# Quality Control Board Health Department Government of Balochistan, Quetta.



# The Balochistan Drug's Rules 1983 with (Amendments)

i.P.P(Q) 48-50-Books-10-2007.

#### GOVERNMENT OF BALOCHISTAN HEALTH DEPARTMENT



Dated Quetta, the 22<sup>nd</sup> September , 1983.

#### NOTIFICATION

No. So.II(H) 14-1/82. In exercise of the power conferred by section 44 of Drugs Act, 1976 (XXXI of 1976), the Government of Balochistan, is pleased to make the following rules, namely:-

- PART I PRELIMINARY

  1. Short title and commencement :- (1) Those rules may be called the Balochistan Drugs Rules, 1983.
- (2) They shell come into force at once.
   2. Definitions:- In these rules, unless there is anything repugnant in the subject or context:-
  - (a) 'Act' means the Drugs Act, 1976 (XXXI of 1976).

    (b) 'Board' means the Provincial Quality Control Board for Balochistan.
  - (c) 'Form' means form specific in Schedule A: (d) 'Government' means the Government of Balochistan.
  - (d) 'Government' means the Government of Baiochistan.

    (c) 'Licensing authority' means the authority specified in rule 14:
    (e a)\*2 "Narcotics & other control drugs" Means the drugs specified in Schedule "B"
  - (e b) \*3 "Pharmacy" Means a shop, store or a place where drugs are compounded or prepared or prescription; it shall include a place, which bears the words pharmacy; Pharmacist shall confirm to requirement lay down the Schedule "E".

(e c)\*4 "Veterinary" Means shop, store or place where Veterinary drugs are sold by way of retail sale / whole sale.

(f) \*1 "Provincial appealed authority". Means the authority established under section 9-A of the Act.

(g) 'Retail sale' means sale other than sale by way of whole sale dealing:-

(h) 'Schedule' means section of the Act:

<sup>\*1-</sup> Inserted by the drug rules amendment 30th May 2005 Notification No.SO (Admn)2-4/10429-10504.

<sup>\*2, \*3, \*4-</sup> Inserted by the drug rules amendment February 26<sup>th</sup> 2007. Notification No.SO (Admn)2-4/2007/4662-716.

<sup>(</sup>j) 'Whole sale' means sale to a person who buys for the purpose of selling again and includes sale to a registered medical

practitioner, hospital dispensary or an institution:(k) 'Appellate Board' means the Provincial Appellate Board,

### PART – II PROVINCIAL QUALITY CONTROL BOARD GOVERNMENT ANALYST AND PROVINCIAL DRUG INSPECTOR.

#### 3. Provincial Quality Control Board:-

- (1) The Board shall consist of the following members, namely:-
  - (a) "Chairman" As government appoint from time to time. \*1

(b) an officer of the Provincial Drugs Administration who shall, as far as possible, be a pharmacy graduate:

(c) one member from the pharmacy profession who shall be at least graduate in pharmacy to be nominated by Government having no financial interest in pharmaceutical trade and industry.

(d) One pharmacologist to be nominated by Government having no financial interest in pharmaceutical trade and industry and.

(e) Secretary Provincial Quality Control Board, who shall be pharmacy graduate to be appointed by Government and registered in Register A by the Pharmacy Council with minimum B-Pharmacy degree.

- The board may Co-opt a legal advisor or an advocate, the Inspector, the Government Analyst concerned and where considered necessary, specialist in the field concerned for technical examination of case.
- 3. The Board may Co-opt any other qualified expert having formal training and experience in the pharmaceutical field.
- 4. The members of the Board may elect from among themselves a Vice Chairman who shall function as Chairman in the absence of the Chairman.
- The nominated members of the Board shall hold office for three years and shall be eligible for re-nomination.
- 6. The quorum to constitute a meeting of the Board shall be three including its Chairman.
- 7. No act or proceeding of the Board shall be invalid merely in the ground of the existence of any Vacancy in, or any defect in the constitution of the Board.

<sup>\*1-</sup> Inserted by the drug rules amendment February 26th 2007 Notification No.SO (Admn)2-4 / 2067/ 4662-716

- 4. PROCEDURE OF THE BOARD: (i) The Inspectors and Analysts shall submit monthly returns in Form 1 and Form 2, respectively, to the Board and a summary on the overall situation of quality control in the area under their respective jurisdiction; and the Board shall maintain such information in a manner so as to monitor. The quality of all the drugs sold and to keep watch on the performance of all manufacturers.
- (2) The Board shall, as far as possible, meet at least once in a month and review the situation of the quality control of drugs on the whole, including consideration of any specific point arising during the period on working of various, firms, drug testing laboratories and Inspectors.
- (3) The Board shall examine carefully the cases referred to it by any Inspector under the Act and provide an opportunity of hearing to the accused to explain this position before directing the Inspector to prosecute accused.
- (4) Before referring any case to the Drug Court, the Board shall ascertain the names of the Directors, partners and employees of the company, corporation, firm or institution who are prima-facie responsible for the commission of the offence under the Act, or the rules and allow an Inspector to institute prosecution only against such persons.
- (5) Where a drug is found to be sub-standard or adulterated, the Board before referring the case to the Drug Court, on the request of the accused, shall cause the sample of the Drug lying with the Board concerned under sub-section (III) of Section 19 to be sent for test or analysis to the Federal Drug Laboratory or any other laboratory specified for the purpose by the Federal/Provincial Government, which shall make the test or analysis and report, in writing signed by or, under the authority of, the person for the time being in charge of the Federal Drug Laboratory, or, as the case may be such other laboratory, the result thereon and such report shall be conclusive evidence of the facts stated therein.
- (6) On receipt of the test report from the drug laboratory, a copy of the test report, along with method of analysis (Protocol of test) shall be conveyed to the dealer.
- (7) The Board may, in case of miner offences, in its discretion, advise to bring improvement or if considered necessary, issue a warning to the accused and take other action including recall of the batches.
- Qualification etc of Provincial Inspectors and Provincial Government Analysts.

(i) No persons shall be appointed as a Provincial Inspector unless he possess a degree in pharmacy from a Pakistan University or any other institution recognized for this purpose by the Pharmacy council of Pakistan and must be registered in Register A with minimum B-Pharmacy Degree and has at least one year's experience in the manufacture, sale, testing or analysis of drugs or in the Drugs Control Administration or in a hospital or pharmacy.

No person shall be appointed as a Provincial Government Analyst unless he possesses a degree in pharmacy from a Pakistani University or any other institution recognized for this purpose by the pharmacy council of Pakistan and has at least one year's experience in the manufacture, sale, testing or analysis of drugs or in the Drugs Control Administration or in a hospital or pharmacy.

Provided that if a person of the requisite qualification is not available, a person possessing degree in Medicine or Masters Degree in Pharmaceutical Chemistry, or pharmacology with three years, experience in testing of drugs and medicines in public health laboratories may be appointed.

Provided further that the provisions of these rules shall not apply to the Inspectors and the Analysts who were appointed as such on a regular basis before the coming into force of these rules.

(3) The Government may by notification in the official Gazette appoint a person possessing a degree in pharmacy, Medicines or a Master's Degree in pharmaceutical Chemistry or Microbiology or pharmacology as an exofficio Inspector from amongst its officers working in the Drugs Administration or, in any other recognized pharmacy or medical institution, who other wise does not fulfill the qualifications laid down in sub-rule (1).

Provided that the ex-Office Inspector shall be appointed for the purpose of:-

- (i) conducting inspection of any premises wherein any drug is sold or is stocked or exhibited for sale or is distributed, and seeing the storage arrangements and all relevant records and registers and.
- (ii) Taking samples of any drug which is being sold or is stocked or exhibited or sold or is being distributed.

- (4) The Government may by notification in the official Gazette for the exercise of such power as may be specified in the notifications appoint as ex-officio Analyst any person who holds a degree in pharmacy of Medicine or a Master's Degree in Pharmaceutical Chemistry or Microbiology or pharmacology and is engaged is testing laboratory or in a Chemical Examiner's Laboratory or is working in a Pharmaceutical or Medical Educational or Research Institution.
- 6. <u>DUTIES OF INSPECTORS:</u> Subject to the instructions of the licensing authority, It shall be the duty of an Inspector.
  - (a) To inspect not less than twice a year all establishments of drugs licensed for sale and once a year all establishment licensed for manufactures of drugs within the area assigned to him, and to keep record of such inspections.

(b) To satisfy himself that the conditions of the licenses are being observed:

(c) To take and send for test or analysis, if necessary, samples of any drug which the has reason to suspect is being manufactured or sold or stocked or exhibited for sale in contravention of any or the provisions of the Act or these rule:

(d) To investigate any complaint in writing which may be made to him and furnish the report in respect is of to the licensing authority.

(e) To institute prosecution in respect of contraventions of

the Act and these rules;

To maintain record of all inspections made and action taken by him in the performance of his duties, including the taking of samples and the seizure of stocks and submit reports of such record as may be required by the licensing authority; and

(g) To make such enquiries and inspections as may be necessary to top manufacture and sale of drugs in contravention of the act, and these rules.

- 7. PROHIBITION OF DISCLOSURE OF INFORMATION: Except the purposes of official business or when required by a court of law, an Inspector or an Analyst shall not disclose to any person any information acquired by him in the course of his official duties.
- 8. FORM OF ORDER NOT TO DISPOSE OFF STOCK: An order in writing by an Inspector under clause(i) Sub Section (i) of Section 18 requiring a person not to dispose of any stock in his possession shall be in Form 3.

#### FORM OF INTIMATION OF PURPOSE OF TAKING SAMPLES: 9.

- Where a Provincial Inspector takes a sample of drug under clause(c) of Sub-Section (i) of section 18 fort the purpose of test or analysis, he shall intimate such purpose in writing in Form 4 to the person from whom he takes it and where he seizes stock of a drug or other material under clause(f) of section 18 the receipt for such drug and material shall be in Forms 5.
- The Provincial Inspector shall send a portion of the sample or the container to the Government Analyst for test or analysis under clause (i) of sub-section (3) of section 19 through a memorandum in Form 6.
- In case the sample is delivered to the Government Analyst by an indirect (iii) means such as post a copy of the memorandum a specimen impression of the seal, or mark used to scal the packet, shall be sent to the Analyst separated by registered post or by hand.

#### DUTIES OF GOVERNMENT ANALYST: 10.

- A Government Analyst shall cause to be analyzed or tested such samples of (1)drugs as may be sent to him under the Act and shall furnish reports of the results of test along with protocol of tested and analysis in accordance with the And these
- A Government Analyst shall cause to be tested and analyzed such samples of (2) drugs as may be sent to him in writing from a Government Department or any other public institution and shall furnish the report of the result of test and protocol of test (method of analysis to the Department or the public institution concerned).
- A Government Analyst shall forward monthly reports giving results of samples tested and analyzed during the period under report with a view to their publication at the discretion of the Federal Government and furnish such other information as may be required by that Government.
- PROCEDURE ON RECEIPT OF SAMPLES FROM INSPECTOR: On 11. receipt of a package from an Inspector containing a sample for test and analysis the Government Analyst shall note the seals on the packed with the specimen impression received separately and shall note the condition of the seal on the package and after the test of analysis has been completed. He shall forthwith supply to the Inspector a report of the result of the test and analysis with protocols in Form

#### 12. FEE FOR TEST AND ANALYSIS OF DRUGS:

The fee for test and analysis of drugs in respect of samples sent by persons other than an Inspector or a Government Institution. Shall be determined by the Analyst or the person in charge of the Government Laboratory in accordance with the fees specified in Schedule "C".

(7)

13. PAYMENT OF COST OF SAMPLES: As provided under Section 18(a) of the Drug Act, the payment of the cost of samples taken by the Inspector of drugs, may be arranged out of the Government funds, on the availability of funds.

14. LICENSING AUTHORITY:

- (i) The Secretary to the Government in the Health Department shall be the licensing authority for the purpose of these rules. The licensing authority may, by order in writing, authorized any person under its control to sign the licenses and to exercise such other powers, and in respect of such areas, as may be specified in the order.
- 15. TYPES OF LICENCES TO SELL DRUGS:
  The licenses under these rules shall be of the following types, namely:
- License to sell drugs by way of retail sale.
- (ii) License to sell drugs by way of whole-sale.
- (iii) \*1 License to sell narcotics and other control drugs.
- (iv) \*2 License to sell in Pharmacy/Veterinary.

16. APPLICATION FOR LICENSE TO SELL DRUGS AND FEES THEREOF:

(1) Application for the grand or renewal of any license referred to in clauses (i) to (ii) (iii) (iv) of rules 15 shall be made in Form 8 to the licensing authority and shall be accompanied by a fee of:

(a)\*1 "A fee of Rs.5000/- for grant of retail sale License and Rs.10,000/- for

grant of Whole sale License".

- (b) \*2 "A fee of Rs. 2500/- for renewal of a retail sale license and a fee of Rs.3000/- for renewal of a whole sale license.
- (2) The license may be renews if the provisions of these rules have been complied with and the requirements specified in Form 8 are fulfilled.
- (3) \*3 "A fee of Rs.3000/- shall be paid for any change of proprietor or qualified person or a duplicate copy of the license if the original is defaced, damaged or lost and such copy of the license shall bear the words "duplicate copy".

17. FORMS OF LICENSES TO SELL DRUGS:

- (1) A license to sell, stock, exhibit for sale or distribute drugs by way of retail sale shall be issued in Form 9.
- (2) A license to sell, stock exhibit for sale or distribute drugs by way of whole sale shall be issued in Form 10.
- (3) \*1 " A license to sale, store, exhibit Narcotics and other control drugs for sale or distribute as specified in Schedule B, shall be in Form-11.
- (4) \*2 " A license to sale drugs in Pharmacy/Veterinary shall be in Form-12.

<sup>\*1 \*2 \*3-</sup> Inserted by the drug rules amendment February 26<sup>th</sup> 2007 Notification No.SO (Admin)2-4/2007 4662-716

18. SALE AT MORE THAN ONE PLACE: If drugs are sold, stocked, exhibited for sale or distributed at more than one place or go down, the license shall notify along with application for grant of license the promises which shall be used by him as godown and the Provincial Rules making authorities shall be empowered to visit and inspect such godowns.

#### 19. DURATION OF LICENSES:

(1) A license issued under these rules shall, unless sooner suspended or cancelled, remain in force for two years from the date of issue and if an application for renewal of license is not made within one month of the expiry of the license, the license, the license shall stand cancelled.

Provided that if application for renewal of a license is made before the expiry of the period of validity of the license, or where it is not done so for reasons beyond the control of the license and the application is made within one month of the expiry of license, the license shall continue to be in force until orders are passed on the application.

Provided further that section 5 and 12 of the limitation Act, 1908 shall be applicable in the matter of renewal of license.

- (2) An application for grant of renewal shall be disposed of with in three months of the receipt of such application.
- (3) The authority to whom licensing has delegated powers to issue or renew Drugs sale licenses, shall submit monthly report to the licensing Authority or the following subjects.
- (4) The license issued under sub-rule (3) and (4) of rule 17 shall be subject to sub rule (1) of rule (19) of these rules.
- (a) Name and address of the applicant who submitted application for issue/renewal of a
- (b) Date of receipt of application.

(c) Number of application.

(i) Granted Number Date
(ii) Renews Number Date
(iii) Suspended Number Date
(iv) Cancelled Number Date

(v) Reasons for suspension cancellation of license.

(vi) Reasons for delay in disposal of application within a specified period of 3 months.

#### PRE-CONDITIONS FOR THE ISSUE OF LICENSE:-

Licenses in Form 9 Unless: (1) The licensing authority shall not issue:-(a)

The premises have proper and adequate facilities for storage of drugs and for their protection from direct sunlight, dust or dirt including refrigeration facilities, where necessary, for preserving the properties of the drugs;

The premises are clean and in hygienic and tidy condition.

Licenses in Form 10 unless the applicant is an indenter, importer, (b)

(ii) Of clause (a;) manufacturer or distributor of a manufacturer and fulfils the conditions laid down (ii) Of clause (a;) (i) and in sub-clauses.

\*1- Inserted by the drug rules amendment February 26th 2007 Notification No.SO (Admn)2-4/2007 4662-716

The applicant has never been convicted of any offence under the Act; The sale of drugs shall be supervised.

(d) \*1 License in Form-11, unless the applicant possess a license in form-9 or Form-10 or Form-12 and fulfills the conditions laid down in sub clauses (i) and (ii) of clause (a) and (c) of sub Rule (1) of Rule 20.

Under license in Form 9 and 10 by a person who is registered under clause (a) or clause (b) of Sub-Section (i) of section 24 of the Pharmacy Act, 1967 (XI of 1967).

Provided that the persons of the following categories may also be approved. as qualified persons for the grant of license in Form 9 and 10.

(i) A person who was approved as qualified person for registration under clause (b) of sub-section and registered in Register B by Provincial Pharmacy Council or;

(ii) A person who was on the 19th day of June, 1972 qualified for registration under clause (b) of sub-section and registered in Register B by Provincial Pharmacy Council; or.

(iii) A person who has before the commencement of these rules, passed the examination of compounders, or dispensers and has completed two years period of apprentice-ship under clause (c) of the aforesaid sub-section.

#### CONDITIONS OF LICENCES: 21.

Licenses in Form 9,10, 11 and 12\* shall be issued subject to the conditions stated there in and to the following general conditions, namely;

(a) The supply by way of retail sale of any drug shall be recorded suitably such records, bills or counterfoils, shall be preserved for a period of at least three years from the date of such sale;

(b) The drugs specified in Schedule "B" and "E"\* shall not be retail sale except on and in accordance with the prescription of a registered medical practitioner:

- (c) The sale of any drug specified in the Schedule "E" by way of retail sale shall be recorded at the time of sale in a register specially maintained for the purpose and the scrial Number of the entry in the registers shall be entered in the prescription and the following particulars shall be entered in the register namely;
- (i) Serial Number
- (ii) Date of sale
- (iii) Name of the prescribe
- (iv) Name of the patient/purchaser
- (v) Name of the drug
- (vi) Name of the Manufacturer
- (vii) Quantity
- (viii) Batch No.
- (xi) Signature of the Qualified Person.

Provided that if the drug specified in Schedule "E" is sold on a prescription on which the drug has been sold on a previous occasion, it shall be sufficient if the entry in the register includes. S.No the date of Salem the quantity sold, and sufficient reference to any entry in the register recording the dispensing of the drug on a previous occasion.

- \*- Inserted by the drug rules amendment February 26<sup>th</sup> 2007 Notification No.SO (Admn)2-4/2007 4662-716
- (2) For the purpose of this rule. A prescription shall:
  - (a) Be in writing be signed by the person giving it with his usual signature and be dated by him:
  - (b) Specify the name and address of the person for whose treatment it is given and;
  - (c) Indicate the total quantities of drugs to be supplied and doses to be taken.
- (3) All invoices and bills of purchases of drugs shall be preserved for a period of at least three years.
- (4) Records shall be maintained of all purchases and sale of drugs by way wholesale and such records shall be preserved for three years except where an expiry dates specified, in which case the records shall be preserved for three years from the date of expiry and shall include the following particulars namely;
  - (a) The date of purchase and sale;
  - (b) The name and address of the concerned from which purchase and the concerns applicable, and the quantities and;
  - (c) The name of the manufacturer.

- Excepts as otherwise provided in these rules all registers and records maintained under these rules shall be preserved for a period of not less than three years from the date of the last entry.
- The license shall produce for inspection by an Inspector on demand all registers and records maintained under these rules, and shall supply to the Inspector such information as he may require.
- The license shall maintain the Inspection Book provided by the Licensing authority at the time of issuance or renewal of the license on which any member of the Board or an Inspector shall record proceeding of each of his visit, his impressions and the defects or irregularities noticed if any, by him and such Inspection Book shall be signed by him as well as the licenses or the qualified person.
- Substances failing under schedule "B" and "F"\* shall be stored in the retail (8) shop:
  - (a) In a part of the premises to which customers do not have access: or
  - (b) In an almirab or cupboard or drawer reserved solely for the storage of such drugs.
- Substances failing under the list of poisons mentioned in Schedule "E" Shall be stored in containers imperious to the poison and sufficiently stout to prevent leakage arising from the ordinary risks of handling and transport.
- A substances falling under the list of poisons mentioned in Schedule "F" shall be stored in containers imperious to the poison and sufficiently stout to prevent leakage arising from the ordinary risks of handling and transport.

#### CANCELLATION AND SUSPENSION OF LICENSES: 22.

The licensing authority may, on the report of an Inspector or on its own (1)

\*- Inserted by the drug rules amendment February 26th 2007 Notification No.SO (Admn)2-4/2007 4662-716 motion, after giving the license an opportunity to show cause by an order in writing stating the reasons after giving the licenses an opportunity to show cause by an order in writing stating the reasons therefore, cancel a license issued under these rules or suspend it for such period as it thinks fit. Either wholly or in respect of some of the drugs to which it relates, If in its opinion the license has failed to comply with any of the conditions of the license or with any of the provision of the Act of these rules when the offence is of serious nature.

A license whose license has been cancelled or suspended may appeal to the Provincial Appellate Board within sixty days of the date of such order, whose decision shall be final.

#### PROVINCIAL APPELLATE AUTHORITY

- Any person aggrieved by an order of the Licensing Authority may prefer an appeal to the Provincial Appellate Authority within sixty days of the date of such
- The Additional Chief Secretary, Balochistan shall be the Provincial Appellate (2) Authority for the purpose of hearing appeals against the order of Licensing Authority and for this purpose he may coordinate any person having experience in
- The Provincial Appellate Authority shall, after giving the appellant an (3) opportunity of being heard, pass such order as it thinks fit and such order shall be

<sup>\*-</sup> Inserted by the drug rules amendment February 26th 2007 Notification No.SO (Admn)2-4/2007 4662-716

# Progress report for the Month of DRUG TESTING LABORATORY FORM - II

		Percentage.				month	month.
than	standard.	with	14		W.W.St	during the	beginning of
pendir	below	to standard	Tested	lia n		received	Samples in the
Details	Samples	Samples up	Iotal	New Old	lotal	Samples	Number of

Sub-standard Spurious

Counterfeit Adulterated

Others

Total

DETAILS OF DRUG FOUND IN CONTRAVENTION OF THE LAW DURING THE MONTH OF

S.No Name and Regn: No of Drugs | Batch No. | Manufactured by Test Report No. date and nature of contravention

### FORM 3

(See rule 8)

Order under section 18(1) (i) of the Drugs Act, 1976, requiring a person not to dispose of stock in this possession.

section of the Drug Act, 1976.
section of the Drug Act, 1976.

Date

days from this date.

Inspector\_

Details of stock of drage

SCHEDULE-A

(See rule 2(c)) MONTHLY REPORT FROM INSPECTOR

(See rule 4(1)) FORM-I

FOR THE MONTH OF

SUMMARY OF INSPECTIONS

Remarks No. of samples drawn No of Firms found violating Law (Specify main offences) No of firm Inspected Place Inspected Manufacturers

Shops Chemist and Druggist.

Other Places (specify)

DETAILS OF VOILATIONS IN RESPECT OF DRUGS

Reports of samples of drugs not in compliances with law

				J. J	Date of consist	Artion 19Ken
Name of Drugs	Regn: No and	Batch No.	Place of taking	Date of dispatch of	Date of feether	Tellon manen
	Manufacturers		sample	sample and name of	of test report	including details
	Name			Laboratory	, with nature of	of seizures and
					result	sale restriction

#### 15 FORM 4 (See Rule 9(1))

I have this day ta	iken from the premise	es to		and the same of		
	s specified below for drawn.					
Name of Drug	Name of Manufacturer	Regn. No	B.No	Quantity	Bill No.	Value
	(E) 122 100 100 100 100 100 100 100 100 100	FORM 5 e rule 9(1) )		84/80		12
Receipt for stoc	k of drug and other	materializ	ed sei	zed under	section	3 (1) th
Drugs Act 1976.	₩ W				# V	
The Stock of d	rugs details below	has this da	ay bee	n seized	by me u	nder th
provisions of class The premises of Dated at	use (f) of sub-section (	1) 18 of the	Drugs	Act, 1976		
provisions of class The premises of Dated at	use (f) of sub-section (	1) 18 of the	Drugs	Act, 1976		~********
provisions of class The premises of Dated at	use (f) of sub-section (	1) 18 of the	Drugs	Act, 1976	ized.	
provisions of class The premises of Dated at	use (f) of sub-section (	1) 18 of the	Drugs	Act, 1976	ized.	
provisions of class The premises of Dated at	use (f) of sub-section (	1) 18 of the	Drugs	Act, 1976	ized.	
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provisions of clar The premises of Dated at Inspector Details Serial No. of Me Analyst. Portion of samp	Memora (So	erial and ar Inspect FORM 6 Indum to Are rule 9 (2)	ticles o	Act, 1976  f drugs se	ized.	ysis.

#### GOVERNMENT OF THE BALOCHISTAN HEALTH DEPARTMENT

Dated Quetta the 30th May 2005

#### NOTIFICATION

No.S.O In exercise of the powers conferred by Section 44 of the Drugs Act, 1976 (XXXI of 1976), the Government of Balochistan is pleased to make the following amendments in the Balochistan Drugs Rules, 1983, namely;

1. For clause (f) of rule 2, the following shall be substituted:-

- (f) "Provincial Appellate Authority" means the Authority established under Section9-A of the Act.
- In Rules 22:-
- (i) In sub rule (I) the brackets and figures (I) shall be omitted and

(ii) Sub rule (2) shall be deleted.

After rule 22, the following new rule 23 shall be added;

"23 Provincial Appellate Authority (I) Any person aggrieved by an order of the Licensing Authority may prefer an appeal to the Provincial Appellate Authority within sixty days of the date of such order.

(2) The Additional Chief Secretary, Balochistan shall be the Provincial Appellate Authority for the purpose of hearing appeals against the order of Licensing Authority and for this purpose he may coordinate any person having experience in the relevant field.

(3) The Provincial Appellate Authority shall, after giving the appellant an opportunity of being heard, pass such order as it thinks fit and such order shall be final."

#### BY ORDER OF GOVERNOR BALOCHISTAN

No & DATE EVEN:

Copy forwarded to the Superintendent, Government Printing Press, Balochistan Quetta, for Publication of the above notification in the Extra ordinary Government Gazzette. The Publication of this notification is expeditiously required under Drugs Act 1976, for adaptation of these amendments in Balochistan Drugs Rules, 1983.

Deputy Secretary (Admn) FOR SECRETARY HEALTH

#### NO & DATE EVEN

Copy is forwarded for Information to:-

- 1) The Deputy Chairman , Planning & Development Divisions (Health Section ) Government of Pakistan , Islamabad.
- 2) The Secretary Government of Pakistan , Ministry of Health Islamabad.
- 3) The Chief Plan Coordination Section Planning & Development Division, Government of Pakistan, Islamabad.
- 4) The Director General (Health) Government of Pakistan, Ministry of Health Islamabad.
- 5) The Chief Secretary, Balochistan Quetta.
- 6) The Additional Chief Secretary, Balochistan Quetta.
- 7) The Director General Health Services, Balochistan Quetta.
- 8) The Chairman Drug Courts Quetta.
- 9) All District Coordination Officers, Balochsitan.
- 10) All Executive District Officers (Health) Balochistan.
- 11) The Chief Drugs Inspector / Secretary Provincial Quality Control Board, Balochistan, Health Department Quetta.
- 12) The Director, Drugs Testing Laboratory, Balochistan Quetta.
- 13) P.S.O to Secretary Health.
- 14) All Drugs Inspector Balochistan

Deputy Secretary (Admn) FOR SECRETARY HEALTH

## FORM 7 (See rule 11) CERTIFICATE OF TEST OR ANALYSIS BY THE DRUGS TESTING LABORATORTY / GOVERNMENT ANALYST.

Cert	ified that the samples , ber	ring number
bar bor ting	to be a sample of	received on
		n No-
	from	bee been tested (
analyzed an	id that the result of such te	est / analysis is as stated below:-

- 2. The condition of the scals on the packet on receipts was as follow:-
- 3. In the opinion of the undersigned the sample is not / is adulterated / substandard / misbranded/spurious as defined in the Drugs Act 1976 for the reasons given below:-

Director Drugs Testing Laboratory/ Or other authorized officer, Government Analyst

Details of results of test or analysis: (with protocols of tests applied)

Director Drugs Testing Laboratory / or other authorized officer/ Government Analyst

#### 19 FORM 8 (See rule 16 (I) )

Application for a license to sell, stock and exhibit for sale and distribute drugs.

I/we		
	1-	
	apply for a license to sell.	
1.	Drugs by way of retail sale	w.*
2.	Drugs by way of whole sale	
3.	* License to sale Narcotics and other	
4.	*License to sale in Pharmacy/Veterin	nary.
		16 1. Sec.
On the	premises situated at	
2.	The sale of drugs will be under the perso	onal supervision of
	(Qua	
(Name)	(Qua	lification)
5.	I/we am/are submitting herewith the	
(i)	Attested copies of the qualifications of q	
(ii) I	Photostat copy of National Identity Care	d of the proprietor and qualified
pers		(E)
	Two attested copies of the photograph of	of qualified person.
(iv)	Affidavit binding the proprietor and th	ne qualified person to inform the
licer	nsing authority as soon as either of the p	party ceases to have interest in the
	nse issued under these rules.	
	Attested Photostat copy of the valid regi	stration issued by the C.O.I & E in
	of indenter / importer.	ra propieta en la primita de la companya de la com Primita de la companya de la company
	Manufacturer's Authority as agent / dis	stributor.
Tre	asury challan(s) for Rs.	
27/5/27/	*	
Del	lete whichever is not applicable.	
		T 25
	**	Signature
		Nameand

\*- Inserted by the drug rules amendment February 26<sup>th</sup> 2007 Notification No.SO (Admn)2-4/2007 4662-716

Permanent Home Address

#### FORM 9 (See rule 19 (1))

45						is h	ereby
licensed to sell stock and exhib	it for	sale	on	the	premises	situate	d at
of the Drugs Act, 1976, and the rules		8			ow and to t	he prov	ision
This license will be in force i					ars from t	he date	giver
This license will be in force the bellow.	or a p		of tw		ars from t	he date	giver
This license will be in force f	or a p	eriod	of tw		ars from t	he date	giver
This license will be in force to bellow.  Name (s) of qualified person (s)	or a p	eriod	of tw		ars from t	he date	giver

#### CONDITIONS OF LICENCE

This license shall be displayed in a prominent place in part of the premises open to the public.

The license shall comply with the provision of the Drugs Act, 1976 and the rules made there under for the time being in force.

The license shall report forthwith to the Licensing Authority any change in the qualified staff incharge.

No drug requiring special storage conditions of temperature and humidity shall be stored or sold unless the precautions necessary for preserving the properties of the contents have been observed throughout the period during which it has been in possession of the license.

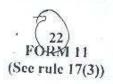
#### FORM 10 (See rule (17) (2))

	premise situated at	fied below and to the provisions
of the	Drug Act, 1976, and the rules made there un	der.
or the		100
2	The license will be in force to two years	from the date given below.
2.	Name (s) of qualified persons (s)	Photograph (s)
	Manie (a) or dans	
(i)	1	N L L L
(ii)		W
	E. C.	hall be etore
Ä	Addresses of Godown (s)	where drugs shall be store
Date	· · · · · · · · · · · · · · · · · · ·	LICENSING AUTHORIT

#### CONDITIONS OF THE LICENSE

- (i) The license shall be displayed in prominent place in part of the premises open to the public.
- (ii) The license shall comply with the provisions of the Drugs Act ,1976 and the rules made there under for the time being in force.
- (iii) The licenses shall report forthwith to the licensing Authority any change in the qualified staff incharge.
- (iv) No drug requiring special storage conditions temperature and humidity shall be sold unless the precautions necessary for preserving the properties of the contents have been observed throughout the period during which it has been in possession of the license.

Address of the godown / godowns where the drugs are stocked should also be given.



License to sell Narcotics and o	other control drugs specified	l in Schedule-B.	
	Holder of lice	ense No.	*TE
on Form 9/10 to sell drugs sto- other drugs specified in Sched	ck, exhibit for sale or distrib	oution of narcotics and	
		Subject to the	
conditions specified as under rules made thereunder;	and to the provisions of the	Drugs Act, 1976, and	the
2. This license will be in force	for a period of two years fro	m the data is a finite	
3. Name(s) of qualified person(	(s).	in the date given belov	٧.
i) Name			
ii) Name	Qualification		
W M		The Table of the T	
4.Address of godown / godown	s in which drugs be stored.		W
5. Name of Proprietor(s)		No. 10	
Dated	LICENSING AU	I a	

#### CONDITIONS OF THE LICENSE

- (1) The license shall be displayed in prominent place in part of the premises open to the public.
- (2) The licenses shall report forthwith to the licensing Authority any change in the qualified staff in charge.
- (3) No drug to which this license applies shall be sold unless the precautions necessary for precautions necessary for preserving the proprietors of the contents have been observed throughout the period during which it has been in possession of the license.
- (4) Address of the godown / godowns where the drugs are stocked should also be given.

<sup>\*-</sup> Inserted by the drug rules amendment February 26th 2007 Notification No.SO (Admn)2-4/2007 4662-716

#### 23 FORM 12 (See rule 17(4))

License to sell Drugs in Pharm	acy / Veterinary.	TE M
License to sell Drugs in pharm	acy / Veterinary 🔀	
as her	eby beensed to sompound or pr	epare the drugs and
sell, distribute, drugs. By way	of retail sale on the premises situ	rated at
	subjecte	ed to the conditions
specified below and to the provunder.	vision of the Drug Act, 1976 and	the rules made there
2. This license will be in force l	or a period of two years from th	e date given below.
3. Name(s) of qualified persons	s (s) •	100
i) Name	Qualification	
ii) Name	Qualification	
型 平		
4. Address of godown/godown	s in which drugs be stored.	
16		
5. Name of Proprietor(s)		1,8
Dated	LICENSE A	LTHORITY

#### CONDITIONS OF THE LICENSE

- (1) The license shall be displayed in prominent place in part of the premises open to the public.
- (2) The license shall comply with the provisions of the Drugs Act ,1976 and the rules made there under for the time being in force.
- (3) The licenses shall report forthwith to the licensing Authority any change in the qualified staff in charge.
- (4) No drug requiring special storage conditions temperature and humidity shall be sold unless the precautions necessary for preserving the properties of the contents have been observed throughout the period during which it has been in possession of the license.

Address of the godown / godowns where the drugs are stocked should also be given.

<sup>\*-</sup> Inserted by the drug rules amendment February 26th 2007 Notification No.SO

LIST OF POISIONS

11111

ame of Poisonous substance	Percentage of poison content below which the substance or its preparation is exempted from the provisions of Rule 20(10)
cetanilide, alkyl acetanilide	0
Cetylmethadol, its salts.	
conite roots of	***************************************
Alkaloids the following their salts; Their esters, salts their esters, their qu	unternary
Compounds.	
Compounds. 1	2
Acetyldihydrcodeine	
Acetyldihydrcodeinone	
	0.02
Aconite,	0.20
Apomorphine	0.15
Atrophine	
Elladonna, alkalo ids of	0,15
Dimes	calculated as hyoseyamine.
Enzaylmophine	
Enaylmorphine	
Rucine	
Alabar Beans, alkaloids of	
Ocaine	
91	graph property for the second
Odeine	0.50
Olchicum	calculated as calchicume.
Ø	0.10
Onine -	
Odeine	10-
Olehicum	. calculated as calchicume.
	0.10
Online	0,20
Otarnine	0.20
Urare alkaloids of curare bases	

Ihydrocodeine	25		*********	
1	-		2	
Ihydrocodeinone				
lhydrohydroxycodince	a i		********	********
Ihydromorphine				0.10
Eegonine +		/	*******	
Emetine				1.00
Ephedra alkaloids of		****	*******	
Ethylmorphine				0.20
Gelsemimum, alkaloids of				0.10
Homatropine				0.15
Hyoscine				0.15
Jaborandi , alkaloids of		********	***	0.50
Lobelia , alkaleids of				0.50
Morphine				0.20
	Ca	lculated as anl	ydrous morph	nine.
Nicotine	0			0.20
Papaverine				1.00
Pomegranate, alkaloids of				0.50
Quebracho, alkaloids of other	than alkaloids	of red quebra	che	/ <u></u>
Rauvolfia, alkaloids of	10	10.		
Sabadilla , alkaloids of		***************************************		
So lanaceous alkaloids not othe	erwise specified	l in this list	w. à	0.15
		Calculated	l as hyoseyami	ine.
Stav - sacre, alkaroids of		*********		0.20
Strychnine				0.20
Thebainc	4- 9		*******	1.00
Tropacocaine (Benzoy ipsenod	tropine)			-
Veratrum, alkaloids of	CONTRACTOR			1.00
Yohimba , alkaloids of	24		bed and a	
N-Allylmorphine land any oth	er pentavalent	morphine der	ivatives:	950
Allylprodein; Its salts				
The state of the same		10		

Apha - acetylmethadol; its salts

1		2		
Sylphonates their derivatives;		-		
their salts.		42		
Amino - alcohols etherified with benzoic acid,				
Phenylacetic acid, phenypropionic acid	197			
Or the derivatives of these acids; their salts	10.00 of esteri	lies amino <i>t</i>	lcohols	
Aminopterin		N town on	Vil Society	
Ammonia ·		Smelling:	salts.	
Amylnitrite				
Anileridine; its salts	-			
Antimony, oxides of antimony; sulphides of	Equivalent of	1.00 percen	t	
Antimony , organic compounds of antimony.				
Apoil				
Arsenic; halides of arsenic; oxides of arsenic,	7 1 6	22		
Aresenites, organic compounds of alsenic	Equivalent of (	0.01 percen	t	
322 0 3235	Of arsenic trioxide.			
Abituric acid, its salts; derivatives of barbturic				
Acid, their salts; compounds of barituric acid,				
lts salts, its derivatives, their salts with anyother		-	-	
Substance.	A 10		60	
Barium Chloride	***************************************		**********	
Barium sulphide	<u> </u>			
Benzethidine, its salts	*******		*************	
Bota – acetyimethadol ; its salts	2000	S **	-	
Beta-aminopropylbenzene (Amphetamine) its sal	lts			
its N-alkyl derivatives, their salts Beta – Aminois	opropy- 1			
lbenzene, its salts; its N-Alkyl derivatives, their s	alts.		156	
Beta-Meprodine; its salts		*******	-	
Beta- methadol; its salts			*********	
Beta- prodine , its salts;	*******			
Busulphan (1:4) dimethanesulphon - oxybutane); its	salts			
Sand Clafford to do				

1		2	
Cannabis; extract and tinctures of		7.0	
Cannabis; cannabin tannate		<del></del> 0.10	of cantheridine
Cannthridine; cantharidates			
4-Carbmethoxy1-3 dimethyl 4 -Phen	yl hexamethylene	eimine;	****
its salts;			1
Carbutamids		*******	*******
Chloral formamice			//
Chloral hydrate	****		) memoran ar training as
Chlorambucil; its salts	***************************************		6 11 11 10 p 10 10 10 10
Chloroform		Substances	containing less
£	2	than 10 pe	rcent chloroform.
Chloropropamide; its salts			
Clonitazene (2-P Chlorobenzyl)I- die	thylaminecthyl-5	********	0
Nitrobenzimidazole; its salts	2 <del>-20-2-08-08-0</del>	*******	*********
Greesote from wood	<u> </u>	substances	containing 50
21	Percent of c	reosote from	wood.
Croton oil and seeds of	******		an eo o e do a
Oyclophosphamide; its salts			********
Datura, herb and seeds preparation	of Datura	0.15 calcul	ated as
111 20		hyosoyami	me.
Desmorphine; its sults			
Dextromoramide; its saits			
Dextrophan; its salts	-n	********	
Diacetyl-N-allymorphine, its saits			-
Diaminodipheynyl sulphone, its salts	and derivatives	8	
Digiltalis, glycosides of, other active	principles of		
Digital is D-isorpropyiflourophospho	nate	*********	******
Dimenaxado I, its salts	*******	*********	6
Dimethylthiambufene, its salts	********		
Dinitrocresols , their compounds with	a motal or a bas	se	*******

<u> </u>		2	
Diphenoxylate; its salts	********		********
Dipipanone; its salts	********		*****
Disodium stillheestrol diphosphate	********		i o <del>bravana</del>
Diculfiram			
Dithienylallylamines, Dithienylallylly laminess)		*******	-
Elaterin			*********
Epinephrine , its salts;		-	
Ergot (the scelerotia of any species of Olaviceps	) extraot of	*	
Ergot, incture of ergot.	-		
Erythrityl tetranitrate.			
Ethosuximide.	*******		4
Ethylmethylthiambutene, its salts;	*******		
Etoxeridine, its salts.			
Formaldehyde	*********	substance o	ontaining
	less than 5 pe		
Formic Acid		****	11 d
Furethidine, its salts;	*****		
Galamine, its salts, itq quaternary compounds		12 4	
Gryceryl trinitrate (nitroglycerine)	- 8 8		<u></u>
Guanidines ,the following;	7-	1	74-21
Polymothylene diguanidlines di-paraanisyl phen	etyl	M	
Guanidine			1774
Hydro chloric acid	Substance co	ntain less th	an 9% of
a 2	Hydrochloric		17.0
Hydrocyanic acid, cyanides			0.15
Hydromorphinol; its salts	- ×		+
12-Hydroxy-5-9 dimethyl-2-(2-phenylethyl)		91	01 100
6-7 benzomorphan its salts			
Insulin			
Isopropylester of I-methyl-4-phenyl		18	3
carboxylic acid (Phroperidine) its salts			

Mannity lhexanitrate. 6-mercaptopurine, its salts. Meroury Mercuric chloride, mercuric Ammonium chloride Mercuriciodin Mercuric nitrate Mercury (Hg) Mercury, oxides of Equivalent of 1.00 Mercuric potassium iodine. Percent of mercury (Hg) Metamizol Metazocine, its salts; Metformin, its salts

Retobemidone, its salts

Laudeaxium, its salts

Levarternol; its salts.

Levo-methrophan; its salts

Levomoramide, its salts

Mannomustine, its salts.

Levorphanol, its salts

Levophenacy Imorphan, its salts

Methadone (Amidone), its salts

Methyl- desorphine, its salts

Methyl-Phenidate, its salts;

Methyl-dihydromorphine, its salts;

Methotreate, its salts

Methanol

Methruximide

Methyl-4-phenylpl-peridine-4-carboxylic acid, esters of, their salts.

Metapon (Methyl dihydromorphin one) its salt			
(2-Methyl-phenethylamino)propylpropionanili	ta ite calta	2	
Morphoridine, its salts	16, 115 34113	***********	1
Morphine-N-Oxide, its derivatives, their salts	Dati		V DATE OF TAXABLE
Mustine, its salts;	The Publisher State Stat	***************************************	
Nitrie acid	oteruses.	********	
I Will Caclu		bstances cont	
Nitrobenzone .	than nine p	ercent of nitr	ic acid.
	********	**************************************	
Nitrophenals, or the meta or para	*****	*****	
Norocacine, its salts;			
Narlevorphanol, its salts;		d	
Normorphine, its salts;			******
Nux vomics, seeds of prepration of nux vomica.	the art incomplete, introduced the control of the c		
Opium	0.20 calculated as anhydrous		
	morphine.		10
Ocaine, its salts;		****	*****
Ouabain			
Oxazolidine, its derivatives of their salts, their o	esters.	********	
Oxymerphone, its salts.			*********
Para - aminobenzene sulphenamide, its salts, e	ferivatives of p	oara-aminobe	enzene
Sulphonamide having any of the hydrogen atom	ns of the para-	amino sulpho	onaimae
having any of the hydrogen atoms of the Para-a			
group substitute by another radical their salts.			
	Substance in	ntended for to	opical of
	external use		
Para aminobenzoie acid, its salts, its esters their		(4.00)	
Para amethaoine.	4	********	********
Phenampromide, its salts			
Phenfoumin its salts	******		
	N.		ecessyrratoriffe
Phenols (any member of the series of phenols of	which (i) Su	bstances con	tuining
the first member is obenoland of which the	13/15/- 13	than one ner	

Molecular compesition veries from member to m			
by one from or carroot and the		shes, pessaties	
# 2)		positors contai	90 NO.
- 9	thai	a 2.50 percent	of phenol.
Phenomorphad, its salts			******
Phenoperidine, its salts			
Phensuximide			
Phenylacetylaruca	***************************************		
Phenylbutazone, its salts, its derivativ their salts	ş		******
Phenylcinchonine acid, its salts , its elbers, the sa		ers.	
Phenyl-(P-tolymethoxy) ethyldimethylanine, its	salts	************	
Pholeodine, its salts		*********	1.0
Phosphorus , yellow		bstances conta	4.5
Pieric acid	Than nine	percent of orc	hid acid.
Picrotoxin		*******	
Piminoudine, its salts	*****		**********
Piperdine-I-Pheyl bid, clopepty neyl Pecpanol		bstance contai	ning than
The Mind-proposed Proposed Pro	1 percent	of potassium f	luoride.
Potassium hydroxide, its salts	****		
Recementhorphan, its salts		per	
Reserpine, its salts, its derivative, their salts			
Salicyleinchonine acid its salts others the salts of	f its esters.		
Savin oil of	Substances containing less		
Sodium Fluoride	than I percent of sodium chloride.		
The second secon		194	
Sodium hydroxide	S	ubstances cont	aining less
	than 12% of sodium hydroxide.		
Sodium Nitrate			
Strophanthas, glycosides of strophanthus			
Sulphurice acid.	Substanc	e containing lo	ss than 9%
of sulphuric acid.			

Thallium, salts of			*********
1		2	
Thio carbanalide			2000000
Thyroid gland, the active principles of their salts	3		
Tolbutamide	V <del></del>		
Tribromethylalchol	Various services	VERNORSH DESERT	
Tri-(2 chlorethyl) a mine, its salts.		*****	
Tricthylendethiophosphormalde			****
Trimeperidine, its salts.			*****
Tropine diphenylmethyl esters, their salts.	******		*******

NOTE:- Preparations containing the above substances are not covered by this Schedule.

#### SCHEDULE - "B"

(See Rules-2(g),15(iii) and 21 (1) (B&C)

#### NARCOTICS & OTHER CONTROLLED DRUGS

Acetorphine

Acetylmethadol

Allyiprodine

Alphacetylemethadol

Alphamethadol

Alphaordine

Benzethidin

Benzylmorpine

Betacetylethadol

Betaprodine

Bezitramide

Cannabis

Clonitzaone

Coca leaf

Cocaine

Codoxime

Concentrate of poppy straw

Desmorphine

Dextromoramid

Diampromid

Diampromid

Diethylthiambutene

Difenoxin

Dihydromorphine

Dimenoxadol

Dimephetenol

Dimethylthiambutene

oxaphetyl butyre

Ddiphenoxylate

Dipianone

Dorotebano

Eccoonine

Etylmethylhiambutene

Etonitazene

Etorphine

Etoxerdine

--Fantayl

Furchidine

Heroin

Hydrocodone

Hydromorphinon

Hydromorphine

Hydroxypethidne

Isomethadone

Levomethorphen

Levomoramid

Levophenacylmorphan

Levolphanol

Methazocine

Madintone '

Methadone-Intermediate

Methyldeserphine

Methyldihydromorphine

Metopon

Moramid-Intermediate

Morpheridine

Morphine

Morphine Methorbomide and other pentavalent nitrogen morphine

Derivatives include in particula the morphine-N-oxide derivatives one of which is

Codeine-N-oxide

Morphine-N-Oxide Myrophine Nicomorphine Noracynethadol Norvlevorphanol Normathadone Normophine Norpipanene Opium Oxycodone Oxymorphone Phethidine Pethidine-Intermediate-B

Phethidine-Intermediate-A

Pethidine-Intermediate-C

Phenadoxone

Phenampromide

Phenazoeine

Phenomorphan

Phenoperidine

Pininodine

Piritrmeide

Propheptazine

Properidine

Recamethorphane

Recomoramide

Recamorphan

Thebacon

Thebaine

Trimeparidine

Acetyldihdrocodine

Codeine

Dyhydrocoaine

1: 1 :

Ethylmorphine

Nicodine

Nicodlecodine

NorcoJine

Pholcodine

Propiyam