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GOVERNMENT OF RALOCHIS AN .
es" PRIMARY AND SECC INDARY HEAL HCARE
DEPARTMENT

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EXTRAORDINARY ISSUE OF
BALOCHISTAN GAZE PTE
BALOCTUSTAN
DRUGS RULES, 2021
NOTIFICATION

Dated Quetin, 30 September, 2021

No. SOV (H)L-8/2019-20/3259-78, In exercise of the powers conferred by Section 44 of Drugs Act, 1976 (NXNE 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 premesi :
premesis where drugs and the ood
Stored, sold or offered for sale; & lerapeutic goods are

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“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;

“Veterinary” means premises where Veterinary drugs are stored, sold by way of retail sale / wholesale;

“Manufacturer” means a manufacturer of a Drug and Therapeutic good;

“Narcotics, psychotropic or controlled drug” mean a drug specified in the Schedule “B”;

‘Retail sale” means sale of drugs and therapeutic goods on retail other than the sale by way of whole sale;

“Rule” means Balochistan Drug and therapeutic good Rules 2021;

“Wholesale” means sale to a person, buying for the purpose of selling again who is authorized agent of a manufacturer or importer or indenter;

“Schedule” means Schedule annexed to these rules;
“Section” means Section of the Act;
“Analyst” means a persone notified under section 16 of Drug Act;

“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

(v)

medicine or medical devices or biologicals or other related products as may be notified by the DRAP and as notified in the Act;

“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
wwweezqanoon.com BO ART) 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;

www Sat Senior officer from the Drug Control Administration as 4 technical expert, who

“holds a graduate or higher degree in Pharmacy and has more than fifteen years

professional and field experience, having no financial inte
trade and industry, from respective Division, as member;

rest in Pharmaceutical

(d) Pharmacy Professional who holds a graduate or higher degree in en ep anos
more than ten years professional experience, having no financial in ‘— i
Pharmaceutical trade and industry, appointed as a member at Division level. by
Government for a term of three years;

(ce) The Government shall appoint Secretary of the Provincial Quality Control Board
from the each division amongst the senior most officer of Drug Contro
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 concemed 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 concermed.

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 | 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 SAY 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 de-sealing 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 Py i rata holdsardegree in pharmacy from a University or an institution recognize ; bly in the Council of Pakistan and has atleast least three years' experience preierabDly manufacture, testing or analysis of Drugs/ therapeutic goods.

7. Duties of Inspectors:- Subject to the instructions of the licensing sepenss oe as prescribed in Drug Regulatory Authority of Pakistan Act 2012 and Drugs Act (No.XXX1), 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 assign 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;

Gj) 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

wwwqxhenokequired by a Court of law, an Inspector or a Government Analyst 7
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, Sub-section (1), clause (i) of the Drug Act, 1976 in Form 3.

10. Form of intimation of purpose of taking samples:- (1) 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.

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t Analyst shall Perform all tests according to the o
a ates P a Current edition), British Pharmacopoeia (BP)

1e., United States Pharmacopoeia (USP) (B .
(Current edition), European Pharmacopoeia (EU)(Current edition), National Formulary of

Pakistan (Current edition).

ort produce all procedure,

(6) The Government Analyst shall, in case of negative rep long with its

methods applied in the performance of test / analysis to the Drug Inspector a
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 aes and service experience having no financial interest in Phamaceutical trade and industry.

CHAPTER III
SALE OF DRUGS

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ng authority for the purpose of
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16. licensing authority:- 7 Prim
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these rules. The licensing authority may, by order in writing,

licences and to exercise such other powcrs, and in respect of
in the order and the licensing authority may issuc licenses speci

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 tules shall be of the following types, namely:-

(1) 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

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(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.

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if the original is defaced, damaged
“duplicate copy”.

(4) A fee of Rupees Six thousand (6000) sha be p
www.ezAhalified or premesis) or a duplicate copy of the licence
or acl such copy of the licence shall bear the words

ods:- (I) The licensing authority

: nd therapeutic go
20. Forms of licences to sell drugs a P Fretail sale in Form 9.

shall issue a licence to sell, stock, exhibit for sale by way 0

(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) Ifa 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:- (I) 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.

“3 The agensing authority shall issue a receipt of an application of a license or renewal of a

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(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:- (I) 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 sub-section (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 requriements 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;

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(f) the sale of any drug specified in Schedule “E”, “B’ and “G"by yey ot he purpose and

be recorded at the time of supply in a register specially math rescri fon and the
www-ezqanoqe.com cial number of the entry in the register shall be entered in the p p

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 concems 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 dru
of a drug and shall preserve the record for at
particulars:

g shall maintain record of purchase or sale
least three yerars containing the following

(a) The date of purchase or sale;

} ic : srapeutic ood
“ezganoo"%b) The name and address of the concern from which the drug, and eee g
is purchased or the concern to whom the drup, and therapeutic good 18 sold,

" : . s date of its
(c) The name of the drug and therapeutic goods], its batch number, the date o

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 i aereag nin!
these rules shall be preserved for a period of not less than three years from the date o
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 cach 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) ina 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:- (I) 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 O1 Wie pruvioiuie we sw 4 ewe we

these rules,
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celled or suspended may appeal to the

icensee whose licence has been can 0
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Provincial Appellate Authority within sixty days of the date of such o
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:-

The Senior member Board of Revenue Balochistan.

The Additional Chief Secretary (Dev)GoB, P&D Department, Quetta.

The Chairman Chief Ministrer Inspection Team, Quetta.

The Chairman Balochistan Public Service Commission, Quetta.

The Prinicpal Secretary to Governor Balochistan, Quetta.

The Principal Secretary to Chief Minister Balochistan, Quetta.

The Secretary to GoB, Law and Parliamentary Affairs Department, Quetta.

NAVA wH

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iti i i of the provisions of the Act or
omply with any of the conditions of the licence or with any p

www.e2iane
these rules,
ce has been cancelled or suspended may appeal to the

(2) A licensee whose licen in sixty days of the date of such order whose decision

Provincial Appellate Authority with
shall be final.

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

sing authority may prefer an

i der of the licen
(2) Any person aggrieved by an order o hin sixty days of the date of

appeal to the Provincial Appellate Authority wit
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:-

The Senior member Board of Revenue Balochistan.

The Additional Chief Secretary (Dev)GoB, P&D Department, Quetta.

The Chairman Chief Ministrer Inspection Team, Quetta.

The Chairman Balochistan Public Service Commission, Quetta.

The Prinicpal Secretary to Governor Balochistan, Quetta.

. The Principal Secretary to Chief Minister Balochistan, Quetta.

- The Secretary to GoB, Law and Parliamentary Affairs Department, Quetta.

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S$. All the administrative Sceretaries Government of Balochistan,

9. The Accountant General Balochistan, Quetta,

10. The Director General Primary and Secondary Healthcare
Balochistan, Quetta,

UL, The Deputy Seeretary (Stal) to Chief Secretary Balochistan, Quettn. ,

12, All Additional Seeretaries/Deputy Sceretaries/Under Secretariey Section Officers in
Primary and Secondary Healtheare Department Department, Quetta,

13. The Private Sceretary to Sceretary SQGAD Balochistan, Quetta,

14. The PA to Additional Seeretary (Regulations) SQGAD, Quetta,

18, Chairman Quality Control Board / Addl; Sceretary (Development) Primary and
Secondary Healtheare Department Balochistan.

16. Master file.

Department Services

Section officer (V)
Health Department
081-9203 167

16

Schedule-A
[Sce rule 2 (d)]

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

SUMMARY OF INSPECTIONS

No. of the “No. of the»

cases in cases in Drug

FOR THE MONTH OF

No. of the Firm found No. of the.
in a violates of law Sample

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

Action taken
including detail
of seizure and
sale restriction

Date of dispatch | Date of receipt
of sample and of test report
name of with nature of

laborato

Reason in case
Renewal not

Total No. of the
licenses in the
District

_ Name and Purpose of fee Copies of the | Remarks
Address of | (Grant/ renewal / treasury office Challans
Medical other changes) (yes or not) verified

Store

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.

FORM-2

www.ezqanoon.com See Rule 5(1)

DRUGS TESTING LABORATORY
Progress report for the month of

Samples Samples Details of Remark/
up to below samples Reasons
standard standard pending
with for more
percentage

Spurious =
Sub-standard =
Adulterated =
Counterfeit =
Others =

ll

Total

DETAILS OF DRUG FOUND IN CONTRAVENTION OF THE LAW DURING THE
MONTH OF
nature of contravention

~ | Name and Regn:
No ofDrugs __

Form 3
[See rule 9]

www.ezqanoon.com
(i) paragraph (1) of Powers of

Order under section 18(1)(i) of the Drug Act 1976 / clause
erson not to dispose of stock in

inspectors of Schedule-V of DRAP Act 2012 , requiring a p

his possession.

ck of drugs in your possession detailed
of the Drug Act, 1976

aid stock for a

Whereas I have reason to believe that the sto

below contravenes the provision of Section
/DRAP Act 2012 Now, therefore I hereby direct you not to dispose of the s
period of ____days from this date.

Date Inspector

Details of stock of drugs and therapeutic goods.

Date Inspector

19

www.ezqanoon.com

Form 4
www.ezqanoon.com [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 Name of
Drug and Manufacturer
therapeutic

Dated: Inspector

20

Form 5
[See Rule 10(1) J

> Recstee § i ized under
i d other materials seize
i f drug and theraputic good an ed ne
pean aie Drag Act 1976 and under clause (f) of paragraph (1) of Po
inspectors of Schedule-V of DRAP Act 2012.

Serial No.

The Stock of drugs and theraputic goods, materials / articles deta f Section! wis
day been seized by me under the provision of clause (f) of sub-section (oe epectors of
the Dmug Act, 1976 and under clause (f) of paragraph (1) of Powers
Schedule-V of DRAP Act 2012 from the premesis of__ _
situated at

Dated: Inspector: _

Details of Drugs, other material and articles seized including:

Dated: Inspector:

orm v

www.ezqanoon.com MEMORANDUM TO GOVERNMENT ANALYST
—_ [See Rule 1 0(2) J
d: ;
Serial No. of Memorandum Dated: _
To
The Government Analyst

d below is sent herewith for test /

(3) of Section 19 Drug Act, 1976

The portion of samples / container describe
V of DRAP Act

analysis under the provisions of clause (i) of sub-section
and under clause (a) paragraph (3) of Procedure for inspectors of Schedule-

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]

Dated

i-
‘Test Report No:

CERTIFICATE OF TEST OR ANALYSIS
BY THE PROVINCIAL DRUG TESTING LABORATORY!/ /GOVERNMENT

ANALYST.
r _ _purporting to
with memorandum No

Certified that the samples, bearing numbe
be a sample of received on —
_ has been tested /

Dated from
analyzed and that the result of such test/ analysis is as stated below:-
ts was as follow:-
/ is adulterated / Substandard /

2. The condition of the seals on the packet on receip
for the reason

3. In the opinion of the undersigned the sample is not
Act 1976 DRAP Act 2012]

misbranded/ Spurious as defined in the Drug
given below:-

Government Analyst
Provincial Drug Testing Laboratory

DETAILS OF RESULTS OF TEST OR ANALYSIS (with protocols of tests applied)

Method of testing according to ; Method.
Sample of Registration No. Batch No._ 7
Date of Mfg Date of Exp ; claimed to be manufactured by__

Sterility(if a alicable):

Result: ce

Test Report forwarded to:
1. The Inspector of Drugs __
through Secretary concerned of Provincial Quality Control Board,

2. The Chairman

Government of Balochistan, Quetta.

Government Analyst
Provincial Drug Testing Laboratory

Form 8
[See rule 19 (D]

www.ezqanoon.com

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

1.1/ 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

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

on the premises situated at (complete address)

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

(Name) _
(Name) ___ (Qualification) 7

(Qualification) __ —

3. 1/ We, am / are submitting herewith the following documents:

a)

g)
h)

attested copies of the testimonials of Qualified person including Pharmacy council registration certificate.

two copies of national identity card of the proprietor and qualified person

four attested copies of the photograph of qualified person

attested Photostat copy of the valid registration issued by the C.O.I & E in case of indenter / importer.

Manufacturer’s Authority as agent / distributor.

Affidavit of the Proprietor duly verified from Class-I Magistrate that:

(i) will abide by the provisions of Drugs Act, 1976, DRAP Act 2012 and Theraputic goods Rules, 2021.

(ii) will inform authorities well in time if any change in service or address occurred or any irregularity or any violation of Drug Act 1976, DRAP Act 2012 is noted.

(iii) Shall not sell / stock any expired, spurious, sub-standard, unregistered, misbranded, unwarranted, counterfeit or any drugs and therapeutic goods in violation to the drugs laws in force.

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).

Treasury Challan(s) No. & Dated amounting to Rs. in the Head of Account C- -Health and Other receipts.

Dated: Dated:

Signature:

- Signature:

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

Form 9
[See rule 20 (1)]

, Wwww.ezqanoon.com

License to sell, stock and exhibit for sale and distribute drugs and therapeutic goods

by way of retail sale.
M/S_
a

is hereby licensed to sell /stock and exhibit for sale drugs and therapeutic goods on the

premesis situated at

_ subject to

the conditions specified below and to the provisions of the Drug Act 1976, DRAP Act 2012

and the rules made thereunder.

Dated

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

LICENSING AUTHORITY

CONDITIONS OF THE LICENSE:

(i)

(ii)
(ii)
(iv)

(v)

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 ublic

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

The licensee shall report forthwith to the licensing Authority any change in the qualified staff incharge

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.
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__

nen
is hereby licensed to sell / stock and exhibit for sale drugs and therapeutic goods on the

premesis situated at ‘subject to the

conditions specified below and to the provisions of the Drug Act 1976, DRAP Act 2012,

and the rules made there under.

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

CONDITIONS OF THE LICENSE:

(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

ublic.

(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

lified 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 coflcs and other controlled drugs and therapeutic goods specified in

schedule B and G

M/S__--- holder of license Now
/ "
(on Form 9 / Form 10) is hereby licensed to sell, stock, exhibit for sale or distribution of

ics and othe i ;
narcotic tr 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 (Ss) of qualified person (s)
Name of Proprietor Protege

Addresses of Godown (s) where drugs shall be stored

Dated LICENSING AUTHORITY
CONDITIONS OF THE LICENSE:

(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.

Form 12
[See Rule 20(5)]

License to sell drugs in Pharmacy / by way of formulation

——

M/S =

is hereby licensed to sell / compound or prepare on prescription the drugs and sell all types of registered drugs and therapeutic goods on the — premesis situated

at Subject to the conditions specified as under and to the

provisions of the Drugs 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
CONDITIONS OF THE LICENSE:

(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 qualified 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.

Horm 13
www.ezqanoon.com [See Rule 2A)

License fo sell, stock and exhibit for snle and distribute Veterinary drugs

is hereby licensed to is hereby licensed to sell / stock and exhibit for sale Veterinary dugs

on the premesis oo __ subject

to the conditions specified as under and to the provisions of the Drugs Act 1976, DRAP Act

9012 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 Proprictor

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

Dated LICENSING AUTHORITY

CONDITIONS OF THE LICENSE:

(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 012 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.

(iv) The licensee shall report forthwith to the licensing Authority any change in the qualified staff incharge 7 a

(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.

29

Form 14
www.ezqanoon.com [See rule 20(6)]

License to sell, stock and exhibit for sale and distribute Medical Devices.

M/S

js hereby licensed to sell / stock and exhibit for sale Medical Devices on the premesis situated at

. Se a Sort to
the conditions specilied as under and to the provisions of the Drug Act, 1976 or DRAP

Medical Devices Rules, 2017 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)

Phot h (s
Name of Proprietor otograph (s)

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

Dated LICENSING AUTHORITY

CONDITIONS OF THE LICENSE:

(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.

(vi) 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”
www.ezqanoon.com [[See Rules 2(L), 18(iii) and 24(1) (e]]

NARCOTICS, PSYCHOTROPIC, ANTI-DEPRESSEANTS AND OTHER CONTROLLED

pRUGS_ _
Acetorphine Acetylmethadol _ Allylprodine

Alphace Imethadol Alphamethadol a Alphaprodine ;

j

prodine Bezitramide ;
Buprenorphene [Cannabis SSSS~S~s Cloniitazone, =
Coca leaf [Cocaine SSSS~S~«d Codoxime

Concentrate of poppy straw _| Desmorphine
Diamprom! Diethylthiambutene

phine
Dimethy|thiambutene
Dipipanone
[Etoxeridine —*d Fantanyl =
[Heroin SSSC*d yddrocodone
Hiydromorphinon
isomethadone
Levomeramide Levophenacylmorphen
Methazocine
Methyldeserphine | Methyldihydromorphine | Metopen
Moramide intermediate Morphine
“Morphine,Morphine methobromide and other pentavalent nitrogen morphine derivatives include in particular the morphine-N-oxide derivatives, one of which is Codeine-N-oxide and the drug

Morphine-M-oxide [Myorphine _—_—=——«| Nicomorphine

dD
@

|

Dextromoramide

E FI
3

Noracynethadol | Norvlevorphanol __

Normophine [Norpipanene | Opium
Pethidine-intermediate-A Pethidine-intermediate-B Pethidine-intermediate-C

Phenaxone
Phenomorphan

Piritrameide
Recomoramide

A i

Thebacon a

Codine

-
Alprazolam _

c
-Paroxeine _
Bupropion
oxapine

: Fluphenazine
Trifluperazine Aripiprazole_ .

Oo

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=a
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g
5 |

fl

Diaze pam

Fluoxetine
enlafaxine

Amitriptyline

i

Des
|Quetiapine
anzapine

31

SCHEDULE ‘C’
[See Rule 13]

“Preliminary examinati
miscibility etc.
Clarity of solution:

Physical examination

2 Chemical examination

“Completeness of solution r 450

Se tines — 1200
‘| Leakage test injectable = -—— 450

Weight variation / Mass variation

ay |
nN H
|

Determiantion of jelly streng

Determination of ash, acid insoluble ash, water soluble ash, sulphated ash, alcohol soluble extractive totoal solids, etc each
Readily carbonisable substances test
Determination of alcohol in the pre

Vacuum distillation
Determination of unsaponifi
balsamicacids, etc each

Determination of volatil

e oils in drug

b

d) Similar other tests

terminatio
purityLimit test for the presence of:

Fiber identification test
Disinfectants / insecticides: _
hemical test

b) Bacteriostati bactericidal activi

Test for complete extraction of alkaloids

xtraction of dextrants

(a) Measurement 0
asurementof diameter
ih

Surgical dressing etc:
_ (a) determination of Yarn number cach

j esive stren
ermination of starch in dressin
Identi in BS:
a) Pharmacopeal each
b) Non officail each

test in pulverized dru
a) official drugs each

—
—_
C -
oa
as
aa
—_*
eet
Led
—_
a
oe
a
a:
73
PL
P|
| 80 |

Other pharmacological test
ical Pharmacological trials

All other imported Vaccines, sera and Interferon
ote: .
Pa 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, estrogenic 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

[Erythromycin | Framaycetin Ss [Grmicidin Cd

leandom c
omomycin
ancomycin

O
P

Str 7
Amitriptyline, its salts

Tsothidtendyl, N-Dimethyl
amino iso propyl thiophenyl,
Pyridalamine

3 Di Nebutyl, aminoethyl, 1-4,
9,6, tri hydroxyphthalide

Thenalidine, (1 Methyl 4 amine | Azapetine, its salts
N-Phenyl N 2 Phenyl) pioridine | Aenactyzine, its salts
| €. Substances being tetra
| Substituted N-Derivatives of
Poylenediamine
Brethylium Tesylate

Captodine,its salts

Clidinium Bromide
Dithiazinine Iodide
prednisone a
prednisololne Pe

Triameinolone and pO
Dexamethasone, their esters,
their derivatives and esters of
their derivatives
Ethionamide

Hexocyclium Methy! sulphate
Hexadimethnine

_ Bromide
Hydroflume thiazide, iron | Isocarbon acids
preparations for parenteral use ;

Isoxsurprine | Mepromade

Hydrochlorthalazide,
ipramine, its sats _
Jsonicotinic acid

Hydrzide and other hydrazine
derivatives isoncotinic acid,
their derivatives, salts,
Methaualone, its salts

| Methaqualone, its salts a

:

tronidazole

Methypenpynol, its ester and | Me
7 other derivatives

- Oxytocine, prepaid from the Paraminosalicylic acid,its salts,
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

Mialamide, its salts

Derivatives and salts of its
derivatives not otherwise
pecified in this schedule

Pivazide

Promazine, its salts 7 _

Spirinololactone _

Sorbide nitrate

Tranylcypromine, its salsts “Trimeprazine, its salts
pituitary body of by synthesis - _
Note: Preparations containing the above substances, excluding preparations intended for

topical or external use, also covered by this schedule.

vor op AEEAD AVE moe eine oe BY THE QUALIFIED PERSON
SUPERVISING THE SALE OF DRUGS [AND THERAPUTIC GOODS|
(DULY VERIFIED FROM CLASS I MAGISTRATE)
[See Rule 19]

S/o,D/o Re

ar/Ms

gistration No. Degree No. —sPharrmacist, resident of

] am not registered in any other council of Pakistan;
| 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, [have not been convicted of any offence from any Court of Law;

y with the provisions of the Drugs Act, 1976, DRAP Act 2012 and the

4. 1 will comp!
Balochistan Drug and Theaputic goods Rules,2021.
cording to Pharmacy Act 1967.

5. | will practice ac
ode of ethics and conduct of Pharmacy council.

6. I will follow the c
1 will not sell / stock expired, spurious,
it or any drugs in violation to the drugs |
remesis.

sub-standard, unregistered, misbranded,

unwarranted, counterfe aws in force.

8. I will display my original Registration Certificates within the p
DEPONENT

Dated: _

SCHEDULE ‘Ee

Www.ezqanogn

de, alkyl acetanilides
thadol, its salts
tes, roots

ds, the following, their salts, their esters,

Belladone, alkaloids calculated as hyosc amine ros.

Calabar beans alkaloids of Cocoa alkaloids

olfia, alkaloids of

Sabadil

a, alkaloids of TEE 0.15
"olanacous, alkaloids not otherwise specified in

the list

Stychnt V-sacre, alkaloids of |

cohol esterified with benzoic acid

. al ; .
0 propionic acid or the derivatives of these

ic; halides of arsenic; oxides of arsenic,
Assenites, OTB? ic compounds of arsenic
Barbituric acid, its salts; derivatives of
parbiturics acid, their salts; compounds of
harbituric acid, its salts, its derivatives, their salts
with any other substance. _
Barium chloride __
Barium sulphate
Beta acetyl methadol; its salts
Beta-aminopropylbenzene (Amphetamine) its
salts, its N-alkyl derivatives, their salts Beta-
aminoisopropylbenzene, its salts; its N-alkyl
derivatives, their salts.

Beta-prodine; its salts / :
an nea papa [=
| salts - - - 7

tyl chloral hydrate
Cannabis (Indian hemp);Cannabisresin;galenical
Preparations of cannabis, extract and tincture of
cannabis and cannabin tannates
Canthridine, Cantharidates
Carbacol,4-carbamithoxy
bexameth:

Croton oil and seeds
als hosphamide; its salts

=
fe oo

0.15
Calculated as hyoscyamus

Sd

oars
en eee

Disodium stillbesterol Di phosphate aaa
pale geass ee

Epinephrine; its salsts Se

ar eeeenane

Desmor,
Dextro mormide; its salts
Dextrophane; its salts
“‘Diacety! N-allylmorphine; its salts _
Di amino di phenyl sulphone, its salts and
derivatives _

Digitalis, glycosides of, othe
digitalis

Digitalis D-isopropyl fluro
Dimenaxadol; its derivatives
Dimethyl! thiambutene; its salts _
Dinitro cresols, their compounds with a metal or

Ergot (the sclerotia of any species 0
extracts of ergot, tincture of ergot

~) Substances containing less than 5 percent of
formaldehyde

.
-
Ne

slycerine) Ee
Substances containing less than 9% of
Hydrochloric acid

drocyanic acid, c anides
Hydromorphinol; its salts, 12-Hydroxy,5-9
dimethyl-2-(2-phenylethyl)6-7 benzomorphan its
salts

| Isopropyl ester of |-methyl 4-phenly carboxylic acid (Phroperidine); its salts, Retobemidone, its salts
Laudeaxium, its salts
Lead acetates, compounds of lea from fixed oils

Levarterinol; its salts _ Ee

Levomethorphan; its salts _

Me

Tevophemey Imorphan, its salts

‘Levomoramide, its salts
ergapoened its salts = ;
“Mannonmustitte, its salts_____—}

Atannothyt hexanitrate

“Mannotl aunt

o-Memaplopurine, its salts

er. Alert we “3 oT a bd H niu
Mercury, Merurte chloride, Mereuric aluminium

ehtoride ____
Mereuric iodine ;

| Mercurie nitrate ee —— oF of Meron
| Menry, osides of Mercuric potassium iodine Equivalent of 1% ofMercury uivalent of 1% of Mercu

1.00% of Mercuric chloride

i Metamizole
| Metazecines its salts
\etformine, its salts
Methadone (amidone); its salts
| Methanol _
Methotrexate: its salts
"\Methu-ximide
i Methyl desorphine; its salts
Nlethyl dihydromorphine: its salt
Methyl Phenidate, its salt
| Methyl4-phenyl piperidine-4-carboxylic acid
esters, their salts _
| Metapone (Methyl dihydromorphinone; its salts
N(2-methylphenethy! amino
{ propvlpropionanilite; its salts __
" Morphine-N-onide, its derivatives; their salts ro
| Nitric acid 7

ea angen
anna
TT
ee
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ee
eal Ce
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ee

Substances containing less than 9% of nitric
} acid

Nitrobenzene Po

Nix

salts.

|
| Narlevorphanol, its salts TY
| N

‘ux vomica, seeds of preparation of nux vomica | 0.20
calculated as strychnine

Opium $0.20

calculated as anhydrous morphine

| Orthocaine, its salts
Quabain

Oxazolidine,its derivatives of their salts, their Po
salts

Oxvmorphone, its salts

Para aminobenzene sulphonamide, its salts,
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 en
]

Substances intended for topical or external use

salts
Picsspenie fess ————————[
Phenampromide, its salts Phenformin, its salts _
Phenfoumine, its salts _
Phenols (Any member of the series of phenols of | Substances containing less 1% of phenol

hich | Nasal sprays, mouth washes, pastilles lozer

ee member snob and of w
the first member Is phe less than 2.5% of phenol

wht gh be ’ Wi { hs
ut Slee ce composition varies by one atont of capsules,ointments
. the mc Py Leva arene

: carbon and (wo MOMS of hydrogen, halogens

derivatives of phenol, compounds ol phenols

with ametal . en
“Phenomorphan, UO SONS renee

Phenoperidine, Ws SANS -

Phensuxamide ae

Phenylacetylurea — =
Phenylbutazone, ity sults, its derivatives, their -

salts.

Phenylcinchoninic eid
salts of its_esters _
Phenyl-(P-tolymethoxy) ethyldimethylamine, its

salts
Substances containing less than 9% of picric

Piscean, OW
ee

eridine-1-Phen | bicylohepteny! propanol Penna

Potassium fluoride Substances containing less than 1% of
potassium fluoride

|, its salts, ils esters, the

Recomenthorphan, its s2 - = -

Reserpine, its salts, its deriv

Salicylcinchoninic acid, its salts esters, the salts
of its esters
Savin oil of Sodium flu

of Sodium

oride Substances containing less than1%

| fluoride

Substances containing less than12% of Sodium

Sodium hydroxide
hydroxide

| Sodium nitrate _
phanthus,

Glycosides of strophanthus

Sulphuric acid Substances containing less than 9% of

Sulphuric acid

Thiocarbanalide —

Thyroid gland, the active principles of , their
salts

Tolbutamide E
Tribromomethyl alcohol a |
Tri-(2-Chlorethyl)amine, its salts

Tri ethylene thio phoramide

|
|
|

Nephosphide OO

SCHEDULE “er”
Www.ezqanoon.com [See Rule 24(1) KO

LIST OF MINIMUM REQUIREEMNTS FOR A PHARMACY

1. Entrance: The front of a Pharmacy shall be an inscription “Pharmacy .

ivat
II. Premesis: The premesis of a pharmacy shall ve separaies ato or Pe
. ,

use. The premesis shall be built dry, well lit and ven ila on

dimensions to allow the good in stock, especially drugs and poison le - mr "

a clearly visible and appropriate manner. The area of the Section are

dispensing department shall not be less than 6 sq Meters for one person ig ki

therein with additional 2 sq Meters for each additional person. The heig

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.

[.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
“ezganoon™ Balances Count. capacity 3 kg. sensitivity | 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

sonra Provisions: A Pharmacy shall be conducted under the continuous personal
lon Of a qualified person referred to in Rul
conspicuously in the nremiven ule 19 whose name shall be displayed

The Qualified person shall always put on clean white overalls.

The Premesis and the fitti

ao ngs of the P
maintained and everything must be in s © Eyarmacy shall be properly kept and

good order and clean.

wow.ezqanoont bhrecorss and registet shall be maintained in accorda au
gainer taken from the poison CUP board shall be replaced therein

nd the cupboard locked. The keys of the poison cupboard shall be

dy of the responsible person.

Any cont
-mediately after use 4
Kept in the personal custo
Drugs when supplied shall have labels conforming to the provisions of laws in force.
ts are subject to modification oF the directions of
opinion that having regards to the nature

it is necessary to relax the

Note: The above requiremen
the Licensing Authority, if the Authority is of the
of drgus dispensed. compounded or prepared by the licensee
above requirements in the circumstances ofa particular case.

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Se

Oon.com
Dinoprostone
Gemepost

8. Alpha Blocker
Prazocin LIC
Daxazocin

9, Biotechnological Products

Tranylcipromine, ;

~ Amantadine HCl

_ Ribavirin
Fameiclovir—SSSs~C—~—~—S~dYSCSSCSidarain
[——Inosine pranolsex.——SSSCS~SCSCSTeifluridine

12, Thrombolytic Enzymes —_—
Alteplase [Anisieplase SSCS
Produ weln Diya So

Peritoneal Dialysis & Haemodialysis Lysine solution (Irrigation solution) _
Hypertonic solution | Isotonic solution

Creams and aerosols steroidal preparations a
| Beclomethasone ——SSSCSCSC~CS~SC~dCSCSCSC*Wyddrocortisome =
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15. Hormones __

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Somatropln

‘Testoserone
Progesterogens oe

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