manufacturer.	**Decision recorded in 242nd Meeting upheld. Further, all firms will submit Bio-comparability data followed by regular Pharmaco-vigilance report.**

Decision in 242nd Meeting: The Board after through discussion on the import and use of raw material for the drug substance noted with concern that only those raw material should be imported and used that are also in use for the manufacture of finished drug in the country of origin; this is mandatory in order to safe guard the health of the patients and to avoid experimentation on local population. Further it was agreed that the existing products already in the market also need to be evaluated on similar pattern by the Committee constituted earlier i.e.,

1. Gen Gen (R) Karamat A Karamat Member Registration Board
2. Brig (R) Muzammil H Najmi Member Registration Board
3. Dr. Muhammad Arshad Member Registration Board
4. Mr. A.Q. Javid Iqbal Director QA, DRAP, Islamabad.
5. Mr.Sheikh Ansar Ahmed Director, DBER, DRAP, Islamabad.

*Area FID will co-ordinate the inspection.

Decision in 243rd Meeting: Decision recorded in 242nd Meeting upheld.

Case No. 2: New license for local manufacture by M/s Nextar Pharma (Pvt) Limited, Karachi:

M/s Nexter Pharma (Pvt) Limited, Karachi has communicated to this Division on Feb 01, 2014 that they have received the DML No. 000777 on 15th March 2013 for the local manufacture of Biological Drugs by way of formulation. The firm has acquired the technology from the United Nation's International Centre for Genetic Engineering and Biotechnology (Italy).

	Applicant	Product specifications	Present registration status	Decision of the Board in its 242nd Meeting	Decision of the Board in its 243rd Meeting.

37.	**M/s Nextar Pharma (Pvt) Ltd., Karachi** Concentrate import from: M/s Pooyesh Darou, Co., Ltd., Tehran Iran and local filling and packing.	**Nexfil 150 Injection** Each Prefilled syringe contains: Filgrastim 150 mcg (B.P.)/ml **Shelf life 2 years** **Storage +2˚ to +8˚ C** **Pack size 1x1 PFS** Recombinant Human Granulocyte Colony Stimulating Factor	**NIL**	Approved, however, cGMP / COPP is required of the finished Drug manufactured using this particular drug substance in the country of origin. Bio-similarity data of locally manufactured drug needs to be disclosed by the local manufacturer.	**Decision recorded in 242nd Meeting upheld. Further, all firms will submit Bio-comparability data followed by regular Pharmaco-vigilance report.**
38.	M/s Nextar Pharma (Pvt) Ltd., Karachi Concentrate import from: M/s Pooyesh Darou, Co., Ltd., Tehran Iran and local filling and packing.	**Nexfil 300 Injection** Each Prefilled syringe contains: Filgrastim 300 mcg (B.P.)/ml **Pack size 1x1 PFS** **Shelf life 2 years** **Storage +2˚ to +8˚ C** Recombinant Human Granulocyte Colony Stimulating Factor	**Reg No. 041123 for import in finished form**	Approved, however,cGMP / COPP is required of the finished Drug manufactured using this particular drug substance in the country of origin. Biosimilarity data of locally manufactured drug needs to be disclosed by the local manufacturer.	**Decision recorded in 242nd Meeting upheld. Further, all firms will submit Bio-comparability data followed by regular Pharmaco-vigilance report.**

39.	M/s Nextar Pharma (Pvt) Ltd., Karachi Concentrated pegylated interferon alpha 2a will be imported from: M/s Pooyesh Darou, Co., Ltd., Tehran Iran and local filling and packing.	**Pegaron Injection** Each prefilled syringe contains: Pegylated Interferon alpha 2a-180mcg/ml **Pack size 1x1 PFS Shelf life 2 years Storage +2˚ to +8˚ C** Antiviral agent	**Reg No. 059281 for import in finished form**	Approved, however,cGMP / COPP is required of the finished Drug manufactured using this particular drug substance in the country of origin. Biosimilarity data of locally manufactured drug needs to be disclosed by the local manufacturer.	**Decision recorded in 242nd Meeting upheld. Further, all firms will submit Bio-comparability data followed by regular Pharmaco-vigilance report.**
40.	M/s Nextar Pharma (Pvt) Ltd., Karachi Concentrate import from: M/s Pooyesh Darou, Co., Ltd., Tehran Iran and local filling and packing.	**NP-POETIN 2000 INJECTION** Each prefilled syringe contains: Erythropoietin –2000IU (B.P.)/ml **Pack size 1x1 PFS Shelf life 2 years Storage +2˚ to +8˚ C** Hamatopoietic agent	**Reg No. 047557 for import in finished form**	Approved, however,cGMP / COPP is required of the finished Drug manufactured using this particular drug substance in the country of origin. Biosimilarity data of locally manufactured drug needs to be disclosed by the local manufacturer.	**Decision recorded in 242nd Meeting upheld. Further, all firms will submit Bio-comparability data followed by regular Pharmaco-vigilance report.**

41.	M/s Nextar Pharma (Pvt) Ltd., Karachi Concentrate import from: M/s Pooyesh Darou, Co., Ltd., Tehran Iran and local filling and packing.	**NP-POETIN 4000 INJECTION** Each prefilled syringe contains: Erythropoietin –4000IU (B.P.)/ml **Pack size 1x1 PFS Shelf life 2 years Storage +2˚ to +8˚ C** Hamatopoietic agent	**Reg No. 047558 for import in finished form**	Approved, however,cGMP / COPP is required of the finished Drug manufactured using this particular drug substance in the country of origin. Biosimilarity data of locally manufactured drug needs to be disclosed by the local manufacturer.	**Decision recorded in 242nd Meeting upheld. Further, all firms will submit Bio-comparability data followed by regular Pharmaco-vigilance report.**

Decision in 242nd Meeting: The Board relied upon the inspection report of the license panel that had confirmed the presence of the technology and expertise along with GMP compliance of the facility for the above mentioned product and allowed the registration. It was also noted that this firm had no other products except the ones mentioned above for manufacture in the newly licensed facility.

Decision in 243rd Meeting: Decision recorded in 242nd Meeting upheld

Bio-similars Position paper

Unlike the more common pharmaceutical small-molecule drugs produced by a chemical process, biologics can only be produced by cells (bacterial, yeasts, mammalian) and exhibit high molecular complexity, are very sensitive to the cell line and process used for manufacturing. Biologicals have large molecular weights and high structural complexity, are heterogeneous in terms of molecular species, are heterogeneous in terms of impurities, are sensitive to physical conditions like temperature and light, are depending on the starting materials like the master cell banks or expression systems. Most of the biologics are the results of post-translational modifications (a.o. glycosylation, deamidation, oxidation, phosphorylation, acetylation…) on the amino acid chain of the protein. These post-translational modifications have distinctive consequences for correct folding, potency, effector functions/receptor binding, immunogenicity, pharmacokinetics and stability of the biological. All these modifications determine the host that can be used for the production of the biological. These modifications are only controlled by the cell and cannot be manipulated easily. Nearly undetectable differences in impurities and/or breakdown products are also known to cause serious health implications.

Even small manufacturing process changes could alter the characteristics, efficacy and safety of the biologics. In the EU a specially-adapted approval procedure has been authorized for certain protein drugs, termed "similar biological medicinal products". This procedure is based on a thorough demonstration of " comparability" of the "similar" product to an existing approved product. In the US the Food and Drug Administration has taken a similar position. Biosimilars (or Follow-on biologics in the US) is the official term used to describe copies of the innovator biologic, following patent expiry.

The biosimilar manufacturer does not have access to the originator's molecular cell clone and original cell bank, nor to the exact fermentation, purification and formulation process. This has created a concern that copies of biologics perform differently than the innovator product. Similar concerns also apply to any major manufacturing changes by the maker of the original branded version. For this reason new versions of biologics are not authorized the European Union (or in the US) through the simplified procedures allowed for small molecule generics. Small molecules are produced by a sequence of chemical reactions that can be sufficiently and accurately controlled in contrast with the control of the biological organisms.

Division of Biological Evaluation and Research proposes the following outlines for the regulatory approval process for biosimilars;

1. The comparability of a biosimilar to originator product needs to be based on non-clinical and clinical proof of safety and efficacy.

2. The physician should have the decision autonomy between innovator product and biosimilar(s)

3. The same pharmacovigilance conditions should be applied and adverse events should be unequivocally be traced to the particular product. A distinctive International Naming Nomenclature (INN) for each product will be necessary to support the pharmacovigilance monitoring.

4. When authorizing the common names for biosimilar medicines, only authorise unique brand names for biosimilar medicines, that are meaningfully different from the brand names or trademarks in common use for other medicinal products and thus do not lead to any confusion. To preserve patient safety, a modified naming and labelling regulation is recommended to ensure physicians, patients and pharmacists make informed decisions.

5. The 'summary of product information' of the biosimilar clearly states the approved indications that should be supported by appropriate non-clinical and clinical studies of the biosimilars.

6. Any legislation establishing a pathway for approval of biosimilars must preserve incentives for innovation by respecting intellectual property rights, continuing to protect trade secrets, establishing a workable and fair mechanism for resolving patent disputes, and providing a robust and appropriate period of data exclusivity for the innovator product.

7. The post-IP economic and marketing conditions and incentives

8. All approvals be designated as Bio-Similars at the best based on comparability.

Decision in 243rd Meeting: All the proposals of Division of Biological Evaluation and Research were approved by the Registration Board *except No. 6&7* which is not related the Registration Board.

Case No. 03: IPV Registration in Pakistan

Federal Expended Programme of Immunization (EPI) has forwarded a reference to DRAP, Islamabad stating Pakistan is planning to introduce one dose of inactivated Polio Vaccine (IPV) in its routine immunization in compliance with the WHO/GAVI recommendations fulfillment of the GAVI application requirements and international obligations. The programme has stated that they understand that the process of IPV registration in Pakistan is being processed. In this regard they would like to mention that multi dose IPV will be exclusively used by the EPI for its routine immunization.

M/s Sanofi Aventis Pakistan, Korangi, Karachi has stated that their new registration application **Imovax Polio** 1 vial of 5ml (10doses of 0.5ml)x10 vials packing and 5ml (100 doses of 0.5ml) **10 dose vial packing** is already approved in Drug Registration Board 240th Meeting held on 7th November, 2013. Since Imovax polio 10 doses vial is intended to be supplied for EPI purpose only and not to the private market therefore the price fixation for the product is not required. The single dose of Imovax in Prefilled syringe (single dose) 0.5ml is already registered vide registration No. 045700. UNICEF intends to supply EPI Pakistan, Imvox Polio 10 dose vials, for the Polio Eradication Campaign, as advised by WHO, recommending use of injectable polio vaccine, in additional to oral polio vaccine. **The firm has requested for**

issuance of registration letter of Imvox Polio 10 dose vial so that they are able to provide supplies to UNICEF for EPI Pakistan.

The Drug Registration Board in its 240th Meeting has already approved, this product will be registered for use in EPI and institution only as per following details: -

Sl. #	Applicant	Brand name and composition	Demanded MRP	4th ECBD Recommendation	Decision of Registration Board
25.	Sanofi Aventis Pakistan Limited, Karachi. M/s Sanofi Pasteur, SA 2, Avenus du Post Posteur, 69 007 Lyon, France.	**Imovax Polio** Suspension for injection in multi dose Poliomyelitis Vaccine (Inactivated against type 1,2 & 3 polio Virus One dose 0.5ml Contains: - Poliovirus Type 1, Mahoney strain (inactivated)…..40DU Poliovirus Type2, MEF-I strain (inactivated)…..32DU	1 vial of 5ml (10doses of 0.5ml) Rs. 4240/- 10vial of 5ml (100 doses of 0.5ml) Rs.42400/-	Recommended Each packing will be registered separately	Approved This product will be registered for use in EPI and institution only.

The firm has demanded price of Rs. 424 per dose (Rs.4240/- for 1 vial packing and 42400/- for 10 vial packing. Now the firm has stated that the product shall be supply to EPI therefore, the price fixation of the product is not required.

There are some other requests under consideration like Sind Medical Stores, Karachi for Poliomyelitis Vaccine (inactivated, Suspension for injection – 0.5 ml vial/1 dose. Under such cases it is proposed that the Registration Board may delegate its power to the head of the division or chairman of the board to approve the request for issuance of the letter. Matter is placed before the Registration Board for its consideration and direction.

Decision: The Board decided that the Directorate (Biological) may send the reference to the Pricing Section and decide the matter accordingly.

Case No. 04: Constitution of Expert Committees on Biological Drugs

The Federal Government has constituted an Expert Committee on Biological Drugs under section 10 of the Drugs Act, 1976.

As per requirement of sub section 2 of section10, the members appointed by Federal Government from time to time can hold office for the pleasuring of the Federal Government.

One of the honourable member of the committee has rendered his resignation due to increased official assignments in his parent department and has requested the Federal Government that he may not continue his assignment as member of expert committee on biological (ECBD). Moreover another member Dr. Syed Uzair-ul-Ghani is on long leave and is out of country and it is not possible for him to join the committee for next 4 months.

Under the situation explain above it is not possible to convene the meeting due to the issue of quorum.

In order to speed up the process of evaluation by the experts committee department has following two proposals for consideration by the board: -

Proposal No. 01

The resignation of Dr. Khalid Mehmood, be approved and the recommendation be forwarded to Federal Government through Authority.

Proposal No. 02

In order to speed up the process of the evaluation, recommendation of the registration board is solicited under sub section 04 of section 29 to create two separate experts committees on biological drugs **human** as well as **veterinary** to evaluate applications for their safety efficacy and quality or where public interest so requires, and forward its recommendations for registration of Biological Drugs to Drug Registration Board.

Opinion of Registration Board to above proposals is solicited

The same will be submitted to authority of the DRAP for forwarding it to the Federal Government for necessary notification.

Decision: The Board acceded to both the proposals for above mentioned committees according to the Drugs Act, 1976 and rules framed there under.

Case No. 05: M/s Pakcure Pharma, Islamabad

M/s Pakcure Pharma, Islamabad was awarded DML No. 000763 by way of Basic Manufacture on 16.10.2012 and DML No. 000745 by way of Formulation on 19.12.2012. The firm has applied for the registration of only five product i.e., allergy vaccines similar to that of M/s NIH, Islamabad. The firm had submitted the updated dossiers on 08.10.2013 and revised fee on 16.07.2013. **The Board has allowed the Product Specific Inspection in order to address the issues noted in the DRB 241:**

Applicant	**Product specifications**	**Registration No. of similar product already in the market as manufactured by NIH, Islamabad**	**Decision**
M/s Pakcure Pharma, Rawat, Islamabad.	**Allergex-MP** Each ml contains: Beef protein extract…….10mcg Chicken protein extract. 10mcg Egg protein extract……...10mcg Fish protein extract……..10mcg Mutton protein extract..10mcg **Shelf Life: 6 months when stored at +2 to +8˚C** **Allergy vaccine, immunostimulant**	**016742**	**Deferred for Product specific inspection by the panel.**

M/s Pakcure Pharma, Rawat, Islamabad.	**Allergex-Px1** Each ml contains: *Cannabis sativa* protein extract 10mcg *Acacia niloticaa* protein extract 10mcg *Eucalyptus globulus* protein extract 10mcg *Pininus longfolia* protein extract 10mcg House dust extract 10mcg **Shelf Life: 6 months when stored at +2 to +8˚C** **Allergy vaccine, immunostimulant**	**-do-**	**Deferred for Product specific inspection by the panel.**
M/s Pakcure Pharma, Rawat, Islamabad.	**Allergex-Px2** Each ml contains: *Cannabis sativa* protein extract 10mcg *Acacia niloticaa* protein extract 10mcg *Eucalyptus globulus* protein extract 10mcg *Pininus longfolia* protein extract 10mcg Mixed grass extract of *Lolim temulentum* + *Cynodon dactylon* …10mcg House dust extract ..10mcg **Shelf Life: 6 months when stored at +2 to +8˚C** **Allergy vaccine, immunostimulant**	**-do-**	**Deferred Product specific inspection by the panel.**

M/s Pakcure Pharma, Rawat, Islamabad.	**Allergex-Px3** Each ml contains: *Cannabis sativa* protein extract 10mcg *Acacia niloticaa* protein extract 10mcg *Eucalyptus globulus* protein extract 10mcg *Pininus longfolia* protein extract 10mcg House dust extract ..10mcg Paper mulberry extract…10mcg Thrasher extract…10mcg Raw cotton extract…10mcg **Shelf Life: 6 months when stored at +2 to +8˚C** **Allergy vaccine, immunostimulant**	**-do-**	**Deferred for Product specific inspection by the panel.**
M/s Pakcure Pharma, Rawat, Islamabad.	**Allergex-Px4** Each ml contains: *Cannabis sativa* protein extract 10mcg *Acacia niloticaa* protein extract 10mcg *Eucalyptus globulus* protein extract 10mcg *Pininus longfolia* protein extract 10mcg House dust extract ..10mcg Paper mulberry extract…10mcg Thrasher extract…10mcg **Shelf Life: 6 months when stored at +2 to +8˚C** **Allergy vaccine, immunostimulant**	**-do-**	**Deferred for Product specific inspection by the panel.**

Following panel of the Drug Registration Board was advised to conduct panel inspection:

1. Gen Gen (R) Karamat A Karamat	Member Registration Board
2. Brig (R) Muzammil H Najmi	Member Registration Board
3. Dr. Muhammad Arshad	Member Registration Board
4. Mr. A.Q. Javid Iqbal	Director QA, DRAP, Islamabad.
5.Mr.Sheikh Ansar Ahmed	Director, DBER, DRAP, Islamabad.
6. Mr. Zeeshan Nazir Bajar	Area FID as coordinator/member.

Inspection of the firm was conducted on 7th May, 2014. Mr. A.Q. Javaid Iqbal could not participate in the inspection due to tour abroad. The concluding remarks of the inspection are as follows:

i) M/s Pakcure Pharma production unit for the production of allergy vaccine against various available allergenic. The firm has filed 05 product applications which were earlier evaluated by the department and the shorting coming notice therein were conveyed on 20th September, 2013 highlighting serious concern on the submitted material alongwith the dossiers and various quality issues / parameters adopted if permitted. The company accordingly replied to the DRAP on 08.10.2013 informing that he has attended all the observations. Case was then submitted before the honourable board in its 242 sitting who ordered product specific inspection.

ii) The nominated panel of the Registration Board visited the premises on 7th May, 2014 and notice no considerable reason to considered the submitted 05 applications for various allergic extracts and following the reasons.

a) M/s Pakcure Pharama was inspected. The building was designed for Pharma production as per approved plan only for the production of allergy vaccines. As such there are serious shortcomings towards design, allied manufacturing facilities i.e. water system, lab facilities are lacking, microbiological processing and handling. There is no proper arrangement for material handling and transport. Q.C. lab also laking opitical check equipment and microbiologial clearance. Approved technical staff was also absent. Processing, screening of biological material and in process testing was not available.

b) Employees record was also not present.

c) No office staff, computer and accounts record available

Keeping in view the above, panel is of the view that the products applied namely Allergen-MP, Allergen – Px-1, ` Allergen – Px-2, Allergen – Px-3, Allergen – Px-4 have not sufficient

matching facilities required for protein production. Hence panel unanimously not recommended the grant of registration applied by the firm.

Decision: - The Board decided to defer the case till removal of deficiencies. Reference may also be sent to the Licensing Board to ensure compliance as per requirement of Biological Drugs.

Item No.XIV: Clinical Trial

Case No.01: *A clinical Trial submitted by Dr. Yousuf Khan, Head of Clinical Research, GlaxoSmithKline, 35 – Dockyard Road, West Wharf, Karachi on Phase – III, Ramdomized, Observer – blind, Placebo – Controlled, Multicentre Study to Assess the Safety and Immunogenicity of Herpes Zoster HZ Vaccine. The Clinical Trial was sent to following three experts. Comments of three experts are tabulated as below: -*

Sl. #	Name of Experts	Opinion
1.	Dr. Kamran Rasheed, Department of Oncology, Shifa International Hospital, Islamabad.	I have been reviewed the trial and strongly recommended the study to assess the safety and humoral vaccine response of HZ vaccine in the specific population.
2.	Prof. Dr. Zeba Aziz, Hameed Latif Hospital, Abu Bakar Block, New Garden Town, Lahore	The trial is relevant for our patient population it should be allowed to proceed according to the protocol.
3.	Prof. Dr. Syed Muhammad Irfan, Head Department of Hematology, Liaquat National Hospital & Medical College, Karachi.	After reviewing the provided synopsis I have not found any harmful or safety concern regarding the participants/trial subject. There is no other justification or plausible cause to withhold the trial. Therefore, I recommend you to grant the positive confirmation for the conduct of this clinical trial in Pakistan.

Meanwhile expert opinion is also received from Dr. Muneeb Nasir, Consultant Oncologist, Doctor Hospital & Medical Centre, Lahore through Director (Pharmacy Services) with the remarks that the Clinical trial is well written and objectives are well defined. The trial is relevant for our patient population, it should be allowed to process according to the protocol.

The firm have also requested for the import of :

Herpes Zoster (HZ) vaccine (VZV gE/AS018 A)……20 (twenty).
VZV Placebo / NaC1……...20 (twenty).
The manufacturer is GSK Biologicals, rue de 1' Institute 89, B-1330 Rixensart, Belgium.

The trial was referred to the then Director (Biological) on the recommendation of Chairman (Registration Board), DRAP. On behalf of the then Director (Biological), the Director, National Control Laboratory has elaborated the case and discussed with the head of Clinical Research Dr. Yousuf who has provided the following information as per tabulation: -

IB Section	***Status***	***Summary of Changes***
Summary	Updated	Updated with new data from Clinical Studies Zoster – 001 and Zoster – 015
Introduction	Updated	Section 2.2.3 (Current status of herpes Zoster Vaccination) has been updated to include information about persistence of the immune response after *Zostavax* vaccination.
Phsysical, Chemical and Pharmaceuticals Properties and Formulation of Vaccine	No change	
Non – Clinical Studies	Updated	Results from a comparative immunogenicity study of subcutaneous vs. intramuscular administration of HZ/su were added in a new section, Section 4.2. Section 4.3.2, which includes toxicity studies with VZV gE AS01B was updated with results from a single dose subcutaneous (SC) administration study in Section 4.3.2.6 and a repeat dose SC administration study in Section 4.3.2.7. These studies were also added to Section 4.3.1, which provides a summary of toxicity studies for VZV gE AS01B A summary of toxicity studies with AS01B was added to Section 4.3.3. Toxicity studies for the components of AS01B were added to a new section, Section 4.3.4: Section 4.3.4.1 includes MPL toxicity studies and Section 4.3.4.2 includes QS21 toxicity studies.

Effects in humans	Updated	This section has also updated with new data from clinical studies Zoster-001 and Zoster-015. Specifically, data has been added from the active phase of Zoster-015 and the following-up phase of Zoster-001. SAE data for ongoing studies have been provided upto the new data lock point of 28th November, 2012.
Summary of Data and Guidance for the Investigator	Updated	This section has been updated to be in line with the latest version of the Development Core Safety. Information and guidance for study investigators. Changes were made to the introduction, pharmaceutical presentation, posology and method of administration, contraindication and special warnings, use during pregnancy and lactation and undesirable effects. All solicited adverse events from the protocols are listed as potential undesirable effects. Gastrointestinal symptoms were added as solicited adverse events per the protocol template; therefore, gastrointestinal were also added as potential undesirable effects to Section 6.8(undesirable effects)

The Director, NCL, has recommended that the clinical data may be reviewed by the experts on the safety point of view.

Decision: The Board approved the clinical trial along-with permission to import of vaccine as mentioned above.

Case No: 02. Tranexamic Acid For The Treatment Of Postpartum Hemorrhage: An International, Randomized, Double Blind, Placebo Controled Trial Protocol# Isrctn 7612190 The Woman Trial.

Haleema Shakur, Project Director, The WOMAN Trial, London School of Hygiene & Tropical Medicine and National Coordinator wherein they have requested for extension of the ongoing approved clinical trial. They have requested for inclusion of following hospitals for said clinical trials: -

Sl.#	***Hospital***	***Principal Investigator***	***Institutional Review Board for Bioethics (IRBB)***
1.	Liaqat Memorial Women & Children Hospital KCB – III, 198, Shimla Paharee Road, Near Old Felix Cinema Kohat Cantt	Dr. Fouzia Gul, MBBS, MCPS,FCPS.	You study entitled ***"World Maternal Anitfibrinolytic (Woman) trial: Tranexamic acid for the treatment of postpartum haemorrhage: an international randomized, double blind, placebo controlled trial"*** was submitted to this office for approval or otherwise. Your study protocol /procedure provided per proforma was thoroughly evaluated and approved by majority of members in the 9th meeting. No ethical issue was involved and nothing was found hindering in your research work. Please feel free to contact us in case of any query. All future correspondence most include the IRBB Protocol number and the title of the study.
2.	Nishtar Hospital Obstetrics and Gynecology Unit-II, Nishtar Road, Multan	Prof. Dr. Huma Quddusi, MBBS, FCPS.	Approved for study after minor corrections in urdu translation of Appendixes & consent proforma. Approved for study after minor correction in the informed consent proforma.

These hospitals have been assessed by the sponsor of the trial (LSHTM) as suitable to carry out the study based on the following key information: -

- ❖ The Principal Investigator is a registered, qualified Obstetrician.
- ❖ The Site cares for a reasonable number of women with PPH.
- ❖ The Principal Investigator has complete GCP training.
- ❖ Other trial team members are willing to complete the GCP training.
- ❖ The site provides the minimum level of emergency WHO comprehensive obstetric services (basic services plus Caesarean sections and blood transfusions).
- ❖ The Principal Investigator has put together a trial team at their site and takes responsibility for the trial team and the care of the women in the trial.
- ❖ Additional responsibilities of the Sites and Investigators are detailed in the Protocol and Principal investigator Agreement (which is signed by the Principal Investigator and site).
- ❖ The hospital ethics committee has given approval for the trial to be conducted.

The matter of inclusion of Clinical Trial Centers in already approved Clinical Trial centres as approved by the Chairman Registration Board.

Decision: The Board approved the inclusion of above mentioned centers in the already approved clinical trial.

Item No:XV. Miscellaneous cases.

Case No.01: Voltral 12.5 Suppositories – Novartis Pharma.

Drug Registration Board in its various meetings approved the registration of following drugs in the name of M/s. Novartis Pharma (Pakistan) Limited, Karachi subject to inspection of manufacturer abroad, verification of storage facilities and price fixation / calculation etc as per policy:-

S. #	Name of Manufacturer.	Name of Drug (s)/ Composition.	DMRP/ Pack Size	Meeting.
1.	M/s. Delpharm Huningue S.A.S, 26, rue de la Chapelle, Huningue, France.	Voltral 12.5 Suppositories Each suppository contains:- Diclofenac sodium 12.5mg.	Rs.187.50/Per 10 Suppository Rs.18.75/Per Suppository	238th meeting held on 05-06th August, 2013.
2.	M/s. Novartis Pharma S.A.S, Huningue, France.	Voltral 50mg Suppositories Each suppository contains: - Diclofenac sodium 50mg.	Rs.380/10's	-do-

The firm was advised to provide CoPP from country of origin i.e. France but the firm M/s. Novartis informed that above mentioned drugs are not registered for free sale in its country of origin i.e France.

Decision: The Board discussed matter of non-availability of finished drug in country of origin. It was deliberated that finished drug should be permitted for import only if it is for free sale in country of origin. Thus the Board decided to call firm's representatives for presentation of their case in next meeting.

Case No.02 Change of company name for YAZ and Angeliq.

M/s. Bayer Pakistan (Private) Limited, Karachi have informed that due to a Bayer Group-wide initiative to change the name of the pharmaceutical company, they have requested to approve the change of the manufacturer name of their following registered imported drugs as follows:-

S#	Reg. No.	Name of Drug (s)	Current Name & Address of Manufacturing Site	Proposed Name & Address of Manufacturing Site (As per CPP attached)
1.	059088	Angeliq Tablets 2mg.	M/s. Bayer Schering Pharma AG, Germany.	**Manufactured by:** M/s. Bayer Weimar GmbH und Co. KG, Weimar, Germany. **Release by:** M/s. Bayer Pharma AG, 13342 Berlin, Germany.
2.	059087	YAZ Tablets.	M/s. Bayer Schering Pharma AG, Germany.	**Manufactured by:** M/s. Bayer Weimar GmbH und Co. KG, Weimar, Germany. **Release by:** M/s. Bayer Pharma AG, 13342 Berlin, Germany.

M/s. Bayer Pakistan (Private) Limited, Karachi have deposited fee Rs.50000x2=100000/- and submitted following supporting documents:-

- Copy of Registration letters and acknowledgement of renewal applications.
- Original Notarized Declaration from their Principal regarding the Name Change from Bayer Schering Pharma AG to Bayer Pharma AG.
- Original Certificate of Pharmaceutical Product Angeliq Tablets 2mg.
- Australian Register of Therapeutic Good Certificate Angeliq Tablets 2mg.
- Original Certificate of Pharmaceutical Product YAZ Tablets.
- Drug Establishments Current Registration Site List from FDA official Website.
- FDA submission as notification.

Registration of the drugs is valid as change of company name was granted on 21st October, 2010.

M/s. Bayer Pakistan (Private) Limited, Karachi was advised to clarify about approval of release site from approving authority and submit legalized document for approval of TGA.

In response, firm has requested to waive off the requirement of legalized approval from TGA as per the amended Import Policy. Since the Import Policy has been amended, process their application for above said products, based on Original Legalized CoPP's from country of origin, which have already been submitted.

M/s. Bayer Pakistan (Private) Limited, Karachi was advised to clarify that as per registration letter the name of manufacturer for "Angeliq Tablets 2mg (Reg. No.059088)" is M/s.

Schering AG, Berlin, Germany, but now as per applied CoPP the manufacturer is M/s. Bayer Weimar GmbH und Co. KG, Weimar, Germany this is change of manufacturing site and not the change of name. Furthermore, they have also requested for inclusion of release site in the new permission but release site is not mentioned in the new CoPP submitted, which needs clarification. The status of license holder is also need clarification.

In response, firm have submitted that the manufacturing site for Angeliq and YAZ is M/s. Bayer Weimar GmbH und Co. KG, Doebereinerstrass 20, 99427 Weimar, Germany and product license holder as per the submitted CPP is M/s. Bayer Vital GmbH, 51368 Leverkusen, Germany.

Decision: Request of firm was acceded to by the Board.

Case No.03: Nomination of expert

This office issued letter for expert opinion for following products to Lt. Col. Dr. Farhan Ahmad Majeed, Surgeon, Combined Military Hospital, Rawalpindi, Professor Tanwir Khaliq, Professor of Surgery, Department of General Surgery, Pakistan Institute of Medical Sciences, Islamabad and Dr. Khalid Gondal, Professor of Surgery, Kind Edward Medical College, Lahore:-

S.No.	Name of Drug (s).
1.	Propilen Surgical Suture with Needle
2.	Silk Non Absorbable Surgical Sutures
3.	Pegelak and Pegelak Rapid Synthetic Absorbable Surgical Sutures with Needle
4.	Tektel Non Absorbable Surgical Sutures with Needle
5.	Pedesente Synthetic Absorbable Surgical Sutures with Needle
6.	Pegesorb and Pegesorb Rapid Synthetic Absorbable Surgical Sutures with Needle

Lt. Col. Dr. Farhan Ahmad Majeed, Surgeon, Combined Military Hospital, Rawalpindi and Professor. Tanwir Khaliq, Professor of Surgery, Department of General Surgery, Pakistan Institute of Medical Sciences, Islamabad has send their recommendation/ expert opinion and Dr. Khalid Gondal, Professor of Surgery, Kind Edward Medical College, Lahore has not reply so far , two reminders were issued to Dr. Khalid Gondal, but reply is still pending.

The applicant has requested to nominate another expert, as their manufacturer has threatened to cancel there sole agency agreement.

Mr. Rashid Shaikh, FID, Lahore to personally visit the Dr. Khalid Gondal, he contacted them and informed via telephonically that Dr. Khalid Gondal is not willing to give their opinion due to some of his personal reasons. Out of three experts two has send their opinion as under:-

a) Prof. Dr. Tanwir Khaliq, PIMS, Islamabad has recommended the products.
b) Lt. Col. Dr. Farhan Ahmad Majeed, MH, Rawalpindi has not recommended the products.

Decision: Registration board referred the case for expert opinion of Dr.I.U.Beg, FGSH, Islamabad.

Case No. 04. **De-Registration of drug – violation of SRO. 1103(I)/2006**

The Drug Registration Board in its 240th meeting discussed the HRC Case No. 4740/2013 filed in the Honorable Supreme Court of Pakistan. Pharmaceutical Evaluation & Registration Directorate informed the Board that M/s Sarco Laboratories, Multan had applied for extension in contract manufacturing of Y-Zee Injection (Ceftriaxone Sodium USP) but the Board deferred the application due to incomplete documents. Thus presently registration of the product is in-valid. Moreover, Registration Board recommended that Directorate of Costing & Price may take action against violation of SRO. 1103(I)/2006 against the instant manufacturer.

Accordingly the decision of the Registration Board was communicated to Directorate of Costing & Price. Directorate of Costing & Price has now forwarded a letter wherein it has been stated that the Pricing Committee in its 7th meeting held on 21-08-2013 discussed the case and under the Section 5 of SRO 1103(I)/2006, referred the case to the Pharmaceutical Evaluation & Registration Division for de-registration of the drug by the Drug Registration Board. Section 5 of SRO 1103(I)/2006 is reproduced as under:

> "De-registration of the Drug: The Drug, the price of which is not fixed in accordance with these rules shall de-registered after giving an opportunity of being heard to the concerned company or firm, as the case may be".

It has further been stated that only the Drug Registration Board has the power to de-register a drug and therefore, Directorate of Costing & Pricing in not able to take any further action under SRO 1103(I)/2006.

Decision: Registration Board after thorough deliberations decided to provide opportunity of personal hearing to both the firms i.e. M/s Sarco Chemical Industries, Multan and M/s Florence Pharmaceutics, Islamabad in next meeting.

Case No. 05. **Change in formulation of cough syrup.**

M/s. Star Laboratories (Pvt.) Ltd; Lahore has requested for change of formulation of their following drug as they want to replace Ephedrine HCl to Aminophyline:-

Reg. No.	Name of Drug with existing formulation.	Name of Drug with demanded formulation.
038488	Alvenol Cough Syrup Each 100ml contains:- Chlorpheniramine Maleate …. 100mg Terpin Hydrate …… 200mg Potassium Bicarb ……..…… 2mg Ammonium Chloride …….. 500mg Tr. Senega …… 1ml Menthol …… 20mg Ephedrine HCl ……. 100mg Potassium Guaiacol Sulph. ….. 100mg Potassium Citras ……... 2mg Tr. Ipecac …….. 0.5ml Ext. Glycyrrhiza …… 2ml	Alvenol Syrup Each 5ml contains:- Chlorpheniramine Maleate …. 120mg Aminophylline …… 768mg Ammonium Chloride …….. 600mg Menthol …… 24mg Terpin Hydrate …… 240mg Potassium Guaiacol Sulfonate .. 120mg Potassium Bicarbonate …… 2.400mg Potassium Citrate ……..…. 2.400mg Ext. Glycerrhiza …….. 2.400ml Ipecac Tincture …… 0.600ml Senega Tincture …… 1.200ml

The firm has deposited fee of Rs. 20,000/- for this purpose, however the required data has not been provided on Form-5.

Decision: The Board deferred the case till the firm provides required data on Form-5.

Case No. 06. **Change of brand name-English Pharma, Lahore**

The Drug Registration Board in its 239th meeting had approved the following product of M/s. English Pharmaceutical Industries, Lahore with the condition that the firm will change the brand name of "Zital Tablet":-

S.No.	Name of Drug(s)	Pack Size	Demanded Price
1	Zital 20mg Tablet Each tablet contains:- Escitalopram (as oxalate) …. 20mg	10's	As per S.R.O

Now the firm has informed that they already have registration of "Zital 10mg Tablet" (Reg. No. 067989) and they want to manufacture the above mentioned product with the brand name "Zital 20mg Tablet". They have furnished copy of initial letter of registration of "Zital 10mg Tablet".

Decision: Request of the firm was acceded by the Board.

Case No. 07. **Change in specifications of Diclofenac Sodium Injection.**

M/s. Fynk Pharmaceuticals, Lahore has requested for change of specification of their following product in general appearance / colour of the solution from "Amber glass ampoule containing colourless to light yellow solution":-

S. No.	Name of Drug(s)	Reg. No.
1.	Voveron Injection Each 3ml contains:- Diclofenac Sodium ……. 75mg	062729

They have deposited fee of Rs. 5000/- for this purpose along with copy of initial letter of registration and furnished stability studies along with undertaking that there is no case under consideration before any court of law and other Government organizations.

It is submitted that Diclofenac Sodium in white to slightly yellowish and slightly hydroscopic crystalline powder. Most of the leading manufacturers including brand leader M/s. Novartis prepare diclofenac sodium injection in clear colour less solution which may attain yellowish tinch with the passage of time reflecting the occurrence of chemical changes.

In light of above mentioned arguments such permission may not be granted in toto which may lead to the negative precedence and various complications for the Government Analyst in the Drug Testing Laboratories while analyzing such samples.

Decision: Registration Board did not accede request of the firm for change of specifications.

Case No. 08. **Approval of WHO approved ORS.**

The Drug Registration Board in its 241st meeting has approved the following product of M/s. Paradise Pharma, Lahore. The formulation was written as in column no 2 inadvertently while the WHO approved formulation and request of the firm is mentioned in column no. 5.

S.No.	Name of Drug(s)	Pack size	Demanded MRP	Name of Drug(s) with demanded formulation.
1.	Parasalt Sachet Each sachet contains:- Sodium Chloride……. 3.5g Glucose,anhydrous……13.5g Potassium Chloride……..1.5g Trisodium citrate dehydrate……..20.0g	1×1's 1×20's	As per S.R.O	Parasalt Sachet Each sachet contains:- Sodium Chloride……. 2.6g Glucose,anhydrous…..… 13.5g Potassium Chloride…….. 1.5g Sodium Citrate ……..….. 2.9g

The firm has requested to grant them the registration with WHO approved formulation

Decision: Request of the firm was acceded by the Board.

Case No. 09. **Deferred Products- Wilshire Labs, Lahore**

The Drug Registration Board in its 236th meeting deferred the following products of M/s Wilshire Labs; Lahore for following reasons:-

S. No.	Name of Drug(s)	Pack size	MRP	Decision
1.	Vinqo Injection 500mg Each vial contains:- Vancomycin hydrochloride…….500mg (Glycopeptide Antibacterials)	Per vial	As per SRO	Deferred for further clarification about manufacturing facility.
2.	Vinqo Injection 1gm Each vial contains:- Vancomycin hydrochloride…….1gm (Glycopeptide Antibacterials)	Per vial	As per SRO	-do-
3.	Teflaro Injection Each vial contains:- Ceftaroline Fosamil……..400mg (Cephalosporins)	Per vial	As per SRO	Deferred for confirmation of formulation in developed countries like USA & UK etc.

4.	Teflaro 600mg Injection Each vial contains:- Ceftaroline Fosamil……600mg (Cephalosporins)	Per vial	As per SRO	-do-

The firm has provided undertaking signed by Ghazanfar Ali Jawa that they will manufacture products at Sr. No. 1 & 2 in Dry Powder Injection and they have furnished approval of Dry Powder Injection by Licensing section and they have deposited remaining fee of Rs. 12000/- for each product at Sr. 1 & 2. The firm has also provided documentary evidence of international availability of the products at Sr. 3 & 4 from US FDA and also deposited remaining fee of Rs. 84000/- for products at Sr. No 3 & 4. They have requested to issue the registration of above mentioned product.

Decision: Registration Board deferred products at serial no. 1 and 2 for further deliberation regarding manufacturing requirement of the products. Products at serial no. 3 and 4 were deferred for expert opinion by a committee comprising Brig. Muhammad Aslam, Military Hospital, Rawalpindi, Dr. Rehana Kousar, PIMS, Islamabad & Dr. Shazli Manzoor, Quaid-e-Azam International Hospital, Peshawar Road, Rawalpindi.

Case No. 10. **Registration of Tramadol containing formulation.**

The Drug Registration Board in its 226th meeting deferred the following products of M/s Fynk Pharmaceuticals Sheikhupura, Lahore for conformation of separate section from licensing.

1.	Trama 50mg Capsule Each capsule contains:- Tramadol HCl……..50mg	10's	Rs60.00	Deferred for confirmation of separate section from licensing.

The firm has deposited balance fee amounting Rs.12000/- and has requested to issue the registration accordingly as other firms have been granted the registration of same molecule in the general section in the light of earlier decision of Registration Board in this regard.

Decision: Registration Board referred above products to Pharmaceutical Evaluation Cell for scrutinization in light of check list approved by Registration Board on priority.

Case No. 11. **Nomination of experts for opinion.**

The Registration Board in 239th meeting deferred the following application of M/s. English Pharma Lahore for expert opinion by panel of experts as follows:-

S. No.	Name of the drugs with composition	Experts
1.	Ucholin 10mg Tablet Each tablet contains:- Bethanechol Chloride equiv. to Bethanechol …..10mg	Gen.Dr. Tassawar Husain, Dr. Falak Sher Bhatti, Nescom. Prof. Shoaib Shafi, RMC.

The experts were sent dossiers on 19-11-13 for expert opinion and none of the expert has replied so far.

Decision: Registration Board referred above product for expert opinion of Prof.Dr.Ghias Butt, PIMS; Prof.Mumtaz Ahmad, Benazir Bhutto hospital and prof.Muzamil Tahir, Sh Zayed Hospital, Lahore.

Case No. 12. **Grant of registration for export purpose**

M/s English Pharmaceuticals Lahore has requested for registration of following products for export purpose only:-

S. No.	Name of Drug(s)
1.	Suprastelin 20mg Injection Each ampoule contains:- Chloropyramine Hydrochloride …… 20mg
2.	Suprastelin 25mg Tablet Each tablet contains:- Chloropyramine Hydrochloride …… 25mg

The firm has provided following documents:-

a. Challans fee of Rs. 20000/- for each product.
b. Applications on form-5.
c. Undertaking on stamp paper.
d. Export order.

Decision: The Board approved registration of above products for export purpose only.

Case No. 13. **Constitution of panel of expert.**

The Registration Board has constituted different panels for conducting product specific inspections of M/s Medipak, Lahore in its 241st, 239th and 227th meeting for grant of registration of products mentioned below. The firm has now requested to conduct all these inspections by the panel constituted in 241st meeting of the board i.e. Director DTL, Lahore & area FID:

S. No.	Name of Drug(s) with formulation	Decision of the Board
1.	Voluven Infusion Solution. Each 1000ml Contains:- Poly(O-2-Hydroxyethyl) starch (Hydroxyethyl starch 130/0.4)……60.0gm Sodium Chloride……..9.0gm	Registration Board deferred application for product specific inspection for confirmation of manufacturing and QC facility by Director DTL, Lahore and area FID. **(M-241)**
2.	Moxidex Eye Drops Each ml contains:- Moxifloxacin HCl eq. to Moxifloxacin…….5mg & Dexamethasone sodium phosphate eq. to Dexamethasone phosphate……..1mg (Anti bacterial + Corticosteriod)	The Registration Board deferred case for product specific and GMP inspection of the firm by Chief Drug Inspector, Punjab; Director DTL, Lahore; DDG E&M, Lahore and Area FID. **(M-239)**
3.	Medisol ½+5% Infusion. Each 1000ml contains:- Dextrose Monohyrate…….55gm. Sodium Chloride….4.5gm. (BP)	Registration Board deferred case for product specific and GMP inspection of the firm by Chief Drug Inspector, Punjab; Director DTL, Lahore; DDG E&M, Lahore and Area FID. **(M-239)**
4.	Napro Tablet Each tablet contains:- Naproxen (as sodium)…….550mg (Nonsteroidal Anti-inflammatory)	Approved subject to the recommendation of panel comprising Dr. Farzana Ch., FID and ADC. **(M-227)**
5.	IPM-F Chewable Tablet Each tablet contains:- Iron (III) Hydroxide Polymaltose Complex…..100mg Folic Acid……0.35mg (Iron preparation(Haematonic)	-do-
6.	IPM Chewable tablet Each tablet contains:- Iron (III) Hydroxide Polymaltose complex…..100mg (Iron preparation(Haematonic)	-do-
7.	L-Citrazine Tablet	-do-

	Each tablet contains:- Levocetrizine Dihydrochloride…..5mg (Anti-histamine)	
8.	Cefezim Capsule Each capsule contains:- Cefixime (as Trihydrate) USP…..200mg (Cephalosporin)	-do-
9.	Napro Tablet Each tablet contains:- Naproxen (as sodium)……..275mg (Nonsteroidal Anti-inflammatory)	-do-
10.	Medi-Oflox 200mg Tablet Each tablet contains:- Ofloxacin (USP)…..200mg (Antibiotics)	-do-
11.	Noltren-P 75mg tablet Each tablet contains:- Diclofenic Postassium (USP)….75mg (Anti inflammatory)	-do-
12.	Cefezim 200mg/5ml Each 5ml contains:- Cefixime (as Trihydrate) 200mg/5ml (powder for suspension) (Cephalosporin)	-do-
13.	Cefezim 100mg/5ml Each 5ml contains:- Cefixime (as Trihydrate) 100mg/5ml (powder for suspension) (Cephalosporin)	-do-
14.	Medi-Oflox 400mg Tablet Each tablet contains:- Ofloxacin (USP)….400mg (Anti-Biotics)	-do-
15.	Medi-Oflox 200mg I.V Infusion Each ml contains:- Ofloxacin (USP)……..200mg (Antibiotics)	-do-
41.	Cefezim 400mg Capsule Each capsule contains:- Cefixime (as Trihydrate) USP….400mg (Cephalosporin)	-do-

Decision: The Board constituted panel comprising of Director DTL, Lahore & Area FID for product specific inspections of the above products.

Case No. 14.

The Drug Registration Board in its 238th meeting has deferred the following product of M/s. Hyan Pharma, Lahore for bulk import & local toll repacking by M/s. Pulse Pharmaceuticals, Lahore for the purpose of confirmation of section, Form-5 & balance fee of Rs. 15000/- :-

M/s. Hyan Phama Lahore	M/s. Pulse Pharmaceuticals, Lahore	017877	Q-10 Extra (Normorol) Capsules Each capsule contains: Ubidecarenone …. 30mg	15-04-2013 Rs.15000.00 30-06-2010 Rs.20000.0	Probiotics	Deferred for confirmation of section, Form-5, balance fee of Rs.15000/-,

It is submitted that the case was presented in 238th meeting of the Board as toll manufacturing of the product by M/s. Pulse Pharmaceuticals, Lahore, inadvertently. The firm has informed that they have applied for extension in permission of bulk import and local toll repacking by M/s. Pulse Pharmaceuticals, Lahore. The firm has deposited fee of Rs. 50000/- in this regard. The firm has therefore, requested to approve their request for extension of bulk import and local toll repacking permission of above mentioned product. They have further stated that the product is "Enzyme" not a "Probiotic".

Decision: The Board approved bulk import (blister packaging) and secondary repacking by local contract repacking (secondary packaging) of the above product by M/s. Pulse Pharmaceuticals, Lahore till 30-06-2015. Board further decided that M/s. Pulse Pharmaceuticals, Lahore shall be responsible for quality control and batch release of the product.

Case No. 15. M/s. Kakasian Pharmaceuticals (Pvt.) Ltd; Lahore has requested for extension of toll manufacturing of following products through toll manufacturing by M/s. Kings Pharmaceuticals Lahore. They had deposited fee of Rs. 8000/- on 24 June, 2010 for each product and Rs. 42000/- for each product on 11 April, 2013. At the time of application the firm had submitted incomplete information and now complete documents have been provided. Initially the

products were registered through toll manufacturing by M/s. Mass Pharma, Lahore and it was transferred from M/s. Mass Pharma, Lahore to M/s. Kings Pharmaceuticals, Lahore vide letter dated 21 June, 2011:-

Applicant firm	**Toll manufacturing by**	**Name of Drugs(s) with formulation**	**Reg. No.**	**Fee deposited**	**Approved section**
M/s. Kakasian Pharmaceuticals (Pvt.) Ltd; Lahore	M/s. Kings Pharmaceuticals Lahore	Medixone 250mg Injection Each vial contains:- Ceftriaxone as Sodium equivalent to Ceftriaxone ……250mg	057328	11-04-2013 42000.00 Form-5	Dedicated Cephalosporin facility.
-do-	-do-	Medixone 500mg Injection Each vial contains:- Ceftriaxone as Sodium equivalent to Ceftriaxone ……500mg	057329	-do-	-do-
-do-	-do-	Medixone 1gm Injection Each vial contains:- Ceftriaxone as Sodium equivalent to Ceftriaxone ……. 1gm	057330	-do-	-do-
-do-	-do-	Izafaxim 250mg Injection Each vial contains:- Cefotaxime as Sodium equivalent to Cefotaxime ……250mg	057335	-do-	-do-
-do-	-do-	Izafaxim 500mg Injection Each vial contains:- Cefotaxime as Sodium equivalent to Cefotaxime ……500mg	057336	-do-	-do-
-do-	-do-	Izafaxim 1gm Injection Each vial contains:-	057337	-do-	-do-

		Cefotaxime as Sodium equivalent to Cefotaxime ……. 1gm			
-do-	-do-	Kakaxim 400mg Capsule Each 5 ml contains:- Cefixim trihydrate equivalent to Cefixim ……. 400mg	057338	-do-	-do-
-do-	-do-	Kakaxim 100mg Dry Suspension Each 5 ml contains:- Cefixim trihydrate equivalent to Cefixim ……. 100mg	057339	-do-	-do-
-do-	-do-	Kakaxim 200mg DS Suspension Each 5 ml contains:- Cefixim trihydrate equivalent to Cefixim ……. 200mg	057340	-do-	-do-
-do-	-do-	Maxonil 1gm Injection Each vial contains:- Cefoperazone as Sodium ……. 500mg Sulbactum as Sodium …….. 500mg	057341	-do-	-do-
-do-	-do-	Maxonil 2gm Injection Each vial contains:- Cefoperazone as Sodium ……. 1gm Sulbactum as Sodium …….. 1gm	057342	-do-	-do-

Decision: The Board approved extension of contract manufacturing till 30-06-2015 subject to provision agreement between contract manufacturer and giver in light of contract manufacture policy.

Case No. 16.

The Drug Registration Board in its 241st meeting deferred the following products of M/s. CCL Pharmaceuticals, Lahore for expert opinion. Similarly following experts have provided their opinion as under:-

S. No.	Name of Drug(s)	Pack size	Pack size	Name of Expert	Opinion
1.	Lina-Met 2.5/500 Tablet Each tablet contains: Linagliptin.....2.5mg Metformin HCI……500mg	14's	As per brand leader	Prof. Dr. Rauf Niazi	Both drugs as suggested by M/s. CCL Pharmaceuticals, Lahore are standard, safe and efficacious for treatment of type II diabetics and are being prescribed, all over the world. However of the price of the drug, if can be brought down, keeping in mind the economic status of our population these drugs would be very useful addition to present drug, available to treat type II diabetes.
				Abdul Latif Sheikh	The combination has been approved by various regulatory authorities around the globe and is sold freely. The addition of Linagliptin/metformin treatment in patients with type 2 diabetes mellitus. The addition of Linagliptin/Metformin treatment in patients with type 2 diabetes was well tolerated and resulted in significant and clinically relevant

				Reply of the 3rd expert is awaited.	improvements i9n glycaemic control with increase economically compliance, therefore, Lina-Met (Linagliptin/Metformin) is recommended for registration.
2.	Lina-Met 2.5/850 Tablet Each tablet contains: Linagliptin….....2.5 mg Metformin HCI……850mg	14's	As per brand leader	-do-	-do-
3.	Lina-Met 2.5/1000 Tablet Each tablet contains: Linagliptin .....2.5mg Metformin HCI…….1000mg	14's	As per brand leader	-do-	-do-

Decision: The Board approved the registrations of above mentioned products.

Case No. 17.

The Drug Registration Board in its 241st meeting deferred the following products of M/s. Highnoon Labs; Lahore advising the firm to submit all supporting documents for verification and expert evaluation by Prof. Dr. Zafar Iqbal, University of Peshawar, Prof. Dr. Mehmood Ahmad, Islamia University, Bahawalpur & Dr. Shahid Nasir. The Experts has provided their opinion as under:-

Name of Products	**MRP/ Pack Size.**	**Name of Expert**	**Comments by the expert**

Pidogrel-CAP 75 Each capsule contains:- Clopidogrel (as bisulphate) ……75mg Aspirin (as enteric coated pellets) 75mg	Rs.215.00/10's	Prof. Dr. Zafar Iqbal Prof. Dr. Mahmood Ahmad Syed Shahid Nasir	Briefly the literature cited showed these combinations are safe and effective and such combinations are already available in Pakistan & abroad. The technical data provided showed the similar dissolution profile for the capsules and comparison with other products available in the market also did not showed any significant difference. Therefore, the registration of these combinations may please be allowed. The given combination is already approved by European Medicine Agency, Therapeutic Goods Administration (Australian Government Department of Health) and Indian Government. This combination is also registered in Pakistan in tablet form even by M/s. Highnoon Labs, Lahore. The registration of these combination may be allowed subject to satisfactory provision of cost effectiveness data of the products. The updated dossiers has been studied and noted that the firm has submitted satisfactory data/information against points 2-5 of my above previous letter. In view of this it is recommended that the two products Pidogrel Cap 75 & Pidogrel-Cap 150 may be registered. The issue of high price (point 6) may be taken up with the firm by the specific forum.

Pidogrel-CAP 150 Each capsule contains:- Clopidogrel (as bisulphate) ……75mg Aspirin (as enteric coated pallets) 150mg	Rs.225.00/10's	-do-	-do-

Decision: The Board deferred product for clinical data.

Case No. 18.

The Registration Board in its 241st meeting deferred following drugs of M/s. Highnoon Labs; Lahore for expert opinion by Dr. Rauf Niazi, Prof. Dr. Muhammad Umer & Mr. Abdul Latif Shaikh:-

S. No.	Name of Products	MRP/ Pack Size.	Name of Expert	Comments by the expert
1.	Tagipmet XR 100/1000 Tablet Each bilayered tablet contains:- Sitagliptin (as phosphate) …. 100mg Metformin HCl (as sustained release) ……. 1000mg (Anti-Diabetic)	NA	Prof. Dr. Rauf Niazi Prof. Muhammad Umer	I strongly recommended registration of Tagipment XR 100/1000, 50/1000, 50/500, which woul add flexibility and various ranges of dosages to diabetic patients, however if the price of the drug can be brought down. In light of the

			Reply of 3rd expert is awaited.	above, the registration of Tagipmet XR 50mg/500mg , Tagipmet XR 50mg/1000mg & 100mg/1000 mg is considered.
2.	Tagipmet XR 50/500 Tablet Each bilayered tablet contains:- Sitagliptin (as phosphate) …. 50mg Metformin HCl (as sustained release) ……. 500mg (Anti-Diabetic)	NA	-do-	
3.	Tagipmet XR 50/1000 Tablet Each bilayered tablet contains:- Sitagliptin (as phosphate) …. 50mg Metformin HCl (as sustained release) ……. 1000mg (Anti-Diabetic)	NA	-do-	
4.	Axesom 10 Sachet Each sachet contains:- Esomeprazole (as Magnesium trihydrate) …… 10mg as Gastro-resistant Granules.		Prof. Dr. Rauf Niazi	Esomeprazole sachets (granules) are available in European states and are approved by FDA, they would also be very useful for children and elderly patients who have difficulty to swallow tablet ro capsule and are needed in this country. I

			Prof. Muhammad Umer Reply of 3rd expert is awaited.	highly recommended registration of this drug on fast track basis. In light of data submitted Axesom 10 Sachet is considered for registration.

Decision: The Board approved the above products for registration.

Case No. 19.

The Drug Registration Board in its 241st meeting advised M/s. Highnoon Labs; Lahore to provide valid documents about registration status of following product in Spain for consideration of registration Board**.**

Sr.No.	Product Name with composition	Pack size	Demanded price	Date of submission and fee	**Remarks**
1.	Ebernet 1% Cream Each gram contains:- Eberconazole (as nitrate)….10mg (anti fungal)	10gm	Rs.320.00	21-06-2011 Rs. 8000/- 27-06-2011 Rs. 7000/- 10-7-2013 135000/- (Total: Rs. 150000/-) Form-5D	Not available in FDA, EMA, Australia and Japan

The management of the firm has provided photocopy of CoPP issued for Egypt by Spain for the above mentioned product and other relevant documents including original outer pack of product registered in Spain. The firm has requested to grant them registration accordingly.

Decision: The Board decided to defer the product for further deliberations.

Case No. 20.

The Drug Registration Board in its 242th meeting deferred the following products of M/s. Aptcure (Pvt.) Ltd Lahore till resumption of production / withdrawal of show cause by Licensing Section:-

S/N	1. Brand Name 2. Dosage Form 3. Composition 4. Pharmacological group / Applicant	1. Brand Name 2. Dosage Form 3. Composition 4. Pharmacological group	1. Type of Form 2. Type of application 3. Demanded Price / Pack size 4. Initial date, diary of Date which fee becomes complete according to type of application /or Form (total Fee)	1. Type of Form 2. Type of application 3. Demanded Price / Pack size 4. Initial date, diary of Date on which fee becomes complete according to type of application /or Form (total Fee)	1. Finished Product Specification 2. Me-too Status 3. Last GMP inspection report with date & status	1. Finished Product Specification 2. Me-too Status 3. Last GMP inspection report with date & status.	Decision
1.	1. Acinil 2. Tablets 3. Each tablet contains Famotidine USP 40 mg 4. H_2 blocker Me-too	1. Form-5 2. Fast Track 3. Alu/PVC blister 01 ×10's As per SRO 4. 23-12-10, 5. 13-05-13 Rs. 60,000 Me-too	1. USP 2. 17-06-09 Satisfactory	Deferred till resumption of production / withdrawal of show cause by Licensing section			
2.	1. Acinil 2. Tablets 3. Each tablet contains Famotidine USP 20 mg 4. H_2 blocker Me-too	1. Form-5 2. Fast Track 3. Alu/PVC blister 01 ×10's As per SRO 4. 23-12-10, 5. 13-05-13 Rs. 60,000 Me-too	1. USP 2. 17-06-09 Satisfactory	Deferred till resumption of production / withdrawal of show cause by Licensing			

				section
3.	1. Artinac SR 2. Enteric coated Tablets 3. Each enteric coated tablet contains Diclofenac sodium BP 100 mg 4. NSAID Me-too	1. Form-5 2. Fast Track 3. Alu/ PVC blister in unit carton of 3 × 10's as per SRO 4. 27-01-11 5. Not mentioned	1. BP 2. 17-06-09 Satisfactory	Deferred till resumption of production / withdrawal of show cause by Licensing section
4.	1. Artinac 2. Enteric coated Tablets 3. Each enteric coated tablet contains Diclofenac sodium BP 50 mg 4. NSAID	1. Form-5 2. Fast Track 3. Alu/ PVC blister in unit carton of 2 × 10's as per SRO 4. 27-01-11 5. Not mentioned	1. BP 2. 17-06-09 Satisfactory	Deferred till resumption of production / withdrawal of show cause by Licensing section

Now the firms has provided copy of resumption/ withdrawal of show cause notice and licensing board resumption of production in all section vide letter dated 6-2-2014. The firm has requested to issue the registration of above products.

Decision: The Board approved the above products for registration.

Case No.21. Correction in minutes of 242 meeting Registration Board.

The Drugs Registration Board in its 242nd meeting held on 24th-25th February, 2014 has approved the veterinary product with remarks for packs sizes "as per SRO". The veterinary product are de-controlled therefore as per practice we grant their pack sizes as demanded by the firm.

2. The following firms have applied for under mentioned products as per pack sizes mentioned in last column.

S. No.	Name of Applicants	Name of Drugs/Composition	Decision of Board.	Firm applied packs size.

1.	M/s Myrtle Pharma Plot # E-100, Northern West Industrial Zone, Port Qasim, Karachi.	1. Gentamyr 2. Injection 3. Each ml contains, Gentamycin sulphate…100mg 4. Antibiotic/ Antibactrial	1.Form-5 2.Fast Track 3.As per SRO 4. 17-12-2013, Dy No.557 Rs.60000/-	50ml 100ml
2.	-do-	1. Myrotocin 2. Injection 3. Each Vial contains. Oxytocin …10 iu/ml 4. Harmones	1.Form-5 2.Fast Track 3.As per SRO 4. 17-12-2013, Dy No.559 Rs.60,000/-	1 x 50ml vial 1 x 100ml vial
3.	M/s.Elegance Pharmaceuticals Chak Belli, Pandori Road, District Rawalpindi	1.Florobex-C Liquid 2.Oral Liquid 3. Each 100ml contains: Florfenicol .. 10gm Colistine Sulphate 50MIU 4. Antibacterial	1. Form 5 2. Fast Track 3. not mentioned Not mentioned 4. Dy. No.51 dated 09-09-2013 5. 09-09-2013 Rs.60,000/-	30ml 50ml 100ml 500ml 1 Lit. 2.5 Lit. 5 Lit. 10 Lit.
4.	M/s Evergreen Pharmaceuticals, Lahore.	1.Flomax Plus Suspension 2. Suspension 3. Each ml contains Florphenicol USP…230mg Colistin Sulphate…50MIU 4.Antibacterial	1. Form 5 2. Fast Track 3. As per SRO 4. Dy. No.72 DDC(Reg-I) dated 21-01-14 5. 03-12-2013 Rs.60,000/-	100ml 500ml 1 Litre
5.	-do-	1.TYLOTAR FORTE Solution. 2.Solution 3.Each 1000ml contains Tylosin Tartrate BP 200gm Doxycycline Hcl 250gm Colistin Sulphate BP 500MIU Bromhexine HCl BP 12gm. 4.Macrolide	1. Form 5 2. Fast Track 3. As per SRO 4. Dy. No.288 dated 05-12-13 5. 05-12-2013 Rs.60,000/-	100ml 250ml 500ml 1000ml

		Antibiotic		
6.	-do-	1.ENFLOX PLUS Solution 2.Solution 3.Each 100 ml contains Enrofloxacin BP(Vet) …10 gm Colistin sulphate BP…3.5gm Amantadine Hcl …4gm. 4.Antibiotic	1. Form 5 2. Fast Track 3. As per SRO 4. Dy. No.288 dated 05-12-13 5. 05-12-2013 Rs.60,000/-	100ml 250ml 500ml 1000ml

It is also found that for the under-mentioned products the name of M/s. Nawal Pharmaceutical, Taxila is typed as **"Naval Pharmaceutical"** which is typographic mistake and needs correction.

1.	M/s. Naval Pharmaceuticals, Plot no. 11-A, Punjab Small Industrial Estate Taxila, Rawalpindi	1.Cocci Raft W/S Powder. 2. Water soluble powder. 3. Each 1000gm Powder Contains Sulphaquinoxaline Sodium…..200gm Sulphadimidine Sodium…..82.5gm Diaveridine Hcl.. 50gm Vitamin A…2.5 MIU Vitamin K3…2gm Colistin Sulphate…500MIU 4.Anticoccidial	1.Form 5. 2.Fast track. 3.Decontrolled/100 gm, 250gm, 500 gm, 1 kg,2.5kg,5kg,25,kg . 4.20.5.2013/60000 /528	Approved (M-242)
2.	-do-	1.Dox-T Wal W/S Powder 2.Water soluble Powder. 3.Each 1000gm contains, Doxycycline HCl…200gm, Tylosin tartrate..100gm, Amantadine HCl..40gm 4.Antibacterial/Antiviral.	1.Form 5. 2.Fast track. 3.Decontrolled/100 gm, 250gm, 500 gm, 1 kg,,5kg,10,kg,25kg . 4.20.5.2013/60000 /518	Approved (M-242)

3.	-do-	1.Respi Wal-S powder 2.water soluble powder 3.Each 1000gm contains, Doxycycline HCl 200gm, Tylosin Tartrate…100gm, Colistin Sulphate…500MIU, Bromhexine HCl ..5gm Steptomycin sulphate..20gm. 4.Antibacterial/ bronchodilator	1.Form 5. 2.Fast track. 3.Decontrolled/100 gm, 250gm, 500 gm, 1 kg,,5kg,10,kg,25kg . 4.20.5.2013/60000 /538	Approved (M-242)
4.	-do-	1.N-72 Powder. 2.Water soluble powder. 3.Each 100gm contains, Neomycin sulphate…72gm 4.Antibacterial	1.Form 5. 2.Fast track. 3.Decontrolled/100 gm, 250gm, 500 gm, 1 kg,,5kg,10,kg,25kg . 4.20.5.2013/60000 /521 5.20.5.2013/60000 /521	Approved (M-242)
5.	-do-	1.Flush Wall W/S Powder 2.Water soluble powder. 3Each 1000gm contains, Furosemide..20gm, Potassium chloride..4gm Calcium carbonate…45gm, Manganese sulphate..1gm, Sodium chloride…35gm, Magnesium sulphate..35gm. 4.Diuretic/Anti- infective/Minerals	1.Form 5. 2.Fast track. 3.Decontrolled/100 gm, 250gm, 500 gm, 1 kg,,5kg,10,kg,25kg . 4.20.5.2013/60000 /524 5.20.5.2013/60000 /524	Approved (M-242)
6.	-do-	1.Respi Raft Powder. 2.Water soluble powder. 3.Each 1000gm contains, Doxycycline HCl…200gm, Tylosin Tartrate…100gm, Colistin sulphate…500MIU, Amantadine HCl..40gm. 4.Antibacterial/Antiviral	1.Form 5. 2.Fast track. 3.Decontrolled/100 gm, 250gm, 500 gm, 1 kg,,5kg,10,kg,25kg . 4.20.5.2013/60000 /537	Approved (M-242)

7.	-do-	1.Neo Raft Powder. 2.Water soluble powder. 3.Each 1000gm contains, Neomycin sulphate..70gm, Colistin sulphate..4gm, Chlortetracycline HCl…80gm, Bromhexine HCl…5gm. 4.Antibacterial	1.Form 5. 2.Fast track. 3.Decontrolled/100 gm, 250gm, 500 gm, 1 kg,,5kg,10,kg,25kg . 4.20.5.2013/60000 /514	Approved (M-242)
8.	-do-	1.Spec-LA W/S Powder. 2.Water soluble powder. 3.Each 100gm powder contains, Lincomycin HCl..5gm, Spectinomycin HCl…10gm Amantidine HCl..3gm. 4.Antibacterial	1.Form 5. 2.Fast track. 3.Decontrolled/100 gm, 250gm, 500 gm, 1 kg,,5kg,10,kg,25kg . 4.20.5.2013/60000 /539	Approved (M-242)
9.	-do-	1.Rafta Dine Powder. 2.Water soluble powder. 3.Each 100gm contains, Enrofloxacin HCl..10gm, Colistin Sulphate..4gm, Amantadine HCl…4gm, 4.Antibacterial/Antiviral	1.Form 5. 2.Fast track. 3.Decontrolled/100 gm, 250gm, 500 gm, 1 kg,,5kg,10,kg,25kg . 4.20.5.2013/60000 /541 5.20.5.2013/60000 /541	Approved (M-242)

Decision: Registration Board approved pack sizes as approved by registration board. Moreover, the Board also corrected manufacturer name as that for veterinary drugs, p ack size as Nawal Pharmaceutical, Taxila.

Item No. XVI. **Grant of Registration to new DML / New Section**

a) Cases deferred in M-242 (14 – Applications)

b) Applications for grant of registration to new Drug Manufacturing Licenses (73- Applications)

c) Applications for grant of registration to newly approved sections (18- Applications)

d) Applications for grant of registration to newly approved sections whose applications are still remaining (10 products per section) (5 - Applications)

a) Cases deferred in M-242 (14 – Applications)

S/N.	Name and address of manufacturer/Applicant	1. Brand Name 2. Dosage Form 3. Composition 4. pharmacological group	1.Type of Form 2. Type of application 3. Demanded Price / Pack size 4. Initial date, diary. 5. Date on which fee becomes complete according to type of application /or Form (total Fee)	1. Me-too status	Decision in M-242 meeting of Reg. Board	Decision
1.	M/s Wyeth Pak. Ltd. S-33, Hawkes Bay Road, SITE, P.O.Box 167, Karachi.	1.Caltrate Plus 2.Oral Tablet 3.Each film coated tablet contains: Calcium Carbonate…….1500 mg (Eq. to elemental calcium 600mg) Vitamin D……400 IU 4.Calcium Supplement	1.Form5-D 2.Fast Track 3.Rs.150/30's 4-10-2011 Dy.No.746 Rs.8000/- Rs.12,000/- 26-11-2012 23-1-2013 Rs.40,000/- The product has been applied of form 5D	Reply has been received.	Deferred for balance fee & confirmation of international status of the	Approved

Evaluator – I

1.	M/s Wnsfeild Pharmaceuticals, plot # 122 Block A Phase V, Industrial Estate Hattar	1. Alfa-Block 2. Capsule 3. Each capsule contains:- Tamsulosin Hydrochloride SR pellets……..50mg 4. (Selective Alpha-a Adrenergic Blocing Agents)	1. Form-5 2. Fast Track 3. As Per SRO N.A. 4. 27-04-2011 Rs.8000/= (351) 5. 29-10-2013 Rs.52,000/= (3311)	Alfamax (platinum)	Deferred for the submission of following 1. GMP of source 2. Stability studies 3. COA 4. Differential fee in case of imported source	Approved

Evaluator – III

3.	M/s.Glaxo Smith Kline Pakistan Limited, F-268 S.I.T.E Karachi.	Panadol Forte Suspension Suspension Each 5ml contains: Paracetamol.. 250mg NSAID BP	Rs.60.00 for 90ml Suspension Rs.45.00 for 60ml Suspension	Form 5 Fast Track Dy. No.1462 dated 29-07-2013 30-07-2013 Rs.68,000/- challan form is photocopy	Me too (Febrol Suspension of Barrett & Hodgson) Inspection of the firm was conducted on 07-01-2014, 21-01-2014, 14-02-2014 by the area FID and concluded that "Firm has well maintained/ retained its unit/ operation/ qualified personals from a long time. Endeavor to sustain a good level of GMP compliance is a continuous process and implemented from time to time"	Approved
4.	M/s Global Pharmaceuticals, Islamabad	Dipof Capsules Capsule Each capsule contains Olanzapine 3mg + Fluoxetine 25mg Antidepressant Manufacturer	As per SRO/ Pack of 10,20,30's	Form 5 Fast Track 27/11/2010 Dy No 10901 Rs 15000/- 17/05/2013 Dy No 3081 Rs 45000 11-12-2013 Dy	Symbayax of Eli Lilly Lenzif of Martin Dow Karachi Inspection of the firm was carried out on 26-02-2013 by area FID and considered to be	Approved

				No 7880 Rs 90000/-	GMP compliant	
5.	-do-	Dipoff Capsules Capsule Each capsule contains Olanzapine 6mg + Fluoxetine 25mg Antidepressant Manufacturer	As per SRO/ Pack of 10,20,30's	Form 5 Fast Track 10904 dated 27/11/2010 Rs 15000/- 17/05/2013 Dy No 3081 Rs 45000 11-12-2013 Dy No 7899 Rs 90000/-	Symbayax of Eli Lilly Lenzif of Martin Dow Karachi Inspection of the firm was carried out on 26-02-2013 by area FID and considered to be GMP compliant	Approved

Evaluator – IV

6.	M/s Amarant Pharmaceuticals (Pvt.) Ltd. 158-D, Tore Gadap Road, Super Highway, Karachi.	Orli Capsules Capsules Each capsule contains Orlistat pellets 50% w/w ……120 mg (Lipase inhibitor) Finished product specifications are Manufacturer. **Source of pellets is: M/s Spansules Formulations. Sy. No. 172, Plot No. 154/A4, IDA, Bollaram Village, Jinnaram Mandal, Medak District, Andhra Pradesh.**	Alu/ PVC blister As per PAC	1. Form 5 2. 15-02-13 3. 15-02-13 Rs. 60,000/- 29-04-2014 Rs. 240,000	1. Xenical Cap 120mg 2. Osker Cap 120mg 3. 11-12- 2012 Conclusion of inspection report has not been mentioned on report	Approved. Firm will provide legalized GMP certificate of source, COA and stability and Chairman, RB will permit issuance of registration letter.
7.	M/s Amarant Pharmaceuticals (Pvt.) Ltd. 158-D, Tore Gadap Road, Super Highway, Karachi.	Orli Capsules Capsules Each capsule contains Orlistat pellets 50% w/w …… 60 mg (Lipase inhibitor) Finished product specifications are Manufacturer. **Source of pellets is: M/s Spansules Formulations.**	Alu/ PVC blister As per PAC	1. Form 5 2. 15-02-13 15-02-13 Rs. 60,000/- 3. 29-04-2014 Rs. 240,000	1. Alli Cap 60mg 2. Osker Cap 60mg 3. 11-12- 2012 Conclusion of inspection report has not been mentioned on report	Approved. Firm will provide legalized GMP certificate of source, COA and stability and Chairman, RB will permit issuance of registration letter.

		Sy. No. 172, Plot No. 154/A4, IDA, Bollaram Village, Jinnaram Mandal, Medak District, Andhra Pradesh.				
8.	M/s Amarant Pharmaceuticals (Pvt.) Ltd. 158-D, Tore Gadap Road, Super Highway, Karachi.	Asenap sublingual tablet Sublingual Tablet Each sublingual tablet contains Asenapine Maleate 5mg (Antipsychotic) Finished product specifications are Manufacturer.	20's/ As per SRO	1. Form 5 D 2. 21-08-13 Dy.No.809 Rs.20,000/- 18-12-2013 Rs.40,000/- 3. 29-04-2014 Rs. 90,000	1. Saphris sublingual tablet 5 mg 2. New drug 3. 11-12- 2012 Conclusion of inspection report has not been mentioned on report	Deferred for expert opinion of Prof.Iqbal Afridi JPMC, Prof.Rizwan Taj PIMS and Dr.Wajid Ali HMC
9.	M/s Amarant Pharmaceuticals (Pvt.) Ltd. 158-D, Tore Gadap Road, Super Highway, Karachi.	Asenap sublingual tablet Sublingual Tablet Each sublingual tablet contains Asenapine Maleate 10mg (Antipsychotic) Finished product specifications are Manufacturer.	20's/ As per SRO	1. Form 5 D 2. 21-08-13 Dy.No.809 Rs.20,000/- 18-12-2013 Rs.40,000/- 3. 29-04-2014 Rs. 90,000	1. Saphris sublingual tablet 10 mg 2. New drug 3. 11-12- 2012 Conclusion of inspection report has not been mentioned on report	Deferred for expert opinion of Prof.Iqbal Afridi JPMC, Prof.Rizwan Taj PIMS and Dr.Wajid Ali HMC

10.	M/s GlaxoSmith Kline Pakistan Limited, 35-Dockyard Road, West Wharf, Karachi.	Panadol Joint Tablet Each modified release tablet contains Paracetamol Ph Eur 665 mg modified release (Non narcotic Analgesic) Finished product specifications are Manufacturer	20's Rs 200/-	1. Form 5 A 2. 22-06-12 3. 18-04-13 Rs. 150,000/-	1. Paracetamol- Osteo 665 mg modified release tablets approved by TGA 2. New Drug 3. Firm was inspected on 20-01-2011 and GMP compliance was good.	Approved (with change in brand name)

Evaluator – V

11.	M/s. M.S. Enterprises Ltd. 3.5Km, Raiwind, Kot Radha-Kishan Road, Kasur.	Paksol 5% Infusion Each 100ml contains:- Dextrose Anhydrous …… 5.0gm Hypotonic water and carbohydrate source Manufacturers' specifications.	Rs. 49.06/- per 100ml vials	Form-5 (Fast Track) 10/9/2013 160 R&I 10/9/2013 (Rs. 60,000/-)	5% Dextrose Injection B. Braun, USA (250, 500 & 1000ml) Inspection report dated 26/12/2013	Approved (Confirmation of particle counter and TOC by area FID)
12.	M/s. M.S. Enterprises Ltd. 3.5Km, Raiwind, Kot Radha-Kishan Road, Kasur.	Paksol NS Infusion Each 100ml contains:- Sodium Chloride…….0.9gm Isotonic crystalloid salt solution Manufacturers' specifications.	Rs. 45.95/- per 100ml vial	Form-5 (Fast Track) 10/9/2013 159 R&I 10/9/2013 (Rs. 60,000/-)	0.9% Sodium Chloride Injection B. Braun, USA (250, 500 & 1000ml) Inspection report dated 26/12/2013	Approved (Confirmation of particle counter and TOC by area FID)
13.	M/s Amarant Pharmaceuticals (Pvt) Ltd., 158D Tore, Gadap Road, Super Highway,	GEROX CAPSULE 20 MG Capsule	As per S.R.O; 10's.	Form-5D (Fast Track) 21/05/2013, 1025	Under evidence of international availability firm has provided reference of BRISDELLE	Deferred for confirmation of international availability

	Karachi	Each capsule contains: Paroxetine as Hcl …. 20mg Psychotherapeutic drugs. Manufacturers specification.		(R&I) Rs.60,000/- Rs. 90,000/- (29/04/2014)	(Paroxetine as mesylate) 7.5mg capsules. cGMP report dated 11/12/2012 and 18/06/2013 is provided. In the last inspection report it is mentioned that "production operation are not underway due to some law and order situation".	
14.	M/s. Hoover Pharmaceuticals (Pvt) Ltd., Plot No. 16, Zain Park, Sagian bypass Road, Lahore.	Calferol Tablets Each tablet contains:- Calcium Carbonate ……...1250mg Cholecalciferol (Vitamin D3)……...400 IU Calcium supplement Manufacturers specifications.	As per SRO2x10's & 10x10's	Form-5 (Fast Track) 31/7/2013 9392 R&I 31/7/2013 (Rs. 60,000/-)	Inspection report dated 11/02/2013 provided.	Deferred for confirmation of me too status

b) Applications for grant of registration to new Drug Manufacturing Licenses (73 - Applications)

Evaluator – II

S/N	Name and address of manufacturer/Applicant	Brand Name Dosage Form Composition (pharmacological Group) Finished product specification	Demanded Price / Pack size	1. Type of Form 2. Initial date, diary. 3. Date on which fee becomes complete according to type of application /or Form (total Fee)	1. International status in stringent regulatory agencies 2. Me-too status 3.GMP status as depicted in inspection report (dated)	Decision
1.	M/s. Jaskan Pharmaceuticals (Pvt) Ltd, Plot No. 50, Sundar Industrial Estate, Lahore. **New License** 1. **Oral Dry Powder**	Ciprokan 125mg Dry Suspension Each 5ml contains:- Ciprofloxacin Hydrochloride (USP) eq. to Ciprofloxacin….125mg (Quinolone) (USP)	As Per SRO/30ml,60ml	1. Form-5 2. 3-4-2014(1344) 3. 3-4-2014 (Rs.20,000/-)	1. Required 2. Novidat (Sami) 3.Grant of DML recommended (19-02-2014)	Deferred for confirmation of approval of formulation in 125 mg strength by Stringent Regulatory Agencies.

	Suspension (General) Section Vide letter No. F.6-3/2014-Lic (M-234) dated 3rd April, 2014.					
2.	-do-	Ciprokan 250mg Dry Suspension Each 5ml contains:- Ciprofloxacin Hydrochloride (USP) eq. to Ciprofloxacin….250mg (Quinolone) (USP)	As Per SRO/30ml,60ml	1. Form-5 2. 3-4-2014 (1343) 3. 3-4-2014 (Rs.20,000/-)	1. Required 2. Novidat (Sami) 3.Grant of DML recommended (19-02-2014)	Approved. Letter will be issued after rectification of shortcomings.

3.	-do-	Levokan 125mg Dry Suspension Each 5ml contains:- Levofloxacin….125mg (Quinolone)	As Per SRO/60ml	1. Form-5 2. 3-4-2014(1339) 3. 3-4-2014 (Rs.20,000/-)	1. Required 2. Levaq (Global) 3.Grant of DML recommended (19-02-2014)	Deferred for clarification of formulation from firm as applied product is approved as solution in stringent DRA's
4.	-do-	Levokan 250mg Dry Suspension Each 5ml contains:- Levofloxacin….250mg (Quinolone)	As Per SRO/60ml	1. Form-5 2. 3-4-2014 (1338) 3. 3-4-2014 (Rs.20,000/-)	1. Required 2. Levaq (Global) 3.Grant of DML recommended (19-02-2014)	Deferred for clarification of formulation from firm as applied product is approved as solution in stringent DRA's
5.	-do-	Klarax 125mg Dry Suspension Each 5ml contains:- Clarithromycin (USP)….125mg (Macrolide Antibiotic) (USP Spec.s)	As Per SRO/15ml,30ml, 60ml	1. Form-5 2. 3-4-2014 (1342) 3. 3-4-2014 (Rs.20,000/-)	1. BNF 61 (Klaricid (Abbott) 2. (Klaricid (Abbott) 3.Grant of DML recommended (19-02-2014)	Approved. Letter will be issued after rectification of shortcomings.

6.	-do-	Azomak 200mg Dry Suspension Each 5ml contains:- Azithromycin dehydrate eq. to Azithromycin….. 200mg Macrolide antibiotic	As Per SRO/60ml,25ml	1. Form-5 2. 3-4-2014 (1341) 3. 3-4-2014 (Rs.20,000/-)	1. BNF 61 (Zithromax (Pfizer) 2. Zetamax (Pfizer) 3.Grant of DML recommended (19-02-2014)	Approved. Letter will be issued after rectification of shortcomings.
7.	-do-	Roxikan 50mg Dry Suspension Each 5ml contains:- Roxithromycin…. .50mg (Macrolide antibiotic)	As Per SRO/60ml,30ml	1. Form-5 2. 3-4-2014 (1340) 3. 3-4-2014 (Rs.20,000/-)	1. Required 2. Required 3.Grant of DML recommended (19-02-2014)	Deferred for confirmation of me too status
8.	-do-	Malarid 15/90mg Dry Suspension Each 5ml contains:- Artemether……15mg Lumefantrine….90mg (Anti-Malarial)	As Per SRO/30ml,60ml	1. Form-5 2. 3-4-2014 (1345) 3. 3-4-2014 (Rs.20,000/-)	1. Required 2. Artem Plus (Hilton) 3.Grant of DML recommended (19-02-2014)	Approved. Letter will be issued after rectification of shortcomings.
9.	-do-	Nofung 50mg Dry Suspension	As Per SRO/35ml	1. Form-5 2. 3-4-2014	1. BNF 61 (Diflucan (Pfizer)	Approved. Letter will be issued after rectification of shortcomings.

		Each 5ml contains:- Fluconazole….50 mg (Antifungal)		(1337) 3. 3-4-2014 (Rs.20,000/-)	Oral suspension, orange-flavoured, fluconazole for reconstitution with water, 50 mg/5 mL, ; 200 mg/5 mL, 2. Diflucan (Pfizer) 3.Grant of DML recommended (19-02-2014)	
10.	-do-	Mytekan 4mg Dry Suspension Each 5ml contains:- Montelukast Sodium eq. to Montelukast…..4 mg (Leukotriene Receptor Antagonist)	As Per SRO/25ml,60ml	1. Form-5 2. 3-4-2014 (1346) 3. 3-4-2014 (Rs.20,000/-)	1. Required 2. Required 3.Grant of DML recommended (19-02-2014)	Deferred for review of formulation by review committee.

Evaluator - III

11.	M/s Jaskan Pharmaceuticals (Pvt) Limited, 50 Sunder Industrial Estate Raiwind Road, Lahore (Sachet section)	Osteoguard 2g Sachet Sachet Each sachet contains …..Strontium Ranelate 2g Antiosteoporotic	As per SRO/Pack of 7's	Form 5 New License Dy No 1334 dated 03-04-2014 02-04-2014 Rs.20,000	Protos of Servier Labs Australia Osstium of Atco Laboratories Karachi Inspection of the firm was conducted on 24-12-2103 by the panel of inspectors and recommend for grant of DML for sections namely Tablet (general), Capsule (general), Sachet (general) and Suspension (general)	Approved. Letter will be issued after rectification of shortcomings.
12.	-do-	Calkan 1000 Sachet Sachet Each sachet contains Calcium lactate gluconate…1000mg	As per SRO/Pack of 10's	Form 5 New License Dy No 1335 dated 03-04-2014 02-04-2014 Rs.20,000	Not provided by firm Ambiguous details are submitted Inspection of the firm was	Deferred for confirmation of international availability and me too status

		Vitamin C…500mg Calcium carbonate…327mg Folic acid … 1mg Vitamin B12…250mcg Calcium and Vitamin Supplement			conducted on 24-12-2103 by the panel of inspectors and recommend for grant of DML for sections namely Tablet (general), Capsule (general), Sachet (general) and Suspension (general)	
13.	-do-	Gutkan 250mg Sachet Sachet Each sachet contains ….Saccharomyces boulardii 250mg Probiotic Yeast	As per SRO/Pack of 10's	Form 5 New License Dy No 1333 dated 03-04-2014 02-04-2014 Rs.20,000	Not provided Enflor of Hilton Pharma Karachi Inspection of the firm was conducted on 24-12-2103 by the panel of inspectors and recommend for grant of DML for sections namely Tablet (general), Capsule (general), Sachet (general) and Suspension (general)	Referred to directorate of HOTC

14.	-do-	Jasom 20mg Sachet Sachet Each sachet contains …Omeprazole 20mg/ Sodium bicarbonate 1680mg Proton Pump Inhibitor Manufacturer	As per SRO/Pack of 10's	Form 5 New License Dy No 1331 dated 03-04-2014 02-04-2014 Rs.20,000	Zegrid of Santarus Inc Risek Insta of Getz Pharma Karachi Inspection of the firm was conducted on 24-12-2103 by the panel of inspectors and recommend for grant of DML for sections namely Tablet (general), Capsule (general), Sachet (general) and Suspension (general)	Deferred for review of formulation by review committee
15.	-do-	Jasom 40mg Sachet Sachet Each sachet contains …Omeprazole 40mg/ Sodium bicarbonate 1680mg Proton Pump Inhibitor	As per SRO/Pack of 10's	Form 5 New License Dy No 1327 dated 03-04-2014 02-04-2014 Rs.20,000	Zegrid of Santarus Inc Risek Insta of Getz Pharma Karachi Inspection of the firm was conducted on 24-12-2103 by the panel of	Deferred for review of formulation by review committee

		Manufacturer			inspectors and recommend for grant of DML for sections namely Tablet (general), Capsule (general), Sachet (general) and Suspension (general)	
16.	-do-	Monteken 4mg sachet Sachet Each sachet contains …….Montelukast as sodium 4mg Leukotriene Receptor Antagonist	As per SRO/Pack of 10 & 14 ‘s	Form 5 New License Dy No 1332 dated 03-04-2014 02-04-2014 Rs.20,000	Montelukast Sodium granules of Mylan Pharmaceticals Inc Myteka of Hilton Pharma Karachi Inspection of the firm was conducted on 24-12-2103 by the panel of inspectors and recommend for grant of DML for sections namely Tablet (general), Capsule (general), Sachet (general) and Suspension (general)	Approved. Letter will be issued after rectification of shortcomings.

17.	-do-	Orak sachet Sachet Each sachet contains ….sodium chloride 3.5mg Sodium citrate 2.9mg Potassium chloride 1.5mg Dextrose 20mg Electrlyte	As per SRO/ pack of 20's	Form 5 New License Dy No 1329 dated 03-04-2014 02-04-2014 Rs.20,000	Ambiguous Needs confirmation Inspection of the firm was conducted on 24-12-2103 by the panel of inspectors and recommend for grant of DML for sections namely Tablet (general), Capsule (general), Sachet (general) and Suspension (general)	Approved as per WHO formulation. Letter will be issued after rectification of shortcomings.
18.	-do-	Jasmec 3gm sachet Sachet Each sachet contains …dioctahedral smectite 3gm Anti diarrhoeal agent	As per SRO/ Pack of 30's	Form 5 New License Dy No 1328 dated 03-04-2014 02-04-2014 Rs.20,000	Not found in stringent regulatory agencies however firm has submitted the reference of Smecta powder for oral suspension of Pharmaplan Pvt Limited, South Africa	Approved. Letter will be issued after rectification of shortcomings.

					Dioctahedral smectite of Atco Laboratories Karachi Inspection of the firm was conducted on 24-12-2103 by the panel of inspectors and recommend for grant of DML for sections namely Tablet (general), Capsule (general), Sachet (general) and Suspension (general)	
19.	-do-	Artefix 15mg, 120mg Sachet Sachet Each sachet contains…Dihydro artemisinin 15mg Piperaquine Phosphate 120mg Antiprotozoal/ Antimalarial	As per SRO/ Pack of 16's	Form 5 New License Dy No 1330 dated 03-04-2014 02-04-2014 Rs.20,000	Not provided Dipip of Hilton Pharma Karachi Inspection of the firm was conducted on 24-12-2103 by the panel of inspectors and recommend for grant of DML for sections namely	Approved. Letter will be issued after rectification of shortcomings.

					Tablet (general), Capsule (general), Sachet (general) and Suspension (general)	
20.	-do-	Mucotropic 200mg Sachets Sachets Each sachet contains ….Acetylcysteine 200mg Mucolytic	As per SRO/ Pack of 30's	Form 5 New License Dy No 1336 dated 03-04-2014 02-04-2014 Rs.20,000	Not found in stringent regulatory agencies however the firm has provided reference of Acetylcysteine instant sachets of Sedico pharmaceuticals Egypt. Mucolator of Abbot Labs Karachi	Approved. Letter will be issued after rectification of shortcomings.
21.	-do- (Tablets)	Levokan Tablets 250mg Tablets Each film coated tablet contains … Levofloxacin hemihydrates 250mg Quinolone	As per SRO/ Pack of 10's	Form 5 New License Dy No 1361 dated 03-04-2014 02-04-2014 Rs.20,000	Lavaquin tablets of Janssen Inc Brodin of Werrick Pharmaceuticals Islamabad	Approved. Letter will be issued after rectification of shortcomings.
22.	-do-	Levokan Tablets 500mg Tablets	As per SRO/ Pack of	Form 5 New License Dy No 1356 dated	Lavaquin tablets of Janssen Inc	Approved. Letter will be issued after rectification of shortcomings.

		Each film coated tablet contains … Levofloxacin hemihydrates 500mg Quinolone	10's	03-04-2014 02-04-2014 Rs.20,000	Brodin of Werrick Pharmaceuticals Islamabad	
23.	-do-	Ciprokan Tablets 250mg Tablets Each film coated tablet contains…. Ciprofloxacin as hydrochloride 250mg	As per SRO/ Pack of 10's	Form 5 New License Dy No 1365 dated 03-04-2014 02-04-2014 Rs.20,000	Cipro tablet of Bayer Health Care Inc Cipro tablet of Bayer Healthcare Karachi	Approved. Letter will be issued after rectification of shortcomings.
24.	-do-	Ciprokan Tablets 500mg Tablets Each film coated tablet contains…. Ciprofloxacin hydrochloride 250mg	As per SRO/ Pack of 10's	Form 5 New License Dy No 1364 dated 03-04-2014 02-04-2014 Rs.20,000	Cipro tablet of Bayer Health Care Inc Cipro tablet of Bayer Healthcare Karachi	Approved. Letter will be issued after rectification of shortcomings.
25.	-do-	Azomak tablet 250mg Tablet Each film coated tablet contains Azithromycin dihydrate …250mg Macrolide antibiotic	As per SRO/ pack of 6's	Form 5 New License Dy No 1360 dated 03-04-2014 02-04-2014 Rs.20,000	Zithromax of Pfizer Inc Zithromax of Pfizer Karachi	Approved. Letter will be issued after rectification of shortcomings.

		Manufacturer				
26.	-do-	Azomak tablet 500mg Tablet Each tablet contains Azithromycin dihydrate …500mg Macrolide antibiotic Manufacturer	As per SRO/ pack of 6's	Form 5 New License Dy No 1359 dated 03-04-2014 02-04-2014 Rs.20,000	Zithromax of Pfizer Inc Ambiguous	Approved. Letter will be issued after rectification of shortcomings.
27.	-do-	Montekan Tablets 10mg Tablet Each film coated tablet contains ….montelukast sodium 10mg Bronchodilator/Anti-asthmatic Manufacturer	As per SRO/pack of 10's	Form 5 New License Dy No 1366 dated 03-04-2014 02-04-2014 Rs.20,000	Montelukast sodium of Mylan Pharmaceuticals Inc Myteka of Hilton Pharma Inc	Approved. Letter will be issued after rectification of shortcomings.
28.	-do-	Piroxcan Tablets 20mg Tablet Each tablet contains Piroxicam	As per SRO/pack of 10's	Form 5 New License Dy No 1357 dated 03-04-2014 02-04-2014	Brexidol of Chiesi Abxicam of Invotek	Approved. Letter will be issued after rectification of shortcomings.

		Beta cyclodextrin equivalent to piroxicam…… 20mg Nonsteroidal Anti-inflammatory		Rs.20,000		
29.	-do-	Frokan Tablets 100mg Tablet Each film coated tablet contains ….Flurbiprofen 100mg NSAID USP	As per SRO/pack of 30's	Form 5 New License Dy No 1363 dated 03-04-2014 02-04-2014 Rs.20,000	Froben of Abbot Inc Froben of Abbot Labs Karachi	Approved. Letter will be issued after rectification of shortcomings.
30.	-do-	Mecokan tablets 500ug Tablet Each film coated tablet contains ….mecobalamin 500ug Co-enzyme type Vitamin B12	As per SRO/Pack of 20's	Form-5 New License Dy No 1363 dated 03-04-2014 03-04-2014 Rs 20,000/-	Methycobal tablets of Eisai Co Ltd Japan Mecobal of Nabiqasim	Approved. Letter will be issued after rectification of shortcomings.

Evaluator – IV

31.	M/s Hiranis Pharmaceutical Pvt. Ltd. Plot.No. E-145-149, North western Industrial Zone, Port Qasim, Karachi. **Capsule (General)**	Dilast Capsule 10mg Capsule Each capsule contains Ibudilast JP 10mg (Phosphodiesterase inhibitor) Finished product specifications are Manufacturer.	Rs. 500/ pack of 10's Rs 50/ capsule	1.Form-5 D 2.06-03-2014 Dy.No. 216 3.04-03-2014 Rs.50,000/- (The firm applied on form 5 D but in agenda the form erroneously mentioned as form 5)	1. Not present in reference drug agencies, however, Ibudilast capsule 10 mg is present in Japan while MHLW Japan does not show Ibudilast capsule 2. New drug 3. Firm was inspected on 17th & 23rd September 2013, for grant of DML by way of formulation	Deferred for confirmation of indication.
32.	-do- **Capsule (General)**	Tobacin Capsule Capsule Each capsule contains: Tobramycin USP 28 mg (Aminoglycoside) Finished product specifications are Manufacturer.	Rs. 2250/ 15's pack Rs. 150/ 1's	1.Form-5 D 2.06-03-2014 Dy.No. 204 3.06-03-2014 Rs.50,000/-	1. Tobi podhaler 28mg 2. New drug 3. Firm was inspected on 17th & 23rd September 2013, for grant of DML by way of form formulation	Deferred for expert opinion

33.	-do- **Capsule (General)**	Lomac Capsule Capsule Each capsule contains Esomeprazole magnesium trihydrate enteric coated granules eq. to Esomeprazole MS 20mg (Proton Pump Inhibitor) Finished product specifications are Manufacturer. **Source of Esomeprazole Magnesium Trihydrate is M/s Titan Laboratories Pvt. Ltd. Address: E-27/1, E-27/2, M.I.D.C. Mahad Village Jite, Raigad. District Raigad,**	As per PRC	1.Form-5 2.05-03-2014 Dy.No. 203 3.05-03-2014 Rs.100,000/-	1. Nexium capsule 20mg 2. Nexum capsule 20mg 3. Firm was inspected on 17th & 23rd September 2013, for grant of DML by way of form formulation	Approved. Firm will provide legalized GMP of source, COA of pellets and stability study data and Chairman will approve issuance of registration letter.

		Maharashtra. India.				
34.	-do- **Capsule (General)**	Lomac Capsule Capsule Each capsule contains Esomeprazole magnesium trihydrate enteric coated granules eq. to Esomeprazole MS 40mg (Proton Pump Inhibitor) Finished product specifications are Manufacturer. **Source of Esomeprazole Magnesium Trihydrate is M/s Titan Laboratories Pvt. Ltd.**	As per PRC	1.Form-5 2.05-03-2014 Dy.No. 204 3.05-03-2014 Rs.100,000/-	1. Nexium capsule 40mg 2. Nexum capsule 40mg 3. Firm was inspected on 17th & 23rd September 2013, for grant of DML by way of form formulation	Approved. Firm will provide legalized GMP of source, COA of pellets and stability study data and Chairman will approve issuance of registration letter.

		Address: E-27/1, E-27/2, M.I.D.C. Mahad Village Jite, Raigad. District Raigad, Maharashtra. India				
35.	-do- **Capsule (General)**	Aclidum Capsule Capsule Each capsule contains Aclidinum Bromide 400 mcg eq to Aclidinum 343 mcg (Anticholinergic) Finished product specifications are Manufacturer	Rs. 2250/ pack of 15's Rs 150/ capsule	1.Form-5 D 2.04-03-2014 Dy.No. 188 3.04-03-2014 Rs.50,000/-	1. FDA & EMA approved Aclidinum inhalation powder in inhaler device, not capsule for inhalation 2. New drug 3. Firm was inspected on 17th & 23rd September 2013, for grant of DML by way of formulation	Deferred for PSI & international availability status in capsule dosage form.
36.	-do- **Liquid Syrup (General)**	Olivestin Syrup Syrup Each 5 ml contains Ebastine BP 5mg (Histamine H_1 receptor	As per PRC	1.Form-5 2.06-03-2014 Dy.No. 221 3.06-03-2014 Rs.20,000/-	1. Not present in reference drug agencies, however, Ebastine syrup is present internationally. 2. Atmos syrup 3. Firm was inspected on 17th & 23rd September 2013, for grant of DML by way of formulation	Approved

		antagonist) Finished product specifications are Manufacturer				
37.	-do- **Liquid Syrup (General)**	Privituss Oral Suspension Oral suspension Each 5 ml contains Levocloperastine Fendizoate 35.4 mg eq to Levocloperastine Hydrochloride 20 mg Finished product specifications are Manufacturer	Rs. 100 per 60 ml Rs 200/ 120ml	1.Form-5 D 2.04-03-2014 Dy.No. 185 3.04-03-2014 Rs.50,000/-	1. Not present in reference drug agencies, however, Levocloperastine Fendizoate oral suspension is present in India, Mexico, and Korea. 2. New drug 3. Firm was inspected on 17th & 23rd September 2013, for grant of DML by way of formulation	Deferred for expert opinion
38.	-do- **Liquid Syrup (Steroid)**	Prelone Oral Syrup Oral Syrup Each 5 ml contains Prednisolone USP 15mg (Glucorticosteroid)	Rs. 65/ 60 ml	1.Form-5 2.06-03-2014 Dy.No. 214 3.06-03-2014 Rs.50,000/-	1. FDA approved Prelone Syrup 15mg/5ml 2. Steron Syrup 3. Firm was inspected on 17th & 23rd September 2013, for grant of DML by way of formulation	Approved

		Finished product specifications are USP				
39.	-do- **Liquid Syrup (Steroid)**	Safcort Oral Suspension Oral Suspension Each 5 ml contains Deflazacort 6mg (Glucorticosteroid) Finished product specifications are USP Medicine Compendium	Rs. 120/ 30 ml	1.Form-5 D 2.04-03-2014 Dy.No. 221 3.04-03-2014 Rs.50,000/-	1. Not found in reference drug agencies, however, Deflazacort oral suspension **22.75mg/ml** manufactured by M/s Sanofi Aventis is available internationally & Dcortz Suspension **6mg/ml** available in India. 2. New drug 3. Firm was inspected on 17th & 23rd September 2013, for grant of DML by way of formulation	Deferred for safety & clinical trial data
40.	-do- **Mouth Wash (General)**	Oracure Mouthwash Mouthwash Each 100ml contains:- Diclofenac acid BP 0.074gm (NSAID) Finished product specifications are Manufacturer	Rs 200/ 150 ml Rs 266/ 200 ml	1.Form-5 D 2.06-03-2014 Dy.No. 36 3. 06-03-2014 Rs.50,000/-	1. Not found in reference drug agencies, however, Diclofenac acid 0.074% mouth wash is present internationally in Italy, India, and China. 2. New Drug 3. Firm was inspected on 17th & 23rd September 2013, for grant of DML by way of formulation	Deferred for safety & clinical trial data

41.	-do- **Mouth Wash (General)**	Helenil Mouth Wash Mouth Wash Each ml contains:- Ketoprofen (as lysine salt) 16mg (NSAID) Finished product specifications are Manufacturer.	Rs 250/ 150ml	1.Form-5 D 2.04-03-2014 Dy.No. 206 3.04-03-2014 Rs.50,000/-	1. Not found in reference drug agencies however, Ketoprofen Lysine salt mouth wash (Oki mouth wash) manufactured by Domp Farmaceutici SPA Italy, is available internationally. 2. New drug 3. Firm was inspected on 17th & 23rd September 2013, for grant of DML by way of formulation	Deferred for safety & clinical trial data
42.	-do- **Cream / Ointment/ Gel (General)**	Avogel Gel Dental Gel Each gram contains:- Metronidazole Benzoate eq to Metronidazole BP 10 mg 1%w/w (Anti bacterial) Finished product specifications are BP.	As per PRC	1.Form-5 2.06-03-2014 Dy.No. 215 3.06-03-2014 Rs.20,000/-	1. FDA approved Metronidazole **topical gel** 1%, however, Metronidazole in combination with Chlorhexidine Gluconate is present in Russian Federation States (Ukraine) 2. Me too 3. Firm was inspected on 17th & 23rd September 2013, for grant of DML by way of formulation	Deferred for confirmation of me too status

43.	-do- **Cream / Ointment/ Gel (General)**	Relever ointment Ointment Each gram contains Bacitracin USP 500 Units Neomycin as Sulphate USP 3.5mg Polymixin B Sulphate USP 5000 Unots Lidocaine USP 40mg Finished product specifications are USP.	Rs. 80 per 20 gram	1.Form-5 2.06-03-2014 Dy.No. 208 3.06-03-2014 Rs.20,000/-	1. Not present in reference drug agencies, however, Tribiotic LC ointment is present in USA as OTC. 2. Mycitracin plus ointment 3. Firm was inspected on 17th & 23rd September 2013, for grant of DML by way of formulation	Deferred for me too status
44.	-do- **Cream / Ointment/ Gel (General)**	Lamanil Cream Each gram contains Terbinafine HCL BP 10 mg Finished product specifications are manufacturer.	As per PRC	1.Form-5 2.06-03-2014 Dy.No. 210 3.06-03-2014 Rs.20,000/-	1. Lamisil Cream 1% 2. Terbiderm cream 1% 3. Firm was inspected on 17th & 23rd September 2013, for grant of DML by way of formulation	Approved
45.	-do- **Tablet Steroides**	Safcort Tablet Tablet Each Tablet contains	Rs. 180/ 10's pack	1.Form-5 D 2.04-03-2014 Dy.No. 186 3.04-03-2014	1. Not present in reference drug agencies, however, Deflazacort tablet (Calcort) manufactured by M/s Sanofi	Deferred for submission of safety & clinical data

		Deflazacort 6mg (Glucorticosteroid) Finished product specifications are USP MC		Rs.50,000/-	Aventis is available internationally. 2. New drug 3. Firm was inspected on 17th & 23rd September 2013, for grant of DML by way of formulation	
46.	-do- **Ointment /Gel/ Cream Steroides**	Lumacort Cream Cream Each gram contains Hydroquinone USP 40 mg Fluocinolone as Acetate USP 0.1 mg Tretinoin USP 0.5 mg (Skin bleach, Vitamin A derivative, Corticosteroid) Finished product specifications are Manufacturer.	15 gram, 30 gram As per PRC	1.Form-5 2.06-03-2014 Dy.No. 212 3.06-03-2014 Rs.20,000/-	1. Tri Luma cream approved by FDA 2. Hydroquin Plus Cream 3. Firm was inspected on 17th & 23rd September 2013, for grant of DML by way of formulation	Approved
47.	-do- **Ointment /Gel/ Cream Steroides**	Candacort Cream Each gram contains	As per PRC	1.Form-5 2.06-03-2014 Dy.No. 209 3.06-03-2014	1. Hydrozole cream approved by TGA 2. Hydrozole Cream 3. Firm was inspected on	Approved

		Clotrimazole BP 10 mg Hydrocortisone BP 10 mg (Antifungal, Corticosteroid) Finished product specifications are Manufacturer.		Rs.20,000/-	17th & 23rd September 2013, for grant of DML by way of formulation	
48.	-do- **Mouth Wash (General)**	Pentadent Mouthwash Mouthwash Each ml contains:- Benzydamine HCL BP 1.5 mg Hexetidine BP 1mg (NSAID & Antiseptic) Finished product specifications are Manufacturer	Rs 200/ 150 ml	1.Form-5 D 2.06-03-2014 Dy.No. 36 3. 06-03-2014 Rs.50,000/-	1. Not found in reference drug agencies, however, Bouchex Forte mouth wash is present internationally in Argentina. 2. New Drug 3. Firm was inspected on 17th & 23rd September 2013, for grant of DML by way of formulation	Deferred for safety & clinical trial data
49.	-do- **Mouth Wash (General)**	Dentassium Mouth Wash Mouth Wash Each ml contains:- Potassium Nitrate BP 10	150ml & 300ml As per PRC	1.Form-5 2.06-03-2014 Dy.No. 206 3.06-03-2014 Rs.20,000/-	1. Not found in reference drug agencies however, Potassium Nitrate mouthwashes in combination with Fluorine available internationally 2. Prodent 1% w/v 3. Firm was inspected on	Deferred for clarification of following observation. 1. The applicant has mentioned Vitamin B5 & Vitamin E as inactive ingredients while these have pharmacological actions and their use as inactive ingredient or as excipients requires

		mg (Desensitizing) Finished product specifications are Manufacturer.			17th & 23rd September 2013, for grant of DML by way of formulation	scientific justification..
50.	-do- **Tooth Paste (General)**	Oradent Tooth Paste Each gram contains:- Permethol 2.5mg (Analgesic, Anti inflammatory) Finished product specifications are Manufacturer.	As per PRC	1.Form-5 2.06-03-2014 Dy.No. 206 3.06-03-2014 Rs.20,000/-	1. Not found in reference drug agencies however, toothpaste containing Permethol available internationally. 2. Hi Paradent tooth paste 3. Firm was inspected on 17th & 23rd September 2013, for grant of DML by way of formulation	Deferred for clarification of following observation. 1. The applicant has mentioned Vitamin B5 & Vitamin E as inactive ingredients while these have pharmacological actions and their use as inactive ingredient or as excipients requires scientific justification..
51.	-do- **Tooth Paste (General)**	Dentisept Tooth Paste Each gram contains:- Benzydamine HCL BP 5 mg (Analgesic, Anti inflammatory) Finished product specifications are Manufacturer.	75 g plastic tube Rs 175/-	1.Form-5 D 2.06-03-2014 Dy.No. 213 3.06-03-2014 Rs.20,000/-	1. Not found in reference drug agencies however, Benzydamine tooth paste 0.5% is present in Italy. 2. New drug 3. Firm was inspected on 17th & 23rd September 2013, for grant of DML by way of formulation	Deferred for submission of safety & clinical trial data

52.	-do- **Tooth Paste (General)**	Dentassium Tooth Paste Each gram contains:- Potassium Nitrate BP 50 mg (Desensitizing) Finished product specifications are Manufacturer.	40 g & 100 g As per PRC	1.Form-5 2.06-03-2014 Dy.No. 206 3.06-03-2014 Rs.20,000/-	1. Not found in reference drug agencies however, Potassium Nitrate toothpastes available internationally. 2. Prodent 5% w/w 3. Firm was inspected on 17th & 23rd September 2013, for grant of DML by way of formulation	Deferred for clarification of following observation. 1. The applicant has mentioned Vitamin B5 & Vitamin E as inactive ingredients while these have pharmacological actions and their use as inactive ingredient or as excipients requires scientific justification..
53.	-do- **(Tablet General)**	Tofastib tablet Tablet Each film coated tablet contains Tofacitinib Citrate 8 mg eq to Tofacitinib 5mg (Janus Kinase JAK Inhibitor, Immunosuppressant) Finished product specifications are Manufacturer.	Rs. 1500/ 10's Rs. 150/ tablet	1.Form-5 D 2.06-03-2014 Dy.No. 205 3. 06-03-2014 Rs.50,000/-	1. Xeljanz tablet 5mg 2. New drug 3. Firm was inspected on 17th & 23rd September 2013, for grant of DML by way of formulation	Deferred for following reason. 1. Firm has no separate facility for manufacturing of Immunosuppressant products..
54.	M/s Jaskan Pharmaceuticals	Noacid Capsule	10's, 14's As per SRO	1.Form-5	1. Prilosec capsule 40mg 2. Benzim capsule 40mg	Approved. Letter will be issued after rectification of shortcomings.

	(Pvt.) Limited. Plot No. 50, Sundar Industrial Estate, Lahore.	Capsule Each capsule contains enteric coated pellets of Omeprazole Magnesium Trihydrate (8.5%) 40 mg (Proton pump Inhibitor)		2.03-04-2014 Dy. No.1373 3.03-04-2014 Rs.20,000 /-	3. Firm was inspected on 19-02-2014 for grant of DML by way of formulation.	
55.	M/s Jaskan Pharmaceuticals (Pvt.) Limited. Plot No. 50, Sundar Industrial Estate, Lahore.	Essomax Capsule Capsule Each capsule contains enteric coated pellets of Esomeprazole Magnesium Trihydrate (24.24%) 20 mg (Proton pump	14's As per SRO	1.Form-5 2.03-04-2014 Dy. No.1373 3.03-04-2014 Rs.20,000/-	1. Nexium capsule 20mg 2. Nexium capsule 20mg 3. Firm was inspected on 19-02-2014 for grant of DML by way of formulation.	Approved. Letter will be issued after rectification of shortcomings.

		Inhibitor) Finished product specifications are Manufacturer.				
56.	M/s Jaskan Pharmaceuticals (Pvt.) Limited. Plot No. 50, Sundar Industrial Estate, Lahore.	Nofung Capsule Capsule Each capsule contains Fluconazole USP 150 mg (Antifungal)	1's As per SRO	1.Form-5 2.03-04-2014 Dy. No.1373 3.03-04-2014 Rs.20,000/-	1. Cansoral Capsule 150mg 2. Beconazole Capsule 3. Firm was inspected on 19-02-2014 for grant of DML by way of formulation.	Approved. Letter will be issued after rectification of shortcomings.
57.	M/s Jaskan Pharmaceuticals (Pvt.) Limited. Plot No. 50, Sundar Industrial Estate, Lahore.	Diclonak Capsule Capsule Each capsule contains enteric coated pellets (100%) of Diclofenac sodium 50mg (NSAID) Finished product	20's As per SRO	1.Form-5 2.03-04-2014 Dy. No.1373 3.03-04-2014 Rs.20,000/-	1. Capsule dosage form not found in reference drug agencies. Difen 50 mg enteric coated capsule present in Ireland. 2. Dicloras Capsule 50mg 3. Firm was inspected on 19-02-2014 for grant of DML by way of formulation.	Approved. Letter will be issued after rectification of shortcomings.

		specifications are Manufacturer.				
58.	M/s Jaskan Pharmaceuticals (Pvt.) Limited. Plot No. 50, Sundar Industrial Estate, Lahore.	Diclonak SR Capsule Each SR capsule contains enteric coated pellets (50%) of Diclofenac sodium 100mg (NSAID) Finished product specifications are Manufacturer.	20's As per SRO	1.Form-5 2.03-04-2014 Dy. No.1373 3.03-04-2014 Rs.20,000/-	1. Capsule dosage form not found in reference drug agencies. DSR 100mg SR capsule (Diclofenac Sodium Sustained release pellets) is present in Bangladesh. 2. Dicloras SR Capsule 100mg 3. Firm was inspected on 19-02-2014 for grant of DML by way of formulation.	Approved. Letter will be issued after rectification of shortcomings.
59.	M/s Jaskan Pharmaceuticals (Pvt.) Limited. Plot No. 50, Sundar Industrial Estate, Lahore.	Azomak Capsule Capsule Each capsule contains Azithromycin USP 250mg (Tetracycline) Finished product	6's As per SRO	1.Form-5 2.03-04-2014 Dy. No.1373 3.03-04-2014 Rs.20,000/-	1. Zithromax Capsule 250mg 2. Azi-once Cap 250mg 3. Firm was inspected on 19-02-2014 for grant of DML by way of formulation.	Approved

		specifications are USP.				
60.	M/s Jaskan Pharmaceuticals (Pvt.) Limited. Plot No. 50, Sundar Industrial Estate, Lahore.	Linca Capsule Capsule Each capsule contains Lincomycin Hydrochloride USP 500 mg (Lincosamide Antibiotic) Finished product specifications are Manufacturer.	6's & 12's As per SRO	1.Form-5 2.03-04-2014 Dy. No.1373 3.03-04-2014 Rs.20,000/-	1. Lincocin Capsule 500mg 2. Ibucin Cap 500mg 3. Firm was inspected on 19-02-2014 for grant of DML by way of formulation.	Approved
61.	M/s Jaskan Pharmaceuticals (Pvt.) Limited. Plot No. 50, Sundar Industrial Estate, Lahore.	Fungikure Capsule Capsule Each capsule contains Itraconazole	4's & 10's As per SRO	1.Form-5 2.03-04-2014 Dy. No.1373 3.03-04-2014 Rs.20,000/-	1. Sporanox Capsule 100mg 2. Icon Capsule 100mg 3. Firm was inspected on 19-02-2014 for grant of DML by way of formulation.	Approved

		USP 100 mg (Azole Antifungal) Finished product specifications are Manufacturer.				
62.	M/s Jaskan Pharmaceuticals (Pvt.) Limited. Plot No. 50, Sundar Industrial Estate, Lahore.	Pantox Capsule Capsule Each capsule contains pellets of Pantoprazole Sodium 40 mg (Proton Pump Inhibitor) Finished product specifications are Manufacturer.	10's & 14's As per SRO	1.Form-5 2.03-04-2014 Dy. No.1373 3.03-04-2014 Rs.20,000/-	1. Capsule dosage form not found in reference drug agencies. Delayed release tablets and enteric coated granules in sachet are present. 2. Hoze Capsule 40mg 3. Firm was inspected on 19-02-2014 for grant of DML by way of formulation.	Deferred for confirmation of SRA approved dosage form.
63.	M/s Jaskan Pharmaceuticals (Pvt.) Limited. Plot No. 50, Sundar Industrial Estate, Lahore.	Pruvacid Capsule Capsule Each capsule contains pellets	10's & 14's As per SRO	1.Form-5 2.03-04-2014 Dy. No.1373 3.03-04-2014 Rs.20,000/-	1. Lansoprazole delayed release capsule 30 mg 2. Selanz Capsule 30 mg 3. Firm was inspected on 19-02-2014 for grant of DML by way of formulation.	Approved. Letter will be issued after rectification of shortcomings.

		of Lansoprazole Sodium 30 mg (Proton Pump Inhibitor) Finished product specifications are BP.				

Evaluator – V

64.	Genesis Pharmaceuticals (Pvt) Ltd., 25 Sundar Industrial Estate, Raiwind Road, Lahore. New License:	**Moxifin 400mg** Tablets Each film coated tablet contains:- Moxifloxacin as HCl ……400mg Quinolones, antibiotic	Rs.475/5's	Form-5 01/04/2014 644 R&I Rs.20,000/-	AVELOX 400mg f/c tablet Bayer, USA AVELOX 400mg Bayer, Pakistan	Approved
65.	-do-	**Patogen 40mg** Tablets Each delayed release tablet contains:- Pantoprazole as sodium sesquihydrate…..40mg Proton pump inhibitor	Rs.472.50/14's	Form-5 01/04/2014 643 R&I Rs.20,000/-	PROTONIX 20mg Delayed release tablets USFDA ZENTRO 40mg tablets Bosch	Approved
66.	-do-	**Genecip 250mg** Tablets Each tablet contains:- Ciprofloxacin (as HCl)…..250mg Quinolones/ antibiotic USP Specification	Rs.199/10's	Form-5 01/04/2014 642 R&I Rs.20,000/-	CIPRO 250mg film coated tablets Bayer USFDA AXCIN 250mg tablet Novartis	Approved
67.	-do-	**Genecip 500mg** Tablets	As per SRO/10's	Form-5	CIPRO 500mg film coated	Approved

		Each tablet contains:- Ciprofloxacin (as HCl)…..500mg Quinolones/ antibiotic USP Specification		01/04/2014 639 R&I Rs.20,000/-	tablets Bayer USFDA AXCIN 500mg tablet Novartis	
68.	-do-	**Levotab 500mg** Tablets Each tablet contains:- Levofloxacin as Hemihydrate….500mg Quinolones/antibiotic	As Per SRO/10's	Form-5 01/04/2014 R&I Rs.20,000/-	LEVAQUIN 500mg film coated tablet Janssen Pharmaceuticals US FDA LEFLOX 500mg tablet Getz Pharma	Approved
69.	-do-	**Levotab 250mg** Tablets Each tablet contains:- Levofloxacin as Hemihydrate….250mg Quinolones/antibiotic	Rs. 380/10's	Form-5 01/04/2014 638 R&I Rs.20,000/-	LEVAQUIN 250mg film coated tablet Janssen Pharmaceuticals US FDA LEFLOX 250mg tablet Getz Pharma	Approved
70.	-do-	**Genzolid**	Rs.2000/2 x 6's	Form-5	ZYVOX	Approved

		Tablets Each tablet contains:- Linezolid…..600mg Antibiotic Authorized USP Pending Monograph		01/04/2014 640 R&I Rs.20,000/-	600mg f/c tablets US FDA LYZON 600mg tablet Getz	
71.	-do-	**Estalogen 10mg** Tablets Each film coated tablet contains:- Escitalopram as Oxalate ……...10mg Anti-depressant, 5ht reuptake inhibitor	Rs.350/14's	Form-5 01/04/2014 647 R&I Rs.20,000/-	LEXAPRO Escitalopram (as Oxalate) 10mg film coated tablets Lundbeck USFDA CIPRALEX 10mg tablet Lundbeck	Approved
72.	-do-	**Gemigen 320mg** Tablets Each tablet contains:- Gemifloxacin as Mesylate ……..320mg Floroquniolones Manufacturers' Specifications	Rs.1050/7's	Form-5 01/04/2014 645 R&I Rs.20,000/-	FACTIVE 320mg Film coated tablet Merus Labs US FDA GEMGLOW 320mg tablet Searle	Approved
73.	-do-	**Bexagen 20mg**	Rs.175/20's	Form-5	Brexidol	Approved

		Tablets Each tablet contains:- Piroxicam as Beta cyclodextrin….20mg Anti-rheumatics		01/04/2014 646 R&I Rs.20,000/-	Cheisi BNF BCD 20mg tablet Genome, Pakistan	

c) Applications for grant of registration to newly approved sections (18 - Applications)

Evaluator – I

S/N	Name and address of manufacturer/ Applicant	Brand Name Dosage Form Composition (pharmacological Group) Finished product specification	Demanded Price / Pack size	1. Type of Form 2. Initial date, diary. 3. Date on which fee becomes complete according to type of application /or Form (total Fee)	1. International status in stringent regulatory agencies 2. Me-too status 3.GMP status as depicted in inspection report (dated)	Decision
1	M/s Wise Pharmaceuticals, Plot # 3-A, Street S-1, RCCI Industrial Estate, Rawat, Rawalpindi	1.Ketowise 2.Injection 3.Each ml contains, Ketorolac Tromethamine….30mg 4.NSAID(Pyrrole) 5.USP Specifications	As per SRO/1x5 ampoules	1.Form 5 2.444/18-02-2014 3.Rs.20000,17-02-2014	1.Toradol (Roch) Australia 2.Toradol (Barrett Hodgson) 30mg/ml 3..Firm has been recommended new section as per panel inspection dated 29-11-2013	Approved
2	M/s Wise Pharmaceuticals, Plot # 3-A, Street S-1, RCCI Industrial Estate, Rawat, Rawalpindi	1.Iris 2.Injection 3.Each 5ml contains, Iron Sucrose….100mg 4.Haematinic 5.USP Specifications	As per SRO/1x1 ampoules	1.Form 5 2.450/18-02-2014 3.Rs.20000,17-02-2014	1.Venofer (Luitpold) FDA 2.Venofer RG Pharma 3..Firm has been recommended new section as per panel inspection dated 29-11-2013	Approved

3	M/s Wise Pharmaceuticals, Plot # 3-A, Street S-1, RCCI Industrial Estate, Rawat, Rawalpindi	1.Vita 2.Injection 3.Each ml contains, Cholecalciferol….5mg 4.Fat soluble Vitamins 5.USP Specifications	As per SRO/1x1 ampoules	1.Form 5 2.451/18-02-2014 3.Rs.20000,17-02-2014	1.Not found 2. Indrop-D (Neutro) 2..Firm has been recommended new section as per panel inspection dated 29-11-2013	Approved
4	M/s Wise Pharmaceuticals, Plot # 3-A, Street S-1, RCCI Industrial Estate, Rawat, Rawalpindi	1.Mewise 2.Injection 3.Each ml contains, Mecobalamin….500mcg 4.Coenzyme type vitamin B12 5.Manufacturer's Specifications	As per SRO/1x10 ampoules	1.Form 5 2.453/18-02-2014 3.Rs.20000,17-02-2014	1. Baesukang (500mcg/ml) Taiwan provided by the firm 2. Methylcobal (Hilton) 3..Firm has been recommended new section as per panel inspection dated 29-11-2013	Approved
5	M/s Wise Pharmaceuticals, Plot # 3-A, Street S-1, RCCI Industrial Estate, Rawat, Rawalpindi	1.Amik 2.Injection 3.Each 2ml contains, Amikacin sulphate….500mg 4.Aminoglycoside antibiotic 5.USP Specifications	As per SRO/1x1 ampoules	1.Form 5 2.454/18-02-2014 3.Rs.20000,17-02-2014	1. Amikacin sulphate (500mg/2ml) Heritage Pharmaceuticals. Dailymed 2.Amikacin Zafa 3..Firm has been recommended new section as per panel inspection dated 29-11-2013	Approved
6	M/s Wise Pharmaceuticals, Plot # 3-A, Street S-1, RCCI Industrial Estate, Rawat, Rawalpindi	1.Armizole 2.Injection 3.Each ml contains, Artemether….80mg 4.Antimalarial 5.USP Medicines compendium Specifications	As per SRO/1x1 ampoules	1.Form 5 2.446/18-02-2014 3.Rs.20000,17-02-2014	1.Artem 80mg/ml (Kunming) China 2.Artem (Hilton) 3.Firm has been recommended new section as per panel inspection dated 29-11-2013	Approved

7	M/s Wise Pharmaceuticals, Plot # 3-A, Street S-1, RCCI Industrial Estate, Rawat, Rawalpindi	1.Wigesic 2.Injection 3.Each 2ml contains, Paracetamol….300mg 4.Aniline analgesic 5.Manufacturer's Specifications	As per SRO/1x1 ampoules	1.Form 5 2.449/18-02-2014 3.Rs.20000,17-02-2014	1.Paratanda 300mg/2ml (Arroui Pharma) Newziland 2.Provas (Sami) 3..Firm has been recommended new section as per panel inspection dated 29-11-2013	Approved with change of brand name
8	M/s Wise Pharmaceuticals, Plot # 3-A, Street S-1, RCCI Industrial Estate, Rawat, Rawalpindi	1.Aqua Wise 2.Injection 3.Sterile water for injection 5ml 4.Solvent/diluent 5.USP Specifications	As per SRO/1x100 ampoules	1.Form 5 2.452/18-02-2014 3.Rs.20000,17-02-2014	1.Steriluer (Pfizer) Australia 2.Aqua Pro (Elixir) 3..Firm has been recommended new section as per panel inspection dated 29-11-2013	Approved
9	M/s Wise Pharmaceuticals, Plot # 3-A, Street S-1, RCCI Industrial Estate, Rawat, Rawalpindi	1.Metazole 2.Liquid Infusion 3.Each 100ml contains, Metronidazole….500mg 4.Imidazole antibacterial 5.USP Specifications	As per SRO/1x1vial	1.Form 5 2.445/18-02-2014 3.Rs.20000,17-02-2014	1.Metronidazole 500mg/100ml (Sandoz) Australia 2.Flagyl (Sanofi) 3..Firm has been recommended new section as per panel inspection dated 29-11-2013	Approved
10	M/s Wise Pharmaceuticals, Plot # 3-A, Street S-1, RCCI Industrial Estate, Rawat, Rawalpindi	1.Linzo 2.Liquid Infusion 3.Each 300ml contains, Linezolid….600mg 4.Oxazolidinone antibiotic 5.Manufacturer's Specifications	As per SRO/1x1 vial	1.Form 5 2.455/18-02-2014 3.Rs.20000,17-02-2014	1.Zyvox 600mg/300ml (Pharmacia) Dailymed 2.Ecasil (Sami) 3..Firm has been recommended new section as per panel inspection dated 29-11-2013	Deferred for following reasons: (i) Confirmation of manufacturing facility for LVP. (ii)

						Verification of Particle counter and and TOC. (iii) Justification of formulation as FDA approved formulation contains Glucose.
11	M/s Wise Pharmaceuticals, Plot # 3-A, Street S-1, RCCI Industrial Estate, Rawat, Rawalpindi	1.Wigesic 2.Liquid Infusion 3.Each 100ml contains, Paracetamol….1000mg 4.Aniline Analgesic 5.Manufacturer's Specifications	As per SRO/1x1 vial	1.Form 5 2.448/18-02-2014 3.Rs.20000,17-02-2014	1.Ofirmev (Cadence) FDA 2.Provas (Sami) 3..Firm has been recommended new section as per panel inspection dated 29-11-2013	Approved with change of brand name
12	M/s Wise Pharmaceuticals, Plot # 3-A, Street S-1, RCCI Industrial Estate, Rawat, Rawalpindi	1.Qezan 2.Liquid Infusion 3.Each 100ml contains, Levofloxacin as hemihydrate….500mg 4.Quinolone antibiotic 5.Manufacturer,s Specifications.	As per SRO/1x1 vial	1.Form 5 2.447/18-02-2014 3.Rs.20000,17-02-2014	1. Evoxil (500mg/100ml) Beacon Pharmaceutical UK. 2.Leflox (Getz) 3..Firm has been recommended new section as per panel inspection dated 29-11-2013	Approved

13	M/s Wise Pharmaceuticals, Plot # 3-A, Street S-1, RCCI Industrial Estate, Rawat, Rawalpindi	1.Moximag 2.Liquid Infusion 3.Each 250ml contains, Moxifloxacin as HCl….400mg 4.Floroquinolone antibiotic 5. Manufacturer's Specifications	As per SRO/1x1 ampoules	1.Form 5 2.443/18-02-2014 3.Rs.20000,17-02-2014	1. Avelox (Bayer) UK 2.Avelox (Bayer) 3..Firm has been recommended new section as per panel inspection dated 29-11-2013	Deferred for following reasons: (i) Confirmation of manufacturing facility for LVP. (ii) Verification of Particle counter and and TOC.

Evaluator – V

14.	M/s. Vision Pharmaceuticals, Plot No. 22 & 23, Industrial Triangle Kahuta Road, Islamabad **Additional Section:** Large Volume and Small Volume Parenterals Vide letter No. F. 6-3/2014 – Lic (M-234) dated 10th April, 2014	**Visoline IV Infusion** Each 100ml contains: - Sodium Chloride USP …….. 0.9% Water for injection Q.s …… 100ml Electrolyte	As fixed by Govt. / 100ml	Form-5 17-04-2014 1691 R&I Rs.20,000/-	0.9% Sodium Chloride Injection B. Braun, USA (250, 500 & 1000ml) PLASALINE 0.9% w/v (100, 500 & 1000ml) Otsuka	Approved (Confirmation of Particle counter and TOC by Area FID)
15.	-do-	**Dexsol 5% IV Infusion** Each 100ml contains: - Dextrose USP …. 5% Water for injection Q.s …… 100ml Carbohydrate caloric solution	As fixed by Govt. / 500ml	Form-5 17-04-2014 1693 R&I Rs.20,000/-	5% Dextrose Injection B. Braun, USA (250, 500 & 1000ml) PLADEX 5 5% w/v (100, 500 & 1000ml) Otsuka	Approved (Confirmation of Particle counter and TOC by Area FID)

16.	-do-	**Dexsol – DS IV Infusion** Each 100ml contains: - Dextrose USP …. 5% Sodium Chloride USP …….. 0.9% Water for injection Q.s …… 100ml Electrolyte	As fixed by Govt. / 500ml	Form-5 17-04-2014 1692 R&I Rs.20,000/-	5% Dextrose and 0.9% Sodium Chloride Injection B. Braun, USA (500 & 1000ml) PLADEXSAL 5% / 0.9% w/v (500 & 1000ml) Otsuka	Approved (Confirmation of Particle counter and TOC by Area FID)
17.	-do-	**Visolact IV Infusion** Each 1000ml contains: - Calcium Chloride 2H2O USP …… 0.2g Potassium Chloride USP ……. 0.3g Sodium Chloride USP ……. 6.0g Sodium Lactate USP …….3.1g Water for injection Q.s …… 1000ml Electrolyte	As fixed by Govt. / 500ml	Form-5 17-04-2014 1690 R&I Rs.20,000/-	Lactated Ringer's Injection USP RINGOLACT 500 & 1000ml Otsuka	Approved (Confirmation of Particle counter and TOC by Area FID)
18.	-do-	**Kidsol IV Infusion** Each 100ml contains: - Dextrose USP …… 4.3% Sodium Chloride USP	As fixed by Govt. / 500ml	Form-5 13-03-2014 879 R&I	PLADEXAL 1/5 500ml Otsuka	Approved (Confirmation of Particle counter and TOC by Area FID)

		……. 0.18% Electrolyte		Rs.20,000/-		

d) Applications for grant of registration to newly approved sections whose applications are still remaining (10 products per section)

(5 - Applications)

Evaluator – II

S/N	Name and address of manufacturer/Applicant	Brand Name Dosage Form Composition (pharmacological Group) Finished product specification	Demanded Price / Pack size	1. Type of Form 2. Initial date, diary. 3. Date on which fee becomes complete according to type of application /or Form (total Fee)	1. International status in stringent regulatory agencies 2. Me-too status 3.GMP status as depicted in inspection report (dated)	Decision
1.	M/s. Life Pharmaceutical Company 24-III Industrial Estate Multan. Less than 10 products in Additional Section Cream/Oint	Lacticare-H Cream Each gram contains:- Fusidic Acid (B.P)…..20mg Hydrocortisone Acetate (B.P)…..10mg (Corticosteroids combinations)	Rs.100.00/5gm Rs.170.00/10gm Rs.260.00/15gm	Form-5 Rs.8000/23-5-2011(5965) Rs.12000/12-12-2013 (Total: 20,000/-)	1. BNF 61: Fucidin H (LEO) Cream, hydrocortisone acetate 1%, fusidic acid 2% 2.Curoderm-H (Epla Lab. 3. (i)Grant of Additional sections recommended (12-04-2011) (ii) Advised to	Deferred for (i) Completion of Form 5 (ii)Confirmation of manufacturing facility.

	ment (General) Vide letter No. F. 1-30/84-Lic (Vol. I) (M-227) dated 24-06-2011)				remove shortcomings. (28-01-2014)	
2.	-do-	Lacticare-B Cream Each gram contains:- Betamethasone (as valerate) (B.P)….0.1 % w/w Fusidic acid (B.P)….2% w/w (corticosteroids combinations)	Rs.120.00/5gm Rs.300.000/15gm	Form-5 Rs.8000/23-5-2011 (5966) Rs.12000/12-12-2013 (Total: 20,000/-)	1. BNF 61. (Fucibet (LEO)) 2.Dermodic-B (Swiss Pharma) 3. (i)Grant of Additional sections recommended (12-04-2011) (ii) Advised to remove shortcomings. (28-01-2014)	Deferred for (i) Completion of Form 5 (ii)Confirmation of manufacturing facility.
3.	-do-	Clomet Cream Each gram contains:- Betamethasone (as dipropionate) (B.P)…0.05% Clotrimazole (B.P)…..1% w/w (corticosteroids	Rs.160.00/5gm Rs.130.00/15gm	Form-5 Rs.8000/23-5-2011(5970) Rs.12000/12-12-2013 (Total: 20,000/-)	1. FDA (Lotrisone (Merck & Co.) 2.Betazole (Xenon Pharma) 3. (i)Grant of Additional sections recommended (12-04-2011) (ii) Advised to remove shortcomings. (28-	Deferred for (i) Completion of Form 5 (ii)Confirmation of manufacturing facility.

		combinations)			01-2014)	

Evaluator –III

4.	M/s Fredmann Pharmaceuticals Mirpur, AJK	Sensid 20mg Capsules Each capsule contains:- Omeprazole enteric coated Pellets 8.5% eq. to Omeprazole Activity (USP)…….20mg Antipeptic Ulcerant (Proton Pump inhibitor Source: Vision Pharmaceuticals Islamabad USP	2x7's /As Per SRO	Form-5 Section 07-11-2013 Dy.No.2090 Rs. 20,000/-	Me too (Omega of Ferozsons) Inspection of the firm was conducted on 23-03-2014 by the area FID and overall GMP was found "satisfactory" however certain shortcoming were found in different sections and firm was advised to rectify them within three weeks and submit compliance report.	Approved after the submission of verification of compliance report regarding shortcomings in inspection report dated 23-03-2014 by the area FID. The Board authorized its Chairman to dispose of the case.

5.	-do-	Sensid 40mg Capsules Each capsule contains:- Omeprazole enteric coated Pellets 8.5% eq. to Omeprazole Activity (USP)……40mg Antipeptic Ulcerant (Proton Pump inhibitor Source: Vision Pharmaceuticals Islamabad USP	2x7's /As Per SRO	Form-5 Section 07-11-2013 Dy.No.2090 Rs. 20,000/-	Me too (Omega of Ferozsons) Inspection of the firm was conducted on 23-03-2014 by the area FID and overall GMP was found "satisfactory" however certain shortcoming were found in different sections and firm was advised to rectify them within three weeks and submit compliance report.	Approved after the submission of verification of compliance report regarding shortcomings in inspection report dated 23-03-2014 by the area FID. The Board authorized its Chairman to dispose of the case.

Item No.XVII. Medical Devices.

Case No.01

The Registration Board considered the following applications of medical devices for local manufacture and decided as mentioned against each. Approved applications have already been recommended by Expert Committee on Medical Devices.

A: <u>CANNULAS:</u>

S.No	Name of Manufacturer	Name of Medical Device	Price & Pack size	Shelf Life	Decision
1	M/s Lasani Health Care, Plot No. 29-A/R-1, Industrial Estate, Gadoon Amazai Swabi, Khyber Pakhtunkhwa	Neofix I. V Cannula (with small wings and with injection stopper, with needle)	Decontrolled till policy decision by the Policy Board/ Federal Government 50/100 per pack (18G, 20G, 22G, 24G)	02 years	**Approved**.
2	-do-	Veinofix I. V Cannula (with wings and with injection port, with needle)	Decontrolled till policy decision by the Policy Board/ Federal Government 50/100 per pack (14G, 16G 18G, 20G, 22G, 24G)	02 years	**Approved**.
3	-do-	Easyfix I. V Cannula (with butterfly wings and with injection stopper, with needle)	Decontrolled till policy decision by the Policy Board/ Federal Government 50/100 per pack (18G, 20G, 22G)	02 years	**Approved**.
4	M/s Lasani Health Care, Plot No. 29-A/R-1, Industrial Estate, Gadoon	Flocath I.V Cannula (without wings, Pen Type with needle)	Decontrolled till policy decision by the Policy Board/ Federal	02 years	**Approved** .

	Amazai Swabi, Khyber Pakhtunkhwa		Government 50/100 per pack (18G, 20G, 22G, 24G)		

B**) INFUSION SETS.**

S.No	Name of Manufacturer	Name of Medical Device	Price & Pack size	Shelf Life	Decision
1	M/s Lasani Health Care, Plot No. 29-A/R-1, Industrial Estate, Gadoon Amazai Swabi, Khyber Pakhtunkhwa.	Infucan I.V. Infusion Set	Decontrolled till policy decision by the Policy Board/ Federal Government 1's	02 years.	**Approved** .

C) **SYRINGES**

S.No	Name of Manufacturer	Name of Medical Device	Price & Pack size	Shelf Life	Decision
1	M/s Lasani Health Care, Plot No. 29-A/R-1, Industrial Estate, Gadoon Amazai Swabi, Khyber Pakhtunkhwa	L-D Disposable Syringes.	Decontrolled till policy decision by the Policy Board/ Federal Government 1CC 3CC 5CC 10CC	02 years	**Approved**.

Case No.02: Applications for registration of Medical Devices for import.

Registration Board considered the following applications of medical devices for import and decided as mentioned against each. Approved applications have already been

recommended by Expert Committee on Medical Devices and are subject to inspection of manufacturer abroad, verification of storage facilities etc as per policy. The inspection of all manufacturing/processing sites which are not exempted from the inspection of manufacturing unit abroad shall be carried out as per prevailing policy and the Section will confirm all the manufacturing/processing sites before conduction of inspection.

A) CATHETERS

S.No.	Name of Importer and Manufacturer/Exporter	Name of Medical Device	Price & Pack size	Shelf life	Decision
1.	M/s Allmed Solutions, A-21/3, KDA Scheme No.1 Ext, Karachi. **Legal Manufacturer:** M/s Bactiguard AB, Biblioteksgatan 25, P.O.Box.5070, SE-102 42 Stockholm, Sweden. **Production of Bactiguard ® coating concentrate, <u>QC Inspection & Final QA release site.</u>** M/s Bactiguard AB, Jarnvagsgatan 9, PO Box 12, 285 21 Markaryd, Sweden. **Production site for coating process of the catheter & packaging** Amsino Medical (Shanghai) Co., Ltd, Build No.1-3, Lane 355,Songjiang Export Processing Zone, 201613 Shanghai, P.R.China. **Supplier of raw latex**	BIP Foley Catheter (Latex) (Bactiguard Coated Urinary Catheter) **Sizes of Two way** 8Fr 5cc 10Fr 5cc 12Fr 10cc,30cc 14Fr 10cc, 30cc 16Fr 10cc, 30cc 18Fr 10cc, 30cc 20Fr 10cc, 30cc 22Fr 10cc, 30cc 24Fr 10cc, 30cc 26Fr 10cc, 30cc 28Fr 10cc, 30cc 30Fr 10cc, 30cc **Sizes of Three way** 16Fr 30cc 18Fr 30cc	Decontrolled till policy decision by the Policy Board/ Federal Government	3 years	**Approved.**

	Foley catheter M/s Uro Technology Sdn.Bhd, Pontian Johar, Malaysia. **Subcontractor sterilization.** Synergy Health Ede, B.V, Morsestraat 3, 6716 AH Ede, The Netherland.	20Fr 30cc 22Fr 30cc 24Fr 30cc 26Fr 30cc			
2.	M/s Allmed Solutions, A-21/3, KDA Scheme No.1 Ext, Karachi. **Legal Manufacturer:** M/s Bactiguard AB, Biblioteksgatan 25, P.O.Box.5070, SE-102 42 Stockholm, Sweden **Production Site for coating process, <u>QC and final release</u>** M/s Bactiguard AB, Jarnvagsgatan 9, PO Box 12, 285 21 Markaryd, Sweden. **Supplier of raw silicone catheters** Well Lead Medical Co. Ltd, A4-1 Jinhu Industrial Estate, Hualong, Panyu, Guangzhou, 511434, P.R. China. **Subcontractor Sterilization** Synergy Health Venlo, Morsestraat 3, 6716 AH Ede, The Netherland.	BIP Foley Catheter Silicone (Bactiguard Coated Urinary Catheter) (2 way and 3 way catheters) **Sizes of Two way** 6Fr 3cc 8Fr 5cc, 10Fr 5cc 12Fr 10cc 14Fr 10cc 16Fr 10cc, 30cc 18Fr 10cc, 30cc 20Fr 10cc, 30cc 22Fr 10cc, 30cc 24Fr 10cc, 30cc 26Fr 10cc, 30cc **Sizes of Three way** 16Fr 10cc, 30cc 18Fr 10cc, 30cc 20Fr 10cc, 30cc 22Fr 10cc,	Decontrolled till policy decision by the Policy Board/ Federal Government	3 years.	**Approved.**

		30cc 24Fr 10cc, 30cc 26Fr 10cc, 30cc			

Case No.03: Miscellaneous cases

Case No.a. Relaxation in the condition of Drug (Labeling & Packaging) Rules, 1986

M/s Universal Trades, Quetta was granted registration of following medical devices for import manufactured by M/s Endocor GmbH, Esplanade 41, Hamburg, Germany :-

S.No	Reg.No.	Name of medical device(s)
1	074679	Cardioglide PTCA Catheter
2.	074680	Phantom Aspiration Catheter
3.	074681	Discovery Peripheral Vascular Stent.
4.	074682	Constellation Cobalt-Chromium Coronary Stent
5.	074683	Prodigy Paclitaxel-Eluting Coronary Stent
6.	074684	Spirit Stainless Steel Coronary Stent

The firm has requested for exemption from Drug (Labeling & Packaging) Rules, 1986 based on the following arguments:-

(a) These products implanted by highly professional cardiologist/physicians. These are not consumed by patients directly. Thus language translation or "Urdu" may not be required.

(b) Above mentioned products being medical devices are labeled as per the requirement of medical devices as approved by EU Directive on medical devices. The quantity imported in Pakistan depends upon the demand/requirement of individual cardiologist/physicians. Each device is available in various sizes, therefore, quantity imported is very small and it will be very difficult to print registration number and distributors name and address on the packs.

The firm has requested that they may be allowed to print the same on the packs once the consignment arrives to Pakistan as per Drug Act, 1976.

Decision: **The Registration Board allowed relaxation of labeling of Urdu version for import of above mentioned medical devices for a period of one year to M/s Universal Trades, 5-2/27 Moti Ram Road, Quetta. However, all other conditions of labeling and packing under the Drugs (Labelling and Packing) Rules, 1986 shall be strictly complied with.**

Item No. XVII1. M/s Forward Solutions and M/s Well Pharma and Civil Court Stay Order.

M/s Forward Solution Animal Health Company, 80-A, Judicial Colony Thokar Niaz Baig, Lahore has applied for the registration with original COPP certified by the Pakistan Embassy in Italy of following veterinary vaccines, whereas M/s Well Pharma, Lahore has approached this Division and the Lahore Civil Court for stopping this registration citing that reasons that they are the real distributor of these named vaccines, further the firm provided the registration letters..

Manufacturer	***Vaccines***
FATRO S.P.A. ITALY	1. OL-VAC ONE DAY
FATRO S.P.A. ITALY	2. AL-OLVAC H9
FATRO S.P.A. ITALY	3. G-OLVAC
FATRO S.P.A. ITALY	4. OLVAC A+B
FATRO S.P.A. ITALY	5. OL-VAC
FATRO S.P.A. ITALY	6. IBA-VAC ST
FATRO S.P.A. ITALY	7. IBA-VAC
FATRO S.P.A. ITALY	8 EDS-VAC
FATRO S.P.A. ITALY	9. EDS-OLVAC
FATRO S.P.A. ITALY	10. BIO-VAC ND-IB
FATRO S.P.A. ITALY	11. BIO-VAC LS-H 120
FATRO S.P.A. ITALY	12. BIO-VAC CLONE
FATRO S.P.A. ITALY	13. BIO-VAC LA SOTA

Decision in 242nd Meeting: Since the case is sub-judice and under the consideration of the honourable court, the firm M/s Well Pharma will be asked to substantiate their claim of sol agents of the manufacturers, in order to satisfy the legal procedures.

The following products are part of petition filed by M/s Well Pharma, Lahore.

Sl. No.	Registration NO.	Name of Drug(s)	Date of Registration.
1.	015428	IBA-VAC	08.06.1994
2.	012890	BIO-VAC LASOTA	12.06.1994
3.	018805	G-OLVAC	07.04.1996
4.	018806	BIO-VAC ND – IB	07.04.1996
5.	018807	EDS-VAC	07.04.1996
6.	012893	LO-VAC	04.06.1996
7.	012889	LARVAC	21.08.1996
8.	012891	BIO-MAREK HVT	21.08.1996
9.	012892	OLVAC A+B	21.08.1996
10.	012986	ORI-VAC	21.08.1996
11.	020772	ENCEFAL-VAC	08.12.1997
12.	020772	MG-OLVAC	08.12.1997

13.	020774	GUMB-VAC	08.12.1997
14.	026426	BIO-VAC CLONE	14.10.2000
15.	027483	BIO- MAREK HVT +SB-1	15.05.2003
16.	029655	IBA-VAC ST	20.03.2003
17.	033226	REO-VAC	11.11.2004
18.	033227	BIO-VAC REO	11.11.2004

The firm M/s Well Pharma, Lahore has prayed to the Court that: -

> "It is therefore most respectfully prayed that the vaccines manufactured by defendant no.1 registered in the name of the plaintiff company, shall not be registered in the name of any other person/company without the revocation of the rights and interest of the plaintiff company for the last 20 years as sole agent in Pakistan of Neuva-Fatro Italy company.
>
> It is further prayed that defendant no.1 may kindly be restrained from creating any other persons or company as a second agent of the vaccines already registered in the name of the plaintiff company.
>
> It is further prayed that defendant no1 may kindly be directed / ordered not to proceed with any of the registration about the said vaccines (live and inactivated) without notice and consent of the plaintiff regarding the poultry vaccines.
>
> It is further prayed that the defendant no.1 may kindly be ordered to supply the above said poultry vaccines to the plaintiff company as per the orders booked for the year 2012".

Decision: - The Board decided that since the case is sub-judice and under the consideration of the honourable court, the firm M/s Well Pharma will be asked to substantiate their claim of sole agents of the manufacturers, in order to satisfy the legal procedures. M/s Forward Solution Lahore may also be asked to produce all the notarized documents (duly certified by concern embassy) in their favour and update the Board for cases in the court along with decision's certified copies of the honourable court. Complete case may be placed before the board for information.

Dr. Obaid Ulah

Digitally signed by Dr. Obaid Ulah
DN: cn=Dr. Obaid Ulah, o=Drug Registration Board, ou=Secretary, email=obaiddr@yahoo.com, c=PK
Date: 2014.06.07 10:33:07 +05'00'