# GOVERNMENT OF BALOCHISTAN PRIMARY AND SECONDARY HEALTHCARE DEPARTMENT

# TO BR PUBLISHED IN THE ENTRAORDINARY ISSUE OF BALOCHISTAN GAZI(TTE

# BALOCHISTAN DRUGS RULES, 2021

# **NOTIFICATION**

# Dated Quetta, 30th September, 2021

No. SO-V (H)1-8/2019-20/3259-78. In exercise of the powers conferred by Section 44 of Drugs Act, 1976 (XXXI of 1976), the Government of Balochistan, is pleased to make the following rules:

#### CHAPTER I PRELIMINARY

1. Short title and commencement:--(1) These rules may be called as the Balochistan Drugs and therapeutic goods Rules, 2021.

(2) They shall come into force at once.

2. Definitions:- (1) In these rules, unless there is anything repugnant in the subject or contents,

- (a) "Act" Means the Drugs Act, 1976 (XXXI of 1976);
- (b) "Board" means the Provincial Quality Control Board for Balochistan constituted under rules 3;
- (c) "DRAP Act" means Drugs Regulatory Authority of Pakistan (DRAP) Act 2012;
- (d) "Form" means Form mentioned in the Schedule A;
- (c) "Government" means the Government of Balochistan;
- (f) "Inspector" means a Provincial Drug Inspector appointed under Section 17 of the Act;
- (g) "Licensing authority" means the authority as specified in rule 16;
- (h) "Medical Store" means premesis where drugs and therapeutic goods are stored, sold or offered for sale;

- (i) "Pharmacy' means a premises where drugs and therapeutic goods are stored, sold, compounded, dispensed or prepared on prescription or distributed in case of authorized agent of manufacturer, indenter or importer;
- (j) "Veterinary" means premises where Veterinary drugs are stored, sold by way of retail sale / wholesale;
- (k) "Manufacturer" means a manufacturer of a Drug and Therapeutic good;
- (I) "Narcotics, psychotropic or controlled drug" mean a drug specified in the Schedule "B";
- (m) "Retail sale" means sale of drugs and therapeutic goods on retail other than the sale by way of whole sale;
- (n) "Rule" means Balochistan Drug and therapeutic good Rules 2021;
- (0) "Wholesale" means sale to a person, buying for the purpose of selling again who is authorized agent of a manufacturer or importer or indenter;
- (p) "Schedule" means Schedule annexed to these rules;
- (q) "Section" means Section of the Act;
- (r) "Analyst" means a persone notified under section 16 of Drug Act;
- (s) "Expert Committee" means committee constituted under rule 17 of these rules;
- "Drug Control Administration" mean, Senior officers of the Drug Control Administration Balochistan, comprising of Drug Inspector (BPS-17), Senior Drug Inspector (BPS-18), Chief Drug Inspector (PBS-19), Drug Controller/ Principal Drug Inspector (BPS- 20);
- (u) "Therapeutic goods" means and includes drugs or alternative medicine or medical devices or biologicals or other related products as may be notified by the DRAP and as notified in the Act;
- (v) "Committee of the Board" means a committee notified under rule 4 of these Rules.
- (2) The word and expression used not defined hereinabove sub-rule (1), shall have the same meaning as assigned to them in the Act.

#### CHAPTER II

# BOARD, GOVERNMENT ANALYST AND INSPECTOR

- 3. Provincial Quality Control Board:-- (1) The Board shall consist of the following, namely:-
  - (i) Chairman and Members Provincial Quality Control Board at Provincial level;
    - (a) Secretary to the Government, Primary and Secondary Healthcare Department as, Ex officio, member and chairperson;
    - (b) Additional Secretary (Development) to the Government, Primary and Secondary Healthcare Department, as a member and vice chairperson who shall act as chairperson in the absence of the Secretary Primary and Secondary Healthcare Department;
    - (c) Pharmacy Professional who holds a graduate or higher degree in Pharmacy and has more than ten years professional experience, having no financial interest in Pharmaceutical trade and industry, appointed as a member by the Government for a term of three years;
    - (d) A Pharmacy Graduate prepherably a Professor having no financial interest in pharmaceutical trade and industry appointed as a private member of the board by the Government for a term of three years;
    - (e) The Government shall appoint a Secretary of the Provincial Quality Control Board amongst the senior most officer of Drug Control administration and has at least ten years professional experience who shall also be the member of the Board.

### (ii) Chairman and Members Provincial Quality Control Board at Devisional level;

As per Sub-Section 6 of Section 11 of the Act, Provincial Quality Control Board may entrust any of its powers and functions mentioned under sub-Section 5 of section 11 of the Act to the following of its member at each administratiove division of Balochistan to facilitate general public for providing relief on their door step.

- (a) Secretary to the Government, Primary and Secondary Healthcare Department as, Ex officio, member and chairperson;
- (b) Commissioner from the concerned administrative Division, as ex-officio member and Vice Chairperson at division level who shall act as chairperson in the absence of the Secretary Primary and Secondary Healthcare Department;

- (c) A Senior officer from the Drug Control Administration as a technical expert, who holds a graduate or higher degree in Pharmacy and has more than fifteen years professional and field experience, having no financial interest in Pharmaceutical trade and industry, from respective Division, as member;
- (d) Pharmacy Professional who holds a graduate or higher degree in Pharmacy and has more than ten years professional experience, having no financial interest in Pharmaceutical trade and industry, appointed as a member at Division level. by the Government for a term of three years;
- (e) The Government shall appoint Secretary of the Provincial Quality Control Board from the each division amongst the senior most officer of Drug Control administration and has at least ten years professional experience who shall also be the member of the Provincial Board at Division level.
- (2) 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 the case.
- (3) The Board may co-opt any other qualified expert having formal training and experience in the pharmaceutical field.
- (4) The quorum for a meeting of the Board at Provincial and Divisional level shall be three including the Chairperson.
- (5) The members of the Board may elect from among themselves a Vice-chairperson who shall function as chairperson in absence of chairperson.
- (6) The nominated private members of the Board shall hold office for three years and shall be eligible for re-nomination for second term only;
- (7) The Board at divisional level shall perform its functions under the direction, general supervision and subject to the control of the Board at Provincial level.
- (8) No act or proceeding of the Provincial Board shall be invalid merely on the ground of the existence of any vacancy or any defect in the constitution of the Board concerned.

4. Committee of the Provincial Quality Control Board:- At each administrative division, Provincial Quality Control Board may constitute a committee of its members including voice Chairperson and secretary under Sub-Section (6) of section 11 of the Act for delegation of any of its powers & functions under sub-section (5) of section 11 of the Act to be exercise within the specified area.

5. Procedure for the Board:--(l) An Inspectors or a Government Analyst shall submit monthly report on Form 1 and Form 2 to the Provincial Board and a summary of the overall situation of quality control in his area of jurisdiction, the Provincial Board shall maintain the information in order to monitor the quality of all the drugs sold and to review the performance of the manufacturers and the sellers.

(2) The Provincial Board may meet at least once in a month to review the situation of the quality control of drugs and therapeutic goods on the whole including consideration of any specific point arising during the period on the working of various firms, drug testing laboratories and inspectors.

(3) The Provincial Board shall examine a case referred to it by an inspector and shall, if an action is proposed to be taken against a person under the Act or the rules, issue a show cause notice to the person and provide him an opportunity for hearing before taking the action about the prosecution of the person or recommending suspension or cancellation of his license to the licensing authority.

(4) Before referring a case to the Drug Court, the Provincial Board shall ascertain the names of the Director, partner and employee 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 may allow an inspector to institute prosecution against such person, responsible person, handlers and facilitators.

(5) Where a drug and therapeutic good 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 and therapeutic good lying with the Board concerned under sub-section (3) of section 19 of the Drug Act 1976 and under clause (b) of paragraph (3) of Procedure for inspectors of Schedule-V of DRAP Act 2012, to be sent for test or analysis to the Federal Drug testing Laboratory or any other laboratory specified for the purpose by the Federal / Provincial Government, which shall make the test and analysis and report in writing signed by or, under the authority of, the person for the time being incharge 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 laboratory, a copy of the test report, alongwith method of analysis (Protocol of test) shall be conveyed to the dealer / manufacturer/importer as the case may be.

(7) The Provincial Board may, in case of minor contravention, direct the manufacturer or the seller to bring improvement, issue a warning to him, order the desealing and take any other action including recall of the batches.

(8) The Provincial Board may forbid a person, for a period not exceeding three months, from removing or disposing off a drug and therapeutic goods, article or other thing likely to be used as evidence in an offence under the Act or the rules.

6. Qualifications, etc. of Inspectors and Government Analysts:- (1) No person shall be appointed as an Inspector unless he holds a degree in pharmacy from a University or an institution recognized by the Pharmacy Council of Pakistan and has at least one year experience in the manufacture, sale, testing or analysis of drugs and therapeutic goods.

(2) No person shall be appointed as a Provincial Government Analyst unless he holds a degree in pharmacy from a University or an institution recognized by the Pharmacy Council of Pakistan and has atleast least three years' experience preferably in the manufacture, testing or analysis of Drugs/ therapeutic goods.

7. Duties of Inspectors:- Subject to the instructions of the licensing authority and as prescribed in Drug Regulatory Authority of Pakistan Act 2012 and Drugs Act 1976 (No.XXXI), an Inspector shall:-

- (a) Inspect a medical store, a pharmacy and a drug and therapeutic goods manufacturing premesis at least once in three months within the area assigned to him, and maintain record of the inspections;
- (b) to satisfy himself that the conditions of the licence are being observed;
- (c) If he has reasons to believe that a drug and therapeutic good is being manufactured, sold, stocked or exhibited for sale in contravention of provision of the Act or the rules, he may take samples of the drug and therapeutic goods and may send it for test or analysis and may seize the drug and therapeutic goods or any equipment;
- (d) investigate any complaint made to him in writing against a person and submit a report of his investigation to Provincial Board;
- (e) Initiate prosecution on the direction of Provincial Board and to pursue cases in the Court;
- (f) Maintain record of actions taken by him in the performance of his duties, including the taking of sample and seizure of drugs and therapeutic goods or equipment and submit reports of such record to the Provincial Board as the case may be;
- (g) To institute prosecution in respect of contravention of the Drug Regulatory Authority of Pakistan Act, 2012 and Drug Act, 1976 and these rules in the Drug court of original jurisdiction;
- (h) To maintiain record of all inspections made and action taken by him in the performance of his duties, including the sample taken, the seizure of stocks and submit reports of such records as may be required by the licensing authority and the Board.
- (i) To make such enquires and inspections as may be necessary to stop manufacture or sale of drugs and therapeutic goods being carried in contravention of the Act and these rules;
- (j) Inspect a place licensed under the Act or the rules before renewal of the license.

8. Prohibition of disclosure of information:- Except for the purpose of official business or when required by a Court of law, an Inspector or a Government Analyst shall not disclose to any unauthorized person any information acquired by him in the course of his official duties.

**9.** Form of order not to dispose off stock:- An order requiring a person not to dispose off a drug and therapeutic good or other material, shall make the order under Section 18, Subsection (1), clause (i) of the Drug Act, 1976 in Form 3.

10. Form of intimation of purpose of taking samples:- (I) An Inspector who takes sample of drugs and therapeutic goods under clause (c) sub-section (1) of Section 18 of the Drug Act 1976 and under clause (c) of paragraph (1) of Power of Inspectors of Schedule-V of DRAP Act 2012 for the purpose of test or analysis, shall intimate the purpose of taking the sample to the person from whom he takes the sample in Form 4 and if he seizes a drug and therapeutic goods or the material under clause (f) sub-section (1) of Section 18 of the Drug Act 1976 and under clause (f) of paragraph (1) of Power of Inspectors of Schedule-V of DRAP Act 2012, shall issue receipt of the seizure in Form 5.

(2) The Inspector shall send a portion of the sample or the container to the Government Analyst for test and analysis through a memorandum in Form 6.

(3) The Inspector shall send a specimen impression of his seal to the Government analyst.

11. Duties of Government Analyst:- (1) A Government Analyst notified for the purpose shall conduct test and analysis of the sample of a drug /therapeutic good sent to him under the Act or the rules and shall furnish reports, the results of test and analysis along with protocol of test and analysis applied in Form 7 in accordance with the Act and these rules.

(2) A Government Analyst shall conduct test and analysis of the samples of a drug / therapeutic good sent to him in writing by an Inspector, a Government Department or any other public institution and shall furnish the report of the result of test and protocol of the test (method of analysis) to the Inspector, the Department or the public institution concerned.

(3) Government analyst shall forward monthly report Containing results of samples tested and analyzed during the month for publication at the discretion of the Government and furnish such other information as may be required by the Government.

(4) The Government analyst shall with the approval of provincial government and by notification in the official gazette make regulations to regulate the conduct of its business.

(5) The Government Analyst shall Perform all tests according to the official monograph i.e., United States Pharmacopoeia (USP) (Current edition), British Pharmacopoeia (BP) (Current edition), European Pharmacopoeia (EU)(Current edition), National Formulary of Pakistan (Current edition).

(6) The Government Analyst shall, in case of negative report produce all procedure, methods applied in the performance of test / analysis to the Drug Inspector along with its report.

12. Procedure on receipt of samples from Inspector:- (1) On receipt of sample of a drug and therapeutic good from an Inspector, the Government Analyst shall compare the seals on the packet with the specimen impression and shall note the condition of the seal on the package and after the test or analysis has been completed, he shall forthwith supply to the Inspector and the Board, within sixty days (60) a report of the result of the test and analysis with protocols applied in Form 7.

(2) The Government Analyst, if unable to submit the report in stipulated sixty days (60) as per rule 11 due to reason beyond his control, shall communicate the reasons to the Inspector in writing and shall endorse its copy to the Provincial Quality Control Board who shall have the sample tested from the same or any other Government Analyst or a Government Drug Testing Laboratory or any other Laboratory and shall ensure the receipt of results of such test and analysis within a further period of 30 days and shall make the test report available to the Inspector for further action.

(3) The Government Analyst shall endorse a copy of test report to the Chairperson of Provincial Quality Control Board through Secretary Quality Control Board as prescribed in regulations of the Provincial Quality Control Board.

13. Fee for test and analysis of drugs:- The fee for test and analysis of a drug and therapeutic good in respect of samples sent by persons other than an Inspector or a Government institution, shall be determined by the Analyst or the person incharge of the Government laboratory in accordance with the fees specified in Schedule 'C'.

14. Payment of cost of samples:- As provided under section 18 (a) of the Drugs Act 1976, the payment of the cost of samples taken by the Inspector of Drugs and therapeutic goods may be arranged out of the Government funds, on the availability of funds.

15. Nomination of Members of Drug Court:- (1) the government shall nominate member of drug court for a period three years from among the Senior Pharmacy Professional who holds a graduate or higher degree in Pharmacy and preferably has more than ten years professional and service experience having no financial interest in Phamaceutical trade and industry.

# CHAPTER III SALE OF DRUGS

16. licensing authority:- The Secretary to the Primary and Secondary Healthcare Department Government of Balochistan shall be the licensing authority for the purpose of these rules. The licensing authority may, by order in writing, authorize an officer to sign the licences and to exercise such other powers, and in respect of such areas, as may be specified in the order and the licensing authority may issue licenses specified under rule 18 of these rules.

17. Experts Committee:- The Licensing Authority / Government shall constitute an expert committee comprising among the officers of Drug Control Administration to investigate any issue reltated to the GMP and to certify or investigate the issues related to Quality Control Board and prequalification for the categorization of manufacturer / supplier / indentor / importer of the pharmaceutical raw material and finished goods.

18. Types of licences to sell drugs and therapeutic goods:- The licences under these rules shall be of the following types, namely:-

- (i) licence to sell drugs and therapeutic goods by way of retail sale;
- (ii) licence to sell drugs and therapeutic goods by way of whole sale / distribution;
- (iii) license to sell Narcotics and other controlled drugs;
- (iv) license to sell Veterinary drugs;
- (v) license to sell in Pharmacy / by way of formulation;
- (vi) license to sell Medical devices.

19. Application and fee for licence:- (1) A person may apply to the licensing authority through area inspector for the grant or renewal of a license referred to in rule 16 in Form "8"

(2) The Applicant shall deposit the fee for a license in the concerned Head of Account at the following rates:

- (a) Twenty (20000)] thousand rupees for a license of a Whole Sale /Distributor and Ten (10000) thousand rupees for a license of a Pharmacy/Medical Store (Form 9, 11, 12, 13 and 14); and
- (b) Six (6000) thousand rupees for the renewal of the license of Whole Sale / Distributor and [five Thousand (5000)] rupees for the renewal of license of a Pharmacy / Medical Store (Form 9, 11, 12, 13 and 14).
- (3) The licence may be renewed by the area inspector if the provisions of these rules have been complied with the requirements as specified in Form 8 are fulfilled.

(4) A fee of Rupees Six thousand (6000) shall be paid for any change(s) (proprietor, qualified or premesis) or a duplicate copy of the licence if the original is defaced, damaged or lost, and such copy of the licence shall bear the words "duplicate copy".

20. Forms of licences to sell drugs and therapeutic goods:- (1) The licensing authority shall issue a licence to sell, stock, exhibit for sale by way of retail sale in Form 9.

(2) A licence to sell, stock, exhibit for sale by way of wholesale / Distribution shall be issued in Form 10.

(3) A licence to sell, stock, exhibit for sale or distribute Naroctics and other controlled drugs as specified in Schedule B, shall be issued in Form 11.

(4) A licence to sell, stock, exhibit for sale or distribute Veterinary drugs shall be issued in Form 13.

(5) A licence to sell, stock, exhibit for sale or distribute drugs and therapeutic goods in Pharmacy by way of formulaiton shall be issued in Form 12.

(6) A licence to sell, stock, exhibit for sale or distribute Medical Devices shall be issued in Form 14.

21. Sale at more than one place:- (1) If a person desires to sell, store or exhibit for sale to distribute drugs and therapeutic goods at more than one place, he shall apply for a separate license in respect of each place.

(2) If drugs and therapeutic goods are sold, stored, exhibit for sale or distributed at one place at large scale operation shall apply for separate license under independent supervison of Qualified Person for whole sale / distribution, Narcotics, Veterinary and Medical Devices, in respect of each If drugs and therapeutic goods are sold, stored, exhibit for sale or distributed at one place with small scale in a single room / Shop shall apply for separate license under the supervisson of same Qualified Person for retail/ whole sale / distribution, Narcotics, Veterinary and Medicasl Devices, in respect of each.

(3) Provisions of sub-rule (1) shall not apply in case the drugs and therapeutic goods are properly stores in a godown, used only for storage of drugs and therapeutic goods and which meets the storage conditons and is enlisted along with its complete address on the license.

22. Duration of license:- (1) A licence issued under these rules shall, unless suspended or cancelled, remain in force for two years or until from the date of issue.

(2) If a person fails to apply for the renewal of a license within Sixty days after the expiry of the license, his license shall stand cancelled.

(3) If a person applies for the renewal of a license within Sixty days after the expiry of the license, his license shall remain enforce until an order on the application is passed by the licensing authority.

(4) The licensing authority shall issue a receipt of an application of a license or renewal of a license.

(5) The licensing authority shall dispose off an application for a license or renewal of a license within 90 days of the receipt of the application.

(6) If in the opinion of the licensing authority, it is not expedient in public interest to grant a license, it may refuse the application.

(7) The area drug inspector shall submit the monthly report of renewed drug and therapeutic good sale licenses to the licensing Authority.

23. Pre-conditions for the issuance of licence:- (1) The licensing authority shall not issue Licences as per Form 9, 10, 11, 12, 13 and 14 unless:-

- (a) The premises have proper and adequate facilities for storage of drugs and therapeutic goods and for their protection from direct sunlight, dust or dirt including adequate temperature controls, refrigeration facility, where necessary, for preserving the properties of the drugs and therapeutic goods;
- (b) Licences as in Form 10 unless the applicant is an indenter, importer, distributor of manufacturer and fulfils the conditions laid down in sub- rule (1) of rule 23;
- (c) License as in Form 11, unless the applicant possess a license on Form 10 or Form 9 and fulfill the conditions laid down in sub Rule (1) of rule 23;
- (d) The applicant has never been convicted "who has been sentenced for imprisionment for a period of one year or more or sentenced to pay fine of thiry thousand rupees or more" in contravention of Drug Act 1976 or DRAP Act 2012.
- (e) The concernced officer of Drug Control administration shall make feasibility report (inspection report) for issuance of license on Form 9, Form 10, Form 11, Form 12, Form 13 and Form 14 by considering the conditions laid down in sub rule (1) of rule 23.
- (f) The covered area of the premesis of a Pharmacy is not be less than 96 squrare feet with minimum breadth of 8 feet in the front and height of 8 feet and in case of Medical Store, 96 square feet with minimum breadth of 8 feet and height of 8 feet;
- (g) The Qualified person who has applied for any type of license prescribed under Rule 18 shall supervise the sale of Drugs and therapeutic goods personally.

- (2) The sale of drugs and therapeutic goods shall be supervised:-
  - (i) under licence as per Forms 9, Form 10, Form 11, Form 12 and Form 13 by a person who is registered under clause (a) of sub-section (1) of Section 24 of the Pharmacy Act, 1967 (XI of 1967) while a person who is registered under clause (b) of sub-section (1) of Section 24 of the Pharmacy Act, 1967 (XI of 1967) under license in Form 13;
  - (ii) under license in per Form 14 for Medical Devices by a person who is registered under clause (a) ) of sub-section (1) of Section 24 of the Pharmacy Act, 1967 (XI of 1967) or Degree in Medical Technology / Biotechnology / Electromedical Technology.

24. Conditions of Licences:- (1) The licensing authority shall issue a licence as per Forms 9, 10, 11, 12, 13 and 14 to the conditions stated in the license and to the following general conditions, namely:-

- (a) A person who is registered under clause (a) of sub-section (1) of Section 24 of the Pharmacy Act, 1967 (XI of 1967 shall personally supervise the sale of drugs and therapeutic goods under license in Forms 9 for Medical Store/ retail sale, Form 10 for whole sale / distribution, Form 11 for narcotics and controlled drugs, Form 12 for sale of drugs in Pharmacy/ by way of formulation, Form 13 for sell, stock and exhibit for sale and distribute veterinary drugs and Form 14 for sell, stock and exhibit for sale and distribute Medical devices while a person who is registered under clause (b) of subsection (1) of Section 24 of the Pharmacy Act, 1967 (XI of 1967) under license in Form 13;
- (b) The supply of a drug shall be recorded suitably and the records, the bills or the counterfoils shall be preserved for a period of at least three years from the date of the sale;
- (c) As manufacturer / importer or the seller of a drug and therapeutic good shall sell the drug and therapeutic good] only through their authorized agent on prescribed Form to a holder of a valid Drug and therapeutic good Sale License or Hospital / institution that is directly supervised by the Government;
- (d) in the case of a license of a pharmacy in which preparation or compounding of a drug is undertaken, the premesis have fulfilled the requirements contained in the Schedule 'F';
- (e) the drugs specified in Schedule "B" and "D" shall not be sold by retail sale except on and in accordance with the prescription of a registered medical practitioner as per PMDC rules;

(f) the sale of any drug specified in Schedule "E", "B" and "G"by way of retail sale shall be recorded at the time of supply in a register specially maintained for the purpose and the serial number of the entry in the register 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 prescriber;	(iv) Name of the patient;
(v) Name of the drug;	(vi) Name of the manufacturer;
(vii) Quantity sold	(viii) Batch No;

- (ix) Signature of the qualified person; and
- (x) Quantity purchased and balance

**Explanation:**- If the drug specified in Schedule 'D' 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 Sr. No., the date of the sale, the quantity sold and a sufficient reference to an entry in the register recording the sale of the drug on a previous occasion.

- (2) For the purpose of this rule a prescription shall:-
  - (a) be in writing and 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 quantity of drugs to be supplied and doses to be taken.
- (3) All invoices and bills for purchase of drugs and therapeutic goods shall be preserved for a period of at least three years.
- (4) Records shall be maintained of all purchases and sale of drugs and therapeutic goods by way of wholesale / distribution and such records shall be preserved for three years except where an expiry date is 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 firm which purchase and the concerns applicable and the quantities;
  - (c) the name of the manufacturer, and
  - (d) The invoices and warranty shall bear the full name and address of the purchaser and shall be signed by the warrantor clearly indicating his name and shall be dated.
- (5) The manufacturer, importer or seller of a drug shall maintain record of purchase or sale of a drug and shall preserve the record for at least three yerars containing the following particulars:

- (a) The date of purchase or sale;
- (b) The name and address of the concern from which the drug and therapeutic good is purchased or the concern to whom the drug and therapeutic good is sold;
- (c) The name of the drug and therapeutic goods], its batch number, the date of its expiry and the quantity of the drug and therapeutic goods, and
- (d) The name of the manufacturuer.
- (6) Except as otherwise provided in these rules, a records required to be maintained under these rules shall be preserved for a period of not less than three years from the date of the last entry.
- (7) The licensee shall produce for inspection, by an inspector on demand a registers and record maintained under these rules, and shall supply to the inspector such information as the inspector may require.
- (8) The licensee shall maintain the Inspection Book provided by the licensing authority at the time of issuance or renewal of the licence on which any member of the Board or an Inspector shall record proceeding of each of his visit, his impression and the defects or irregularities noticed, if any, by him and such Inspection Book shall be signed by him as well as the licensee or the qualified person.
- (9) Substances falling under Schedules 'E' shall be stored in the retail shop:-
  - (a) in a part of the premises to which customers do not have access; or
  - (b) in a locked almirah or cupboard or drawer reserved solely for the storage of the substance or the drug.
- (10) A Substance that falls in the list of poisons under the Schedule 'E' shall be stored in containers impervious to the poison and sufficiently stout to prevent leakage arising from the ordinary risks of handling and transport.
- (11) A substances that fall in the list of poisons under the scheduled E when compounded and dispensed shall be labelled with the word 'Poison.
- (12) Creams, Ointment etc., compunded in Pharmacy should be formulated on a registered medical practitioner prescription and according to lable references of Pharmacopoeia with doesage form as per labeling and printing rules, 1986.

(13) In case of sale by way of Pharmacy, The Government / Licensing authority may add additional requirements in the public interest from time to time.

25. Cancellation and suspension of Licences:- (1) The licensing authority may, on the report of an Inspector or the Provincial Board, after giving the licensee an opportunity to show cause by an order in writing stating the reasons, cancel a licence issued under these rules or suspend it for such period as it deems fit, if in its opinion the licensee has failed to

comply with any of the conditions of the licence or with any of the provisions of the rate of these rules,

(2) A licensee whose licence has been cancelled or suspended may appeal to the Provincial Appellate Authority within sixty days of the date of such order whose decision shall be final.

26. Provincial Appellate Authority:- (1) The Additional Chief Secretary (P&D), Balochistan shall stand the Provincial Appellate Authority; and

- (2) 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.
- (3) The Provincial Appellate Authority may direct an officer of the Drug control administration to assist the authority.
- (4 The Provincial Appellate Authority shall, after giving the appellant an opportunity of hearing, pass such order as it deems fit and the order of the authority shall be final and cannot be called in question before any fourm.

27. Repeal. The Balochistan Drug Rules 2018 are hereby repealed.

## BY ORDER OF GOVERNOR BALOCHISTAN

# CHIEF SECRETARY BALOCHISTAN

The Chief Controller Printing and Stationery Department, Balochistan Quetta for publication and provision of 20 copies of Gazette.

#### No.

#### Even.

# No.

Even.

A copy is forwarded for information to:-

- 1. The Senior member Board of Revenue Balochistan.
- 2. The Additional Chief Secretary (Dev)GoB, P&D Department, Quetta.
- 3. The Chairman Chief Ministrer Inspection Team, Quetta.
- 4. The Chairman Balochistan Public Service Commission, Quetta.
- 5. The Prinicpal Secretary to Governor Balochistan, Quetta.
- 6. The Principal Secretary to Chief Minister Balochistan, Quetta.
- 7. The Secretary to GoB, Law and Parliamentary Affairs Department, Quetta.

comply with any of the conditions of the licence or with any of the provisions of the Act or these rules.

(2) A licensee whose licence has been cancelled or suspended may appeal to the Provincial Appellate Authority within sixty days of the date of such order whose decision shall be final.

26. Provincial Appellate Authority:- (1) The Additional Chief Secretary (P&D), Balochistan shall stand the Provincial Appellate Authority; and

- (2) 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.
- (3) The Provincial Appellate Authority may direct an officer of the Drug control administration to assist the authority.
- (4 The Provincial Appellate Authority shall, after giving the appellant an opportunity of hearing, pass such order as it deems fit and the order of the authority shall be final and cannot be called in question before any fourm.

27. Repeal. The Balochistan Drug Rules 2018 are hereby repealed.

## BY ORDER OF GOVERNOR BALOCHISTAN

## CHIEF SECRETARY BALOCHISTAN

The Chief Controller Printing and Stationery Department, Balochistan Quetta for publication and provision of 20 copies of Gazette.

No.

Even.

No.

Even.

A copy is forwarded for information to:-

- 1. The Senior member Board of Revenue Balochistan.
- 2. The Additional Chief Secretary (Dev)GoB, P&D Department, Quetta.
- 3. The Chairman Chief Ministrer Inspection Team, Quetta.
- 4. The Chairman Balochistan Public Service Commission, Quetta.
- 5. The Prinicpal Secretary to Governor Balochistan, Quetta.
- 6. The Principal Secretary to Chief Minister Balochistan, Quetta.
- 7. The Secretary to GoB, Law and Parliamentary Affairs Department, Quetta,

- 8. All the administrative Secretaries Government of Balochistan.
- 9. The Accountant General Balochistan, Quetta.
- The Accountant Ceneral Datoentant, Secondary Healtheare Department Services Balochistan, Quetta.
- 11. The Deputy Secretary (Staff) to Chief Secretary Balochistan, Quetta.
- 12. All Additional Secretaries/Deputy Secretaries/Under Secretaries/ Section Officers in Primary and Secondary Healthcare Department Department, Quetta.
- 13. The Private Secretary to Secretary S&GAD Balochistan, Quetta.
- 14. The PA to Additional Secretary (Regulations) S&GAD, Quetta.
- 15. Chairman Quality Control Board / Addl; Secretary (Development) Primary and Secondary Healthcare Department Balochistan.
- 16. Master file.

Section officer (V) Health Department 081-9203167

# Schedule-A

[See rule 2 (d)]

### FORM 1 MONTHLY REPORT [See rule 5 (1)]

I	FOR THE N	IONTH OF	SUN		INSPECTION	NS Remarks
Place inspected	No. of the Firm inspected	No. of the Firm found in violation of law (specify main offence)	No. of the Sample drawn	No. of the cases in Board	cases in Drug Court	

# DETAILES OF THE VIOLATION IN RESPECT OF DRUGS Reports of the Sample of Drugs and Theraputic goods not in compliance with Law

Name of the Drug and therapeutic goods	Manufacturer	Batch No.	Place of taking	Date of dispatch of sample and name of laboratory	of test report with nature of	Action taken including detail of seizure and sale restriction

# **RENEWAL OF THE DRUG SALE LICENCES**

Total No. of the		Reason in case Renewal not					
licenses in the District	Form 9	Form 10	Form 11	Form 12	Form 13	Form 14	granted

# DETAIL OF CHALAN SUBMITTED IN THE MONTH

S.No	Name and Address of Medical Store	Purpose of fee (Grant/ renewal / other changes)	Amount	Challan No and Date	Verified from treasury office (yes or not)	Copies of the Challans verified	Remarks	
								1

Dated

Inspector \_\_\_\_\_

Summry of the Market e.g, Pricing, shortage of the medicine, detail of the samples taken for testing / analysis report from DTL may be reported on separate page.

17

# FORM-2

See Rule 5(1)

# DRUGS TESTING LABORATORY

Progress report for the month of \_\_\_\_\_

number of samples in the beginning of month	Samples received during the month	Total	New Old	Total Tested	Samples up to standard with percentage	Samples below standard	Details of samples pending for more than 2 months	Remark/ Reasons
					ļ			
			┨═───					

Spurious=Sub-standard=Adulterated=Counterfeit=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

# [See rule 9]

Order under section 18(1)(i) of the Drug Act 1976 / clause (i) paragraph (1) of Powers of inspectors of Schedule-V of DRAP Act 2012, requiring a person not to dispose of stock in his possession.

Whereas I have reason to believe that the stock of drugs in your possession detailed below contravenes the provision of Section \_\_\_\_\_\_ of the Drug Act, 1976 /DRAP Act 2012 Now, therefore I hereby direct you not to dispose of the said stock for a period of \_\_\_\_\_\_ days from this date.

Date \_\_\_\_\_

1

Inspector\_\_\_\_\_

Details of stock of drugs and therapeutic goods.

Date \_\_\_\_\_

Inspector\_\_\_\_\_

# **Form 4** [See Rule 10(1)]

# Intimation of purpose to person from whom the sample is taken.

I have this day taken from the premises of	
situated at	

samples of the drugs and Therapeutic goods specified below for the purpose test/analysis.

# Details of samples drawn:

Name of Drug and therapeutic goods	Name of Manufacturer	Registration No.	Batch No	Quantity	Bill No	Mfg & Exp date
				<u> </u>		
	_					
		1		1		
					+	

Dated:\_\_\_\_\_

Inspector

-

	<b>Form 5</b> [See Rule 10(1)]	Serial No
section 18 (1) the Drug Act 15 inspectors of Schedule-V of DF	nd theraputic good and other 976 and under clause (f) of pa RAP Act 2012.	
The Stock of drugs and t day been seized by me under th	theraputic goods, materials / article the provision of clause (f) of sub- r clause (f) of paragraph (1) o 12 from the premesis of	f Powers of inspectors of
Dated:	Inspector:	
Details of Drugs, other materia	al and articles seized including	

Dated:\_\_\_\_\_

•

Inspector:\_\_\_\_\_

21

#### Form o

# MEMORANDUM TO GOVERNMENT ANALYST [See Rule 10(2)]

Serial No. of Memorandum \_\_\_\_\_

Dated:\_\_\_\_\_

То

The Government Analyst

The portion of samples / container described below is sent herewith for test / analysis under the provisions of clause (i) of sub-section (3) of Section 19 Drug Act, 1976 and under clause (a) paragraph (3) of Procedure for inspectors of Schedule-V of DRAP Act 2012.

Sample is if the drug and Theraputic goods: \_\_\_\_\_

Quantity:	
Batch No:	
Manufacturing date:	
Expiry date:	
Manufacture by:	
And purports to contain:	

Portion of sample has been marked by me with the following marks.

Dated: \_\_\_\_\_

Inspector \_\_\_\_\_

#### Form 7 [See rule 11]

Test Report No: \_\_\_\_\_Dated\_\_\_\_\_

# CERTIFICATE OF TEST OR ANALYSIS BY THE PROVINCIAL DRUG TESTING LABORATORY/ /GOVERNMENT ANALYST.

Certified that the samples, bearing number \_\_\_\_\_\_purporting to be a sample of \_\_\_\_\_\_received on \_\_\_\_\_\_with memorandum No \_\_\_\_\_Dated \_\_\_\_\_from \_\_\_\_\_\_has been tested / \_\_\_\_\_has been tested / \_\_\_\_\_has been tested /

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 Drug Act 1976 DRAP Act 2012] for the reason given below:-

> Government Analyst Provincial Drug Testing Laboratory

DETAILS OF RESULTS OF TEST OR ANALYSIS (with protocols of tests applied) Method. Marked of testing according to

Methoa of lesting acc	D istuction No	Batch No.
Sample of	Registration No	claimed to be manufactured by
Date of Mfg	Date of Exp	claimed to be manufactured of

Appearance	
Identification	
Volume	

_	
A	ccav.

Assay:	Stated amount	Determined	Percentage	Limits
Assay as	Stated amount	amount	purity	

Sterility(if appalicable):

Result:\_\_\_\_\_

Test Report forwarded to:

- 1. The Inspector of Drugs\_\_\_\_\_ 2. The Chairman through Secretary concerned of Provincial Quality Control Board,
- Government of Balochistan, Quetta.

# **Government Analyst** Provincial Drug Testing Laboratory

[See rule 19 (1)]

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

1. I / we \_\_\_\_ hereby apply for a license to sell:

a. Drugs and therapeutic goods by way of retail sale.

b. Drugs and therapeutic goods by way of whole sale / Distribution

c. License to sale Narcotics and other controlled drugs

d. License to sale in Pharmacy / by way of formulation

f. License to sale Medical devices e. License to sale in Veterinary.

on the premises situated at (complete address)\_\_\_\_\_

2. The sale of drugs will be under the personal supervision of :

(Name)	(Qualification)
(Name)	(Qualification)

- 3. I / We, am / are submitting herewith the following documents:
  - a) attested copies of the testimonials of Qualified person including Pharmacy council registration certificate.
  - b) two copies of national identity card of the proprietor and qualified person
  - c) four attested copies of the photograph of qualified person
  - d) attested Photostat copy of the valid registration issued by the C.O.I & E in case of indenter / importer.
  - e) Manufacturer's Authority as agent / distributor.
  - f) Affidavit of the Proprietor duly verified from Class-I Magistrate that:
    - will abide by the provisions of Drugs Act, 1976, DRAP Act 2012 and (i) Theraputic goods Rules, 2021.
    - will inform authorities well in time if any change in service or address (ii) occurred or any irregularity or any violation of Drug Act 1976, DRAP Act 2012 is noted.
    - Shall not sell / stock any expired, spurious, sub-standard, unregistered, (iii) misbranded, unwarranted, counterfeit or any drugs and therapeutic goods in violation to the drugs laws in force.
  - g) Affidavit of the Qualified person who will supervise the sale of drugs and therapeutic goods, duly verified by Class-I Magistrate (specimen is in Schedule D).
  - h) Treasury Challan(s) No. & Dated amounting to Rs. \_\_\_\_\_ in the Head of Account C-\_\_\_\_-Health and Other receipts.

Dated:\_\_\_\_\_ Signature:

(i) Name, address and Permanent Home address of Qualified person

Dated:\_\_\_\_\_ Signature:

(ii) Name, address and Permanent Home address of proprietor

#### **Form 9** [See rule 20 (1)]

License to sell, stock and exhibit for sale and distribute drugs and therapeutic goods by way of retail sale.

M/S\_\_\_\_\_

This license will be in force for two years from the date given below.

Name (s) of qualified person (s) Photograph (s) Name of the proprietor

Addresses of Godown (s) where drugs and therapeutic goods shall be stored

Dated

# LICENSING AUTHORITY

- (i) The license and the registration certificate (from pharmacy council) of Qualified person shall be displayed in prominent place in part of the premises open to the public
- (ii) The licensee shall comply with the provisions of the Drug Act 1976, DRAP Act 2012 and the rules made there under for the time being in force
- (iii) The licensee shall report forthwith to the licensing Authority any change in the qualified staff incharge
- (iv) No Drug and therapeutic goods 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.
- (v) The licensee shall not sell or store a drug mentioned in the Schedule G.

#### **Form 10** [ see Rule 20 (2)]

License to sell, stock and exhibit for sale and distribute drugs and therapeutic goods by way of wholesale / Distribution.

M/S\_\_\_\_\_

This license will be in force for two years from the date given below.

Name (s) of qualified person (s)Photograph (s)Name of the proprietor

Addresses of Godown (s) where drugs shall be stored

Dated\_\_\_\_\_

# LICENSING AUTHORITY

- (i) The license and the registration certificate (from pharmacy council) of Qualified person shall be displayed in prominent place in part of the premises open to the public.
- (ii) The licensee shall comply with the provisions of the Drug Act 1976, DRAP Act 2012 and the rules made there under for the time being in force
- (iii) The licensee shall report forthwith to the licensing Authority any change in the qualified staff incharge
- (iv) No drug and therapeutic good 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

#### **Form 11** [See Rule 20(3)]

# License to sell Narcotics and other controlled drugs and therapeutic goods specified in schedule B and G

M/S\_\_\_\_\_\_holder of license No.\_\_\_\_\_ (on Form 9 / Form 10) is hereby licensed to sell, stock, exhibit for sale or distribution of narcotics and other drugs specified in schedule B and G in the premises situated at\_\_\_\_\_\_\_subject to the conditions specified as under and to the provisions of the Drugs Act 1976, DRAP Act, 2012

and the control of narcotic substance Act 1997, and the rules made thereunder;

This license will be in force for a period of two years from the date given below

Name (s) of qualified person (s)Photograph (s)Name of ProprietorPhotograph (s)

Addresses of Godown (s) where drugs shall be stored

Dated

# LICENSING AUTHORITY

- (i) The license shall be displayed in prominent place in part of the premises open to the public
- (ii) The licensee shall comply with the provisions of the Drug Act 1976, DRAP Act 2012 and the control of narcotic substance Act, 1997 and rules made thereunder for the time being in force.
- (iii) The licensee shall keep sale and purchase record for a period of three years.
- (iv) The licensee shall reserve separate area for the storage / stocking of narcotics and other controlled drugs.
- (v) The licensee shall report forthwith to the licensing Authority any change in the qualified staff incharge
- (vi) No drug and therapeutic good 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.

[See Rule 20(5)]

# License to sell drugs in Pharmacy / by way of formulation

This license will be in force for a period of two years from the date given below

Name (s) of qualified person (s) Name of Proprietor Photograph (s)

Addresses of Godown (s) if any, where drugs shall be stored

Dated\_\_\_\_\_

LICENSING AUTHORITY

- (i) The license and registration certificate (from pharmacy council) of Qualified person shall be displayed in a prominent place in part of the premesis open to the public.
- (ii) The licensee shall comply with the provisions of the Drug Act 1976, DRAP Act, 2012 and rules made there under for the time being in force.
- (iii) The licensee shall comply with the requirements of the schedule F, if the drugs are compounded, dispensed or prepared on prescription.
- (iv) The licensee shall keep record of sale and purchase for a period of three years.
- (v) The licensee shall report forthwith to the licensing Authority any change in the gualified staff incharge.
- (vi) No drug and therapeutic goods 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.

#### [See Rule 20(4)

# License to sell, stock and exhibit for sale and distribute Veterinary drugs

M/S	
is hereby licensed to is hereby licensed to sell / stock and exhibit f	for sale Veterinary dugs
on the premesis	subject
to the conditions specified as under and to the provisions of the Drug	gs Act 1976, DRAP Act
2012 and the rules made thereunder;	

This license will be in force for a period of two years from the date given below

Name (s) of qualified person (s) Photograph (s) Name of Proprietor

Addresses of Godown (s) if any, where drugs shall be stored

Dated

# LICENSING AUTHORITY

- (i) The license and registration certificate (from pharmacy council) of the Qualified person(s), supervising the sale of drugs shall be displayed in a prominent place in part of the premesis open to the public.
- (ii) The licensee shall comply with the provisions of the Drug Act 1976, DRAP, Act 2012 and rules made there under for the time being in force.
- (iii) The licensee shall keep record of sale and purchase for a period of three years.
- (iii) The licensee shall report forthwith to the licensing Authority any change in the qualified staff incharge
- (v) 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.

[See rule 20(6)]

This license will be in force for a period of two years from the date given below

Name (s) of qualified person (s) Name of Proprietor

Photograph (s)

Addresses of Godown (s) if any, where drugs shall be stored

Dated

# LICENSING AUTHORITY

- (i) The license and registration certificate (from pharmacy council) of the Qualified person(s), supervising the sale of drugs and Medical Devices shall be displayed in prominent place in part of the premises open to the public
- (ii) The licensee shall comply with the provisions of the Drug Regulatory Authority of Pakistan Rules, 2017 and the Provincial Drug Rules 2021 and under sub-para (b) of para 3 of the Schedule 1 of DRAP Act, 2012.
- (iii) The licensee shall not sell or stock any article which is not enlisted in Schedule-A of the SRO 167(1)2017 and time to time amendments by CEO, DRAP.
- (iv) The devices shall be approved by the Regulatory Authorities of USA, Japan, Australia, Canada, Austria, Belgium, Denmark, France, Germany, Netherland, Ireland, Italy, Norway, Spain, Sweden, Switzerland, UK, or CE mark by notified bodies of European Union.
- (v) Schedule-A devices cannot be sold except from above sources.
- (v) Schedule-A devices cannot be bore to be the licensing Authority any change in the licensee shall report forthwith to the licensing Authority any change in the qualified staff incharge
- (vii) No drug and therapeutic good 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.

# SCHEDULE "B" [[See Rules 2(L), 18(iii) and 24(1) (e]]

# NARCOTICS, PSYCHOTROPIC, ANTI-DEPRESSEANTS AND OTHER CONTROLLED

DRUGS	Acatal	
Acetorphine	Acetylmethadol	Allylprodine
Alphacetylmethadol	Alphamethadol	Alphaprodine
Benzethidine	Benzylmorphine	Betacetylethadol
Betaprodine	Bezitramide	Benzodiazepine
Buprenorphene	Cannabis	Clonitazone
Coca leaf	Cocaine	Codoxime
Concentrate of poppy straw	Desmorphine	Dextromoramide
Diampromid	Diethylthiambutene	Difenoxin
Dihydromorphine	Dimenoxadol	Dimepheptenol
Dimethylthiambutene	Dioxaphetyl butyrate	Diphenoxylate
Dipipanone	Dextropropoxyphene	Drotebano
Ecoonino	Ethylmethylthiambuten	Etonitazene
Etorphine	Etoxeridine	Fantanyl
Furethidine	Heroin	Hydrocodone
Hydromorphinon	Hydromorphine	Hydroxypehtidine
Isomethadone	Ketobemidone	Levomethorphen
Levomeramide	Levophenacylmorphen	Levorphanol
Methazocine	Methadone	Methadone-intermediate
Methyldeserphine	Methyldihydromorphine	Metopen
Moramide intermediate	Morpheridine	Morphine
	nide and other pentavalent nitroge	
in particular the morphine-N-or	xide derivatives, one of which is C	odeine-N-oxide and the drugs
Morphine-M-oxide	Myorphine	Nicomorphine
Noracynethadol	Norvlevorphanol	Normathadone
Normophine	Norpipanene	Opium
Oxycodone	Oxymorphone	Pethidine
Pethidine-intermediate-A	Pethidine-intermediate-B	Pethidine-intermediate-C
Phenaxone	Phenampromide	Phenazocine
Phenomorphan	Phenoperidine	Pininodine
Piritrameide	Propheptazine	Recamethorphane
Recomoramide	Recamorphan	Surfentanil
Thebacon	Thebaine	Tramadol
Trimperidine	Acetyldihydrocodine	Codine
	Norcodine	Pholcodine
Dihydrocodine	Nicodine	Nicocodine
Ethylmorphine		Theocounic
Dec		Chlordiazepoxide
Propyiyam	Alprazolam	
Propyiyam Diazepam	Alprazolam Citalopram	Chlordiazepoxide
Propyiyam Diazepam Fluoxetine	Alprazolam Citalopram Paroxeine	Chlordiazepoxide Escitalopram Sertraline
Propyiyam Diazepam Fluoxetine Venlafaxine	Alprazolam Citalopram Paroxeine Bupropion	Chlordiazepoxide Escitalopram Sertraline Mirtazapine
Propyiyam Diazepam Fluoxetine Venlafaxine Amitriptyline	Alprazolam Citalopram Paroxeine Bupropion Amoxapine	Chlordiazepoxide Escitalopram Sertraline Mirtazapine Desipramine
Propyiyam Diazepam Fluoxetine Venlafaxine Amitriptyline Trimipramine	AlprazolamCitalopramParoxeineBupropionAmoxapineFluphenazine	Chlordiazepoxide Escitalopram Sertraline Mirtazapine Desipramine Prochlorperazine
Propyiyam Diazepam Fluoxetine Venlafaxine	Alprazolam Citalopram Paroxeine Bupropion Amoxapine	Chlordiazepoxide Escitalopram Sertraline Mirtazapine Desipramine

# SCHEDULE 'C' [See Rule 13]

.

S.No	Item	Fee per sample (Rs.)
1	Short conclusion / judgement (without experimentation)	200
2	Preliminary examination of character e.g. color, taste, smell, solubility, miscibility etc.	400
3	Clarity of solution:	
	(1) Physical examination	200
	(2) Chemical examination	400
4	Completeness of solution	450
5	Identity test: General	400
6	Identity test: TLC	1200
7	Leakage test injectable	450
8	Weight variation / Mass variation	600
9	Content uniformity	10,000
10	Dissolution Test(Spectrophotometric)	5000
11	Dissolution Test(Chromatorgraphic)	7000
12	Disintegration test (uncoated / film coated / sugar coated Tablets and capsules	800
13	Disintegration test (Enteric coated Tablets and capsules	1200
14	Disintegration test (Sustained release Tablets and capsules	3200
15	pH test	800
16	Determination of solubility quantitatively in one solvent	800
17	Determination of melting point	800
18	Micromelting point in non-declared substance	750
19	Crystallizing point, freezing point, setting point and solidifying point	600
	each Distillation range and boiling point etc.	450
20	Determination of water / humidity	
21	(a) In ointments	450
	(b) In other material	700
		1000
22	Loss on drying	750
23	Weight per ml, density, specific gravity etc.	1000
24	Determination of viscosity	750
25	Determiantion of jelly strength	800
26	Determination of jelly strength Determination of ash, acid insoluble ash, water soluble ash, sulphated	
	ash alcohol soluble extractive totoar sonas, etc carry	750
27	De tite as honischle substances lest	3000
28	Determination of alcohol in the preparations	900
29	Extraction with organic solvents	1200
30	Continuous extraction of drugs	800
31	Isolation by distillation	800
32	Steam distillation	1200
33		800
34	Determination of unsaponifiable matter nee methods	
	balsamicacids, etc each Determination of volatile oils in drugs	500

	Test for the absence of:	700
36	(a) A rachis oil othere oils	700
$ \rightarrow $	(b) Cotton seeds oil in other oils	700
-+	(c) Sesame oil in other oil	700
	(d) Similar other tests	800
	Examination of Nitrogen Kieldahi	800
31-	Determination of of water Karl Fischer	000
30	ImpurityLimit test for the presence of:	800
39	(a) Ions each	800
	(b) Organci substances each	900
	Quantitative test for Lead, Arsenic, Heavy metals etc.	700
70	Determiantion of foreign organic matter	
41	Determination of acidity or alkalinity chemical	800
44	Test for alkalinity of glass	700
43	Determiantion of:	
44	(a) Sulphur dioxide	700
	(b) Methoxyl	700
	(c) Absorption of carbon dioxide by soda lime	700
	(d) Similar other tests	700
	(a) Sililia Oulei (USIS	2000
45	Assay (Spectrophotometric)	5000
46	Assay (HPLC)	1000
47	Assay Titration (Simple)	2000
48	Assay Titration (Potentiometric)	3000
48	Bioassay	700
50	Gasemetric assay	700
51	Oxygen combustion method	700
52	Refractometry	700
53	Polarimetry	1200
54	Flourimetry assay	800
55	Naphelmetry Assay	800
56	Polarography every component	
57	Cl	2000
	(a) Paper or ion-exchange or TLC	1500
	(b) Gas	800
58	Zone Electrophoresis	1000
59	Paper Electrophoresis	1000
60	Proteolytic amylolytic activity	1200
61	Activity of trypsin or chymotrypsin	1200
62	Appearance of solution (Syringes)	1000
63	Absorbance (Syringes)	1200
64	Reducing substances	500
65	Fiber identification test	
66	Disinformente / insecticides:	1500
	a lite chomical ISI	1000
	(h) Proteriostatic / bacleficidal activity	2000
67	Test for complete extraction of alkalolds	1500
68	Test for complete extraction of dextrants	1300
69	Sumainal lightway and suffices:	400
	(a) Measurement of length	400
	(a) Measurement of diameter	400
	(c) Tensile strength	700
<u> </u>	(d) Softening point	700
-	(e) other test	800

.

70	Surgical dressing etc:	700
10	(a) determination of Yarn number cach	400
-	(b) Thread count(wrap and weft) etc (Bandage)	400
	(c) Wt. per unit area (Bandage)	1000
	(d) Elasticity Test (Crepe bandage)	800
	(e) determination of content of wool	400
	(f) setting time	700
	(g) other chemical test each	
	(h) Absorbency (cotton)	700
	(i) Naps etc	400
	(j) Adhesive strength of plasters	400
	(k) other tests	500
71	Determination of starch in dressing	700
72	Identity test in vegetable drugs:	2000
	(a) Pharmacopeal each	
	(b) Non officail each	
73	Identity test in pulverized drugs in mixture:	2000
	(a) official drugs each	
	(b)Non official each	
74	Unknown vegetable drugs	
75	Microscopic evaluation	800
76	Syringability test	700
77	Air Tightness	800
78	Microbiological test	
79	Sterility test (direct)	2500
80	Sterility test (Filter)	3000
81	Endotoxin test (gel Clot method)	3000
82	Endotoxin test (Chromatographic method)	4000
83	Test for infusion bags microbiological	3000
84	Acitivity, potency test:	800
<b></b>	(i) Antibiotics per ingredients	1200
	(ii) Vitamin etc.	1200
85	Other bacteriological examination	1200
86	Toxicity/abnormal toxicity/undue toxicity, safety test	1000
87	Derpessor substances test	1200
88	Pressser substances test	1200
89	Biological adequacy test	1200
90	Biological assay	1500
91	Pyrogen test	1000
92	Other pharmacological test	800
93	Clinical Pharmacological trials	800
94	Clarity test (parentrals)	600
95	Optical rotation	2000
96	Specific gravity	1500
97	Refractive index	1200
98	Limit test (Trace elements)	2500
99	Acid value	2000
100	Saponification value	2000
101	Acetyl value	2000
102	Hydroxy value	2000
103	Friability test	1500
104	Others	1,000
105	Tetanus toxoid (Locally manufactured)	30,000
	The second to A CIA COMPANY AND A COMPANY A	

106 Anti Tetanus Sera (Locally manufactured)	30,000
100 - I Datio Vaccine (Locally manufacture 1)	20,000
101 stanlas Vaccine (Locally manufactured)	20,000
100 - Line Vaccine (Locally manufactured)	30,000
10) statis P. Vaccine (Locally manufacture 1)	20,000
Snake Venom Anti Sera (Locally manufactured)	30,000
111 Snake venom Antribera (Locarly manufactured)   112 Interferon (Locally manufactured)	20,000
112     Interferon       113     All other imported Vaccines, sera and Interferon	20,000

#### Note:

(i) The exact fee will be calculated by the Governement Analyst on the basis of the time spent, reagents and animals etc used for the conduct of test / analysis.

(ii) Fee for other tests not given above is to be calculated by the Governemtn Analyst.

### SCHEDULE 'D'

[See Rule 24 (e)]

# (a) TO BE SOLD BY A RETAILER ON THE PRESCRIPTION OF REGISTERED MEDICAL PRACTITIONER.

Adrenocorticotropic hormone (ACTH), Androgneic anabolic, oestrogenic and progestational substance, benzeestrol, derivatives of stillbene, dibenzyl or naphthalene with oestrogenic activity, their esters, steroids compound with androgenic or anabolic oestrogenic progress to the activity and their esters.

#### Antibiotics specified below, their salts, derivatives and salts of their derivatives

Bacitracin	Carbomycin	Chloramphenicol
Chlortetracycline	Colimycin	Dihydro streptomycin
Erythromycin	Framaycetin	Grmicidin
Griseofulvin	Kanamycin	Neomycin
Novobiocine	Nystatin	Oleandomycin
Oxytertracycline	Penicilline	Paromomycin
Polymxyin	Supramycin	Streptomycin
Tetracyclin	Tyrothricin	Vancomycin
Vincomycin	Cephalosopoin	Amitriptyline, its salts
Antihistamine substances, their s	alts and derivatives of their salts	
Antazoline	Bromazine	Bucidine
Chlorocyclizine	Diphenhydrmine	Diphenpyraline
3 Di Nebutyl, aminoethyl, 1-4,	Isothidtendyl, N-Dimethyl	Meclozine
5,6, tri hydroxyphthalide	amino iso propyl thiophenyl,	
	Pyridalamine	
Phenindamine	Promethazine	Prophen pyridamine
Thenalidine, (1 Methyl 4 amine	Azapetine, its salts	Benzodiazepines
N-Phenyl N 2 Phenyl) nioridine	Aenactyzine, its salts	Bendrofluaxide
ularate. Substances being tetra		Pentazocine
Substituted N-Derivatives of		Buprenorphines
<sup>1</sup> <sup>Cury</sup> leneidamine		Tramadols
Pnoylenediamine		
Brethylium Tesylate	Captodine, its salts	Chlorisondamine
		Cholordies
Chlormozanene	Chlorpyomazine, its salts	Chlorprothixene
Chlorthiazide	Citrated Calcium	Clidinium Bromide
--	---------------------------------	------------------------------------
Chlorunanee	Carbamide	
i sone	Cyclopenthiazide	Dithiazinine Iodide
Cortisone Hydrocortisone		
Hydrocoltisone		
Prednisone		
Prednisololne Triamcinolone and		
Triamcinoione and Dexamethasone, their esters,		
Dexamethasone, their esters, their derivatives and esters of		
their derivatives and esters of		
their derivatives	Glutethimide, its salts,	Hexocyclium Methyl sulphate
Ethionamide	guanethidine	Hexadimethnine
	guaneunume	Bromide
	Hada Game Ali-ita ince	Isocarbon acids
Hydrochlorthalazide,	Hydroflume thiazide, iron	Isocarbon acids
imipramine, its sats	preparations for parenteral use	Manamada
Isonicotinic acid	Isoxsurprine	Mepromade
Hydrzide and other hydrazine		
derivatives isoncotinic acid,		
their derivatives, salts,		
Methaualone, its salts		Maniferrale
Methaqualone, its salts	Methypenpynol, its ester and	Metronidazole
	other derivatives	Paraminosalicylic acid, its salts,
Mialamide, its salts	Oxytocine, prepaid from the	Paraminosalicylic acid, is saids,
	pituitary body or by synthesis.	its derivatives, their salts
Pempidine, its salts	Pecazine, its salts	Pherelzine, its salts
Phenothiazine,	Phenynamidol, its salts	Pituitary gland, the active
,		principle of not otherwise
		specified in this schedule nor
		this schedule and their salts
Derivatives and salts of its		
derivatives not otherwise		
specified in this schedule		
Pivazide	Polythiazide	Promazine, its salts
Pyrvinium its salts	Sorbide nitrate	Spirinololactone
Thiopropazate, its salts	Tranylcypromine, its salsts	Trimeprazine, its salts
Vasopressin, prepared from the		
pituitary body of by synthesis		
pituliary body of by synthesis		

•

Note: Preparations containing the above substances, excluding preparations intended for topical or external use, also covered by this schedule.

36

#### (b) AFFIDAVIT / UNDERTAKING BY THE QUALIFIED PERSON SUPERVISING THE SALE OF DRUGS [AND THERAPUTIC GOODS] (DULY VERIFIED FROM CLASS I MAGISTRATE) [See Rule 19]

\_\_\_\_\_S/0,D/0\_\_\_\_\_Re Mr. \_\_\_\_\_\_\_\_Degree No. \_\_\_\_\_\_Pharmacist, resident of \_\_\_\_\_\_

- 1. I am not registered in any other council of Pakistan;
- 2. 1 will be supervise the said Medical Store / Whole sale / distribution / Pharmacy / Veterinary / Medical Device sale point and will sign the invoices of sold drugs / devices;
- 3. I have not been convicted of any offence from any Court of Law;
- 4. I will comply with the provisions of the Drugs Act, 1976, DRAP Act 2012 and the Balochistan Drug and Theaputic goods Rules, 2021.
- 5. I will practice according to Pharmacy Act 1967.
- 6. I will follow the code of ethics and conduct of Pharmacy council.
- 7. I will not sell / stock expired, spurious, sub-standard, unregistered, misbranded,
- unwarranted, counterfeit or any drugs in violation to the drugs laws in force. 8. I will display my original Registration Certificates within the premesis.

## DEPONENT

Dated:

## SCHEDULE 'E' [See Rule 24]

JSee KI	
Name of Poisonous Substance	Percentage of Poison content below which
-	the substance or its preparation is exempted
Acetanilide, alkyl acetanilides	from the provision of rule.
	•
Acetylineum Aconites, roots Aconites, the following, their salts, their esters	•
Aconites, roots Aconites, the following, their salts, their esters, Alkaloids, the following, their Quaternary compounds	•
	•
Acetylding Acetylding Aconite, alkaloids	0.20
Apomorphine	0.15
	0.15
Atropine Belladona, alkaloids calculated as hyoscyamine	0.15
Benzoylmorphine	-
	0.20
Brucine Calabar beans alkaloids of Cocoa alkaloids	-
	0.10
Cocaine	0.10
Codeine	0.50 calculated as colchicines
Colchicum	0.10
Conine	0.20
Coternine Curare alkaloids of curare basis	-
Diamorphine (Diacetylmorphine hydrochloride)	-
Diamorphine (Diacetyiniorphine nyuroemoride)	-
Dihydrocodeine	
Dihydrocodeinone	0.1
Dihydroxy, dioxycodeine	
Dihydromorhine	-
Ecgonine	1.0
Emetine	1.0
Ephedra Alkaloid	
Ergot Alkaloids	0.20
Ethylmorphine	
Gelsemium, Alkaloids of	0.1
Homatropine	0.15
Hyoscyamine	0.15
Jaborandi, alkaloids of	0.50
Lobelia, alkaloids of	0.50
Morphine	0.20 Calculated as anhydrous morphine
Nicotine	0.20
Paparet	1.0
Papavarine	0.150
Pomegranate, alkaloids of	
Vuebracho, alkaloids of other than the alkaloide	
of red Ouebracha	•
Nauvolfia alkalaida of	1.0
	2.15
and acous all-1, 1- at otherwise spectrum	0.15 Calculated as Hyoscyamine
	0.20
Stav-same II I I I G	
Strychnine	0.20
- Join C	3

	10
Thebaine Thebaine (Benzyl Pseudotropine) Trypacocaine (Benzyl Pseudotropine)	1.0
Table Cocaine (Dens)	
	1.0
rahifildation and any other pentavalant	-
Allyment	-
illy pro-	-
Inha active sealth and any mine	-
10039 OF Line designation of the ingent	
Alphaapropdine; its saits annuopyrine Alphaapropdine; its saits annuopyrine Sulphonates and its derivatives; their salts Sulphonates and its derivatives; their salts Amino alcohol esterified with benzoic acid Amino alcohol esterified with benzoic acid	•
Suprino alcohol esterified with benzoic acid	1.0
Amino alcohol esternied with benzoic acid Amino alcohol esternied with benzoic acid phenyl propionic acid or the derivatives of these	
· Jos MELL Sales	
Aminopterin	•
Ammonia	Smelling salts
	-
Amylninite Anileridine; its salts	•
	Equivalent of 1.0% of trioxide
Antimony, oxfacts of antimony, surplices of antimony, organic compounds of antimony	
antimony, Organie component and interior	
Apoid Arsenic; halides of arsenic; oxides of arsenic,	Equivalent of 1 00/ of amoria triavida
Arsenic; halides of arsenic, oxides of arsenic,	Equivalent of 1.0% of arsenic trioxide
Arsenic; nandes of accompounds of arsenic Arsenites, organic compounds of arsenic	
Arsenites, organic componentiations of Barbituric acid, its salts; derivatives of	-
The second their sails: compounds of	
Libric acid, its salts, its derivatives, their salts	
with any other substance.	
Barium chloride	•
Barium sulphate	-
Benzethidine, its salts	•
Beta acetyl methadol; its salts	-
Beta-aminopropylbenzene (Amphetamine) its	-
salts, its N-alkyl derivatives, their salts Beta-	
aminoisopropylbenzene, its salts; its N-alkyl	
aminoisopropyidelizene, na sana, na re unor	
derivatives, their salts.	
Beta meprodine; its salts	•
Beta-methadol; its salts	•
Beta-prodine; its salts	•
Busulphan(1,4 dimethane sulpha oxybutane), its	-
salts	
Butyl chloral hydrate	-
Cannabis (Indian hemp); Cannabisresin; galenical	-
remember of acception over and tinchire of	
preparations of cannabis, extract and tincture of	
cannabis and cannabin tannates	0.10
Canthridine, Cantharidates	
Carbacol,4-carbamithoxy 1-3, dimethyl 4-phenyl	
hexamethylenemine, its slats; Carbutamide	
Chloral formamide,	•
chloral hydrate	
Chloramhurit	-
Chlorambucil; its slats	Substances containing less than 10% of
Chloroform	chloroform
	-
Chloropropamide; its salts	
	Substances containing 50% creosote
Creosote from wood	Substances come 39
DOOM TIOTI MOOD	

Proton oil and seeds	-
Cyclophosphamide; its salts	0.15
Datura herb and seeds, preparation of Datura	Calculated as hyoscyamus
1 i ite colto	1.5
Desmorphine; its salts	-
Dextro mormide; its salts	•
Dextrophane; its salts	-
Diacetyl N-allylmorphine; its salts Di amino di phenyl sulphone, its salts and	-
derivatives Digitalis, glycosides of, other active principles of	•
Digitalis, glycosides of, other active principles of	
digitalis	-
Digitalis D-isopropyl fluro phosphonates	•
Dimenaxadol; its derivatives	-
Dimethyl thiambutene; its salts	-
Dinitro cresols, their compounds with a metal or	
base	-
Dioxy phetane butyrate; its salts	•
Diphenoxylate; its salts	•
Dipipanone; its salts Disodium stillbesterol Di phosphate	-
	•
Disulfiram	-
Dithienyl allyl amines,	-
Epinephrine; its salsts	•
Ergot (the sclerotia of any species of Olaviceps),	
extracts of ergot, tincture of ergot	
Erythrityl tetranitrate	
Ethosuximide	-
Ethylmethylthiambutene, its salts	
Etoxeridine, its salts	Substances containing less than 5 percent of
Formaldehyde	formaldehyde
Formic acid	•
Furethidine; its salts	-
Galamine; its salts, its quaternary compounds	•
Glyceryl trinitrate (Nitroglycerine)	
Guanidines, polymethylene diguanidines, di-	
paraanisyl phenetyl guanidine	Substances containing less than 9% of
Hydrochloric acid	Hydrochloric acid
	0.15
Hydrocyanic acid, cyanides	0.15
Hydromorphinol; its salts, 12-Hydroxy,5-9	
dimethyl-2-(2-phenylethyl)6-7 benzomorphan it	5
salts	
Insulin	
Isopropyl ester of 1-methyl 4-phenly carboxylic	, , - , , , , , , , , , , , , , , , , ,
acid ( Phroperidine); its salts, Retobemidone, its	5
salts	
Laudeaxium, its salts	
Lead acetates, compounds of lead with acids	-
from fixed oils	
Levarterinol; its salts	·
Levo-3-hydroxyl-N-proparogylmorphanian	•
Levo-J-IIvuloxy1-11 propulogy into prime	

Levophenacy Imorphan, its salts	
harmoramide, its saits	
have a sector of the salts	
A supporting, its sails	
a tempthyl bexanitrate	
Mannonty rites and salts	1.00% of Mercuric chloride
o-mervaptopurine, its saits Mervury, Mervuric chloride, Mercuric aluminium	
shlaride	
Mercuric iodine	Equivalent of 3% of Mercury
is a trately	Equivalent of 1% of Mercury
Mercury, oxides of Mercuric potassium iodine	Equivalent of 178 of Meletary
Metamizole	•
Metazocine; its salts	•
Metformine, its salts	-
Methadone (amidone); its salts	
Methanol	•
Methotrexate; its salts	•
Methodexact, its saids	•
Methyl desorphine; its salts	-
Mellivi desorphine, its saits	
Methyl dihydromorphine; its salt	
Methyl Phenidate, its salt	-
Methyl-4-phenyl piperidine-4-carboxylic acid	
esters, their salts	•
Metapone (Methyl dihydromorphinone; its salts	•
N(2-methylphenethyl amino	-
propylpropionanilite; its salts	
Morphine-N-oxide, its derivatives; their salts	-
Mustine, its salts	-
Nitric acid	Substances containing less than 9% of nitric
	acid
Nitrobenzene	-
Nitrophenols or the meta or para Norcodeine, its	-
salts.	
Narlevorphanol, its salts	-
Nux vomica, seeds of preparation of nux vomica	0.20
Nux volnica, seeds of preparation of nail volnica	calculated as strychnine
0.:	0.20
Opium	calculated as anhydrous morphine
	Culculated as anifyticas merphine
Orthocaine, its salts	·
Quabain	
Oxazolidine, its derivatives of their salts, their	-
salts	
Oxymorphone, its salts	-
Para aminobenzene sulphonamide, its salts,	Substances intended for topical or external use
derivatives of para amino benzene sulphonamide	
having any of the hydrogen atom of the para	
amino group of the sulphonamide group	
substituted by another radical, their salts	
Para aminobenzoic acid, its salts, esters, their	-
salts	
Para amethadione	•
Phenampromide, its salts	Phenformin, its salts
,	
Phenfoumine, its salts Phenols ( Any member of the series of phenols o	f Substances containing less 1% of phenol

•

	t setilles lozer
to the strengt and of which	Nasal sprays, mouth washes, pastilles lozer
which the first member is phenol and of which	capsules, ointments less than 2.5% of phenol
the molecular composition that again halogens	
carbon and two atoms of hydrogen, integeods derivatives of phenol, compounds of phenols	
derivatives of phenon, example	
phonomorphan, its saits	
Phenoperidine, its saids	-
Phensuxamide	•
Phenylacetyluren Phenylbutazone, its salts, its derivatives, their	-
Phenylbutazone, its saits, its derivatives, then	
	-
salts. Phenyleinchoninic acid, its salts, its esters, the	
salts of its esters	-
salts of its esters Phenyl-(P-tolymethoxy) ethyldimethylamine, its	
salts	1.0
Pholeodine, its salts	
Phosphorous, yellow	Substances containing less than 9% of picric
Pierie acid	acid
Picrotoxin	-
Piminodine, its salts	•
Piperidine-1-Phenyl bicyloheptenyl propanol	Substances containing less than 1% of
Potassium fluoride	Substances containing loss than 170 be
	potassium fluoride
Potassium hydroxide	-
Procaine, salts of	Combination of procaine with antibiotics
Proheptazine, its salts	•
Propoxyphene, its salts	
Recomenthorphan, its salts	•
Reserving, its salts, its derivatives, their salts	-
Salicylcinchoninic acid, its salts esters, the salts	-
of its esters	
Savin oil of Sodium fluoride	Substances containing less than 1% of Sodium
Savin on of Sourain Macriae	fluoride
Sodium hydroxide	Substances containing less than 12% of Sodium
Sourium nyuroxide	hydroxide
Sodium nitrate	-
Strophanthus, Glycosides of strophanthus	-
	Substances containing less than 9% of
Sulphuric acid	Substances containing less than 570 of Sulphuric acid
Thallium, its salts	-
Thiocarbanalide	
Thyroid gland, the active principles of, their	-
salts	
Tolbutamide	-
Tribromomethyl alcohol	-
Tri-(2-Chlorethyl)amine, its salts	-
Tri ethylene thio phosphoramide	•
Trimeperidine, its salts	
Tropine di phenyl methyl esters, their salts	
Roxidone	
Nephosphide	

.

.

# SCHEDULE "F"

[See Rule 24(1)[(d)]]

# LIST OF MINIMUM REQUIREEMNTS FOR A PHARMACY

- **I. Entrance:** The front of a Pharmacy shall be an inscription "Pharmacy".
- II. Premesis: The premesis of a pharmacy shall be separated from room for private use. The premesis shall be built dry, well lit and ventilated and shall of sufficient dimensions to allow the good in stock, especially drugs and poison to be kept in a clearly visible and appropriate manner. The area of the Section to be used at dispensing department shall not be less than 6 sq Meters for one person working therein with additional 2 sq Meters for each additional person. The height of the premesis shall at least be 2.5 sq Meters.

The floor of the pharmacy shall be smooth and washable. The walls shall be plastered or tiled or oil painted so as to maintain smooth durable and washable surface devoid of holes cracks and cervices.

A Pharmacy shall be provided with good quality of water. The dispensing department shall be separated by a barrier to prevent the entry of public.

A Pharmacy shall be equipped with fire extinguisher to handle any emergency in case of fire.

**III.Furniture & Apparatus:** The furniture and apparatus of the Pharmacy shall be adopted to the uses for which they are intended and correspond to the size and requirement of the establishment.

The drugs and chemicals shall be kept in a room appropriate to their properties and in such special containers as will prevent any deterioration of contents of containers kept near them. Drawer glasses and other container used for keeping medicaments shall be of suitable size and capable of being closed tightly to prevent the entry of dust.

Every container shall bear label appropriate size, easily readable, with names of medicaments as given in Pharmacopoeias.

A Pharmacy shall be provided with a dispensing bench, the top of which shall be covered with washable and impervious material like stainless steel, laminated or plastics etc.

The containers of concentrated solutions shall bear special label or marked with the word "Poison" in red letters on a white background.

A pharmacy shall be provided with the following minimum apparatus and books necessary for making of official preparation and prescriptions:-

## Apparatus.

Balances with dispensing sensitivity of 30 mg Balances Count, capacity 3 kg, sensitivity 1 gm Beakers lipped, assorted sizes Bottles prescription, un graduated assorted size Choric extractors Evaporating dishes, porcelain Filter papers, Funnels, Glasses Litmus papers, blue and red Measure glasses cylindrical 10 ml, 25 ml, 100 ml Mortar and pestle glass Ointment slab, porcelain, Ointment pot with bakelite or suitable cap Pipettes graduated, 2 ml, 5 ml and 10 ml Ring stand (retort) iron, complete with rings Rubber stamps and pad, scissors, spatula Spirit lamp gas burner Glass stirring rods, Thermometers, 0 to 200C Tripot stand, Watch glasses, Water bath Water distillation still in case eye drops are prepared Weight metric, 1 mg to 100 mg Wire gauze, Pill finisher, Boxwood Pills Machine, Pill box and suppository mould

### Books--

The United State Pharmacopoeia or British Pharmacopoeia (Current Edition) National Formulary of Pakistan(Current Edition) The Drugs Act 1976 and rules framed thereunder The Pharmacy Act 1967 The Dangerous Drugs Act and CNS Act 1997

**IV. General Provisions**: A Pharmacy shall be conducted under the continuous personal supervision of a qualified person referred to in Rule 19 whose name shall be displayed conspicuously in the premises.

The Qualified person shall always put on clean white overalls.

The Premesis and the fittings of the Pharmacy shall be properly kept and maintained and everything must be in good order and clean.

All records and register shall be maintained in accordance with the Any container taken from the poison cup board shall be replaced therein immediately after use and the cupboard locked. The keys of the poison cupboard shall be

kept in the personal custody of the responsible person. Drugs when supplied shall have labels conforming to the provisions of laws in

Note: The above requirements are subject to modification or the directions of the Licensing Authority, if the Authority is of the opinion that having regards to the nature of drgus dispensed, compounded or prepared by the licensee it is necessary to relax the

above requirements in the circumstances of a particular case.

	Carboprost
Dinoprostone	
Gemepost	
8. Alpha Blocker	Indoramine
Prazocin HCI	Alfuzocin
Daxazocin	
9. Biotechnological Products	Erythropoetin
Interferon	
10. Narcotics, Psychotics / Tri Cyclic Anti-depu	ressants
10. Narcones, rsychones / Theyene runnen	
Morphine,	Meprobamate,
Buprenorphine,	Chlordiazepoxide,
Nalbuphine,	Alprazolam,
Fantanil,	Clonazepam,
Pethidine,	Flurazepam,
Lorazepam,	Loprazolam,
Temazepam,   Oxazepam,	Dothiepin,
Lorazepam,	Doxepin,
Amoxapine,	Nortriptyline,
Iprine Dole Codien,	Trimipramine,
Pentazocine,	Tranylcipromine,
Phenelzine,	Flupenthixol,
Lithium,	Tryptophan,
Dextropropoxyphene,	Imipramine,
Clomipramine,	Amitriptyline etc.
Mianserine,	
Maprotiline,	
11. Antiviral	Idoxuridine
Acyclovir	Ribavirin
Amantadine HCl	Vidarabin
Famciclovir	Trifluridine
Inosine pranolsex	Methisozone etc
Zidovudine	Methisozone etc
Ganciclovir	
12. Thrombolytic Enzymes	
Alteplase	Anislreplase
Streptokinase	Urokinase
13. Product used in Dialysis	Lysine solution (Irrigation solution)
Peritoneal Dialysis & Haemodialysis	Isotonic solution
Hypertonic solution	
14. Creams and aerosols steroidal preparat	ions
Prednisolone	Methylprednisone
Tramacinolones	Dexamethasone
Beclomethasone	Hydrocortisone
15. Hormones	
Vasopressin	Finasteride

	Finasteroid
Desmopressin	Somatropin
Stanozolol	Testoscrono
Nandrolone	Progesterogens
Mesterolone	