

AGENDA FOR 229TH MEETING OF THE CENTRAL LICENSING BOARD

A. LICENSING SECTION

Item-I CONFIRMATION OF THE MINUTES OF 228TH MEETING

228th meeting of the Central Licensing Board was held on 8th June 2012 under the Chairmanship of Dr. Abdur Rashid, Drugs Controller (QA)/Member Licensing & Quality Control, Vice-Chairman of the Board. The members are requested to confirm the minutes of the previous meeting (228th) of the Board.

Item-II: GRANT OF DRUG MANUFACTURING LICENSES.

S #	Name of the firm	Type of License/ Date of Inspection	Panel Includes
1.	M/s CSH Pharmaceutical (Pvt) Ltd, Lahore Sections: Tablet (Penicillin) Capsule (Penicillin) Dry Powder for suspension (Penicillin)	Formulation 21-06-2012 Extract at page. 1	Dr. Abdur Rashid, Vice Chairman CLB & Quality Assurance, Islamabad. Madam Majida Mujahid, FID, Lahore Dr. Akbar Ali, ADC, Lahore. <i>Approved</i>
2.	M/s Novartana Pharmaceuticals, Sunder Industrial Estate, Lahore. Sections: Liquid Section Capsule Section Tablet Section	Formulation 26-06-2012 Extract at page. 2-3	Dr. Younas Malik, Member CLB. Mrs. Tehreem Sara, FID, Lahore Dr. Akbar Ali, ADC, Lahore. <i>Approved</i> Remarks. In tablet section Rotary tablet press ZP-17 punch china have been provided.
3.	M/s UNISA Pharmaceutical Industries Ltd, Akora Khattak, KPK Sections: IV Infusion.	Formulation 02-07-2012 Extract at page. 4	Dr. Muhammad Khalid Khan, Member CLB. Mr. Rehmat Ullah Baig Alvi, FID, Peshawar. Mr. Asif Nawaz Khan, ADC, Peshawar <i>Approved</i>
4.	M/s Evergreen Pharmaceuticals, Ferozepur Road Lahore. Sections: Oral Liquid (Veterinary) Court Case. The Inspection was also conducted previously on the directions of Honourable Lahore High Court Lahore but it was after 30-06-2011 so the case was deferred for re-inspection.	Formulation 27-06-2012 Extract at page. 5	Dr. Younas Malik, Member CLB. Mrs. Tehreem Sara, FID, Lahore Dr. Akbar Ali, ADC, Lahore. <i>Approved</i>

5.	M/s Elegance Pharmaceuticals, Chakbeli, Rawalpindi. Sections: Oral Liquid Syrup (Veterinary) Oral Dry Powder (Veterinary) ✓	Formulation 27-06-2012 Extract at page. 6	Dr. GA, Miana, Member CLB. Ch. Zeeshan Nazir, FID-II, Islamabad.
6.	M/s Fintex Cotton Industries, G.T. Road Kamonke Sections: Crepe Bandage. Bandage. Non Sterile Gauze. ✓	Formulation 06-07-2012 Extract at page. 7	Dr. Younas Mallik, Member CLB. Mr. Abdul Rashid Shaikh, FID, Lahore Dr. Akbar Ali, ADC, Lahore.
7.	M/s Paradise Pharma, 23-Km, Sheikhupura Road, Lahore Sections: Oral Liquid. Liquid Repacking. External Preparation. Dry Powder Sachet (General) ✓	Formulation 25-06-2012 Extract at page. 8	Mr. Jamil Anwar, Member CLB. Mr. Abdul Rashid Shaikh, FID, Lahore Dr. Akbar Ali, ADC, Lahore.
8.	M/s Astie Medical Devices Pakistan (Pvt) Ltd, Lahore Sections: Disposable Syringes <i>approved for syringe DML or less</i>	Formulation 25-06-2012 Extract at page. 9	Mr. Jamil Anwar, Member CLB. Mrs. Tehreem Sara, FID, Lahore Mr. Ajmal Sohail, DDC (QA), Lahore Remarks As per panel report currently the firm had only the facility of Endoxin and do not have pyrogen testing the point need to be clarified by member CLB prior to decision of the case.
9.	M/s D-Maarson Pharmaceuticals, Rawat, Rawalpindi Sections: Oral Liquid Syrup (Veterinary) Oral Dry Powder (Veterinary) ✓	Formulation 09-07-2012 Extract at page. 10	Dr. GA, Miana, Member CLB. Ch. Zeeshan Nazir, FID-II, Islamabad. Mr. Ajmal Sohail Asif, DDC (QA) Islamabad.
10.	M/s Pakcure Pharma, Rawat, Rawalpindi Sections: Allergen Extract (Basic) Allergen Extract (Formulation) ✓	Formulation & Basic 10-07-2012 Extract at page. 11	Dr. Iftikhar Rasool Dani, Member CLB. Ch. Zeeshan Nazir, FID-II, Islamabad. Mr. Faizan Siddique, Co-opted Member Remarks The firm layout plan was approved for DML by way of formulation only and they applied for grant of basic manufacturing on the basis of the same layout plan whereas there is no provision for this processing so the point need to be clarified by member CLB before decision of the case.
11.	M/s Apex Pharmaceuticals (Pvt) Ltd Karachi Sections: Capsule (Cephalosporin) Dry Powder (Suspension) Tablet. Capsule. ✓	Formulation 04-07-2012 Extract at page. 12	Prof. Dr. Syed Muhammad Munir, Member Drug Registration Board. Dr. Najam-us-Saqib, DDG (E&M) Karachi. Ms. Umelaila, ADC, Karachi Remarks. In tablet section Rotary tablet press ZP-17 punch china have been provided.

Item-III GRANT OF ADDITIONAL SECTIONS.

Following cases have been recommended by the panel of experts for grant of additional sections:

S No	Name of the firm	Date of Inspection/	Panel Includes
1.	M/s Care Pharmaceuticals, Lahore. Sections: Sterile Eye Drops	Formulation 04-07-2012 Extract at page. 13	Mr. Jamil Anwar, Member, CLB. Mrs. Tehreem Sara, FID, Lahore Dr. Akbar Ali, ADC, Lahore.
2.	M/s Venus Pharma, Lahore Sections: Injectable (Steroid) <u>Court Case.</u> The inspection was also conducted previously on the directions of Honourable Lahore High Court Lahore but the same was after 30-06-2011 so the case was deferred for re-inspection.	Formulation 27-06-2012 Extract at page. 14	Mr. Jamil Anwar, Member, CLB. Mr. Asim Rauf, FID, Lahore Dr. Akbar Ali, ADC, Lahore.
3.	M/s Bio Labs (Pvt) Ltd, Islamabad. Sections: Ampoule (General) Lyophilized vials (General). Infusion 100 ml (General)	Formulation 27-06-2012 Extract at page. 15	Dr. Abdur Rashid, Vice Chairman CLB & Quality Assurance Islamabad. Dr. Muhammad Fakhruddin Aamir, FID, Islamabad. Mr. Abdul Ghaffar, DDC (Pricing) Islamabad.
4.	M/s OBS Pakistan (Pvt) Ltd, Karachi. Sections: Tablet (Hormones)	Formulation 29-06-2012 Extract at page. 16	Dr. Muhammad Khalid Khan, Member CLB. Dr. Najam-us-Saqib, DDG (E&M) Karachi. Muneeza Khan, Area FID, Karachi.
5.	M/s Macter International Karachi Sections: Liquid & Lyophilized recombinant DNA Technology products (biological)	Formulation 29-06-2012 Extract at page. 17	Dr. Muhammad Khalid Khan, Member CLB. Dr. Najam-us-Saqib, DDG (E&M) Karachi. Dr. Saif-ur-Rehman, Area FID, Karachi.
6.	M/s Medisure Laboratories Pakistan (Pvt) Ltd, Karachi Sections: Sterile facility (Ampoules & Vials)	Formulation 29-06-2012 Extract at page. 18	Dr. Obaidullah, Chairman, Quality Control, Islamabad. Dr. Najam-us-Saqib, DDG (E&M) Karachi. Dr. Saif-ur-Rehman, Area FID, Karachi.
7.	M/s Bosch Pharmaceutical (Pvt) Ltd Plant-II, Karachi Sections: Cream/Ointment/Lotion.	Formulation 04-07-2012 Extract at page. 19	Dr. Abdur Rashid, Vice Chairman CLB & Quality Assurance, Islamabad. Dr. Shahid Hussain, Area FID, Karachi. Dr. Saif-ur-Rehman, Area FID, Karachi.
8.	M/s International Pharma labs, Lahore	Formulation 09-07-2012	Dr. Obaidullah, Chairman, Quality Control, Islamabad.

	Sections: Bolus (Veterinary)	Extract at page. 20	Madam Majida Mujahid, FID, Lahore Dr. Akbar Ali, ADC, Lahore.
9.	M/s Genix Pharma (Pvt) Ltd, Karachi Sections: • Biotech Section (rDNA Technology Products excluding products containing micro- organisms). • Liquid Parenteral Area (Vials, Ampoules & Infusion). • Ophthalmic Drops. • Dry Powder Injectable (General)	Formulation 28-06-2012 Extract at page. 21-22	Dr. Obaidullah, Chairman, Quality Control, Islamabad. Dr. Shahid Hussain, Area FID, Karachi. Ms. Umelaila, ADC, Karachi
10.	M/s Highnoon Laboratories (Pvt) Ltd., Lahore. Section Semi Solid Section Dry Powder Suspension (General) and Sachet (Morning/Evening)/Sachet	Formulation 18.05.2012 Extract at page. 23	Syed Shahid Nasir, Member CLB Prof. Dr. Muhammad Jamshaid, Member CLB Dr. Sh. Akhter Hussain, DDG(E&M), Mr. Asim Rauf, FID, Lahore Mr. Akbar Ali, ADC, Lahore <u>Court Case.</u> The inspection was conducted on the directions of the Honourable Lahore High Court Lahore and the panel recommended the grant of additional section.
11.	M/s Medipak Ltd, Lahore. Section IV Set.	Formulation 22.06.2012 Extract at page. 24.	Dr. Abdur Rashid, Vice Chairman CLB & Quality Assurance, Islamabad. Sheikh Abdul Rashid, FID, Lahore Dr. Akbar Ali, ADC, Lahore.

Item-IV: SHOW CAUSE/PERSONAL HEARING.

- Renewal of Drug Manufacturing license of M/s Alfalah Pharma (Pvt) Ltd, Lahore
DML No. 000461 (Formulation).

M/s Alfalah Pharma (Pvt) Ltd, Lahore has not submitted the renewal application on the due date i.e. 24-04-2011 and despite of letter from licensing section, firm failed to submit renewal application within 60 days of expiry of validity of license and thus DML stands in-valid. However, the Board was decided to serve show cause notice to the firm and also called firm's representative for personal hearing. The reply of show cause notice has been received from the M/s Alfalah Pharma (Pvt) Ltd, Lahore.

*Other new license
approved
1. Watson
2. Genme
3. Gulf Royal - 3 sections liquid
4. E.C. Kaluta Road
5. E.C. Kaluta Road
6. E.C. Kaluta Road*

2. Suspension / Cancellation of Drug Manufacturing License (DML) bearing No. 000684 (Formulation) of M/s Brand Pharma International, Karachi.

In the light of decision of the Central Licensing Board in its previous meeting, a show cause notice was issued to the firm and they were also offered opportunity of personal hearing before the Central Licensing Board in its forthcoming meeting. The firm did not reply till to date and also have not confirmed to appear for personal hearing. Submitted for information of the Board.

3. M/s Abbott Laboratories Pakistan Ltd.

As per decision of the Central Licensing Board in its previous meeting, a letter was issued to the firm for personal hearing before the Central Licensing Board in its forthcoming meeting to present their case for cancellation of their Drug Manufacturing license (No. 000005 basic manufacture). The firm has requested to defer the case till the next Board meeting for the needful.

4. M/s English Pharmaceuticals, Lahore

In the light of decision of the Central Licensing Board in its previous meeting, a show cause notice has been issued to the firm for the following.

- Conversion of approved cephalosporin injection area to penicillin area without approval of Central Licensing Board.
- Shifting of Cephalosporin injection area to newly constructed building, which is neither inspected nor approved by Central Licensing Board.
- Manufacturing of dry powder injection (omeprazole, esomeprazole) with penicillin products, which is violation of GMP.

The firm was also offered opportunity of personal hearing before the Central Licensing Board in its forthcoming meeting. The reply of the firm is still awaited. Submitted for information of the Board.

5. Policy regarding establishment of pharmaceutical units located in residential areas.

As per decision of the Central Licensing Board in its previous meeting, show cause notices have been issued to the following firms. They were also offered opportunity of personal hearing before the Central Licensing Board in its forthcoming meeting. The firms did not reply till to date and have not confirmed to appear for personal hearing. Area FID's has also been directed to furnish the current status on the matter and the reports are awaited.

S.#	Company Name
1.	M/s Bliss Industries Ltd, 225/2, J.M. Sadhu Naval Rai Road, Karachi.

2.	M/s Cresent Cotton, Chowk Depalpur, Okara.
3.	M/s Soma Laboratories 692-N, samanabad, Lahore.
4.	M/s Cotton Craft (Pvt) Ltd 10-Km, Multan Road, Lahore
5.	M/s Shamsi Pharma, Samanabad, Lahore

6. Delegation of Powers to the Members of the Board.

Delegation of following powers are proposed to be delegated to different members of the Central Licensing Board for a period of three years under rule 8 (10) of the Drugs (Licensing, Registering & Advertising) rules, 1976 :

Sr #	Powers	Powder to be Delegated to
1.	Site approval	Chairman CLB/Vice Chairman
2.	Panel Constitution	Chairman/Vice Chairman CLB
3.	Approval of change of name of a firm.	Chairman Central Licensing Board.
4.	Approval of drugs for basic, semi basic manufacturing and repacking	Chairman Central Licensing Board.
5.	Monitoring the performance and working of all field officers of DRAP dealing with inspections, clearance of consignments of raw materials and finished drugs and drug testing laboratories.	Chairman / Vice Chairman Central Licensing Board
6.	Constitution / amendments in constitution of panel for inspection for grant of renewal of Drug Manufacturing License, GMP compliance and quality control matters.	Chairman / Vice Chairman Central Licensing Board
7.	Approval of layout plan	Vice- Chairman CLB through DDG (L&A) & DDC (L&A)

**WORKING PAPER FOR 229th MEETING OF
CENTRAL LICENSING BOARD TO BE HELD ON 13-07-2012
QUALITY CONTROL CASES (NORTH)**

ITEM I: CONFIRMATION OF THE MINUTES OF 228th MEETING.

ITEM II: DEFERRED CASES IN 227th MEETING

S No	Title of Firm/ Medical Store & Accused Name	Initiating Officer's Name & Date of Action	Offence	Brief
1.	W. Woodward Pakistan (Pvt) Ltd., Herbal Division, Karachi. i. Junaid Khalil, Director Finance, M/s. Woodward Pakistan, Karachi. (F.4-23/2010-QC)	FID-II Islamabad, 21-04-2010.	Manufacture / Sale of Unregistered Drugs Section 23 (1) (a) (vii) (x), 1 (b) and 1 (i) of Drugs Act, 1976.	<ul style="list-style-type: none"> • Samples of E-Zinc Syrup Batch No 02A10 manufactured by M/s. Woodward Pakistan, Herbal Division, Karachi drawn from M/s. Medika International, Rawalpindi, declared unregistered by Federal Government Analyst for having Elemental Zinc. • Warranty traced back to M/s. Woodward Pakistan, Herbal Division, Karachi. • Show cause notice issued to accused on 07-01-2011 and he was called for personal hearing. • The firm claims that it is a food supplement and not a drug. • On firm's request, the Board deferred the case in 227th meeting. The board in 228th meeting decided to call the firm representative in next meeting. • The representative of the firm has been called again.

ITEM III MISCELLANEOUS CASES

**Case No.2 Manufacture and Sale of Adulterated, Substandard and Spurious Tablet
Isotab-20 by M/s Efroze Chemical Industries, Karachi**

The Board, in its 228th meeting held on 08-06-2012, after discussing the case in details, inter alia, decided that Government of Punjab and Defective Drugs Tribunal Lahore may be approached to get the updated status of the case and then case should be processed in accordance with the Law. The Provincial Quality Control Board, Punjab and the Defective Drugs Tribunal, Lahore were accordingly requested to get the latest status. Their response is awaited. Reminders have also been issued.

Submitted for information of the Board.

ITEM IV: Any Other Item With Permission Of Chair

*Contact
Provincial govt*

**AGENDA/WORKING PAPERS FOR 229th MEETING OF THE CENTRAL
LICENSING BOARD HELD ON 13-07-2012**

**Quality Assurance Cases (GMP)
M/s Marion Laboratories (Pvt) Ltd**

Item No.V (New Case)

Mr. Saif-ur-Rehman Khattak, FID-IV Karachi, inspected M/s. Marion Laboratories (Pvt.) Limited, D-43, S.I.T.E. Karachi, on 02.11.2011 and reported a large number of very severe shortcomings and gross violations of GMP and provisions of the Drugs Act, 1976 and rules framed there under. The firm voluntarily undertook to stop the production activities till rectification of the shortcomings and also submitted an action plan for improvements.

2. FID reported that the firm was asked several times for submission of compliance but they replied that improvements are underway. He further reported that he was informed by some QC personnel of the firm that despite the voluntary closure of the production the firm is continuously involved in the manufacturing of the large & small volume parental without any technical staff. Re-labeling of expired and sub-standard drugs (returned from market) was also underway. He further informed that these illegally manufactured products are not only being sold in Pakistan but also exported to Afghanistan and some African countries.

3. On 19.03.2012, Ms. Ume Laila, ADC inspected the firm with reference to export of firm's products to South Africa for sampling of the stocks for test and analysis and also for confirmation of manufacturing activities at the site. She also confirmed the manufacturing activities, undertaken under very unhygienic conditions without the supervision of any technical/qualified person. She further reported that these illegally manufactured products are being released without any QC test and release. CDL Karachi, declared four samples of products of the firm (taken by ADC) as of Sub-standard quality as detailed below:-

- Two samples of 5% Dextrose were declared substandard on the basis of non-compliance to Bacterial Endotoxin test.
- Two samples of Normal Saline were declared substandard on the basis of non-compliance to assay.

4. A joint inspection of the firm with the provincial team of inspectors was made on 30th March, 2012. The stocks available in the factory warehouse and some record were sealed by the provincial Inspector.

5. The firm exported 5% dextrose to Government of Rwanda through M/s. Royal group Pakistan, and Rwanda Biomedical Centre reported the consignment to be of sub-standard quality.

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*Co consultant
appeared for
hearing asked
to reply in writing*

6. Keeping in view this grave situation of GMP and violation of provisions of the Drugs Act, 1976, the firm was served with a show cause notice in respect of following:

- a. Severe non compliance of the GMP in contravention of rule 20 (a) of the Drugs (Licensing, Registering & Advertising) Rules, 1976.
- b. Manufacturing of sterile drugs in unhygienic conditions in contravention of Rule 19(1) & 20(a) of the Drugs (Licensing, Registering & Advertising) Rules, 1976.
- c. Manufacturing without the direct supervision of the qualified/technical staff, (in contravention of Rule 16(c) & 19(1) of the Drugs (Licensing, Registering & Advertising) Rules, 1976.
- d. Non compliance to remove the defects or irregularities as identified by FID in contravention of Rule 19(5) of the Drugs (Licensing, Registering & Advertising) Rules, 1976.
- e. Manufacture, sale & export of sub-standard, adulterated and expired drugs in contravention of section 23(1)(a)(iv, v vi & x) of the Drugs Act, 1976.

7. The firm was also directed to recall the substandard products exported to other countries and sold in local market and destroy the same in presence of the representatives of DRAP.

8. In response to show cause notice the firm has replied that allegations framed against firm are baseless and if any it was due to negligence of qualified persons, who have been fired due to their unethical practices. The firm requested to conduct a panel inspection to evaluate the GMP compliance and to resume the production. The firm also requested to be heard in person.

9. Accordingly, the firm is called for personal hearing and case is placed before the Board.

ITEM VI: Any Other Item with Permission of Chair
