PUNJAB DRUG RULES
2007

PUNJAB

DRUGS RULES, 2007

NOTIFICATION

No. SO (DC) 814/92 (53) P-II. In exercise of the powers conferred upon him under section 44 of the Drugs Act, 1976 (XXXI of 1976), the Governor of the Punjab, in super-session of the Punjab Drugs Rules 1988, is pleased to make the following rules:

CHAPTER I
PRELIMINARY

1. **Short title and commencement**.– (1) These rules may be cited as the Punjab Drugs Rules, 2007.

(2) These, except application of the Schedule G on the existing licences, shall come into force at once.

(3) The Schedule G, for the existing licences, shall come into force after **ten** years from the date of issuance of this notification.

2. **Definitions**.– (1) In these rules:

(a) "Act" means the Drugs Act, 1976 (XXXI of 1976);

(b) "Committee" means a committee of the Board;

(c) "District Board" means a committee of the Provincial Board in a district to be known as the District Quality Control Board;

(d) "Form" means a form mentioned in the Schedule A;

(e) "Government" means the Government of the Punjab;

(f) "Inspector" means a Provincial Inspector appointed under section 17 of the Act;

(g) "licensing authority" means the Secretary to the Government, Health Department or an officer of the Government duly authorized by the Secretary;

(h) "medical store" means premises where drugs excluding the drugs specified in the Schedule G are stored, sold or offered for sale;

(i) "manufacturer' means a manufacturer of a drug;

(j) "narcotic, psychotropic or controlled drug" mean a drug specified in the Schedule B or the Schedule D;

(k) "pharmacy" means premises where drugs are stored, sold, compounded, dispensed or prepared on prescription **or** distributed in case of authorized agent of manufacturer, indenter or importer;

(l) "Provincial Board" means the Provincial Quality Control Board;

(m) "registered medical practitioner" means a medical practitioner registered under the Pakistan Medical and Dental Council Ordinance 1962 (XXXII of 1962);

(n) "Schedule" means a Schedule to these rules;

(o) "section" means section of the Act;

(q) “seller” means the seller of a drug; and

(p) “wholesale” means sale to a person, buying for the purpose of selling again who is the authorized agent of a manufacturer or importer or indenter.

(2) A word or an expression used in these rules but not defined shall mean the same as defined in the Act.

CHAPTER II
PROVINCIAL BOARD, DISTRICT BOARD, GOVERNMENT ANALYST AND INSPECTOR

3. **Provincial Quality Control Board**.– (1) The Board shall consist of the following:

(a) Secretary to the Government, Health Department, ex officio member and chairperson;

(b) Additional Secretary (Technical) to the Government, Health Department, ex officio member and vice-chairperson who shall act as chairperson in the absence of the Secretary Health;

(c) Provincial Drugs Controller of the Government or a senior most officer of the Provincial Drugs Control administration who shall be a pharmacy graduate, Health Department, ex-officio member;

(d) a pharmacy professional who holds a graduate or higher degree in Pharmacy and has more than five years professional experience, appointed as a private member by the Government for a term of four years;

(e) a pharmacologist preferably a professor of pharmacology, appointed as a private member by the Government for a term of four years;

(f) a professor of medicine, appointed as a private member by the Government for a term of four years;

(g) District Coordination Officer of a district, ex officio member, in respect of cases pertaining to the district;

(h) Executive District Officer (Health) of a district, ex-officio member, in respect of cases pertaining to the district; and

(i) a pharmacist of the Government, Health Department, in a district, appointed [ ]by the Government for a term of four years who shall be the Secretary of the District Board.

(2) The Government shall appoint a secretary of the Provincial Board, who holds a graduate or higher degree in pharmacy and has at least ten years professional experience who shall also be member of the Provincial Board.

(3) The Government may appoint a pharmaceutical expert and an expert of medicine as members of the Provincial Board in respect of a district for a term of four years.

(4) The quorum for a meeting of the Provincial Board shall be five including the chairperson or vice-chairperson and one member from the concerned district.

(5) 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.

(6) The Board may co-opt any other qualified expert having formal training and experience in the pharmaceutical field.

4. **District Board**.– (1) Subject to section 11(6) of the Act, the Provincial Board may constitute a committee in a district to be known as the District Quality Control Board comprising the following members:

(a) District Coordination Officer of the district, ex officio member and convener;

(b) Executive District Officer (Health) of the district, ex-officio member;

(c) a pharmaceutical expert in the district appointed by the Government under rule 3(3);

(d) an expert of medicine in the district appointed by the Government under rule 3(3), private member; and

(e) Secretary of the Committee.

(2) The Government shall appoint a Secretary of a District Board who holds a graduate or higher degree in pharmacy and has at least five years professional experience.

(3) The quorum for the meeting of a District Board shall be four including one private member.

(4) A District Board shall perform its functions under the general supervision and subject to the control of the Provincial Board.

(5) The Provincial Board may issue direction or instruction to a District Board.

5. **Procedure for the Board**.– (1) An Inspector or a Government Analyst shall submit monthly reports on Form 1 and Form 2 to the District and the Provincial Board and a summary of the overall situation of quality control in his area of jurisdiction, the Provincial and the District 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 and the District Board may meet at least once in a month to review the situation of the quality control of drugs 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 or the District 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 licence to the licensing authority.

(4) Before referring a case to a Drug Court, the Provincial or the District Board shall ascertain the name of the director, partner and employee of the company, corporation, firm or institution who is 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.

(5) The Provincial or the District Board may, in case of a 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 batches.

(6) The Provincial and the District Board may forbid a person, for a period not exceeding three months, from removing or disposing of a drug, 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 Analyst**.– (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.

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

7. **Duties of Inspectors**.– Subject to the instructions of the licensing authority, an Inspector shall–

(a) inspect a medical store, a pharmacy and a drug manufacturing premises at least once in three months and maintain record of the inspections;

(b) satisfy himself that the conditions of the licence are being observed;

(c) if he has reasons to believe that a drug is being manufactured, sold, stocked or exhibited for sale in contravention of a provision of the Act or the rules, he may take samples of the drug and may send it for test or analysis and may seize the drug or any equipment;

(d) investigate any complaint made to him in writing against a person and submit a report of his investigation to the Provincial or the District Board;

(e) initiate prosecution on the direction of the Provincial or the District 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 samples and seizure of drugs or equipments, and submit reports of such record to the Provincial and the District Board;

(g) stop manufacture or sale of drugs being carried in contravention of the Act and these rules; and

(h) inspect a place licensed under the Act or the rules before renewal of the licence.

8. **Prohibition of disclosure of information**.– Except for the purpose of official business or when required by a Court, 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 Inspector, requiring a person not to dispose of a drug or other material, shall make the order under section 18(1)(i) of the Act in Form 3.

10. **Form of intimation of purpose of taking samples**.– (1) An Inspector who takes sample of a drug for the purposes 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 or other material, 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 shall conduct test and analysis of the sample of a drug sent to him under the Act or the rules and shall furnish report, the result of test and analysis in Form 7.

(2) A Government Analyst shall conduct test and analyses of the sample of a drug 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 analysis to the Inspector, the Government Department or the public institution.

(3) A Government Analyst shall forward to the Government 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.

12. **Procedure on receipt of samples from Inspectors**.– On receipt of a sample of a drug from an Inspector, the Government Analyst shall compare the seals on the packet with the specimen impression received and shall note the condition of the seal on the package and after the test and analysis has been completed, he shall forthwith supply to the Inspector and the Board, a report of the result of the test and analysis.

13. **Fee for test and analysis of drugs**.– (1) A Government Analyst may receive sample of a drug from a person other than Inspector, the Government Department or a governmental Institution.

(2) If the sample of a drug is received from the person, the Government Analyst shall charge fee for the test and analyses of the sample at the rate specified in the Schedule C.

CHAPTER III
SALE OF DRUGS

14. **Licences under the rules**.– The licensing authority may issue a licence of a pharmacy or a licence of a medical store.

15. **Application and fee for licence**.– (1) A person may apply to the licensing authority for the grant or renewal of a licence referred to in rule 14 in Form 8(A) or Form 8(B).

(2) The applicant shall deposit the fee for a licence in the Head of Account No. 1252-Health-Other Receipt, at the following rates:

(a) three thousand rupees for a licence of a pharmacy and two thousand rupees for a licence of a medical store; and

(b) two thousand rupees for renewal of a licence of a pharmacy and one thousand rupees for renewal of a licence of a medical store.

(3) The licensing authority shall issue or renew a licence subject to the conditions prescribed in the Act and the rules.

(4) The applicant shall pay 50% of the fee for change of the qualified person or the duplicate copy of the licence.

16. **Forms of licenses to sell drugs**.– The licensing authority shall issue a licence of a pharmacy in Form 9 and a licence of a medical store in Form 10.

17. **Sale at more than one place**.– (1) If a person desires to sell, store, exhibit for sale or distribute drugs at more than one place, he shall apply for a separate licence in respect of each place.

(2) Provision of sub-rule (1) shall not apply in case the drugs are properly stored in a godown, used only for storage of drugs and which meets the storage conditions and is enlisted along with its complete address on the licence.

18. **Duration of licences**.– (1) A licence issued or renewed under these rules shall unless suspended or cancelled earlier, remain in force for two years from the date of issue.

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

(3) If a person applies for the renewal of a licence within thirty days after the expiry of the licence, his licence 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 licence or renewal of a licence.

(5) The licensing authority shall dispose of an application for a licence or renewal of a licence within 45 days of the receipt of the application.

(6) If the licensing authority fails to dispose of the application within the specified time, it shall record reasons for its failure.

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

(8) The licensing authority shall not renew a licence without an inspection report of the Inspector.

19. **Conditions for issuance of licences**.– (1) The licensing authority shall not issue a licence in Form 9 (pharmacy) and Form 10 (medical store) unless-

(a) the premises has proper and adequate facility for storage of drugs and for their protection from direct sunlight, dust or dirt, including refrigeration facility;

(b) the premises is clean, hygienic and in tidy condition;

(c) in the case of a licence of a pharmacy in which preparation or compounding of a drug is undertaken, the premises has fulfilled the requirements contained in the Schedule F;

(d) the covered area of the premises of a pharmacy is not be less than 140 square feet with minimum breadth of 8 feet in the front and height of 8 feet and in case of a medical store, 96 square feet with minimum breadth of 8 feet and height of 8 feet;

(e) the applicant is not a convict who has been sentenced for imprisonment for a period of one year or more or sentenced to pay fine of thirty thousand rupees or more for manufacturing or selling spurious drugs; and

(f) a person who is registered under section 24(1)(a) of the Pharmacy Act 1967 (XI of 1967) has agreed to personally supervise the sale of drugs for licence in Form 9 (pharmacy) and a person who is registered under section 24(1)(a) & (b) of the said Act has agreed to supervise sale of drugs for licence in Form 10 (medical store).
Provided that provision of this rule for the licences already issued shall come into force after ten years from the notification of these rules**.**

(2) The licensing authority shall not issue a licence without inspection report by a committee comprising of Secretary of the District Board or the Area Drugs Inspector**.**

20. **Conditions of licences**.– (1) The licensing authority shall issue a licence in Form 9 or Form 10 subject to the conditions stated in the licence and to the following general conditions:

(a) in the case of a pharmacy, the person shall display the word “Pharmacy” outside wall of the pharmacy in white writing on a green coloured signboard having minimum length of 5 feet and width of 2.5 feet and in the case of a medical store, the person shall display the words “Medical Store” in white writing on a blue coloured signboard with the same minimum dimensions as required for a pharmacy;

(b) a person who is registered under section 24(1)(a) of the Pharmacy Act 1967 (XI of 1967) shall personally supervise the sale of drugs under licence in Form 9 (pharmacy) and a person who is registered under section 24(1) of the said Act shall personally supervise sale of drugs under license in Form 10 (medical store);

(c) 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;

(d) a drug specified in the Schedules B and D and a preparation containing such drug shall not be sold except on and in

accordance with the prescription (original to be retained by the pharmacy or the medical store) of a registered medical practitioner; a prescription may be dispensed with in case of an emergency (recorded in writing in the register); and no such prescription shall be required for sale of the drug to a registered medical practitioner, a hospital dispensary or any other institution;

(e) subject to rule 1, a licensee of a medical store shall not sell or store a drug mentioned in the Schedule G; and

(f) the sale of a drug specified in the Schedules B and D 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:

(i) S. No., (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 the 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 sale; the quantity sold; and a sufficient reference to an entry in the register recording the sale of the drug on the previous occasion.

(2) For the purpose of this rule, a prescription shall-

(i) be in writing and be signed by the person giving it with his usual signature and be dated by him;

(ii) specify the name and address of the person for whose treatment it is given; and

(iii) indicate the total quantity of the drug to be supplied and dose to be taken.

(3) An invoice or a bill for the purchase of a drug shall be preserved for a period of at least three years.

(4) A manufacturer, importer or the seller of a drug shall sell the drug only to a holder of a valid drug sale licence or to a registered medical practitioner and shall issue an invoice and warranty at the time of sale of the drug.

(5) In case of sale of a drug to a registered medical practitioner, the manufacturer, importer or seller of a drug shall send a copy of the invoice and warranty to the Inspector.

(6) A registered medical practitioner or a doctor of veterinary medicine is exempted from the requirement of a drug sale licence, if:

(a) the drug is for his patients; and

(b) the record of a drug specified in the Schedules B and D is maintained as prescribed under this rule.

Provided that no pharmacy or medical store shall be allowed except and in accordance with the provisions of these rules.

(7) The invoice 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.

(8) The manufacturer, importer or seller of a drug shall maintain record of purchase or sale of a drug and shall preserve the record for a at least three years containing the following particulars:

(a) the date of purchase or sale;

(b) the name and address of the concern from which the drug is purchased or the concern to whom the drug is sold;

(c) the name of the drug, its batch number, the date of its expiry and the quantity of the drug;

(d) the name of the manufacturer.

(9) Except as otherwise provided in these rules, a record 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.

(10) The licensee shall produce for inspection by an Inspector on demand a register or record maintained under these rules, and shall supply to the Inspector such information as the Inspector may require.

(11) A substance specified in the Schedule E and that fall under the list of poisons and the drug specified in the Schedule B shall be stored in:

(a) in a part of the promises to which customers do not have access; or

(b) in a locked almirah, cupboard or drawer, reserved solely for the storage of the substance or the drug.

(12) A substance that falls under the list of poisons in the Schedule E shall be stored in a container, impervious to the poison, and sufficiently stout to prevent leakage arising from the ordinary risks of handling and transport.

(13) A substance that fall in the list of poisons under the Schedule E when compounded and dispensed shall be labeled with the word “Poison”.

21. **Cancellation or suspension of licences.**– The licensing authority may, on the report of an Inspector or the Provincial and the District Board, after giving the licensee an opportunity to show cause and 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 Act or these rules.

22. **Provincial Appellate Authority**.– (1) A person aggrieved by an order of the licensing authority may prefer an appeal to the Provincial Appellate Authority within thirty days of the date of the order.

(2) The Additional Chief Secretary of the Government shall be the Provincial Appellate Authority for the purpose of hearing appeals against an order of the licensing authority.

(3) The Provincial Appellate Authority may direct an officer or an official of the Government 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 forum.

BY THE ORDER OF THE GOVERNOR

SECRETARY TO THE GOVERNMENT OF THE PUNJAB
HEALTH DEPARTMENT

SCHEDULE A

[See rule 2(n)]

FORM 1

[See rule 5(1)]

MONTHLY REPORT FROM INSPECTOR

For the month of _____

(A) SUMMARY OF INSPECTIONS

Place Inspected	No of Firms Inspected	No of Firms found violating law ------Specify main offences	No of samples drawn, if any	Remarks
Manufacturers				
Pharmacies & medical stores				
Others, please specify				

(B) DETAILS OF VIOLATIONS IN RESPECT OF DRUGS

Report of samples of drugs not in compliance with law

Name of Drug	Regd No and Manufacturer's Name	Batch No	Place of taking sample	Date of dispatch & Name of Lab	Date of receipt of test report with nature of result	Action taken including details of seizure and sale restriction

(C) Copy of inspection report of Pharmaceuticals Manufacturing units should be supplied alongwith comments about the compliance of GMP.

FORM 2

[See rule 5(1)]

DRUGS TESTING LABORATORY ----------

PROGRESS REPORT FOR THE MONTH OF --------

No of samples in the beginning of the month	Samples received during the month	Total	Tested			Samples up to standard with percentage	Samples below standard	Details of samples pending for more than 60 days	Remarks / Reason
			New	Old	Total				

Spurious =
Substandard =
Adulterated =
Drugs /Medicines of other systems found to contain allopathic ingredients =

Total =

DETAILS OF DRUGS FOUND IN CONTRAVENTION OF LAW DURING THE MONTH OF _____

Sr. No.	Name & Regd No of the drug	Batch No	Manufactured by	Test Report No, date and nature of contravention

FORM 3

[See rule 9]

Order under section 18(1) of the Drugs Act, 1976 regarding person not to dispose of stock in his possession.

Whereas I have reason to believe that the stock of drugs, article or other things in your possession detailed below contravenes the provisions of section ……. of the Drugs Act, 1976. Now, therefore I hereby direct you not to dispose of the stock for a period of …….. days from this date.

Date…….. Inspector…….

Details of stock of drugs.

Date……. Inspector…….

FORM 4

[See rule 10(1)]

Intimation of purpose to person from whom the sample (s) is taken.

To

…….

I have this day taken from the premises of ……..situated at samples of the drugs specified below for the purpose of test/analysis.

Date……. Inspector ……..

Details of samples drawn

Name of drug	Name of manufacturer	Registration No	Batch No	Quantity	Bill No	Mfg & Exp date

Date……. Inspector ……..

FORM 5

[See rule 10(1)]

Receipt for stock of drug and other material articles seized under section 18(1) of the Drugs Act, 1976.

The stock of drugs materials/articles detailed below has this day been seized by me under the provisions of clause (f) of sub-section (1) of section 18 of the Drugs Act, 1976 from the premises of……. Situated at ……..

Date……. Inspector ……..

Details of Drugs, other material and articles seized including;

Sr No	Name of drug	Batch No	Name of manufacturer	Quantity	Reason for seizure

Date…… Inspector
……..

FORM 6
MEMORANDUM TO GOVERNMENT ANALYST)
[See rule 10(2)]

Serial No of Memorandum ……
From

To

The Government Analyst

The portion of sample/container described below is sent herewith for test or analysis under the provisions of clause (i) of sub-section (3) of Section 19 of the Drugs Act, 1976.

The portion of sample/container has been marked by me with the following marks.

(Seal---------)

Details of portion of sample/container with name of drug which it purports to contain including;

Name of drug	Name of manufacturer	Registration No	Batch No	Mfg & Exp date	Quantity

Dated …… Inspector……

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FORM 7

DRUGS ACT, 1976 AND DRUGS RULES, 1988 FRAMED THERE UNDER
[See rule (11)(1)]
Report of Test/Analysis by Government Analyst, Punjab

1. Name of Inspector of Drugs from whom received ……
2. Serial Number and date of Inspectors memorandum ……
3. Date of receipt……
4. Name of Drug purporting to be contained in the sample ……
5. The condition of the seals……
6. Result of test/analysis with specifications applied……

In the opinion of the undersigned, the sample referred to above is of standard quality as defined in the Drugs Act, 1976 and rules there-under;

Is adulterated/substandard/misbranded/spurious, as defined in the Drugs Act, 1976 for the reason given above.

(Please score out which is not applicable)

No. TRA……../DTL. Dated ……..

1. The Inspector of Drugs ……..……
2. The Chairman Provincial Quality Control Board, Government of the Punjab, Health Department

Government Analyst _____

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FORM NO. 8(A)

{See rule 15 (1)}

Application for the license to sell, store and exhibit for sale & distribute drugs by way of pharmacy.

1. I / We _____.of M/S _____hereby apply for **Licence of Pharmacy;**

2. The sale of drugs will be under the personal supervision of;
(name, registration No, NIC No & address with qualification).
1._____
_____
2._____
_____

3. I / We am / are submitting herewith the following documents;

A) Testimonials of the person (s), registered under section 24(1)(a) of the Pharmacy Act 1967, who has agreed to personally supervise the sale of drugs for licence in Form 9 (pharmacy)and the proprietor (s)

i) three attested copies of registration certificate issued by a pharmacy council.

ii) four attested copies of National Identity Card & passport size photographs of the proprietor (s) and person (s) incharge who has agreed to personally supervise the sale of the drugs.

iii) Affidavit of the person who will supervise the sale of drugs and the proprietor, duly verified, to the effect that they:-

a) shall comply with the provision of the Drugs Act, 1976 and rules framed there under;

b) have not been convicted of any offence from any Court of law. [See rule 19 (1) (e)];

c) shall inform the Licensing Authority for any change in supervisory staff etc.

d) are not working in any government / semi government / autonomous organization.

e) shall not sell / stock any expired, spurious, substandard, unregistered misbranded, counterfeit or any drugs in violation to the drugs laws in force.

B) Plan indicating the exact location and specification of the premises including covered area, dimensions, signboard, air conditioning and refrigeration facilities and addresses of go-down (if any).

C) Treasury receipt / challan No & dated ------- amounting to Rs.-------
in the Head of Account 1252-Health & Other receipts.

Dated:_____

Signature: ----------

Name, address and Permanent Home Address of the person (s) who will personally supervise the sale of drugs.

Signature: ----------

Name, address and Permanent Home Address of the proprietor (s)

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FORM NO. 8(B)

{See rule 15 (1)}

Application for the license to sell, store, exhibit for sale & to distribute drugs excluding the drugs specified in Schedule "G" by way of Medical Store

1. I / We _____.of M/S _____hereby apply for **Licence of Medical Store;**

2. The sale of drugs will be under the personal supervision of;
(name, registration No, NIC No & address with qualification).
1._____
_____
2._____
_____

3. I / We am / are submitting herewith the following documents;

A) Testimonials of the person (s), registered under section 24(1)(a) or (b) of the Pharmacy Act 1967, who will supervise the sale of drugs for licence in Form 10 (medical store)and the proprietor (s); and
Testimonials of the person (s), registered under section 24(1) of the Pharmacy Act 1967, who will personally supervise the sale of drugs for licence in Form 10 (medical store)and the proprietor (s).

i) three attested copies of registration certificate issued by a pharmacy council.

ii) four attested copies of National Identity Card & passport size photographs of the proprietor (s) and person (s) incharge who has agreed to personally supervise the sale of the drugs.

iii) Affidavit of the person who will supervise the sale of drugs and the proprietor, duly verified, to the effect that they:-

f) shall comply with the provision of the Drugs Act, 1976 and rules framed there under;

g) have not been convicted of any offence from any Court of law. [See rule 19 (1) (e)];

h) shall inform the Licensing Authority for any change in supervisory staff etc.

i) are not working in any government / semi government / autonomous organization.

j) shall not sell / stock any expired, spurious, substandard, unregistered misbranded, counterfeit or any drugs in violation to the drugs laws in force.

B) Plan indicating the exact location and specification of the premises including covered area, dimensions, signboard, air conditioning and refrigeration facilities and addresses of go-down (if any).

C) Treasury receipt /challan No & dated ------- amounting to Rs.------- in the Head of Account 1252-Health & Other receipts.

Dated:_____

Signature: ----------

(i) Name, address and Permanent Home Address of the person (s) who will personally supervise the sale of drugs.

(ii) Name, address and Permanent Home Address of the person (s) who will supervise the sale of drugs (if different from (i) above.

Signature: ----------

Name, address and Permanent Home Address of the proprietor (s)

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FORM NO. 9
{See rule 16}
License to sell drugs in a Pharmacy

1. M/S._____ is hereby licensed to sell / compound or prepare on prescription the drugs and sell **or distribute** all types of registered drugs on the premises situated at _____ subject to the conditions specified below and to the provisions of the Drugs Act, 1976 and the rules framed there under.

2. Name of proprietor(s) along with residential address and National Identity Card No(s).
   1. _____
   2. _____

3. Name(s) of the person(s) incharge who will personally supervise the sale of drugs along with registration number, residential address and National Identity Card No.
   1._____
   2._____

4. Address(s) of go-down(s) if any, where the drugs will be stored. _____
   _____

5. This license shall be valid up to _____.

Dated: _____ **Licensing Authority**

CONDITIONS OF LICENCE

1. The person (s) registered under section 24(1)(a) of the Pharmacy Act 1967 (XI of 1967) shall personally supervise the sale of drugs.
2. This license and registration certificate (from pharmacy council) of the person(s) incharge, personally supervising the sale of drugs shall be displayed in a prominent place in part of the premises open to the public.
3. The licensee shall comply with the provisions of the Drugs Act, 1976 and the rules framed there under for the time being in force.
4. The licensee shall report forthwith to the Licensing Authority, any change in person (s) incharge, personally supervising the sale of drugs.
5. No drug requiring special storage conditions of temperature and humidity shall be stored or sold unless the precautions necessary for preserving the properties of the contents have been observed throughout the period during which it remained in possession of the licensee.
6. The fee for change of premises or name & title of the business will be the same as that for a new license subject to satisfactory inspection report.

7. The licensee shall comply with the requirements of the Schedule F, if the drugs are, compounded, dispensed or prepared on prescription.

Licensing Authority

FORM NO 10

{See rule 16}

License to sell drugs in "Medical Store"

1. M/S _____ is hereby licensed to sell, stock and exhibit for sale and distribute **or sale by way of wholesale** the drugs **excluding the drugs specified in schedule "G"** on the premises situated at _____subject to the conditions specified below and to the provisions of the Drugs Act, 1976 and the rules made there under.

2. Name of proprietor(s) along with residential address and National Identity Card No(s).
   1. _____
   2. _____

3. Name(s) of the person(s) incharge who will personally supervise the sale of drugs along with registration number, residential address and National Identity Card No.
   1._____
   2._____

4. Address(s) of go-down(s) if any, where the drugs will be stored. _____
   _____

5. This license shall be valid up to _____.

Dated: _____ **Licensing Authority**

CONDITIONS OF LICENCE.

1. The person (s) registered under section 24(1) of the Pharmacy Act 1967 (XI of 1967) shall personally supervise the sale of drugs.
2. This license and registration certificate (from pharmacy council) of the person(s), personally supervising the sale of drugs shall be displayed in a prominent place in part of the premises open to the public.
3. The licensee shall comply with the provisions of the Drugs Act, 1976 and the rules framed there under for the time being in force.
4. The licensee shall report forthwith to the Licensing Authority, any change in person (s) incharge, personally supervising the sale of drugs.
5. No drug requiring special storage conditions of temperature and humidity shall be stored or sold unless the precautions necessary for preserving the properties of the contents have been observed throughout the period during which it remained in possession of the licensee.
6. The fee for change of premises or name & title of the business will be the same as that for a new license subject to satisfactory inspection report.

7. The fee for change of premises or name & title of the business will be the same as that for a new license subject to satisfactory inspection report.
8. The licensee shall not sell or store a drug mentioned in the Schedule G;

Licensing Authority

SCHEDULE 'B'

[See rules 20]

NARCOTICS PSYCHOTROPIC, ANTI DEPRESSANT AND OTHER CONTROLLED DRUGS

Acetorphine	Acetylmethadol	Allyiprodine
Alphacelylemethadol	Alphamethadol	Alphaprodine
Atileridine	Benzethidin	Benzylmorpine
Betacoylethadol	Betaprodine	Betamethadol
Betaprodine	Bezitramide	Bezodiazepine
Buprenorphene		
Cannabis	Clonitazone	Coca Leaf
Codoxime	Concentrate of poppy straw	Desmorphine
Dextromoramide	Diampromid	Diethylthiambutene
Difenoxin	Dihydromorphine	Dimenoxadol
Dimepheptenol	Dimethylthiambutene	Dioxaphetyl butyrate
Diphenoxylate	Dipipanone	Dextropropxyphene
Dorotebano	Ecoonino	Ethylmothylhiambutone
Etonitazene	Etorphine	Etoxeridne
Fantayl	Furethidine	Heroin
Hydrocodone	Hydromorphinof	Hydromorphone
Hydroxyperthidine	Isomethadone	Katobemidone
Levomethorphen	Levomeramide	Levophenacylmorphen
Levorphanol	Methazocine	Methadone
Methadone intermediate	Methyldeserphine	Methyldihydromorphine
Metopen	Moramide intermediate	Morpheridine
Morphine, Morphine Methorbromide and other pentavalent nitrogen morphine derivatives include in particular the morphine-N-oxide derivatives, one of which is Codeine-N-oxideand the Drugs listed in schedule to CNS Act 1997.		
Morphine M - oxide.	Myrophine	Nicomorphine
Noracynethadol	Norlevorphanol	Normathadone
Normorphine	Norpipnene	Opium
Oxycodone	Oxymorphone	Pethidine
Pethidine intermediate A	Pethidine Intermediate B	Pethidine Intermediate C
Phenadoxone	Phenampromide	Phenazocine
Phenomorphan	Phenoperidine	Piminodine
Piritrameide	Propheptazine	Properidine
Pentazocine	Recamethorphane	Recomoramide
Racemorphan	Surfatnil	Steroids except topical preparations
Thebacon	Thebaine	Tramadol
Trimeperidine	Acetyl di hydro codein	Ethlmorphine
Nicocodiene	Norcodein	Pholcodein
Propyiyam		

International Non Proprietary Names	**Other non proprietary or trivial names**	**Chemical Names**
	DET DMHP	N N Diethyl trptamine, 3-(1,2 dimethyl heptyl) 1 hydroxy 7,8,9,10

		trimethyl + 6 H, di-benzo(b,d) pyran
	DMT	N N dimethyl trptamine
(+) = Lysergide	LSD, LSD-25	(+) N N diethyl lysergomide
	Mescaline	3,4,5 trimethoxy phenethyl amine
	Parahexyl	3 hexyl 1 hydroxy 7,8,9,10 tetra hydro 6 6 9 trimethyl + 6 H dibenzo(b d) pyran
Psilicocybine	Psilocine, Psilotsin	3 (2 di methyl amino ethyl) 4 hydrooxynidole
		3 (2 di methyl amino ethyl) indol 4 di hydrogen phosphate
	STP, DBM	2 amino 1 (2,5 dimethoxy 4 methyl) phenyl propane
	Tetra hydro canne binoles, all isomers	1 hydoxy 3 pentyl 6,a, 7,1, 10a + tetra hydr 6 6 9 trimethyl 6 H dibenze (b,d) pyran
Amphetamine		(+) 2-amino 1-phenyl propane
Dexamphetamine		(+) 2-amino 1, 1 phenyl phenyl propane
Methamphetamine		(+) 2-methyl amino 1-phenyl propane
Methylphenidate		2+ phenyl +2 +(2+ piperidyl) + acetic acid, methyl ester
Phencyclidine		1-(1 phenyl cyclohescyl) pupe
Phenmetrazine		3+ metyl 2 phenyl morpoline
Amobarbital		5+ ethyl +1, 5 +(3 methyl butyl barbituric) acid
Cyclobarbital		5-(1 cyclihexen+1+yl) 5 ethyl barbituric acid
Glutethimide		2 ethyl 2 phenyl glutarimide
Pentobarbital		5 ethyl 5 (L methyl butyl) barbituric acid
Secobarbital		5 allyl 5 (L methyl butyl) barbituric acid
Ampetramone		2 (di ethyl amino) propiophenone
Barbital		5,5 diethyl barbituric acid
Ethchloro vinyol		Ethyl 1 2 chloro vinyl ethanyl carbinol
Ethinamate		1-ethinyl cyclo hexanol carbamate
Meprobamate		2 methyl 1,2 propyl 1,3 propanediol dicarbamate
Methaqualone		2 methyl 3 ethyl 1, 4 (3 H) quinazolinone
Methyl Phenobarbital		5 ethyl 1 methyl 5 phenyl barbituric acid
Methyprylon		3, 3 diethyl 5 methyl 2 4 piperidine
Phenobarbital		5 ethyl 5 phenyl barbituric acid
Pipradrol		1 1 di phenyl 1 (2 pipridyl) methanol
	SPA	(-) 1 dimethyl amine , 2 2 diphenyl ethane

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SCHEDULE 'C'

[See rules 13 (2)]

1	Short conclusion/judgment (without experimentation)	**Rs.** 50
2	Preliminary examination of character e.g. color taste smell form solubility, miscibility, etc.	115
3	Clarity of solution,	
	(1) Physical Examination	70
	(2) Chemical Examination	115
4	Completeness of solution	150
5	Identity test, chemical	
	(A) (a) Inorganic substance	120
	(b) Organic substances	125
	(B) Unknown sample	
	(a) Inorganic	170
	(b) Organic	225
	(i) Element each	150
	(ii) group each	130
6	Leakage test Injectable	140
7	Disintegration test, dissolution test, weight variation (uniformity of weight) uniformity of diameter, etc.	340
8	Determination of solubility quantitatively in one solvent	260
9	Determination of melting point	
	(a) In-capillary	130
	(b) In non declared substances	240
10	Micro melting point in non-declared substance	250
11	Crystallizing point, freezing point, setting point and solidifying point each	200
12	Distillation range and boiling point, etc.	140
13	Determination of water/humidity	
	(a) In ointments.	140
	(b) In other material	230
14	Residue after evaporation or loss on drying Quantitatively	130
15	Weight per ml, density, specific gravity, etc.	240
16	Determination of viscosity	250
17	Determination of jelly strength.	240
18	Determination of ash, acid insoluble ash, water soluble ash sulphated ash, alcohol soluble extractive total solids, etch each.	240
19	Readily carbonisable substances test	225
20	Determination of alcohol in the preparations.	160
21	Extraction with organic solvents	290
22	Continuous extraction of drugs	385
23	Isolation by distillation	260
24	Steam distillation	240
25	Vacuum distillation	350
26	Determination of unsaponifiabe matter free menthol, cineol, total balsamicacids, etc. each	250
27	Determination of Acid value, Iodine value, saponfication value Acetyl value, eaters value, etc, each	150

28	Determination of volatile oils in drugs	170
29	Test for the absence of	
	(a) a rachis oil in other oils	230
	(b) cotton seeds oil in other oils	230
	(c) seas am oil in other oil	230
	(d) similar other tests	230
30	Determination of Nitrogen Kieldahi	270
31	Determination of water Karl Fischer	285
32	Impurity Limit test for the presence of	
	(a) ions each	250
	(b) Organic substances each	250
33	Quantitative tests for Lead, Arsenic, Heavy metals etc.	300
34	Determination of Foreign organic matter	250
35	Determination of acidity or alkalinity chemical	180
36	Determination of P.H. electrometrically.	280
37	Test for alkalinity of glass	170
38	Determination of	
	(a) Sulphur dioxide	160
	(b) Methoxyl	160
	(c) Absorption of carbon dioxide by soda lime	160
	(d) similar other tests	160
39	Assay Chemical	
	(a) gravimetric each	160
	(b) Titrimetric each	260
	(c) Non aqueous titration each	260
	(d) Complexometric titration each	290
40	Gasemetric assay	160
41	Potentionmetric titration	150
42	Oxygen Combustion method	150
43	Refractomotry	230
44	Polarimetry	140
45	Spectrophotometery in	
	(A) Visible region	
	(a) Sample determination	360
	(b) sample Quantitative determination	390
	(c) Absorption Curves	320
	(d) Flame and atomic absorption	350
	(B) UV-Region	
	(a) Simple Determination	270
	(b) simple Quantitative determination	250
	(c) Absorption curves	240
	(C) IR-Region.	220
46	Fluorimetry assay	390
47	Naphelometry Assay	250
48	Polarography every component	250
49	Chromatography	
	(a) paper or ion-exchange or TLC	570
	(b) Gas	460
50	Zone Electrophoresis	270
51	Paper Electrophoresis	310
52	Proteolytic, amylolytic activity	270

53	Activity of trypsin or chymotrysin	370
54	Disinfectants/Insecticides.	
	(i) Complete chemical test	470
	(ii) Bacterio static / bactericidal activity	320
55	Test for complete extraction of alkaloids	630
56	Test for complete extraction of dextrants	440
57	Saponification	250
58	Surgical ligatures and sutures	
	(a) Measurement of length	130
	(b) Measurement of Diameter	130
	(c) Tensile strength	140
	(d) Softening point	130
	(e) other test	250
59	Surgical dressing etc.	
	(a) determination of Yarn number each	220
	(b) Thread count (warp and weft) etc.	120
	(c) Elasticity	120
	(d) Wt. Per unit area	130
	(d) determination of content of wool	230
	(f) setting time	120
	(g) other chemical test each	230
	(h) Absorbency	220
	(i) Naps etc.	120
	(j) Adhesive strength of plasters	120
	(k) other tests	150
60	Determination of starch in dressing	230
61	Identity test in vegetable drugs	530
	(a) Pharmacopoeial each	-
	(b) Non official each	-
62	Identity test in Pulverized drugs in mixture	550
	(a) Official drugs each	-
	(b) Non official each	-
63	Un known vegetable drugs	-
64	Microscopic evaluation	250
65	Syringability test	220
66	Air Tightness	250
67	Microbiological tests	-
	(i) Sterility of Antibiotics, plasma and other blood preparations	770
	(ii) sterility test	-
	(iii) sterility of sutures	-
	(iv) Vaccines and Sera etc.	-
	(v) test for presence of fungi etc.	-
68	Test for infusion bags microbiological	790
69	Activity, potency test.	250
	(i) Antibiotics per ingredients	330
	(ii) vitamin etc.	350
70	Other bacteriological examination	370
71	Toxicity/abnormal toxicity /undue, toxicity safety test	320
72	Depressor substances test	320
73	Presser substance test	360

74	Biological adequacy test	400
75	Biological assay	360
76	Pyrogen test	360
77	*Other pharmacological test	250
78	*Clinical pharmacological trials	250

Note. i. The exact fee will be calculated by the government analyst on the basis of the time spend, reagents and animals etc used.

ii. Fee for the other tests not given above is to be calculated by the government analyst.

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SCHEDULE 'D'

(See rules 20)

To be sold by a retailer strictly on the prescription of registered medical practitioner.

andrenocortiotrophic hormone (ACTH), androgenic anabolic, oestrogenic, and progestational substance, benzeestrol, derivatives of stilbene, dibenzyl or naphtalene with oesterogenic 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

Bacitracine.	Carbomycin.	Chloramphenicol
Chlortetracycline	Colimycin	Dihydro streptomycin
Erythromycin	Framyceten	Gramicidin
Griseofulvin.	Kanamycin	Neomycin
Novobiocine	Nystatin	Oleandomycin
Oxytetracycline.	Pencilline	Paromomycin
Polymyxin.	Spiramycin	Streptomycin
Tetracycline	Tyrothyricin	Vanocomycin
Viomycin	Cephalosporines	Amitriptylline, its salts

Antihistamine substance, their salts and derivatives salts of their derivatives.

Antazoline	Bromazine	Bucidine
Chlorocyclizine	Diphenhydramine	Diphenpyraline
3 Di Nebutyl, aminoethly, 1-4, 5, 6, tri hydroxyphathalide.	Isothidtendyl, N-Dimethly amino iso propyl thiophenyl, Pyridalamine.	Meclozine.
Phenindamine.	Promethazine	Prophen pyridamine
Thenalidine, (1 Methyl 4 amine N – Phenyl N 2 Phenyl). pioridine tartrate, Substance being tetra substituted N-Derivatives of Ethylenedi amine or propylene di amine.	Azapetine its salts Aenactyzine its salts	Benzodiazepienes Bendrofluaxide Pentazocine, Buprenorphines, Tramadols

Brethyliun Tesylats.	Captodine, its salts	Chlorisondamine Cholordies
Chlormozanene	Chlorpyomazine,its salts	Chlorprothixene.
Chlorthiazide.	Citrated Calcium Carbimide.	Clidinium Bromide.
Cortisone, hydrocortisone, Prednision, prednisolone, triamcinolone and dexamethasone , their esters, their derivatives and esters, of their derivative .	Cyclopenthiazide.	Dithlazinine lodide.
Ethionamide	Glutethimide, its salts, guanethidine,	Hexocyclium Methyl sulphate. Hexadimethrine Bromide.
Hydrochlorth Iazide	Hydroflume thiazide	Hydroxyzine, it salts.
Impiramine, its salts.	Iron preparations for parenteral use	Isocarbon acids
Isonicotinic acid hydrazide and other hydrazine derivatives of isoncotinic acid, their derivatives, salts.	Isoxsurprine.	Mepromade.
Methaqualone, its salts.	Methypenpynol , its ester an other derivatives .	Metronidazole
Mialamide, its salts.	Oxytocin, prepaid from the pituitary body or by synthesis,	Para aminosalicylic acid, its salts, its derivatives, their salts,
Pempidine, its salts,	Pecazine, its salts.	Pherelzine, its salts.
Phenothiazine, derivatives and salts of its derivatives not other wise specified in this schedule.	Phenynamidol, its salts.	Pituitary gland, the active principles of not otherwise specified in this schedule, and their salts.
Pivazide.	Polythiazide.	Promazine, its salts.
Pyrvinium its salt.	Sorbide Nitrate.	Spironolactone.
Thiopropazate, its salts	Trranyllocypromine, its salts.	Trimeprazine, its salts.
Vasopressin, prepared from the pituitary body of by synthesis.		

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

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SCHEDULE 'E'

(See rule 20)

Name of Poisonous substances	Percentage of poison content below which the substance or its preparation is exempted from the provision of rule
Acetanilide, alkyl acetanilides	-
Acetylmethadol, its salts	-
Aconits, roots	-
Alkaldoids the following, their salts, their esters, salts of their esters, their Quanternary compounds	-
Acetyldihdrocodeins	-
Acetyldihdrocodeinone	-
Aconite, alkaloids	0.20
Apomorphine	0.15
Atropine	0.15
Bellodona, alkoloids calculated as hoseyamine	0.15
Benzolymorphine	-
Brucine	0.20
Calabar beans alkaloids of Cocoa, alkaloids	0.10
Cocaine	0.10
Codeine	0.10
Colchicum	0.50 calculated as colchicines
Conine	0.10
Coternine	0.20
Curare alkoloids of curare basis	-
Diamorphine (Diacetylmorphine hydrocholoride)	-
Dihydrocodeine	-
Dihydrocodeinone	-
Dihydroxy di oxy codein	0.1.
Dihydromorphine	-
Ecgonin	-
Emetine	1.0
Ephedra Alkaloids	1.0
Ergot Alkaloids	-
Ethylmorphine	0.20
Gelsemium Alkaloids	0.1
Home Atropine	0.15
Hyoscymine	0.15
Daborandi Alkaloids	0.50
Lobellia Alkaloids	0.50
Morphine	0.20 Calculated as anhydrous Morphine
Nicotine	0.20
Papaverine	1.0
Pomegrante Alkaloids	0.15
Quberacho Alkaloids other than the alkaloids of quebracho red	-
Rauvolfia Alkaloids	-
Sabadilla Alkaloids	1.0

Solananceous Alkaloids not other wise specified in the list	0.15 Caculated as Hyosimine
Stav sacre, Alkaloids of	0.20
Strychnine	0.20
Thebane	1.0
Tropi cocaine (Benzyl Pseudo Tropine)	-
Veratrum Alkaloids	1.0
Youhimba Alkaloids of	-
Allyl iso propyl acetyl urea	-
N-Allyl Morphine and other Pentavalent Morphine Derivatives	-
Allyl prodine, its salts	-
Alpha Acetylmethadol, its salts	-
Amidopyrine, its salts, Amidopyrine Shlphonates and its derivatives & salts	-
Amino alcohol esterified with benzoic acid, phenyl propionic acid or the derivatives of these acids, their salts	1.0
Aminopetrine	-
Ammonia	Smelling salts
Amylnitrie	-
Aniloridine, its salts	-
Antimony, Oxide of Antimony, Ssulphides of Antimony, Organic compounds of antimony	Equivalent of 1.0% of trioxide
Barbituric acid, its salts, Compounds of barbituric acid, its salts, derivatives, their salts with any other substance	-
Barium Chloride	-
Barium Sulphate	-
Beta acetyl methadol, its salts	-
Amphetamine, its N-Alkyl derivatives, their salts	-
Beta meprodine, its salts	-
Beta methadol, its salts	-
Busulphan (1,4 dimethane sulpha oxy butane), its salts	-
Butyl chloride hydrate	-
Cannabis (Indian hemp) cannabisersin, Galenical preparations of cannabis, extract and tincture of cannabis and cannabin tannates	-
Canthridine, Cantharidates	0.10 of canthridine
Carbacol, 4 cabamthoxy 1,3 dimethyl 4 phenyl hexa methyleneminie, its salts, Carbutamide	-
Chloral formamide, chloral hydrate	-

Chlorambucil, its salts	-
Chloroform	Substances containing 1% of 10% chloroform
Chlorpropamide its salts	-
Clonatazene, its salts	-
Creosote from wood	Substances containing 50% creosote
Crotonall and seeds	-
Cyclo phosphamide, its salts	-
Datura herb and seeds, preparation of datura	0.15 calculated as hyoscyamine
Deso morphine, its salts	1.5
Dextrometharphine, its salts	1.50
Dextro mormide, its salts	-
Dextrophane, its salts	-
Di acetyl N – allyl morphine, its salts	-
Di amono di phenyl sulphene, its salts and derivatives	-
Diditalis, Glycosides of other active principles of digitalis	-
Di iso propyl fluro phosphonates	-
Dimenaoxadol, its salts	-
Di methyl thiambutene, its salts	-
Di nitro cresets, their compounds with a metal or a base	-
Di nitro naphthols, di nitro phenols, di nitro thynols	-
Do oxy phetane butyrate, its salt	-
Diphenoxylate, its salts	-
Di phenyl norpholino hephta none, its salts	-
Di pipanone, its salts	-
Di sod stilbestrol di phosphate	-
Di sulpharim	-
Di thienyl allyl amines	-
Epinephrine, its salts	-
Ergot, the sclerotia of any species claviceps, extract of ergot, tincture of ergot	-
Erythrityl tetra nitrate	-
Etho sulphide	-
Ethl metryl thiambutene, its salts	-
Etoxeridine, salts	-
Formaldehyde Formic acid	Substances containing less than 5% of formaldehyde
Furethidine, its salts	-
Callamine, its salts, its quaternary compounds	-
Glyceryl trinitrate (Nitroglycerin)	-
Guinadines, Poly mthylene di guanidine, di para enisyl phenotyl guanidine	-

Hydanton, its salts, its derivaties their slts	-
Hydrochloric acids	Substances containing 9% of Hcl
Hydro cyanic acid, cyanides	0.15
Hydromerphinol, its salts	-
12 Hydroxy 5,9 dimethyl(2 phenyl) 6,7 benzentorphene, it salts	-
Hydroxy pethadine, its salts	-
Insulin	-
Iso propyl ester of 1 methyl 4 phenyl carboxylic acid (Phroperidino) its salts	-
Laudeaxium, its salts	-
Lead acetate, compounds of lead with acids from fixed oils	-
Levariernol its salts	-
Levo 3 hydoxyl N propyl morphinan, its salts	-
Levo metharphane, its salts	-
Leverphanol, its salts	-
Mannomustine, its salts	-
Mannothyl hexanitrate	-
6 mercaptopurine, its salts	-
Mercury, Mercuric chloride, Mercuric aluminium chloride	1.00 of mercuric chloride
Mercuric Iodine	2.0
Mercuric Nitrate	Equivalent of 3% of mercury
Mercury or inorganic compounds of mercury	Equivalent of 2% of mercury
Mercury, Oxides of mercury oxy cyanides of mercuric pot. Iodine	Equivalent of 1% of mercury
Metamizole	-
Metazocine, its salts	-
Metformin, its salts	-
Sulphonyl urea salts	-
Methanol	-
Mthotraxate, its salts	-
Metheruzine	-
Methyl des orphine, its salts	-
Methyl hydro morphine, its salts	-
Methyl 4 phenyl piperidine 4 carboxylic acid, esters their salts	-
Metapone (Methyl di hydro morphinone) its salts	-
N-(2 methyl phenethyl amino) propyl propionalit, its salts	-
Morpheridine, its salts	-
Morphine N oxide, its derivatives, their salts	-
Mustine, its salts	-
Nalorphine, its salts	-

Nitric Acid	Substances containing 9% of Nitric acid
Nitrobenzene	-
Nitrophenols of Meta and Para Norcodeine, its salts	-
Norlevorphanol, its salts	-
Normethadane, its salts	-
Nux Vomica, seeds of nux vomica, preparation of nux vomica	0.20, Calculated as strychnine
Opium	0.20, Calculated as anhydrous morphine
Orthocaine, its salts	-
Quabain	-
Oxazolidine, its derivative	-
Oxy chinchoninic acid, derivatives of their salts, esters	-
Oxymorphone, 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	Substances intended for topical or external use
Para amino benzoic acids its salt, esters, their salts	-
Para amethadione	-
Phenam promide, it salts	Phenformin, its salts
Phenols (Any member of the series of phenol of which the first member is phenol and of which the molecular composition varies by one atom of carbon and two atoms of hydrogen, halogens derivatives of phenol, compounds of phenols with a metal	Substances containing less than 1a5 of phenol Nasal Sprays, mouth washes, pastilles lozer capsules, ointments less than 2.5%of phenol
Phenomorphan, its salts	-
Phenoperidine, its salts	-
Phensuxamide	-
Phenyl acetyl urea	-
Phenylbutazone, its salts, its derivatives, their salts	-
Phenyl chinchoninic acid, its salts, esters, the salts of its esters	-
Pholcodine, its salts	1.50
Phosphorus yellow	-
Picric acid	Substances containing less than 9% of picric acid
Picrotoxin	-
Piminodine, its salts	-
Piperdine 1Phenyl bicycle heptanyl propanol	-
Potassium Flouride	Substances containing less than 1%

	of Pot fluoride
Potassium Hydroxide	-
Procaine, salts of procaine	Combination of procaine with antibiotics
Proheptazine, its salts	-
Propoxyphene, its salts	-
Recomthorphan, its salts	-
Reserpine, its salts, its derivatives, their salts	-
Salicylconchoninic acid, its salts, esters, the salts of its esters	-
Savin oil of sodium fluoride	Substances containing less than 1% of sodium fluoride
Sodium Hydroxide	Substances containing less than 12% of NaOH
Sodium Nitrate	-
Strophanthus, its Glycosides	-
Sulphuric Acid	Substances containing less than 9% of Sulphuric Acid
Thallium, its salts	-
Thiocarbonalide	-
Thyroid, glands, the active principle of their salts	-
Tolbutamide	-
Tribromomethyl alcohol	-
Tri(2 Chlorethyl) Amines, its salts	-
Tri ethylene thio phosphoramide	-
Trimeperidine, its salts	-
Tropine di phenyl methyl esters, their salts	-
Roxidone	-
Nephosphide	-

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SCHEDULE 'F'

[See rule 19(1) (c)]

LIST OF MINIMUM REQUIREMENTS FOR A PHARMACY

1. **Entrance**; The front of a Pharmacy shall be an inscription "Pharmacy".

II. **Premises**; The premises of a pharmacy shall be separated from room for private use. The premises shall be built dry, well lit and ventilated and shall of sufficient dimensions to allow the goods 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 premises 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.

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 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 or of contents of containers kept near them. Drawer glasses and other containers 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 masking of official preparation and prescriptions:-

Apparatus

Balances with dispensing sensitivity of 30 mg
Balances Counter, 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 10ml, 25ml, 100ml and 500ml
Mortar and pestle glass
Ointment slab, porcelain, Ointment pot with bakelite or suitable cap.
Pipettes graduated, 2ml, 5ml and 10 ml
Ring stand (retort) iron, complete with rings
Rubber stamps and pad, scissors, spatula
Spirit lamp or 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, 1mg to 100mg
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 there under
The Pharmacy Act 1967
The Dangerous Drug 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 premises and the fittings of the Pharmacy shall be properly kept and maintained and every thing must be in good order and clean.

All records and register shall be maintained in accordance with the laws in force

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 force.

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 drugs dispensed, compounded or prepared by the licensee it is necessary to relax the above requirements in the circumstances of a particular case.

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Schedule G

[See rule 20(1)(e)]

DRUGS NOT TO BE SOLD/STORED BY LICENCEE IN FORM NO.10

1. **Antileprosy**

i	Rifampicin Injection	iv	Ethionamide
ii	Dapsone	v	Prothionemide
iii	Clofamazine		

2. **immunological products, Vaccines, Sera / Anti Sera**

i	Anthrax Vaccine	ix	Rubella Vaccine
ii	BCG Vaccine	x	Pneumococcal vaccine
iii	Botulisms Antitoxin	xi	Poliomyelitis Vaccine
iv	Cholera Vaccine	xii	Smallpox Vaccine
v	Diphtheria Vaccine	xiii	Typhoid Vaccine
vi	Influenza Vaccine	xiv	Immunoglobulins
vii	Measles Vaccine	xv	Rabies Vaccine
viii	MMR Vaccine	xvi	Homophiles Influenza-Type B Vaccine

3. **Products Related with Malignant Diseases and Immunosupression**

i	Folinic Acid	xiii	Mitozantrone
ii	Doxorubicin HCl	xiv	Methotrexate
iii	Mercaptopurine	xv	Vinblastine
iv	Thioguanine	xv	Carboplatin
v	Vincristine	xvii	Bleoimycin
vi	Cisplastin	xviii	Dactinomycin
vii	Busulphan	xix	Chlorambucil
viii	Carmustine	xx	Dacarbazine
ix	Lomustine	xxi	Amasascrine
x	Cyclophosphamide	xxii	Azathioprine
xi	Melphalan	xxiii	Cyclosporin etc
xii	Fluorouracil		

4. **Drugs of Anesthesia and Inhalation Anesthetics**

i	Propofol	viii	Mitazolam
ii	Enfluran	ix	Naloxone Hcl
iii	Isofluran	xv	Vancuronium
iv	Halothane	xi	Pancuronium
v	Bupivacain	xii	Tubocuraine
vi	Thiopentone	xiii	Suxamethonium
vii	Benzodiazepine	xiv	Neostigmine

5. Antibiotics

i	Spectinomycin	ii	Vancomycin
iii	Teicoplanon	iv	Colistin
v	Sodium Fusidate	vi	Imipenem

6. Inotropics

i	Primacor	ii	Milrinone
iii	Enoximone		

7. Injection Prostaglandins

i	Dinoprostone	ii	Carboprost
iii	Gemeprost		

8. Alpha Blocker

i	Prazosin HCl	ii	Indoramine
iii	Daxazosing	iv	Alfuzosin

9. **Biotechnological Products**

i	Interferon	ii	Erythropoetin

10. **Narcotics, Psychotropic / Tri Cyclic Anti Depressant**

i	Morphine	xviii	Chlorpromazine
ii	Buprenorphine	xix	Meprobamate
iii	Nalbuphine	xx	Chlordiazepoxide
iv	Fantanil	xxi	Alprozolam
v	Pethidine	xxii	Clonazepam
vi	Lorazepam	xxiii	Flurazepam
vii	Temazepam	xxiv	Loprazolam
viii	Oxazepam	xxv	Dothiepin
ix	Amoxapine	xxvi	Doxepin
x	Iprine Dole Codine	xxvii	Nortriptyline
xi	Pentazocine	xxviii	Trimipramine
xii	Phenelzine	xxix	Tranycypromine
xiii	Lithium	xxx	Flupenthixol
xiv	Dextropropoxyphene	xxxi	Tryptophan
xv	Clomipramine	xxxii	Imipramine
xvi	Mianserin	xxxiii	Amipriptyline etc
xvii	Maprotiline		

11. **Antiviral**

i	Acyclovir	Vii	Idoxuridine
ii	Amantadine HCl	viii	Ribavirin
iii	Famciclovir	ix	Vidarabin
iv	Inosine Pranolsex	x	Trifluridine
v	Zidovudine	xi	Methisozone etc
vi	Ganciclovir		

12. **Thrombolytic Enzymes**

i	Alteplase	ii	Anislreplase
iii	Streptokinase	iv	Urokinase

13. **Product Used in Dialysis**

i	Peritoneal Dialysis & Haemodialysis	ii	Lysine Solution (Irrigation Solution)
iii	Hyper tonic Solution	iv	Isotonic Solution

14. **Creams and aerosols Steroidal Preparations**

i	Prednisolone	ii	Methylprednislone
iii	Tramcionolone	iv	Dexamethasone
v	Beclomethasone	vi	Hydrocortisone

15. **Hormones**

i	Vasopressin	vi	Finasteride

ii	Desmopressin	vii	Finasteriode
iii	Stanozolol	viii	Somatropin
iv	Nandrolone	ix	Testosterone
v	Mesterolone	x	Progestrogens

PUNJAB DRUG RULES
Amendment in 2010

GOVERNMENT OF THE PUNJAB
HEALTH DEPARTMENT

Dated 2nd February 2010

NOTIFICATION:

No. SO (DC) 814/2003 (A-97) (P) In exercise of powers conferred upon him under Section 44 of the Drugs Act, 1976 (XXXI of 1976) which empowers the Provincial Government to make rules under the Act subject to previous publication,

And whereas the Governor of the Punjab was pleased to make the Punjab Drugs Rules 1988 and substitute them with the Punjab Drugs Rules, 2007, under the said provision;

And whereas the Governor of the Punjab is further pleased to make the following amendments in the Punjab Drugs Rules, 2007 after previous publication of these amendments;

AMENDMENTS IN PUNJAB DRUGS RULES, 2007

1. **In Rule 1-**
In rule 1, sub rule (3) for the word "three", the word **"ten"** shall be substituted.

2. **In Rule 2-**
In rule 2, sub rule (1), in clause (k) after the word "prescription" the following shall be added;
"or distributed in case of authorized agent of manufacturer, indenter or importer"
In rule 2, sub rule (1), after clause (p) the following new clause (q) shall be inserted;
"(q) "wholesale" means sale to a person, buying for the purpose of selling again who is the authorized agent of a manufacturer or importer or indenter.

3. **In Rule 3-**
In rule 3, sub rule (1), clause (b) after the word "vice-chairperson" the following shall be inserted;
"who shall act as chairperson in the absence of the Secretary Health".
In rule 3, sub rule (1), clause (c), after the word "Government", the following shall be inserted;
"or a senior most officer of the provincial drugs control administration who shall be a pharmacy graduate".
In rule 3, sub rule (1), clause (i), the words **"as a private member",** shall be omitted and after the word "year", the words**, "who shall be the Secretary of the district board"** shall be inserted.
In rule 3, sub rule (2), after the word "experience", the following shall be inserted;
"who shall also be member of provincial board".
In rule 3, after sub rule (5), the following new sub rule shall be inserted;
"(6) the board may co opt any other qualified expert having formal training and experience in the pharmaceutical field"

4. **In Rule 18-**
In rule 18, the sub rule (1), shall be substituted with the following;
"A licence issued or renewed under these rules shall unless suspended or cancelled earlier, remain in force for two years from the date of issue"

5. **In Rule 18-**
In rule 18, sub rule (2) after the word "within", the word **"Sixty"** shall be substituted with the word **"Thirty"**

6. **In Rule 19-**
In rule 19 (1) (e) after the word "more" the words **"for manufacturing or selling spurious drugs"** shall be inserted;
In rule 19 (1) after sub rule (f) the following proviso shall be added;
"Provided that provision of this rule for licences already issued shall come into force after ten years from the notification of these rules"
In rule 19, sub rule (2), the word, **"secretary of the provincial board or the secretary of the district board"** shall be substituted with the word **"by a committee comprising of Secretary of the District Board or the area Drugs Inspector".**

7. **In Rule 20-**
In rule 20, sub rule (6), after clause (b), the following proviso shall be added;
"Provided that no pharmacy or medical store shall be allowed except and in accordance with the provisions of these rules.

8. **In Schedule A-**
In Form 9 at serial No 1, after the word "and sell", the word **"or distribute"** shall be inserted.

9. **In Schedule A-**
In Form 10 at serial No 1, after the word "distribute" the words **"or sale by way of wholesale"** shall be inserted.

BY THE ORDER OF THE GOVERNOR

SECRETARY TO THE GOVERNMENT OF THE PUNJAB
HEALTH DEPARTMENT

PUNJAB DRUG RULES
Amendment in 2014

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(PART-I)

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GOVERNMENT OF THE PUNJAB
HEALTH DEPARTMENT

Dated Lahore, the 20.01, 2014

NOTIFICATION

No.SO (DC) 814/2003 (A-97) (P). In exercise of Powers conferred under Section 44 of Drugs Act, 1976 (XXXI of 1976) and after previous publication, Governor of the Punjab is pleased to direct that in the Punjab Drug Rules, 2007 the following further amendments shall be made:

AMENDMENTS

In the Punjab Drugs Rules 2007:

1. In rule 2, in sub-rule (1):
   (a) after clause (b), the following clause (bb) shall be inserted:
   "(bb) "distributor" means supplier or wholesaler of drugs who stores, sells or distributes drugs to a pharmacy, medical

store or health institution on behalf of pharmaceutical manufacturer or importer as authorized agent;"; and

(b) in clause (k), the words and commas "or distributed in case of authorized agent of manufacturer, indenter, importer" shall be omitted.

2. In rule 6:

(a) in sub-rule (1), the words and commas "and has at least one year experience in the manufacture, sale, testing or analysis of drugs" shall be omitted; and

(b) in sub-rule (2), after the word "drugs", the words "or drug control administration" shall be inserted.

3. In rule 7, in clause (c), after the word "believe", the brackets and words "(recorded in writing on Form 4 or Form 5)" shall be inserted.

4. In rule 11:

(a) for the word "conduct", wherever occurs, the word "cause" shall be substituted; and

(b) in sub-rule (2), after the word and comma "Inspector," wherever occur, the words and comma "a person," shall be inserted.

5. In rule 12, after the word and comma "Inspector," the words and comma "a person or Government institution," shall be inserted.

6. In rule 13, in sub-rule (2), after the word "person", the words "or Government institution" shall be inserted.

7. In rule 14, after the words "medical store", the words "or a license of a distributor" shall be inserted.

8. In rule 15:

(a) in sub-rule (1), after the words, figure and brackets "Form 8 (B)", the words, figure and brackets "or Form 8 (C)" shall be inserted.

(b) in sub-rule (2):

(i) in clause (a), after the words "medical store", the words "and five thousand rupees for a license of a distributor" shall be inserted; and

(ii) in clause (b), after the words "medical store", the words "and three thousand rupees for the renewal of license for the distributor" shall be inserted.

9. In rule 16, after the word and figure "Form 10", the words and figure "and a license of distributor in Form 11" shall be inserted.

10. In rule 19:

(a) in sub-rule (1):

(i) for the words, figure and brackets "and Form 10 (medical store)", the comma, words, figures and brackets ",Form 10 (medical store) and Form 11 (Distributor)" shall be substituted;

(ii) in clause (d), after the words and figure "and height of 8 feet", the commas, words and figures "and, in case of distributor minimum covered area shall not be less than 500 square feet" shall be inserted; and

(iii) in clause (f), after the word and brackets "(pharmacy)", the words, figures and brackets "and Form 11 (Distributor)" shall be inserted;

(b) for sub-rule (2), the following shall be substituted:

"(2) The licensing authority shall not issue a license without inspection report of the Secretary of the Provincial Board or the Secretary of the District Board or the Inspector of the area."; and

(c) after sub-rule (2), the following sub-rule (3) shall be inserted:

"(3) The licensing authority shall not issue a license to a distributor without verification of computerized facility ensuring maintenance of a proper computerized system of inventory control for sale and purchase of drugs."

11. In rule 20:
(a) in sub-rule (1):
(I) in the rider clause, after the word and figures "Form 10", the words and figures "or Form 11" shall be inserted; and
(II) in clause (b), after the word and bracket "(pharmacy)", the words, figures and brackets "or Form 11 (Distributor)" shall be inserted; and
(b) after sub-rule (13), the following sub-rule (14) shall be inserted:
"(14) In case of license of a distributor, the licensee shall maintain the computerized system of inventory control for sale and purchase of drugs."

12. After rule 22, the following rule 23 shall be inserted:
"23. **Good storage and distribution practices.**– A licensee under these rules, a public sector institution or a private organization dealing in distribution and storage of drugs shall comply with the good storage and distribution practices contained in Schedule H."

13. In Schedule A:
(a) in Form 7:
(I) after Sr. No. 5, the following Sr. No. 5A shall be inserted:
"5A. Mark with impression of seal....."
(II) after Sr. No. 6, the following Sr. No. 7 shall be inserted:
"7. Details of result of test/ analysis....."
(b) after Form 8(B), the following Form 8(C) shall be inserted:

"FORM 8(C)
{see rule 15(1)}

Application for the license to sell, store and exhibit for sale and distribute drugs by way of distribution.

1. I / We _____ of M/S _____ hereby apply for License of Distributor;
2. The sale of drugs will be under the personal supervision of: (name, registration No, NIC No & address with qualification).
a._____
_____
b._____
_____
3. I / We am / are submitting herewith the following documents:
A) Testimonials of the person (s), registered under section 24(1)(a) of the Pharmacy Act 1967, who has agreed to personally supervise the sale of drugs for license in Form 11 (distributor)and the proprietor(s):
i) three attested copies of registration certificate issued by a pharmacy council.
ii) four attested copies of National Identity Card & passport size photographs of the proprietor (s) and person (s) incharge who has agreed to personally supervise the sale of the drugs.
iii) Affidavit of the person who will supervise the sale of drugs and the proprietor, duly verified, to the effect those they:
a) shall comply with the provision of the Drugs Act 1976 and rules framed thereunder;
b) have not been convicted of any offence from any Court of law. [See rule 19(1)(e)];
c) shall inform the Licensing Authority for any change in supervisory staff etc.
d) are not working in any Government / semi-Government / autonomous organization.

e) shall not sell / stock any expired, spurious, substandard, unregistered misbranded, counterfeit or any drugs in violation to the drugs laws in force.

B) Plan indicating the exact location and specification of the premises including covered area, dimensions, signboard, air conditioning and refrigeration facilities and addresses of godown (if any).

C) Treasury receipt / challan No & dated -------amounting to Rs.---- in the Head of Account 1252-Health & Other Receipts.

Dated:_____

Signature: ---------- Name, address and permanent home address of the person(s) who will personally supervise the sale of drugs.";

Signature: ---------- Name, address and permanent home address of the proprietor(s)"

(c) In Form 9, in conditions of license, after condition No. 7, the following condition No. 8 shall be inserted:

"8. The licensee shall comply with the conditions contained in Schedule H."

(d) In Form 10, in conditions of license, after condition No. 8, the following condition No. 9 shall be inserted:

"9. The licensee shall comply with the conditions contained in Schedule H."; and

(e) after Form 10, the following Form 11 shall be inserted:

"FORM 11
{see rule 16}
License to sell drugs as a Distributor

1. M/S._____ is hereby licensed to sell stock, exhibit for sale and distribute registered products on behalf of licensed pharmaceutical manufacturer as his authorized agent on the premises situated at _____ _____ subject to the conditions specified below and to the provisions of the Drugs Act, 1976 and the rules framed thereunder.
2. Name of proprietor(s) along with residential address and National Identity Card No(s).
   a. _____
   b. _____
3. Name(s) of the person(s) incharge who will personally supervise the sale of drugs along with registration number, residential address and National Identity Card No.
   a._____
   b._____
4. Address(s) of godown(s) if any, where the drugs will be stored.
   _____
5. This license shall be valid up to _____

Dated: _____ Licensing Authority

CONDITIONS OF LICENCE

1. The person(s) registered under section 24(1)(a) of the Pharmacy Act 1967 (XI of 1967) shall personally supervise the sale of drugs.
2. This license and registration certificate (from pharmacy council) of the person(s) incharge, personally supervising the sale of drugs shall be displayed at a prominent place in the part of the premises open to the public.

3. The licensee shall comply with the provisions of the Drugs Act, 1976 and the rules framed thereunder for the time being in force.
4. The licensee shall report forthwith to the Licensing Authority, any change in person(s) incharge, personally supervising the sale of drugs.
5. No drug requiring special storage conditions of temperature and humidity shall be stored or sold unless the precautions necessary for preserving the properties of the contents have been observed throughout the period during which it remained in possession of the licensee.
6. The fee for change of premises or name and title of the business will be the same as that for a new license subject to satisfactory inspection report.
7. The licensee shall maintain the computerized sale and purchase record of the drugs.
8. The licensee shall comply with the conditions as prescribed in Schedule H.
9. All employees of the licensee shall possess minimum qualification of matriculation."

14. After Schedule G, the following Schedule H shall be inserted:

"SCHEDULE H
[see rule 23]
GOOD STORAGE AND DISTRIBUTION PRACTCETO BE FOLLOWED BY THE LICENCEE AND A PUBLIC SECTOR INSTITUTION OR A PRIVATE ORGANIZATION

A good storage practice is a part of the quality of the pharmaceutical or medical product through various activities at different levels related to storage and distribution operations. A pharmacy, medical store and distributor shall follow the good storage practice and supply chain management accordingly detailed below:

1. At each sale or storage site i.e. a distributor, wholesaler, retailer and community or hospital pharmacy, there shall be an adequate number of qualified personnel available at all working hours to monitor pharmaceutical quality assurance.
2. There shall be adequate segregation of pharmaceuticals, veterinary, food products, cosmetics, chemicals, disinfectants and cleaning materials to eliminate the risk of cross contamination.
3. There shall be proper cleanliness and hygiene. The humidity and temperature shall be maintained within acceptable limits of respective products.
4. Goods and materials shall be stored off the floor, suitably spaced to permit ventilation, cleaning and inspection.
5. The dispensing equipment of pharmacy including temperature and humidity monitoring devices and scales shall be validated.
6. The vehicles deployed to distribute, store, or handle drugs shall be properly designed and equipped to ensure protection from different environmental and weather conditions.
7. Narcotic, psychotropic drugs and radioactive substances shall be stored separately with proper record keeping.
8. The starting material and products used in the dispensing pharmacy shall be isolated and be properly labelled in a way which prevents mix-up and cross contamination.
9. It will be ensured that pharmaceuticals products due to expire first are sold and/or distributed first (FEFO).
10. Adequate controls shall be in place to prevent the sale/distribution of expired products.

11. Expired, broken or damaged items shall be kept/stored separately, properly labelled and marked in the medical store/pharmacy or warehouse.

12. Thermo labile products shall be kept in refrigerator with proper temperature recording device like thermometer, and its temperature shall be monitored to ensure its consistency within the required limits.

13. Storage conditions for products and materials shall be in compliance with the labelling instructions and requirements.

14. All the medicines must be kept on racks and shelves. To allow access for cleaning and to avoid harbouring pests. The stores may be arranged in the store room and shelves as per following general guidelines, pallets are being used, stake the carton:
    - at least 10 cm (4 inches) off the floor;
    - at least 30 cm (1 foot) away from the walls and other stacks; and
    - not more than 2.5 m (8 feet) high,

15. Products shall be protected from excessive climatic conditions during storage and transport such as heat, frost, moisture and direct sunlight.

16. Buildings shall be kept free of vermin, insects, birds & other pests.

17. Temperature above 40° C degree and relative humidity above 70% are considered to be the extremes of temperature and humidity respectively.

18. Drugs products that must be stored under defined conditions require appropriate storage instructions. Unless otherwise specifically stated, deviation may be tolerated only during short terms interruptions or during local transportation.

19. It is important to follow the manufacturer's recommended storage conditions printed on label all products:

    Store frozen: Some products, like certain vaccines, need to be transported within a cold chain and stored at -20° C (4° F). Frozen storage is normally for longer-term storage at higher level facilities;

    Store at 2-8° C (36°-46° F): Some products are very heat sensitive but must not be frozen. These are usually kept in the first and second part of the refrigerator and never in the freezer. This temperature is appropriate for storing vaccines for a short period of time;

    Keep cool; Store between 8°-15° C (45°-59° F)

    Store at room temperature:

    Store at ambient temperature:

    Store at the surrounding temperature. This term is not widely used due to significant variation in ambient temperatures. It means "room temperature" or normal storage conditions, which means storage in a dry, clean, well-ventilated area at room temperatures between 15° to 26° C (59°-77°F) or up to 30° C, depending on climatic conditions.

    Protect from moisture no more than 60% relative humidity.

    In normal storage condition; to be provided to the patients in a light-resistant container.

20. There shall not be any leaks from roofs of storage sites.

21. The storage facility shall be clean and free from litter, dust and pests.

22. Adequate precautions shall be taken against spillage and breakage, attack by microorganism and cross contamination.

23. The manufacturer, importers shall ensure the deliveries only to authorized retailers, wholesalers or distributors under a valid warranty under the law.
24. For all supplies a document shall be enclosed making it possible to identity the stocks to ascertain the date, the name and pharmaceutical firm of the medicinal product, quantity supplied, the name and address of the supplier and addressee.
25. The medicinal products shall be transported in such a way that:
    a) their identification is not lost;
    b) adequate precautions are taken against spillage, breakage or theft; and
    c) they are secure and not subjected to unacceptable degree of heat, cold, light, moisture and such like other factors.
26. Medicinal products requiring controlled temperature storage shall be transported by appropriately specialized means.
27. Defective medicinal products which have been returned shall be kept apart from saleable stock to prevent sale / redistribution until a decision has been reached regarding the disposal."

Babar Hayat

SECRETARY
GOVERNMENT OF THE PUNJAB
HEALTH DEPARTMENT

Dated Lahore, the 20th January, 2014

GOVERNMENT OF THE PUNJAB