GOVERNMENT OF THE PUNJAB
HEALTH AND POPULATION DEPARTMENT

Dated Lahore, the 12th November, 2026

NOTIFICATION

No. SO(DC)2-2/2021 (P-I).- In exercise of the powers conferred under section 44 of the Drugs Act, 1976 (*XXXI of 1976*), the following draft rules made by Governor of the Punjab are published for the information of persons likely to be affected thereby. Notice is hereby given that the objections and suggestions, if any, in respect of the draft rules may reach the office of Secretary to Government of the Punjab, Health and Population Department at **1-Birdwood Road, Lahore** maximum within fifteen (15) days of the publication of this Notification in the official Gazette and the objections and suggestions, if received, shall be taken into consideration on **10.12.2026** at **11:00 AM** in the said office in the presence of those who care to be present. No objection/suggestion will be considered after stipulated time.

Draft Rules

CHAPTER-I
PRELIMINARY

1. Short title and commencement.- (1) These rules may be cited as the Punjab Drugs and Therapeutic Goods Rules 2026.

(2) They shall come into force at once.

2. Definitions.- (1) In the rules, unless the subject or context otherwise requires:

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

(b) "Administrative Department" means the Health and Population Department, Government of the Punjab;

(c) "adverse drug reaction" or "ADR" means the adverse drug reaction as defined under clause (iv) of rule 2 of the Pharmacovigilance Rules, 2022;

(d) "Alternative Medicine" means the alternative medicines as defined under clause (ii) of section 2 of the DRAP Act;

(e) "Alternative Medicine Store" means a premises licensed under the rules where Alternative Medicine and Health Product are stored, stocked, sold or exhibited for sale by way of retail sale only;

(f) "authorized agent" means a distributor or wholesaler duly authorized by a licensed manufacturer, importer or indenter under the Act for distribution of drugs and Therapeutic goods to other distributor as per clause (d) of sub-rule (4) of rule 23 or licensee under the rules;

(g) "company" means a company as defined in the Companies Act, 2017 (XIX of 2017);

(h) "compounding" means a drug or Therapeutic good prepared at small scale from basic ingredients or from ready to dispense pharmaceutical product by the process of combining, mixing or altering ingredients to create a preparation tailored to meet the specification outlined in individualized patients' prescription subject to fulfillment of conditions mentioned in the Schedule-E;

(i) "distributor" means a supplier of the drugs and Therapeutic goods having license under the rules to store, sell or distribute drugs and Therapeutic goods, except Medical Device, to a licensee, health institution or registered prescriber concerned as per rule 27 or, in special circumstances, directly to the patient with permission of the licensing authority;

(j) "District Board" means a committee of the Provincial Quality Control Board in a district;

(k) "DRAP Act" means the Drug Regulatory Authority of Pakistan Act, 2012 (XXI of 2012);

(l) "firm" means a partnership firm registered under the Partnership Act, 1932 (IX of 1932);

(m) "Form" means the Form as set out in the Schedule-A;

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

(o) "license" means a license to sale or distribute the drugs and Therapeutic goods;

(p) "licensee" means a person, company or firm who is the proprietor in the license issued under the rules;

(q) "licensing authority" means the Director General, Directorate of Drugs Control, Punjab or his duly authorized officer from the Administrative Department to act as the licensing authority;

(r) "manufacturer" means the manufacturer of the drugs and Therapeutic goods;

(s) "Medical Device" means the medical device as defined under clause (xviii) of section 2 of the DRAP Act;

(t) "Medical Devices Store" means a premises licensed under the rules where the Medical Devices are stored, sold or distributed to the licensee, health institution, registered prescriber or consumer as authorized agent of the manufacturer or importer of Medical Devices;

(u) "Medical Store" means a premises licensed under the rules where the drugs and Therapeutic goods excluding the drugs and Therapeutic goods mentioned in the Schedule-F are stored, stocked, sold, exhibited or offered for retail sale only;

(v) "online sale" means electronic sale of a drug and Therapeutic good by a licensee, except the licensee having license in Form-11, Form-14 or Form-15, by way of retail sale through any online medium in accordance with the conditions mentioned in the rules;

(w) "Pharmacist" means a person having a degree in pharmacy from a university or institution recognized by Pharmacy Council of Pakistan and is registered in register "A" under clause (a) of sub-section (1) of section 24 of the Pharmacy Act 1967 (XI of 1967);

(x) "Pharmacovigilance Officer" means an officer notified by the Administrative Department to monitor safety of the drugs and Therapeutic goods designated under the Pharmacovigilance Rules, 2022;

(y) "Pharmacy" means a premises licensed under the rules where drugs and Therapeutic goods are stored, stocked, sold, exhibited for sale, compounded on prescription or dispensed by way of retail sale only;

(z) "pharmacy services" means the pharmacy services as defined under clause (xxvi) of section 2 of the DRAP Act;

(aa) "prescriber" means a healthcare professional registered by the Medical and Dental Council,

Council for Tibb, Council for Homeopathy or Pakistan Veterinary Medical Council;

(bb) "Provincial Board" means the Provincial Quality Control Board, Punjab;

(cc) "recall" means the withdrawal or removal of specific batch or a part thereof of a drug and Therapeutic good from the market for quality, safety or efficacy as per rule 15;

(dd) "registered prescriber" means a prescriber registered by the licensing authority;

(ee) "retail sale" means the sale of drugs and Therapeutic goods to patient, customer or health institution for individual patients;

(ff) "rules" means the Punjab Drugs and Therapeutic Goods Rules 2026;

(gg) "Schedule" means the Schedule appended to the rules;

(hh) "seller" means a person who stock for sale or sell the drugs and Therapeutic goods;

(ii) "service provider" means a licensee on Form-9 or a company or firm licensed under the rules to provide services of storage or transportation or storage and transportation of the drugs and Therapeutic goods to the licensee;

(jj) "Therapeutic goods" means the Therapeutic goods as defined under clause (xxxvi) of section 2 of the DRAP Act; and

(kk) "wholesale" means sale to a person who purchases for the purpose of selling again and includes sale to a hospital, dispensary, medical institution, educational or research institute who is authorized agent of a manufacturer, importer or indenter.

(2) A word or expression used but not defined in the rules shall have the same meaning as assigned to it in the Act.

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

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

(a)	Secretary to the Government, Health and Population Department	Chairman
(b)	Special Secretary (Operations) to the Government, Health and Population	Vice-Chairman

	Department	
(c)	Additional Secretary (Drugs Control) to the Government, Health and Population Department	Member
(d)	Director General, Directorate of Drugs Control, Punjab	Member
(e)	Chief Drugs Controller, Punjab	Member
(f)	Deputy Commissioner of the district concerned	Member
(g)	Chief Executive Officer of the District Health Authority concerned	Member
(h)	Pharmacist of the Government, Health and Population Department in respect of a district	Member
(i)	Secretary of the Provincial Board	Member/ Secretary
(j)	one expert of pharmaceutics preferably professor of pharmaceutics	Member
(k)	one expert of pharmacology preferably professor of pharmacology	Member
(l)	one expert of pharmaceutical chemistry preferably professor of pharmaceutical chemistry	Member
(m)	one expert of chemistry preferably professor of chemistry	Member
(n)	one expert of pharmaceutical technology preferably professor of pharmaceutics	Member
(o)	one physician preferably professor of medicine	Member
(p)	one expert of alternative medicines preferably professor or associate professor of pharmacognosy	Member
(q)	one expert of veterinary medicines	Member
(r)	one expert of biotechnology	Member
(s)	one expert of bio-medical engineering	Member
(t)	one expert of pharmaceutical in respect of a district	Member
(u)	one expert of medicine in respect of a district	Member
(v)	one law expert to be nominated by the Public Prosecution Department, Government of the Punjab, not below the rank of BS-18	Member
(w)	one representative of Drug Regulatory Authority of Pakistan not below the rank of Additional Director or Deputy Director or Federal Inspector of drugs nominated	Member

	by the Chief Executive Officer of the Authority	
(x)	any other co-opted member	Member.

(2) The members from clauses (j) to (s) of sub-rule (1) shall be appointed from those who have ten years' experience in the relevant field.

(3) The member at clause (q) of sub-rule (1) shall have qualification of Doctor of Veterinary medicine.

(4) The member at clause (r) of sub-rule (1) shall possess Ph.D degree in biotechnology.

(5) The member at clause (s) of sub-rule (1) shall possess Ph.D degree in bio-medical engineering.

(6) The member at clause (x) of sub-rule (1) shall be co-opted from those who have formal training and experience in any field including but not limited to, Homoeopathic, Herbal, Unani, Ayurvedic, Tibb, Nutraceuticals or Medical Devices.

(7) The members from clauses (j) to (u) shall be appointed by the Administrative Department for a period of five years.

4. Secretary of the Provincial Board.- (1) The Administrative Department shall appoint the Secretary of the Provincial Board who holds a graduate or higher degree in pharmacy and have twelve years' experience in the relevant field.

(2) The Secretary shall:

(a) maintain a complete record of the minutes of the meeting of the Provincial Board;

(b) issue all the personal hearing notices, orders, show cause notices or any other directions; and

(c) perform any other function as assigned by the Provincial Board.

5. Meetings of the Provincial Board.- (1) The Provincial Board shall meet at least once in a month.

(2) The Chairman, or in his absence, the Vice-Chairman shall preside over the meeting of the Board.

(3) The quorum for a meeting of the Board shall be nine members including the Chairman or Vice-Chairman, one member from the district concerned and three non-official members.

(4) In absence of the Secretary of Provincial Board, the Chairman of Provincial Board may authorize any *ex-officio* member to conduct any scheduled meeting.

(5) No act, decision, order or proceedings of the Provincial Board shall be invalid by reason of any vacancy or defect in the constitution of the Provincial Board.

6. Functions of the Provincial Board.- (1) The Provincial Board may constitute a panel in respect of cases related to quality and sale of drugs and Therapeutic goods to inspect or visit any premises and submit a report to the Provincial Board.

(2) The Provincial Board shall periodically ensure quality assurance and safety profiling of compounded drugs and Therapeutic goods as mentioned in the Schedule-E.

(3) The Provincial Board may:

(a) permit the analysis of any sample from one drug testing laboratory to another laboratory due to non-availability of testing facility in that laboratory;

(b) initiate recall of a specific drug and Therapeutic good or its batch as per procedure mentioned in rule 15; and

(c) issue directions or instructions to a District Board.

7. District Quality Control Board.- (1) The Provincial Board may constitute a committee in each district as the District Quality Control Board consisting of the following:

(a)	Deputy Commissioner of the district concerned	Convener
(b)	Chief Executive Officer of the District Health Authority concerned	Member
(c)	one pharmaceutical expert	Member
(d)	one expert of medicine	Member
(e)	Secretary of the District Board	Member/ Secretary
(f)	any other co-opted member	Member.

(2) The members at clauses (c) and (d) shall be the members of the Provincial Board appointed by the Administrative Department under clauses (t) and (u) of sub-rule (1) of rule 3.

(3) In case of a cognizable offence, the District Board shall co-opt one representative of district police not below the rank of BS-18 as member of the District Board for the respective cases.

8. Secretary of the District Board.- (1) The Administrative Department shall appoint the Secretary of the District Board who holds a graduate or higher degree in pharmacy and have eight years' experience in the relevant field.

(2) The Secretary shall:

(a) maintain a complete record of the minutes of the meeting of the District Board;

(b) issue all the personal hearing notices, orders, show cause notices or any other directions; and

(c) perform any other function as assigned by the District Board.

9. Meetings of the District Board.- (1) The District Board shall meet at least once in a month.

(2) The quorum for the meeting of a District Board shall be four members including one non-official member.

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

10. Procedure for the Provincial Board and District Board.- (1) The Inspector and Government Analyst shall submit, manually or electronically, monthly reports in the Form-1 and Form-2 respectively to the Provincial Board and District Board concerned along with summary of the overall situation of quality control and availability in his area of jurisdiction. The Provincial Board and District Board shall maintain the information in order to monitor the quality of the drugs and Therapeutic goods sold and review the performance of the manufacturer, distributor and seller.

(2) The Provincial Board and District Board shall review the situation of the quality control of drugs and Therapeutic goods on the whole including consideration of any specific point arising during the period on the working of the Inspector, Pharmacy, Medical Store, distributor, manufacturer, importer, indenter and drugs testing laboratory.

(3) The Provincial Board or District Board or authorized member of the respective Board, as the case may be, shall examine a case referred to it by an Inspector and shall provide the person concerned an opportunity of hearing before initiating prosecution of the person or recommending suspension or cancellation of his license issued under the rules to the licensing authority or suspension or cancellation of manufacturing or import license or registration or enlistment of the drugs and Therapeutic goods to the Registration Board or Central Licensing Board or Enlistment Evaluation Committee or Medical Devices Board, as the case may be.

(4) Before referring a case to a Drug Court, the Provincial Board or District Board, as the case may be, shall ascertain the name of such director, partner or employee of the company, corporation, firm or institution who are *prima facie* responsible for the commission of the offence under the Act or rules and may allow an Inspector to institute prosecution against such persons.

(5) The Provincial Board or District Board, as the case may be, may:

(a) in case of any contravention, direct the manufacturer, distributor or seller to bring improvement, order de-sealing and take any other action;

(b) decide the fate of case property or direct the Inspector or Secretary of the Board concerned or constitute a committee for disposal of case property or recovered or seized drugs and Therapeutic goods of the case which is not referred for prosecution;

(c) forbid a person for a period not exceeding three months from removing or disposing of a drug and Therapeutic good, article or other thing on the request of an Inspector; and

(d) allow safe custody of the seized stock of the drugs and Therapeutic goods or any other article till decision by the Court if said material is required to be used as evidence in prosecution.

(6) A retired Secretary of the Provincial Board or District Board, or Inspector, while attending the Drug Court for recording of his evidence, shall be entitled to travelling or daily allowance and accommodation, as admissible to the serving officers of equivalent grade, by the office of the Secretary of the Board concerned.

(7) If a member of the Provincial Board or District Board witness a situation where conflict of interest may arise due to his participation in the proceedings of the respective Board, he shall voluntarily quit the participation to the extent of such individual case.

(8) The Provincial Board or District Board or a committee of the Provincial Board, after approval from the Provincial Board, may allow a member, other than Chairman and Secretary of the Board concerned, or relevant person to participate virtually only in case of unavoidable reasons or facilitation of the members subject to following conditions that the:

(a) whole virtual proceeding shall be recorded;

(b) recorded proceeding shall be kept as evidence by the Secretary of the Board or committee concerned;

(c) Secretary of the Board or committee concerned shall ensure that a software-based participation attendance is obtained; and

(d) in case of accused, at least one person shall participate physically.

11. Qualification for appointment of the Inspector, Government analyst, pharmaceutical expert and medical expert.- (1) No person shall be appointed as an Inspector unless he holds a degree in Pharmacy from a university or institution recognized by the Pharmacy Council of Pakistan.

(2) No person shall be appointed as a Government Analyst unless he holds a degree in Pharmacy from a university or institution recognized by the Pharmacy Council of Pakistan and have three years'

experience in the manufacture, testing or analysis of drugs and Therapeutic goods or drug control administration or any other professional experience:

Provided that more than one Government Analyst may be appointed for test and analysis of various drugs and Therapeutic goods as deems appropriate.

(3) No person shall be appointed as pharmaceutical expert or member in Drug Court unless he holds a degree in Pharmacy from a university or institution recognized by the Pharmacy Council of Pakistan and have fifteen years' experience in the manufacturing, testing or analysis of drugs and Therapeutic goods or drug control administration or any other professional experience in the public sector.

(4) No person shall be appointed as medical expert or member in Drug Court unless he holds a MBBS degree or equivalent qualification from a university or medical institution recognized by the Pakistan Medical and Dental Council and have fifteen years' experience in the hospital, medical institute, health institute, health services or health administration in the public sector.

12. Duties of the Inspector.- Subject to section 18 of the Act and instructions of the licensing authority, the Inspector shall:

(a) inspect a premises where drugs and Therapeutic goods are stocked, stored, exhibited for sale, sold, manufactured or distributed, on his own or at a frequency or schedule notified by the licensing authority and maintain record of all such inspections;

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

(c) within thirty days of his appointment, send a specimen impression of his seal to the Government Analyst concerned;

(d) require to a person not to dispose of a drug and Therapeutic good or other material by order in the Form-3 under clause (i) of sub-section (1) of section 18 of the Act;

(e) take samples of the drugs and Therapeutic goods if he has reasons to believe that the drugs and Therapeutic goods are being manufactured, distributed, sold, stocked or exhibited for sale in contravention of provision of the Act or rules and 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 good or

other material, shall issue receipt of seizure in the Form-5A;

(f) issue orders to stop manufacture or sale of drugs and Therapeutic goods being carried out in contravention of the Act and DRAP Act in the Form-5B and lock and seal such premises to halt the manufacture or sale process for a period not exceeding two weeks or as directed by the Provincial Board or District Board concerned for a further period up to three months;

(g) send a portion of the sample or the container to the Government Analyst concerned for test and analysis through a memorandum in the Form-6;

(h) investigate any complaint made to him in writing against a person and submit a report of his investigation to the Provincial Board or District Board concerned and Chief Drugs Controller, Punjab;

(i) initiate prosecution on the direction of the Provincial Board or District Board concerned within thirty days from the date of receipt of order and pursue cases in the Court or seek extension in period after recording reasons from the respective Board;

(j) maintain record of action taken by him in the performance of his duties including taking samples and seizure of drugs and Therapeutic goods or other items and submit reports of such record to the Provincial Board and District Board concerned;

(k) inspect a place licensed under the Act and DRAP Act for the purpose of issuance or renewal of the drugs and Therapeutic goods sale license;

(l) seek information, document names of persons, *prima facie* involved in the commission of offence;

(m) submit the investigation report or forward the matter to the Provincial Board or District Board concerned for grant of permission for prosecution or necessary action in the matter within four months or seek extension in period to complete the investigation of case after recording reasons from the respective Board;

(n) dispatch report of the Government Analyst within seven days as per sub-section (3) of section 22 of the Act;

(o) communicate the request of retesting to the Provincial Board within seven days, if received under sub-section (4) of section 22 of the Act; and

(p) take action against a person or licensee who sell the drugs and Therapeutic goods without prescription of registered medical practitioner except the drugs and Therapeutic goods mentioned in the Schedule-H and submit report to the Provincial Board or District Board concerned or licensing authority for necessary action under the rules.

13. Duties of the Government Analyst.- (1) The Government Analyst shall:

(a) cause test and analysis of the sample of a drug and Therapeutic good sent to him under the Act or rules and shall furnish report of the result of test and analysis in the Form-7;

(b) receive sample of the drugs and Therapeutic goods for test and analysis sent to him in writing by an Inspector or a person or authority or Government Department or any other public institution or hospital and shall furnish the report of the result of test and analysis to the concerned from whom the sample was received; and

(c) forward the monthly report containing result of samples tested and analyzed during the month for publication to the Provincial Board and furnish such other information as may be required by the Provincial Board.

(2) On receipt of a sample of a drug and Therapeutic good from the Inspector, Government institution, hospital or person, the Government Analyst shall compare the seal on the packet of the sample with the specimen impression received and shall note the condition of the seal on the package of the sample and after completion of the test and analysis, he shall forthwith supply a report of the result of the test and analysis to the Provincial Board and Inspector concerned.

(3) For the purpose of sub-section (2) of section 22 of the Act, the further period within which the report shall be made available to the Inspector shall be sixty days.

14. Fee for test and analysis of the drugs and Therapeutic goods.- If the sample of a drug and Therapeutic good is received from a person or Government Institution or hospital, the Government Analyst shall charge fee for the test and analysis of the sample at such rate as mentioned in the Schedule-C.

15. Recall of the drugs and Therapeutic goods.- (1) Subject to the Act and DRAP Act, each manufacturer or importer and his authorized agent, selling the drugs and Therapeutic goods in Punjab shall have a system of surveillance of its marketed drugs and Therapeutic goods and a system to ensure prompt and effective recall.

(2) A manufacturer or importer and his authorized agent may recall a drug and Therapeutic good or its specific batch on its own or upon identification of any problem or defect and intimate all objective evidences thereof to the Provincial Board.

(3) The Provincial Board shall ensure recall assessment, communication, monitoring, evaluation and termination, as soon as information is received from the manufacturer or importer or its authorized agent, Chief Drugs Controller, Punjab, Inspector, Government Analyst, Pharmacovigilance Officer or any other officer or authority authorized to report a problem or defect in a drug and Therapeutic good under the Act and DRAP Act and may share the information to the Drug Regulatory Authority of Pakistan for effective recall at national level.

(4) The manufacturer or importer and his authorized agent shall ensure time line for recall including stoppage of sale or distribution of the stock at manufacturer site or warehouse as per classification and procedure as mentioned in the Schedule-I.

(5) The manufacturer shall submit a recall report with details of batch manufactured, points of sale, recall quantity and status of disposal to the Provincial Board as per specified time line.

(6) The Provincial Board may, while deciding a case referred to it, consider status of recall of the drugs and Therapeutic goods.

(7) Anything related to recall of the drugs and Therapeutic goods not covered in this rule shall be such as mentioned in the Schedule-I.

16. Prohibition of disclosure of information.- Except for the purpose of official business or when required by a Court, the licensing authority, Secretary of the Provincial Board, Secretary of the District Board, Inspector and Government Analyst shall not disclose to any unauthorized person any information acquired by him in the course of his official duties.

CHAPTER-III
SALE OF DRUGS AND THERAPEUTIC GOODS

17. License.- No person or his authorized agent shall sell, stock or exhibit for sale or distribute the drugs and Therapeutic goods or provide a service related thereof without having a valid license under the rules.

18. Application and fee for the license.- (1) A person may apply manually or online to the licensing authority for grant or renewal of a license, or any change therein in the Form-8A, Form-8B, Form-8C, Form-8D, Form-8E, Form-8F or Form-8G:

Provided that the licensing authority may require any additional information or document as part of the application.

(2) The applicant shall deposit fee for the grant or renewal of

a license in the Head of Account, as specified by the licensing authority, at the following rates:

(a) sixteen thousand rupees for a license of the Pharmacy;

(b) ten thousand rupees for a license of the Medical Store;

(c) twenty-four thousand rupees for a license of the distributor or Alternative Medicines or a Medical Devices Store; and

(d) sixteen thousand rupees for a license of the service provider.

(3) There shall be no fee for the Government Drugs and Therapeutic Goods Store.

(4) The licensee shall submit full fee of license for change of title or change of premises, where applicable.

(5) The licensee shall submit fifty percent of the original fee of license for addition or change of godown or extension in size of premises or change or addition of qualified person, where applicable.

(6) Fifty percent of the original fee shall be applicable for provision of online sale in case of a new or an already issued license.

(7) In case any deficiency found in the application, the licensing authority shall inform the applicant and if he fails to rectify the same within a period of thirty days, his application shall be rejected. On request of the applicant, the licensing authority may restore the application for further period of thirty days and if applicant fails to rectify the deficiency in such extended period, the application shall be rejected and the fee shall be forfeited.

19. Qualified person.- (1) A qualified person to supervise licensed premises for the license is as under:

Sr. No.	Category	Qualified Person
(a)	Pharmacy or distributor or Government Drugs and Therapeutic Goods Store	Pharmacist.
(b)	Medical Store	(i) Pharmacist; or (ii) a person who is pharmacy technician or pharmacy assistant having diploma or certificate in pharmacy from a university or an institution recognized by the Pharmacy Council of Pakistan and registered in register

		"B" under clause (b) of sub-section (1) of section 24 of the Pharmacy Act, 1967 (XI OF 1967).
(c)	Medical Devices Store	(i) Pharmacist; or (ii) a person having degree in Bio medical engineering from a university or an institution recognized by the Pakistan Engineering Council of Pakistan.
(d)	Alternative Medicine Store	Pharmacist.

(2) In the absence of qualified person, the licensee shall engage an alternate qualified person on temporary basis as specified by the licensing authority:

Provided that the qualified person engaged for one licensed premises shall not be engaged for any other premises.

(3) If a licensed premises is operating in more than one shift, the number of qualified person shall be appointed accordingly to allow supervision of sale of drugs and Therapeutic goods throughout the working hours.

(4) The licensee shall keep a record of attendance and leave of qualified person and hours of duty.

(5) The qualified person of any license shall inform the licensing authority or Inspector concerned in writing within one month in case of death of proprietor and in case of death of qualified person, the proprietor shall inform the licensing authority or Inspector concerned and immediately stop sale till the appointment of new qualified person, if only one qualified person is approved.

20. Issuance and renewal of the license.- (1) The licensing authority may issue a license of the Pharmacy in the Form-9 or Medical Store in the Form-10 or distributor in the Form-11 or Alternative Medicine Store in the Form-12 or Medical Devices Store in the Form-13 or Government Drugs and Therapeutic Goods Store in the Form-14 or service provider related to sale of drugs and Therapeutic goods in the Form-15.

(2) The licensing authority shall issue or renew the license subject to conditions provided in the Act, rules and guidelines issued by the licensing authority in this regard.

(3) A license issued under the rules shall be non-transferable.

(4) The licensing authority shall:

(a) issue guidelines regarding all the matters for grant or renewal of license or any other relevant procedures or operations;

(b) maintain record of registered prescribers according

to rule 27 of the rules; and

(c) publish the list of valid license issued under the rules and registered prescribers.

(5) The licensing authority may:

(a) cause to perform audit or inspection of licensed premises for compliance of good storage and distribution practice or conditions of the license; and

(b) authorize an officer of the Government or Secretary of the District Board to perform any function with respect to the licensing process on his behalf.

(6) Seventy percent of the fees or fines shall be credited to Government Treasury and the remainder 30% shall be utilized by the licensing authority for the purpose of physical inspection of premises for issuance or renewal of license under the rules.

(7) The already issued drugs sale licenses to dispensers and 20/21 category shall be renewable for life time of those persons subject to fulfillment of all other conditions as specified in the rules and Schedule-F. The already issued licenses shall be non-transferrable.

(8) The licensing authority may, if considers that grant of license is not expedient in public interest, refuse an application subject to providing an opportunity of hearing to the applicant and provisions of sub-rule (1). The refusal of an application for renewal of an already issued license shall be deemed cancellation of such license.

(9) The licensing authority shall decide an application for a license or renewal of a license within forty-five days of receipt of the application subject to fulfillment of all the requirements by the applicant and duly verification of registration certificate of qualified person from the regulatory body concerned.

(10) In case an application is not decided within the specified time, the licensing authority shall record reasons for delay.

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

(2) The provision of sub-rule (1) shall not apply in case the drugs and Therapeutic goods are properly stored in a godown, used only for storage of drugs and Therapeutic goods and which meets the storage conditions mentioned in the Schedule-G and is enlisted along with its complete address on the license.

22. Duration of the license.- (1) The license issued or renewed under the rules shall unless suspended or cancelled earlier, remain in force for a period of five years from the date of issuance or renewal.

(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 enforced until an order on the application is passed by the licensing authority.

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

23. Conditions for the license.- (1) The licensing authority shall not issue or renew a license under the rules unless the applicant or licensee fulfills the following conditions:

(a) the premises have proper and adequate facility for storage of drugs and Therapeutic goods and for their protection from direct sunlight, dust or dirt including refrigeration facility supported by appropriate monitoring mechanism;

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

(c) the applicant or the qualified person have not been convicted under sub-section (1) of section 27 of the Act or paragraph (1) of the Schedule-III of the DRAP Act:

Provided that an applicant or qualified person so convicted shall become eligible for a license after the expiration of three years from the date of such conviction;

(d) satisfactory inspection report of an area Inspector or Secretary of the Provincial Board or Secretary of the District Board or team of officers of the Government as assigned by the licensing authority;

(e) satisfactory compliance of good storage and distribution practice as mentioned in the Schedule-G;

(f) compliance of provisions of the rules and guidelines issued by the licensing authority;

(g) in case of online sale, the applicant has developed his website or mobile application for the purpose and has applied for provision of online sale by depositing such fee as mentioned under sub-rule (2) of rule 18. The licensee in such case may deliver drugs and Therapeutic goods by himself or through a licensed service provider to patient or consumer as per the requirements of good storage and distribution practice as mentioned in the Schedule-G and record of the same shall be maintained;

(h) display of registration certificate of the qualified person in original along with drugs and Therapeutic goods sale license in a conspicuous place of the premises at appropriate level, open and visible to the public;

(i) licensee shall purchase drugs and Therapeutic goods from manufacturer or importer having a valid license under the Act or enlistment certificate issued by the Federal Government or through authorized agent, wholesaler or distributor subject to clause (d) of sub-rule (4);

(j) a manufacturer, importer or distributor shall sell the drugs and Therapeutic goods only to holder of a valid drugs and Therapeutic goods sale license or registered prescriber concerned in accordance with rule 27 and shall issue an invoice and warranty in accordance with rule 26 at the time of sale of the drugs and Therapeutic goods;

(k) drugs and Therapeutic goods mentioned in the Schedule-B and Schedule-D and a preparation containing such drugs and Therapeutic goods and those categorized as poisons shall not be sold except on and in accordance with the prescription of a prescriber subject to rule 26;

(l) tangible record including manual or electronic, of all supplies, invoices, bills, warranties, registers, dispensing, compounding and prescription, where applicable, shall be kept for one year after the expiry of the drugs and Therapeutic goods or as specified by the licensing authority;

(m) inventory management, prescription's dispensing and their record shall be kept electronically as specified by the licensing authority;

(n) a drug and Therapeutic good mentioned in the Schedule-H may be sold by way of retail sale without prescription;

(o) drugs and Therapeutic goods may be sold with their generic name in the Pharmacy in presence of the Pharmacist. The Pharmacist shall declare or display a list of available registered brands having same generic formulation to the patient or consumer along with its price who may select any alternate brand subject to giving a consent in writing. The licensee shall keep record of such consent along with the original prescription in case of the drugs and

Therapeutic goods mentioned in the Schedule-B and Schedule-D;

(p) licensee shall stop the sale or distribution and collect back the stock of a drug and Therapeutic good for which a recall has been notified by the Provincial Board or respective manufacturer or his authorized agent and provide all the relevant record to the Provincial Board under intimation to the licensing authority;

(q) licensee shall comply with the requirements of the Pharmacovigilance Rules, 2022 and report any problem or adverse drug reaction observed with drugs and Therapeutic goods through a channel specified by the licensing authority;

(r) a drug and Therapeutic good categorized as poison and the drugs and Therapeutic goods mentioned in the Schedule-B and Schedule-D shall be stored in part of the premises to which customers do not have direct access. In case of the drugs and Therapeutic goods mentioned in the Schedule-B or those categorized as poisons shall be stored in a cupboard or almirah or drawer reserved solely for the storage of such substance or drug and Therapeutic good;

(s) Pharmacist shall provide pharmacy services on the license issued under the rules;

(t) licensee shall obtain services, if required, related to the drugs and Therapeutic goods only by a licensed service provider under the rules;

(u) licensee shall ensure storage of the drugs and Therapeutic goods completely segregated from other items, if so stored;

(v) licensee shall, in no case, store, sell or exhibit for sale any item including but not limited to tobacco products which are injurious to health; and

(w) premises and all its godowns shall be uniquely identified and the applicant shall provide geocoordinates of all such locations.

(2) **Conditions for license of the Pharmacy (Form-09)**: In case of a license of the Pharmacy, the following requirements, in addition to the conditions mentioned under sub-rule (1), shall be applicable:

(a) display the word "Pharmacy" in front of the premises in white writing on a green colored background signboard of at least 5 feet length and 2.5 feet width;

(b) subject to clause (a) of sub-rule (1) of rule 19, a Pharmacist shall be engaged as an employee by the proprietor who shall personally supervise the sale of drugs and Therapeutic goods;

(c) minimum covered area of the premises shall be 150 squares feet with minimum width of 10 feet;

(d) in the case of a license of the Pharmacy in which compounding of drugs and Therapeutic goods is undertaken, the premises has fulfilled the requirements as mentioned in the Schedule-E; and

(e) Pharmacist shall provide pharmacy services subject to the guidelines issued by the licensing authority.

(3) **Conditions for license of the Medical Store (Form-10)**: In case of a license of the Medical Store, the following requirements, in addition to the conditions mentioned under sub-rule (1), shall be applicable:

(a) display the word "Medical Store" in front of the premises in white writing on a red colored background signboard of at least 5 feet length and 2.5 feet width;

(b) subject to clause (b) of sub-rule (1) of rule 19, a qualified person shall be engaged as an employee by the proprietor who shall personally supervise the sale of drugs and Therapeutic goods;

(c) minimum covered area of the premises shall be 96 square feet with a minimum front of 8 feet; and

(d) a licensee of the Medical Store shall not sell or store drugs and Therapeutic goods as mentioned in the Schedule-F.

(4) **Conditions for license of the distributor (Form-11)**: In case of a license of the distributor, the following requirements, in addition to the conditions mentioned under sub-rule (1), shall be applicable:

(a) display the word "Distributor" in front of the premises in black writing on a Yellow-colored background signboard of at least 5 feet length and 2.5 feet width;

(b) subject to clause (a) of sub-rule (1) of rule 19, a Pharmacist shall be engaged as an employee by the proprietor who shall personally supervise the sale of drugs and Therapeutic goods;

(c) minimum covered area of the warehouse shall be 500 square feet with a minimum front of 8 feet;

(d) distributor or wholesaler having license in the Form-11 shall sell the drugs and Therapeutic goods to other wholesaler or distributor having license in the Form-11 subject to valid authorization;

(e) availability of computerized facility ensuring maintenance of a proper computerized system of inventory control for sale and purchase of the drugs and Therapeutic goods; and

(f) distributor may sell the selected drugs and Therapeutic goods by way of retail sale with the permission of licensing authority.

(5) **Conditions for license of the Alternative Medicine Store (Form-12)**: In case of a license of the Alternative Medicine Store, the following requirements, in addition to the conditions mentioned under sub-rule (1), shall be applicable:

(a) display the word "Alternative Medicine Store" in front of the premises in white writing on a Blue-colored background signboard of at least 5 feet length and 2.5 feet width;

(b) subject to clause (d) of sub-rule (1) of rule 19, a Pharmacist shall be engaged as an employee by the proprietor who shall personally supervise the sale of Alternative Medicine Store; and

(c) minimum covered area of the premises shall be 96 square feet with minimum width of 8 feet.

(6) **Conditions for license of the Medical Device Store (Form-13)**: In case of a license of the Medical Device Store, the following requirements, in addition to the conditions mentioned under sub-rule (1), shall be applicable:

(a) display the word "Medical Device Store" in front of the premises in white writing on a Purple-colored signboard of at least 5 feet length and 2.5 feet width;

(b) subject to clause (c) of sub-rule (1) of rule 19, a qualified person shall be engaged as an employee by the proprietor who shall personally supervise the sale of Medical Devices;

(c) minimum covered area of the premises shall be 200 square feet with minimum width of 8 feet; and

(d) availability of computerized facility ensuring maintenance of a proper computerized system of inventory control for the sale and purchase of Medical Devices.

(7) **Conditions for license of the Government Drugs and**

Therapeutic Goods Store (Form-14): In case of a license of the Government Drugs and Therapeutic Goods Store, the following requirements, in addition to the conditions mentioned under sub-rule (1), shall be applicable:

(a) Medical Superintendent or in-charge of the Government health facility or warehouse shall act as proprietor (*ex-officio*) for the purpose of license;

(b) officer in-charge (Pharmacist) of the Government health facility, nominated by the Medical Superintendent, shall act as qualified person (*ex-officio*) for the purpose of license;

(c) licensee providing dispensing facility shall fulfill the requirements mentioned in the Schedule-E;

(d) licensee shall maintain record according to policy of the Government;

(e) availability of computerized facility ensuring maintenance of a proper computerized system of inventory control for the purchase and distribution of drugs and Therapeutic goods; and

(f) Pharmacist shall provide pharmacy services subject to the guidelines issued by the licensing authority.

(8) **Conditions for license of the service provider (Form-15)**: In case of a license of the service provider, the following requirements, in addition to the conditions mentioned under sub-rule (1), shall be applicable:

(a) applicant is a licensee in the Form-9 or company or firm;

(b) applicant has a registered office premises in the Punjab;

(c) requirements of good storage and distribution practice mentioned in the Schedule-G has been fulfilled for storage of drugs and Therapeutic goods;

(d) in case of storage of drugs and Therapeutic goods, where the applicant is company or firm:

(i) the premises is as per the conditions mentioned under clause (a) and (b) of sub-rule (1);

(ii) the covered area of the premises is such as specified for a Pharmacy under clause (c) of sub-rule (2); and

(iii) subject to sub-rule (1) of rule 19, a qualified person as mentioned under clause (b) of sub-

rule (2) shall personally supervise the storage of the drugs and Therapeutic goods; and

(e) services shall only be provided to the licensee.

24. Cancellation or suspension of the license.- (1) The licensing authority may, after giving the licensee an opportunity of hearing and by an order in writing stating the reasons, cancel or suspend a license for such period as he deems fit, if in his opinion the licensee has failed to comply with any of the provisions of the Act, DRAP Act, rules, conditions of the license or guidelines issued by the licensing authority.

(2) In case of a license of the Government Drugs and Therapeutic Goods Store, the licensing authority, upon identification of violation of the rules, shall seek approval of Secretary of the Administrative Department regarding any action to be taken including cancellation or suspension of such license.

25. 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 such order or date of cancellation of the license.

(2) The Secretary of the Administrative Department shall be the Provincial Appellate Authority for the disposal of appeals preferred under sub-rule (1).

(3) The Provincial Appellate Authority may direct an officer or official of the Administrative Department to assist the Authority.

(4) The Provincial Appellate Authority shall, after giving the appellant an opportunity of hearing, pass such order as he deems fit and the order of the Provincial Appellate Authority shall be final.

26. Requirements for prescription and record.- The purchase and sale of drugs and Therapeutic Goods shall be recorded suitably keeping in view the following requirements:

(a) a prescription shall be issued by a prescriber. Electronic prescription shall be uniquely issued and bear a unique identification code. In case of the drugs and Therapeutic goods mentioned in the Schedule-B and Schedule-D and those categorized as poisons, each prescription shall be dispensed only once, or otherwise a record of re-fills shall be maintained till the duration of complete treatment. Original prescription shall be retained by the licensee;

(b) sale of the drugs and Therapeutic goods mentioned in the Schedule-B and Schedule-D and those categorized as poisons shall be recorded at the time of supply in a register, manually or electronically, specially maintained for the purpose and the serial number of entry in the register shall be entered in

the prescription. The following particulars shall be entered in the register:

(i) serial number;

(ii) batch number;

(iii) date of sale;

(iv) name of the prescriber;

(v) name of the patient;

(vi) name of the drugs and Therapeutic goods;

(vii) name of the manufacturer;

(viii) quantity sold;

(ix) quantity purchased and balance; and

(x) signature of the qualified person;

(c) for the purpose of this rule, a prescription shall include:

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

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

(iii) indication of the total quantity of the drugs and Therapeutic goods mentioned as generic name and suggested brand, if any, to be supplied, dose to be taken, frequency of dosing and duration of treatment;

(d) 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, issued manually or electronically. An invoice and warranty of the Alternative Medicine, health and over-the-counter non-prescription products and Medical Devices shall be issued under the relevant rules framed under the DRAP Act;

(e) each invoice and warranty shall be issued once and bear a unique identification and shall be verifiable electronically;

(f) except otherwise specified by the licensing authority, record of purchase or sale of a drug and Therapeutic good shall be preserved by the manufacturer, importer or licensee for a period of one year after the expiry of such drug and Therapeutic good containing the following particulars:

(i) date of purchase or sale;

(ii) name of the drug and Therapeutic good specifying its batch number, date of expiry and quantity;

(iii) name of the manufacturer;

(iv) name and address of the concerned from whom the drug and Therapeutic good is purchased; and

(v) the name and address of the concerned to whom the drug and Therapeutic good is sold;

(g) licensee shall, on demand, produce a register or record maintained under the rules for inspection by the Inspector and shall supply to the Inspector such information as he may require;

(h) in case of online sale, the licensee shall provide monthly report of purchase and sale of the drugs and Therapeutic goods to the licensing authority and Inspector concerned; and

(i) in case of sale of the drugs and Therapeutic goods to a registered prescriber, the manufacturer, importer, distributor or seller of such drugs and Therapeutic goods shall maintain the copies of the record in duplicate including the invoice and warranty and produce to the Inspector, when required. The Electronic record shall also be maintained for a period of one year after expiry of the drugs and Therapeutic goods.

27. Conditions for registered prescriber.- The registered prescriber is exempted from the requirements of obtaining license under the rules subject to following conditions:

(a) registered prescriber shall have registration under the Punjab Healthcare Commission Act 2010 (XVI of 2010);

(b) registered prescribers shall be allowed to purchase and dispense drugs and Therapeutic goods to their own patients only in their respective discipline;

(c) compliance of relevant provisions of the rules;

(d) no sale of the drugs and Therapeutic goods shall be allowed except in accordance with the provisions of the rules; and

(e) subject to clause (a), no registered prescriber shall purchase any drug and Therapeutic good unless he provides a copy of valid registration certificate duly issued by his council and Computerized National

Identity Card to the licensing authority and manufacturer, importer or authorized agent.

28. Pharmacovigilance.- The licensee shall:

(a) comply with the pharmacovigilance activities to fulfill the legal obligations as defined in the Pharmacovigilance Rules, 2022 and the relevant guidelines;

(b) collect the pharmacovigilance data and submit to provincial or national center through website; and

(c) prepare and maintain the record of pharmacovigilance reports.

29. Provincial Pharmacovigilance Committee.- (1) Subject to sub-rule (3) of rule 5 of the Pharmacovigilance Rules, 2022 the Administrative Department shall constitute a Provincial Pharmacovigilance Committee consisting of the following:

(a)	Director General, Directorate of Drugs Control, Punjab	Convener
(b)	Director (Pharmacy & Pharmacovigilance), Directorate of Drugs Control, Punjab	Member/ Secretary
(c)	one representative from Drugs Control Wing of the Government, Health and Population Department	Member
(d)	one representative of the Director General Health Services, Punjab	Member
(e)	one representative of the Chief Drugs Controller Office, Punjab, Directorate of Drugs Control, Punjab	Member
(f)	one expert of pharmacology preferably professor of pharmacology	Member
(g)	two physicians preferably professor of medicine	Members
(h)	one physician preferably professor of cardiology	Member
(i)	one pediatric physician preferably professor of pediatric medicine	Member
(j)	one surgeon preferably professor of surgery	Member
(k)	one expert of clinical pharmacy or clinical pharmacist	Member
(l)	any other co-opted member	Member.

(2) The members from clauses (f) to (j) of sub-rule (1) shall be appointed from those who have ten years' experience in the relevant field.

(3) The member at clause (k) of sub-rule (1) shall be appointed from those who have ten years' experience in a private sector hospital.

(4) The members from clauses (f) to (k) shall be appointed by the Administrative Department for a period of five years.

(5) The quorum for meeting of the Provincial Pharmacovigilance Committee shall be six members.

(6) The Provincial Pharmacovigilance Committee shall evaluate data of adverse reactions with the use of drugs and Therapeutic goods, causality assessment and signal detection and work in coordination with the Federal and Provincial regulatory bodies related to pharmacovigilance.

(7) The Provincial Pharmacovigilance Committee may recommend action for risk mitigation and refer to the Federal Government, Provincial Board, District Board concerned, Chief Drugs Controller, Punjab or prescribers.

30. Repeal.- The Punjab Drugs Rules, 2007 are hereby repealed.

SCHEDULE A

FORM-1
See rule 10(1)
Monthly report of Drug Inspector

For the Month of _____, Date of Reporting_____

1	2	3	4	5	6
No of the Total Premises inspected	No. of Premises sealed	No. of FIRs Registered	No. of total Samples Taken	No. of Samples Declared Spurious	No. of Samples in which Allopathic ingredients found
7	**8**	**9**	**10**	**11**	**12**
No. of Samples declared Substandard	No. of Samples Declared Misbranded or/and adulterated	No. of Cases Sent to DQCB	No. of Cases sent to PQCB	No. of Cases Under Investigation or Pending with DI	No. of Permission for Prosecution received from DQCB
13	**14**	**15**	**16**	**17**	**18**
No. of Permission for Prosecution received from PQCB	No. of Cases launched in Drug Court	No. of Cases Decided by Drug Court	No. of Cases acquitted by Drug Court	Total Fine Imposed	Details of Imprisonment

Drug Inspector _____ Area_____
Counter signed by Drug Controller/Chief Drug Controller _____

FORM-2
See rule 10(1)
Monthly Report of Government Analyst

For the Month of _____, Date of reporting_____

1	2	3	4	5	6	7
No of total Samples pending at the end of last month	No. of total samples received in the current month	No. of samples received from the market surveillance	No. of samples received from Govt. Supply/ Hospitals	No. of total Samples reported	No. of samples pending from more than 30 days	No. of Samples pending from more than 60 days
8	9	10	11	12	13	14
No. of Samples in which Allopathic ingredients found	No. of Samples declared Substandard	No. of Samples declared Misbranded	No. of samples declared spurious	No. of samples declared adulterated	No. of total samples declared Out of Specification (8+9+10+11+12)	No. of Total Samples Declared of Standard Quality
15	16	17	18	19		
No. of Cases filed due to any reason	No. of method of analysis not responding	No. of cases of non-provision of method referred to PQCB	No. of Samples analyzed by approved methods	Total pending samples at the end of month		

Government Analyst _____, QMS Manager_____, Director DTL _____

Book No._____
Serial No._____

FORM-3
See rule 12(1)(d)
Form of order not to dispose of stock

Whereas I have reason to believe that the stock of therapeutic goods, 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 the stock of therapeutic goods

Date..... Inspector.....

Book No._____
Serial No._____

FORM-4
See rule 12(1)(e)
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 therapeutic goods specified below for the purpose of test/analysis.

Date..... Inspector.....

Temperature..... Humidity.....

Details of samples taken

Brand Name of Therapeutic Goods	Generic Name of Therapeutic Goods	Name of the Manufacturer	Registration/ Enlistment No.	Batch No.	Mfg. Date	Expiry Date	Warranty/ Bill No. & Date	Quantity

Reason of sampling _____

Date..... Inspector.....

Acknowledgement of person from whom sample was taken

Book No._____
Serial No._____

Form-5A
See rule 12(1)(e)
Receipt for stock of therapeutic goods and other material articles seized

The stock of therapeutic goods /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 Drug Act 1976 as amended, and Schedule-V of the DRAP Act 2012, from the premises of.....
Situated at .....

Date..... Inspector.....

Details of therapeutic goods, other material and articles seized including;

Sr. No	Name of therapeutic goods or items	Generic Name of therapeutic goods or items (if applicable)	Batch/Lot No.	Name of manufacturer/Importer	Quantity	Reason for seizure

Date..... Inspector.....
Statement of person from whom stock is seized:

Book No._____
Serial No._____

FORM-5B
See rule 12(1)(f)
SEALING ORDER

In exercise of powers conferred upon me under section 18(1)(h) of the Drugs Act, 1976 and Schedule-VI of the DRAP Act, 2012 I, _____ Drug Inspector,
_____ hereby locked and sealed the premises of _____ M/S_____ Situated at _____ Wherein drugs/therapeutic goods/materials/articles are being sold/ manufactured for sale, stored for sale in violation of provision of section _____ of the Drugs Act, 1976 and Schedule-V of the DRAP Act, 2012.

Dated _____ Inspector _____

Custody of Key:

After sealing the premises, key(s) of the locks were handed over to
_____
_____ for safe custody. Further, owner of premises/person present undertakes that there is no Jewellery, Cash, Amount and any other valuables in the sealed premises.

Signature of Licensee/Qualified Person/Technical Person or Person present

Witnesses:

1..... 2.....

FORM-6
See rule 12(1)(g)
MEMORANDUM TO GOVERNMENT ANALYST

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 and the Schedule-V of the DRAP Act 2012.
The portion of sample/container has been marked by me with the following marks.

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

Details / Particulars of portion of sample/container is as under:

Brand Name of Therapeutic Good	Generic Name of Therapeutic Good	Tests to be performed	Name of Manufacturer	Registration/ Enlistment No.	Batch / Lot No.	Mfg. date	Exp. date	Quantity

Dated .....

Inspector.....

FORM-7
see rule (13)(1)(a)
Report of test/analysis by Government Analyst, Punjab

1. Name of Inspector from whom received .....

2. Serial Number and date of Inspectors memorandum .....

3. Date of receipt.....

4. Name of Therapeutic Good purporting to be contained in the sample .....

5. The condition of the seals.....
6. Mark with impression of seal.....

7. Result of test/analysis with specifications applied .....
8. Details of result of test/analysis.....

In the opinion of the undersigned, the sample referred to above is of standard quality as defined in the Drugs Act 1976 read with Schedule III of the DRAP Act, 2012 and rules framed thereunder and rules there-under;

Is adulterated/substandard/misbranded/spurious, as defined in the Drugs Act 1976 read with Schedule III of the DRAP Act, 2012 and rules framed thereunder for the reason given above.
(Please score out which is not applicable)

No. TRA...../DTL. Dated .....

1. The Inspector .....

2. The Chairman, Provincial Quality Control Board, Government of the Punjab.

Government Analyst

{Photographs of the Proprietor(s)} **{Photograph of Qualified person}**

FORM-8(A)

{See rule 18 (1)}

Application for the license to sell, store and exhibit for sale of drugs or therapeutic goods by way of pharmacy.

1. I / We _____
of M/S _____
situated at _____along with **Godown (s)**_____
hereby apply for;

- ☐ New License
- ☐ Renewal of License
- ☐ Online Sale
- ☐ Dispensing /Compounding Services
- ☐ Change in License, Description ----------

2. The sale of therapeutic goods will be made in the **presence** of Qualified person (Pharmacist) registered under section 24 (1) (a) (in register A only) of Pharmacy Act, 1967; (name, registration No., CNIC No. & address with qualification).

_____

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

A) Testimonials of the Qualified person / Pharmacist, who has agreed to supervise the sale of therapeutic goods for license in Form 9 (pharmacy).

i) Copy of Certificate of registration "A" issued by a pharmacy council.

ii) Copy of CNIC of Pharmacist

iii) Duly verified affidavit of the Pharmacist on judicial stamp paper, as prescribed by the licensing authority in its guidelines.

B) Testimonials of the proprietor (s).

i) Copies of CNIC of the proprietor (s)

ii) Duly verified affidavit of the proprietor (s) on judicial stamp paper, as prescribed by the licensing authority in its guidelines.

C) Site Plan indicating the exact location and dully attested rent deed or property ownership documents of the premises.

D) Website/web app address for online sale (if applicable).

E) Treasury receipt / challan No & dated ---------- amounting to Rs. ---------- in the Account as prescribed by the Licensing Authority.

Date of submission of application: _____

Signature and thumb impression
{Name and address} of proprietor(s)

Signature and thumb impression
{Name and address} of *Qualified Person*

Note: The Licensing Authority may require any additional information or documents as part of the application of the license.

{Photographs of the Proprietor(s)} **{Photograph of Qualified Person}**

FORM-8(B)

{See rule 18 (1)}

Application for the license to sell, store and exhibit for sale of drugs or therapeutic goods by way of Medical store

1. I / We _____
of M/S _____
situated at _____along with **Godown (s)**_____
hereby apply for;

- ☐ New License
- ☐ Renewal of License
- ☐ Online Sale
- ☐ Change in License, Description ----------

2. The sale of therapeutic goods will be under the presence of pharmacist or Pharmacy Technician / Pharmacy assistant (register in Register "B" only); (name, registration No, CNIC No & address with qualification), as the case may be.

_____

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

A) Testimonials of the Pharmacist or Pharmacy Technician / Pharmacy assistant (only), who has agreed to remain present during the sale of therapeutic goods for license in Form 10 (Medical Store).

i) Copy of Certificate of registration 'A' or 'B" issued by pharmacy council.

ii) Copies of CNIC of Qualified Person

iii Duly verified affidavit of the Qualified Person on judicial stamp paper, as prescribed by the licensing authority in its guidelines.

B) Testimonials of the proprietor (s).

i) Copies of CNIC of the proprietor (s)

ii) Duly verified affidavit of the proprietor (s) on judicial stamp paper, as prescribed by the licensing authority in its guidelines.

C) Site Plan indicating the exact location and dully attested rent deed or property ownership documents of the premises.

D) Website/Web app address for online sale (if applicable).

E) Treasury receipt / challan No & dated ---------- amounting to Rs. ---------- in the Account as prescribed by the Licensing Authority.

Dated of submission of application: _____

Signature and thumb impression
{Name and address} of proprietor(s)

Signature and thumb impression
{Name and address} of *Qualified Person*

Note: The Licensing Authority may require any additional information or documents as part of the application of the license.

{Photographs of the Proprietor(s)} **{Photograph of Qualified Person}**

FORM-8(C)

{See rule 18 (1)}

Application for the license to sell, store and exhibit to distribute drugs or therapeutic goods by way of Distribution

1. I / We _____
of M/S _____
situated at _____
along with **Godown (s)** _____
hereby apply for;

☐ New License

☐ Renewal of License

☐ Change in License, Description ----------

2. The sale of therapeutic goods shall be made in the presence of Pharmacist registered under section 24 (1) (a) of The Pharmacy Act, 1967. (in register A only); (name, registration No, CNIC No & address with qualification).

_____

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

A) Testimonials of the Pharmacists (s), registered under section 24(1)(a) of the Pharmacy Act 1967, who has agreed to remain present during the sale of therapeutic goods for license in Form 11 (Distributor).

i) Original and one copy of Certificate of registration "A" issued by a pharmacy council.

ii) Copies of CNIC of Qualified Person (s).

iii) Duly verified affidavit of the Qualified Person on judicial stamp paper, as prescribed by the licensing authority in its guidelines.

B) Testimonials of the proprietor (s).

i) Copies of CNIC of the proprietor (s)

ii) Duly verified affidavit of the Propreitor on judicial stamp paper, as prescribed by the licensing authority in its guidelines.

C) Site Plan indicating the exact location and dully attested rent deed or property ownership documents of the premises.

F) Treasury receipt / challan No & dated ---------- amounting to Rs. ---------- in the Account as prescribed by the Licensing Authority.

Dated of submission of application: _____

Signature and thumb impression
{Name and address} of proprietor(s)

Signature and thumb impression
{Name and address} of *Qualified Person*

Note: The Licensing Authority may require any additional information or documents as part of the application of the license.

{Photographs of the Proprietor(s)} **{Photograph of Qualified Person}**

FORM-8(D)

{See rule 18 (1)}

Application for the license to sell, store and exhibit for sale of Alternative Medicine Store

1. I / We _____
of M/S _____
situated at _____
hereby apply for;

- ☐ New License
- ☐ Renewal of License
- ☐ Online Sale
- ☐ Change in License, Description ----------

2. The sale of Alternative Medicines will be under the personal supervision of Pharmacist registered under section 24 (1) (a) of The Pharmacy Act, 1967. (in register A only); (name, registration No, CNIC No & address with qualification).

_____

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

A)Testimonials of the Qualified Person, who has agreed to personally supervise the sale of alternative medicines for license in Form 12.

i)Copy of registration certificate of Qualified Person issued by a pharmacy council.

ii) Copy CNIC of Qualified Person.

iii) Duly verified affidavit of the Qualified Person on judicial stamp paper, as prescribed by the licensing authority in its guidelines.

B) Testimonials of the Proprietor(s).

i) Copy CNIC of Proprietor(s).

ii) Duly verified affidavit of the Proprietor(s) on judicial stamp paper, as prescribed by the licensing authority in its guidelines.

C) Site Plan indicating the exact location and dully attested rent deed or property ownership documents of the premises.

D) Website address for online sale (if applicable).

E) Treasury receipt / challan No & dated ------- amounting to Rs. ------- in the Account as prescribed by the Licensing Authority.

Date of Submission: _____

Signature and thumb impression
{Name and address} of proprietor(s)

Signature and thumb impression
{Name and address} of *Qualified Person*

Note: The Licensing Authority may require any additional information or documents as part of the application of the license.

{Photographs of the Proprietor(s)} **{Photograph of Qualified Person}**

FORM-8(E)

{See rule 18 (1)}

Application for the license to sell, store and exhibit for sale of Medical Devices by way of Medical Device Store

1. I / We _____
of M/S _____
situated at _____ _____
hereby apply for;

- ☐ New License
- ☐ Renewal of License
- ☐ Online Sale
- ☐ Change in License, Description ----------

2. The sale of Medical Devices will be under the personal supervision of Pharmacist registered under section 24 (1) (a) of The Pharmacy Act, 1967. (in register A only) or Biomedical Engineer registererd with Pakistan Engineering Council; (name, registration No, CNIC No & address with qualification). _____

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

A)Testimonials of the Qualified Person who has agreed to personally supervise the sale of medical devices for license in Form 13.

i) Copy of registration certificate issued by a pharmacy council and/or Pakistan Engineering Council.

ii) Copy CNIC of Qualified Person.

iii) Duly verified affidavit of the Qualified Person on judicial stamp paper, as prescribed by the licensing authority in its guidelines.

B) Testimonials of the Proprietor(s).

i) Copy CNIC of Proprietor(s).

ii) Duly verified affidavit of the Proprietor(s) on judicial stamp paper, as prescribed by the licensing authority in its guidelines.

C) Site Plan indicating the exact location and dully attested rent deed or property ownership documents of the premises.

D) Website address for online sale (if applicable).

E) Treasury receipt / challan No & dated ------- amounting to Rs. ------- in the Account as prescribed by the Licensing Authority.

Date of Submission: _____

Signature and thumb impression
{Name and address} of proprietor(s)

Signature and thumb impression
{Name and address} of *Qualified Person*

Note: The Licensing Authority may require any additional information or documents as part of the application of the license

{Photographs of the Proprietor(s)} **{Photograph of Qualified Person}**

FORM-8(F)

{See rule 18 (1)}

Application for the license of Government Drugs or Therapeutic Goods Store

1. I / We _____
of (Name of Public Health Facility) _____
situated at _____ _____
hereby apply for;

☐ New License

☐ Renewal of License

☐ Change in License, Description ----------

2. The stocking, storing, distribution & dispensing of Medical Devices will be under the personal supervision of Pharmacist registered under section 24 (1) (a) of The Pharmacy Act, 1967. (in register A only); (name, registration No, CNIC No & address with qualification). _____

3. I / We/ am are submitting herewith the following documents;
A)Testimonials of the Qualified Person (ex-officio).
i) Copy of registration certificate issued by a pharmacy council.
ii) Copy CNIC of Qualified Person.
iii) Duly verified affidavit of the Qualified Person on judicial stamp paper, as prescribed by the licensing authority in its guidelines.
B) Testimonials of the Proprietor (ex-officio).
i) Copy CNIC of Proprietor.
ii) Duly verified affidavit of the Proprietor(s) on judicial stamp paper, as prescribed by the licensing authority in its guidelines.
C) Site Plan indicating the exact location and specification of the premises.
Date of Submission: _____

Signature and thumb impression
{Name and address} of proprietor(s)

Signature and thumb impression
{Name and address} of *Qualified Person*

Note: The Licensing Authority may require any additional information or documents as part of the application of the license

{Photographs of the Proprietor(s)} {Photograph of Qualified Person (if applicable)}

FORM-8(G)

{See rule 18 (1)}

Application for the license of Service Provider

1. I / We _____
of M/S _____
situated at _____ _____
hereby apply for;

- ☐ New License
- ☐ Renewal of License
- ☐ Change in License, Description ----------

for the services enlisted below;

- ☐ Storage Services
- ☐ Transportation Services
- ☐ Storage and Transportation Services

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

A) Testimonials of the Qualified Person (if applicable).

i) Copy of registration certificate issued by a pharmacy council (if applicable).

ii) Copy CNIC of Qualified Person (if applicable).

iii) Duly verified affidavit of the Qualified Person on judicial stamp paper, as prescribed by the licensing authority in its guidelines (if applicable).

B) Testimonials of the Proprietor (s).

i) Copy CNIC of Proprietor (s).

ii) Duly verified affidavit of the Proprietor(s) on judicial stamp paper, as prescribed by the licensing authority in its guidelines.

C) Site Plan indicating the exact location dully attested rent deed or property ownership documents of the premises.

D) Treasury receipt / challan No & dated ------- amounting to Rs. ------- in the Account as prescribed by the Licensing Authority.

Date of Submission: _____

Signature and thumb impression
{Name and address} of proprietor(s)

Signature and thumb impression
{Name and address} of *Qualified Person*

Note: The Licensing Authority may require any additional information or documents as part of the application of the license

FORM-9
See rule 20(1)
License to stock, exhibit for sale or sell drugs or Therapeutic Goods in a Pharmacy by way of retail sale

License No: _____
Valid up to: _____

2D QR CODE

1.M/S._____ is hereby licensed to sell on prescription, exhibit for sale / compound or dispense or prepare on prescription the therapeutic goods and sell all types of registered therapeutic goods on the premises situated at _____

Tehsil/ Town _____, District _____, Geo-Coordinates _____ and is authorized to sell such therapeutic goods as below:

Online Sale: Permitted/Not Permitted	**Dispensing/Compounding:** Permitted/Not Permitted

subject to the conditions specified in the provisions of the Drugs Act, 1976/ the DRAP ACT, 2012 and the rules framed there under.

Photographs of the Proprietor(s)
Photograph of Qualified Person (s)

2. Name of proprietor(s) along with residential address and CNIC
_____

3. Name(s) of the pharmacist (s) who will remain present and supervise the sale of therapeutic goods along with registration number, residential address and CNIC
_____

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

5. In case of online sale, URL address of website/Web app is _____

Dated_____ **Licensing Authority**

Map of Premises

Drug Sale License History

Dated_____ **Licensing Authority**

(This License is Computer-generated)

FORM-10

See rule 20(1)

License to stock, exhibit for sale or sell all drugs or therapeutic goods excluding drugs or therapeutic goods specified in Schedule-G, in a Medical Store by way of retail sale

License No: _____

Valid up to: _____

2D QR CODE

1.M/S._____ is hereby licensed to sell on prescription, stock and exhibit for sale the therapeutic goods excluding those specified in Schedule G and sell the registered therapeutic goods excluding those specified in Schedule G on the premises situated at _____ _____,Tehsil/ Town _____, District _____, Geo-Coordinates _____ and is authorized to sell such therapeutic goods as below:

Online Sale: Permitted/Not Permitted

subject to the conditions specified in the provisions of the Drugs Act, 1976/ the DRAP ACT, 2012 and the rules framed there under.

Photographs of the Proprietor(s)
Photograph of Qualified Person (s)

2. Name of proprietor(s) along with residential address and CNIC _____

3. Name(s) of the pharmacist (s)/ Pharmacy Technician/ Pharmacy Assistant who will remain present and supervise the sale of therapeutic goods along with registration number, residential address and CNIC _____

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

5. In case of online sale, URL address of website/Web app is _____

Dated_____ **Licensing Authority**

Map of Premises

Drug Sale License History

Dated_____ **Licensing Authority**

(This License is Computer-generated)

FORM-11
See rule 20(1)
License to stock, exhibit for sale or sell and Distribute all drugs or therapeutic goods except medical devices as a Distributor

License No: _____
Valid up to: _____

2D QR CODE

1.M/S._____ is hereby licensed to sell, stock, distribute & exhibit for sale all types of registered/ enlisted therapeutic goods except medical devices on premises situated at _____,Tehsil/ Town _____, District _____, Geo-Coordinates _____
subject to the conditions specified in the provisions of the Drugs Act, 1976/ the DRAP ACT, 2012 and the rules framed there under.

Photographs of the Proprietor(s)
Photograph of Qualified Person (s)

2. Name of proprietor(s) along with residential address and CNIC
_____

3. Name(s) of the pharmacist (s) who will remain present and supervise the sale of therapeutic goods along with registration number, residential address and CNIC
_____

4. Address(s) of go-down(s), if any, where the therapeutic goods will be stored_____

Dated_____ **Licensing Authority**

Map of Premises

Drug Sale License History

Dated_____ **Licensing Authority**

(This License is Computer-generated)

FORM-12
See rule 20(1)
License to sell, Stock, Exhibit for Sale and Distribute Alternative Medicines and Health Products by way of retail sale only

License No: _____
Valid up to: _____

2D QR CODE

1.M/S._____ Along with address(s) of go-down(s)_____ is hereby licensed to sell, stock, exhibit for sale the Alternative Medicines and Health Products and sale on the premises situated at_____, Geo-Coordinates _____ and is authorized to sell such alternative medicines as below:

Online Sale: Permitted/Not Permitted

subject to the conditions specified in the provisions of the Drugs Act, 1976/ the DRAP ACT, 2012 and the rules framed there under.

Photographs of the Proprietor(s)
Photograph of Qualified Person (s)

2. Name of proprietor(s) along with residential address and CNIC
_____

3. Name(s) of the Qualified Person (s) who will remain present and supervise the sale of therapeutic goods along with registration number, residential address and CNIC
_____

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

5. In case of online sale, URL address of website/web app is_____

Dated_____ **Licensing Authority**

Map of Premises

Drug Sale License History

Dated_____ **Licensing Authority**

(This License is Computer-generated)

FORM-13
See rule 20(1)
License to stock, exhibit for sale or sell and Distribute Medical Devices

License No: _____
Valid up to: _____

2D QR CODE

1.M/S._____ is hereby licensed to sell, stock, distribute & exhibit for sale all types of registered/ enlisted medical devices of the Medical Device Rules 2017, on premises situated at _____,Tehsil/ Town _____, District _____, Geo-Coordinates _____ and is authorized to sell such medical devices as below:

Online Sale: Permitted/Not Permitted

subject to the conditions specified in the provisions of the Drugs Act, 1976/ the DRAP ACT, 2012 and the rules framed there under.

Photographs of the Proprietor(s)
Photograph of Qualified Person (s)

2. Name of proprietor(s) along with residential address and CNIC
_____

3. Name(s) of the Qualified Person (s) who will remain present and supervise the sale of medical devices along with registration number, residential address and CNIC
_____

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

5. In case of online sale, URL address of website/web app is _____

Dated_____ **Licensing Authority**

Map of Premises

Drug Sale License History

Dated_____ **Licensing Authority**

(This License is Computer-generated)

FORM-14
See rule 20(1)
License to stock, store, compound or distribute drugs or Therapeutic Goods in a Government Drugs or Therapeutic Good Store

License No: _____
Valid up to: _____

2D QR CODE

1._____ is hereby licensed to stock, store or dispense or prepare or distribute the therapeutic goods, on the premises situated at _____,Tehsil/ Town _____, District _____, Geo-Coordinates _____
subject to the conditions specified in the provisions of the Drugs Act, 1976/ the DRAP ACT, 2012 and the rules framed there under.

Photographs of the Proprietor(s)
Photograph of Qualified Person (s)

2. Name of proprietor(s) along with residential address and CNIC
_____

3. Name(s) of the pharmacist (s) who will remain present and supervise the sale of therapeutic goods along with registration number, residential address and CNIC
_____

4. Details of sub-store(s), if any, where the therapeutic goods will be stored-
_____

Dated_____ **Licensing Authority**

Map of Premises

Drug Sale License History

Dated_____ **Licensing Authority**

(This License is Computer-generated)

FORM-15
See rule 20(1)
License to provide services related to Drugs or Therapeutic Goods as a Service Provider

License No: _____
Valid up to: _____

2D QR CODE

1.M/S._____ situated at _____,Tehsil/ Town _____, District _____, Geo-Coordinates _____is hereby licensed to provide services related to therapeutic goods, as enlisted below;

_____

subject to the conditions specified in the provisions of the Drugs Act, 1976/ the DRAP ACT, 2012 and the rules framed there under.

Photographs of the Authorized Persons

2. Name of Authorized Person(s) along with residential address and CNIC

_____

Dated_____ **Licensing Authority**

Map of Premises

Drug Sale License History

Dated_____ **Licensing Authority**

(This License is Computer-generated)

FORM-16
see rule (23) (4)(d)
AUTHORITY LETTER BY MANUFACTURER OR IMPORTER OR INDENTER

No._____
Date of Issuance: _____
Valid up-to_____

I, we .....being licensed manufacturer/ importer/ indenter holding license/enlistment No. _____ Valid up-to _____ do hereby authorize M/s..... License No..... to sell or distribute our registered therapeutic goods (as per attached list) and issue warranty in the prescribed form(s) under the Act & Rules framed thereunder on our behalf for the area .....
M/s..... is further authorized to distribute or sell the products given in the list attached to the following licensed distributors/ wholesaler and who shall issue invoice/ warranty (on prescribed form(s)) in this regard on our behalf.

Sr. #	Name	Address	License #	Area

Authorized Signatures
(CNIC # _____)

CONDITIONS:

i. This letter of authorization shall be issued on letter head of the authorizing firm / company.
ii. The person / firm / company shall maintain records of all letters of authorization issued to its Distributors/Wholesalers and will produce the same as and when required by the Licensing Authority or Drug Inspector.
iii. This letter of authorization is non-transferable to any other person, firm or company.
iv. This letter of authorization is valid for mutually agreed period any of the party may terminate it by informing in writing to the other party as well as the licensing authority.
v. This letter of authorization is valid for the approved list of registered drugs duly signed by the marketing authorization holder for the area of distribution or wholesale specified in this letter.
vi. The authorized distributors/wholesalers shall use this authority for the sale of therapeutic goods only to the licensee under these rules.
vii. This authority letter shall subject to having a valid license under these rules.

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SCHEDULE-B
[See Rule 23 & 26]
NARCOTIC, PSYCHOTROPIC AND CONTROLLED DRUGS

1. Serotonin-Norepinephrine Reuptake Inhibitors
2. Tricyclic Antidepressants
3. Tetracyclic Antidepressants
4. Unicyclic Antidepressants
5. Monoamine Oxidase Inhibitors
6. 5-HT2 Receptor Antagonists
7. Benzodiazepines
8. Non-Benzodiazepines Sedatives/Anxiolytics
9. Barbiturates
10. Phenothiazine Derivatives
11. Neuroleptics/Antipsychotics
12. Lithium Compounds
13. Anti-epileptics/Anti-Convulsants
14. Opioid Agonists & Mixed Agonists-Antagonists
15. General Anesthetics
16. CNS Stimulants
17. 1st Generation Anti-Histamines
18. Corticosteroids and related agents except topical & inhalation preparations
19. Ergot Alkaloids/compounds
20. Triptans

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SCHEDULE-C
[See Rule 14]

Serial No.	Detail of Test	Test Analysis Fee	
		Single Ingredient	More than one ingredient
A.	**Fee Schedule for sample received from Government / Autonomous / Semi Government institute.**		
1	i. Solid Dosage Forms; i.e., Tablets, Capsules, Powders, ii. Oral Liquid Dosage Forms i.e., Syrup, Suspension, Linctus, Drops iii. Dry syrup/ Dry Powder, iv. Semisolid Dosage Forms i.e., Cream, Ointment, Suppositories, Lotion etc., v. Ear /Nasal Drops, vi. Antiseptics, Disinfectants, Insecticides, Tinctures, Topical Solutions, vii. aerosol, Inhalers, viii. Liquids / Large volume solution (Dialysis Solution etc.,), and all other oral, topical preparations etc.	4400	5900
2	i. Injectable/ Parenteral Preparations; Ampoules, Vials, Infusions, etc. ii. Eye Preparations	6200	6900

	iii. Semisolid Dosage Forms (Ointments, Creams requiring Sterility)		
3	Samples Containing Suspected allopathic ingredient	5000	10000
4	i. Surgical Disposables ii. Surgical Dressings; Absorbent cotton Wool, Bandages, Gause, Plaster of Paris Bandage, Crepe Bandage etc.,	3500 (Physical test only) and 6000 (Physical & sterility/ pyrogen test only)	
B	**Fee Schedule for sample received from any other person / institute or any other department.**		
1	i. Solid Dosage Forms; i.e., Tablets, Capsules, Powders, ii. Oral Liquid Dosage Forms i.e., Syrup, Suspension, Linctus, Drops iii. Dry syrup/ Dry Powder, iv. Semisolid Dosage Forms i.e., Cream, Ointment, Suppositories, Lotion etc., v. Ear /Nasal Drops, vi. Antiseptics, Disinfectants, Insecticides, Tinctures, Topical Solutions, vii. aerosol, Inhalers, viii. Liquids / Large volume solution (Dialysis Solution etc.,), and all other oral, topical preparations etc.	10,000	
2	i. Injectable/ Parenteral Preparations; Ampoules, Vials, Infusions, etc. ii. Eye Preparations iii. Semisolid Dosage Forms (Ointments, Creams requiring Sterility)	15,000	
3	Samples Containing Suspected allopathic ingredient	20,000	
4	i. Surgical Disposables ii. Surgical Dressings; Absorbent cotton Wool, Bandages, Gause, Plaster of Paris Bandage, Crepe Bandage etc.,	5000	
C	**Fee Schedule for sample received from any other person / company / firm / private institute/ export purpose or any other department with request to perform any specific test / analysis OR on any specific equipment or technique.**		
Serial No.	**Detail of Test : Qualitative / Quantitative determination**	**Test Analysis Fee**	
1.	Spectrophotometer	5000	
2.	Chromatography / HPLC /UHPLC/ UPLC	10000	
3.	GC-MS / LC-MS	10000	
4.	TLC / FTIR / Flame Photometer	5000	
5.	Atomic absorption Spectroscopy	15000	
6.	Refractometry / Polarimetery	3000	
7.	Analysis by any type of Titration	3000	
8.	Any other test / chemical test / Assay / other tests as per MOH / DRAP/ any test for Pharmacopoeial requirements other than those given in this schedule	5000	

	Microbiological tests	
9.	Biological assay /Microbial assay	5000
10.	Sterility test	3000
11.	Microscopic evaluation	2000
12.	Endotoxin / Pyrogen test	3000
13.	Test for presence of fungi / Microbial Enumeration Test etc.	3000
14.	Other bacteriological examination	3000
	Physical Examination Tests	
15.	Disintegration test, dissolution test, weight variation , uniformity of weight, etc.	5000
16.	Leakage test Injectable	2000
17.	Determination of water/humidity	2000
18.	Determination of water Karl Fischer	3000
19.	Determination of pH, electrometrically.	1000
20.	Determination of Acid value, Iodine value, saponfication value Acetyl value, eaters value, etc.	2000
21.	Quantitative tests for Mercury, Lead, Arsenic or any other Heavy metals etc.	15000
22.	Impurity Limit test for the presence	10000
23.	Determination of viscosity	2000
24.	Determination of Specific gravity	1000
25.	Determination of Distillation range and boiling point, etc.	2000
26.	Determination of solubility quantitatively in one solvent	5000
27.	Determination of melting point	1000
	Surgical dressing Test	
28.	Determination of Yarn number each	1000
29.	Thread count (warp and weft) etc.	2000
30.	Elasticity	2000
31.	Weight Per unit area	1000
32.	Absorbency	2000
33.	Adhesive strength of plasters	2000
34.	Other tests as per MOH / DRAP/ Pharmacopoeial requirements regarding surgical dressing	2000

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 rule 23 & 26)
To be sold by a licensee strictly on the prescription of prescriber by the way of retail sale

All registered/ enlisted drugs or therapeutic goods or, biological, medical devices or

Preparations containing ingredients, substances or mixture of substances, or such dosage forms or preparations intended or used for treatment or mitigation of any disease except those mentioned in Schedule-H.

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SCHEDULE-E
[See rule 2 (1) (h)]
LIST OF MINIMUM REQUIREMENTS FOR A COMPOUNDING PHARMACY

I. **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 therapeutic goods 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 square Meters for one person working therein with additional 2 square Meters for each additional person. The height of the premises shall at least be 2.5 square 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 and requirement of the establishment.

The therapeutic goods 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: -

IV. 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

V. **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

VI. **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 everything 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.

Therapeutic Goods when supplied shall have labels conforming to the provisions of laws in force.

Besides, aforementioned requirements for the compounding pharmacy, it must fulfill the requirements of latest edition of pharmacopeia given in the Act. Compounding shall only be done of the formulations given in any of the latest edition of pharmacopeia given in the Act. In case of formulation is different from the pharmacopeial specifications or the formulation is intended for investigational / research purposes, the licensee shall not compound and dispense such formulation unless enrolled in the respective research study having an approval of the syndicate board of the recognized university with defined number of subjects and quantity to be dispensed to each subject, after approval of the licensing authority. The Provincial Board shall publish compounding formulary after obtaining data from the compounding pharmacies on annual basis. Compounding of narcotic, psychotropics or controlled drugs or therapeutic goods shall be prohibited. Compounding shall be strictly done on the prescription of prescriber. In case of sterile dispensing the compounding pharmacy shall ensure appropriate clean room requirements according to the latest pharmacopeia requirements. The procedures of compounding shall be necessarily validated and equipment used shall be periodically calibrated as per latest relevant international guidelines. Purchase of raw material shall be as per regulations laid down by the Federal Government. Whole sale and distribution of compounded products shall be prohibited. Raw material procured by the compounding pharmacy is not allowed to re-sale or re-distribute. In the application, the applicant shall explicitly narrate that he intends to establish compounding facility in his premises. License of such pharmacy shall also bear conspicuous details about compounding facility. The Licensing Authority shall review and publish a list of compounding pharmacies. The Provincial Board shall periodically make sure quality assurance and safety profiling of compounding products.

Additional Requirements to be met by Pharmacy (Form-9 License Holder) Carrying out Compounding Services.

1. **COMPOUNDING SERVICES:**

Compounding is customization of medicines when commercial preparations are not available or suitable to meet the patient needs. It is a practice in which a licensed practitioner (pharmacist, physician) or a person (such as technicians etc.) under their supervision, combines, mixes, or alters preparation (e.g. by reconstitution, dilution, re-packaging in to single dose or reduced volume etc.) of a drug to create a medication tailored to meet the patient needs.

Types of compounding:

A. **Sterile:** Any dosage form of a drug that is free of viable microorganisms, prepared using aseptic techniques e.g. parenteral products (injections, infusions etc.), ophthalmic or inhalation preparations etc.

B. **Non sterile:** It involves the preparation/compounding of medications that are administered in ways that do not have a high risk of infection hence not required to be sterilized. E.g. cream, ointments, mouth washes, syrups, suspensions etc.

General Requirements:

Governance & Oversight

1. Designate a Compounding Quality Officer (CQO) responsible for oversight of quality systems, risk management, deviation control, and regulatory compliance.
2. Implement a Compounding Quality Management System (CQMS) integrating QA/QC, documentation, validation, deviation/CAPA, audit, and change control procedures (modeled on ICH Q10All personnel involved in the compounding, evaluation, packaging, and dispensing of compounded preparations must be initially trained on compounding skills and deemed as qualified by demonstrating proficiency in proper compounding techniques and shall engage in compounding activity under the active supervision of a pharmacist registered in Register A.

Personnel:

1. Training and observation of skills may be performed by the designated person(s) or an assigned trainer, preferably a pharmacist, having sound training and experience in compounded sterile/non-sterile preparations.
2. The basic compounding training parameters should include but not limited to are:
   a) Compounding skills and techniques
   b) Calculation methods and documentation
   c) PPEs, garbing, hand washing, donning and doffing technique
   d) Basic information about PEC and SEC and other equipment used in compounding
   e) Safe handling of chemicals, use of MSDS
   f) Spill management process
   g) Steps to avoid errors and contamination during preparations
   h) Proper labeling techniques
   i) Basic information about quality assurance in compounding
3. Personnel must complete refresher training at least annually in appropriate sterile /non sterile compounding principles and practices.
4. The records for baseline and refresher trainings are maintained for each staff.
5. Hazardous drugs and chemicals shall be stored, prepared, and handled by appropriately trained personnel only under conditions that protect the healthcare workers and other personnel.
6. In addition to initial and annual training, implement:
   i. Quarterly assessments for high-risk sterile compounding staff.
   ii. Competency checklists including aseptic validation, media fill tests, gloved fingertip sampling.

Area:

Area for compounding shall be as per intended purposes, however shall not be less than 60 Sq Ft for one person working therein with additional 10 Sq Ft for each additional person.

1. Establish Environmental Monitoring Program (EMP)
   i. Define alert and action levels with documented investigations for excursions.
   ii. Include trending analysis of viable and non-viable particles.
   iii. Install real-time particle counters and pressure differential monitors with alarms.

Equipment:

1. The equipment, supplies and utensils used for compounding of a drug preparation shall be of appropriate design and capacity and should be of suitable composition such that the surfaces that contact components are not reactive or sportive

2. Automated, mechanical, electronic, and other types of equipment used in compounding or testing of compounded preparations shall be routinely inspected, calibrated as necessary, and checked to ensure proper performance.
3. Before compounding operations begin, the equipment is inspected by the compounding staff to determine its suitability for use.
4. For staff protection, PEC shall be used for HDs preparation, even if these are non-sterile.
5. Extra care should be used when cleaning equipment used in compounding preparations that require special precaution (e.g., antibiotics and cytotoxic and other hazardous materials). When possible, special equipment should be dedicated for such use; but if the same equipment is being used for all drug products, an effective cleaning is performed in between.

Component/Ingredient selection:

1. All Active pharmaceutical ingredients (APIs) and other components (excipients) used must be of good quality and suitable for clinical use.
2. Recommended source of ingredients for compounding preparations include: United States Pharmacopeia (USP), National Formulary (NF), or Food Chemicals Codex (FCC).
3. If above grades are not available, choose chemical grades that have purity ≥95% and are acceptable for medicinal / drug use. E.g. Analytical, reagent grade, or American Chemical Society certified chemicals.
4. Components or products labeled as "not for pharmaceutical use", "not for injectable use", "not for human use", "for animal use" or an equivalent statement, must not be used to compound for these purposes.
5. Compounding staff shall use their professional judgment in selecting an acceptable and reliable chemical source and shall establish purity and safety by reasonable means, which includes: review of Certificate of Analysis (CoA), manufacturer information, and reliability of source.
6. Receipt of components:
    - Upon receipt of each lot of a component, the external packaging must be examined for evidence of deterioration and other aspects of unacceptable quality.
    - Facility personnel must verify the labeling and condition of the component [e.g., whether the outer packaging is damaged, tempered or renders unfit for use by any means].
7. For components in containers that have an expiration date from the manufacturer or distributor, the material may be used in compounding before that expiration date;
    - When the material is stored in its original container under conditions to avoid decomposition of the chemicals unless other conditions are noted on the label,
    - When there is minimal exposure of the remaining material each time material is withdrawn from the container
8. If the component has been transferred to a different container, that container shall be identified with the component name, original supplier, lot or control number, transfer date, and expiration date and shall provide integrity that is equivalent to or better than that of the original container.
9. For components that do not have expiration dates assigned by the manufacturer or supplier, the compounder shall label the container with the date of receipt and assign a conservative expiration date, not to exceed three years after receipt.
10. When compounding for humans, the compounder should consult the list of components that have been withdrawn or removed from the market for safety or efficacy reasons by DRAP, PQCB or other international regulatory authorities.
11. Chemicals are appropriately stored to avoid any cross contamination, cross reactivity (e.g. don't store flammable with oxidizers) or any mishandling leading to errors or accidents
12. Proper spill management arrangements are in place in case chemical spillage occurs and concerned staff are trained to manage the spills in safe manner.

13. All chemicals containers must bear chemical name, strength (if applicable), lot/batch and expiry information along with the relevant caution symbols for appropriate personnel protection and handling precautions. Common caution symbols include:
    - Toxic, irritant, corrosive, bio-hazard, flammable, oxidizer, environmental hazard etc.

Standard Operating Procedure (SOP):

- Compounding facilities must develop relevant compounding SOPs/work instructions, process & procedures, policies, master formula or recipe cards (as required) that are based on sound references and authentic resources.
- SOPs/work instructions must be reviewed periodically (annually or as specified) by the designated person(s) to ensure that they reflect current practices. The review is documented.

Packaging:

1. The compounder shall ensure that the containers and container closures used in packaging are suitable for product safety and preserving efficacy.
2. The container used depends on the physical and chemical properties of the compounded preparation. Container–drug interaction should be considered to avoid problems e.g. adsorption or leaching etc.
3. Packaging materials should protect compounding from damage, leakage, contamination, degradation, and adsorption while preventing inadvertent exposure to transport personnel.
4. If the drug/chemical is sensitive to light, light-resistant packaging materials must be used.
5. Use sterile containers for dispensing according to product type e.g. injections, ophthalmic and inhalation compounded products

Storage:

1. All chemicals, ingredients used in compounding, and the finished products are stored under conditions suitable to preserve their quality and integrity (as recommended by their manufacturer or compounding reference)
2. Chemicals and compounds are protected from loss, theft, errors/accidents or misuse in any form
3. Optimum storage conditions like temperature & humidity controls, light protection (where indicated) etc. are ensured at all times
4. Chemicals or product requiring cold chain maintenance (2-8^{0}C) must be stored at constantly maintained temperatures (including transport/distribution), and any breaches in cold chain must be properly assessed to ensure product integrity. If the product is unfit for use due to temperature excursions, there is an established procedure to segregate it from rest of the stock and dispose in a proper manner

Spill Management:

1. All personnel who may be required to clean up a spill of chemicals/drugs including HDs, must receive proper training in spill management and the use of PPEs and appropriate respirators.
2. Spills must be contained and cleaned immediately only by qualified personnel with appropriate PPE.
3. Warning signs must be available for restricting access to the spill area.
4. Spill kits containing all the materials needed to clean HD spills must be readily available.
5. Contents of spill kit are defined and uniform across the compounding facility
6. All spill materials used for HDs spill cleaning must be disposed of after use as hazardous waste.
7. For HDs, the circumstances and management of spills (equivalent to 5ml or more) must be documented.

Compounded Product Labeling:

1. Compounded medicine are labelled in a manner that they remain traceable after preparation (e.g., through barcode, QR code, prescription number, order number, or specific lot/batch number etc.).
    i. Generally, if an item is prepared in a batch form (more than one unit), a specific lot/batch number should be assigned to it.
    ii. Otherwise, reference to its order/prescription and with that of patient identification will suffice.
2. Label should also contain
    iii. Composition (ingredient(s), their amounts, percentage or concentrations).
    iv. Storage conditions: e.g. refrigeration (2-8^{0}C) or room temperature etc.
    v. Beyond Use Dating (BUD) / date of expiry
    vi. Total amount or volume if it is not obvious from the container.
    vii. Important instructions (e.g. shake well before use, not for oral use etc.)
    viii. Patient identification
    ix. Route of administration, dose and frequency

Align BUD assignment strictly with USP <795>/<797> and documented stability-indicating studies.

Labeling should include layperson-friendly instructions, precautionary pictograms, and contact information for queries.

Quality control:

As a final check, the compounder shall:

1. Match prescription or order with calculation / compounding record to avoid any wrong preparation, calculation or component errors.
2. Review compounding procedure /master formula as applicable to rule out in preparation error.
3. Check and adjust pH where indicated (as per master formula).
4. Perform visual inspection to ascertain it appears as expected.
5. To ensure accuracy and completeness of all the record and that of label to be affixed to the compounded product.
6. Ensure that right compounded medicine is dispensed to the right patient in right quantity and at right time

The compounder shall investigate any discrepancies and take appropriate corrective action before the product is dispensed.

7. For sterile CSPs, include provisions for:
    i. Sterility testing (USP <71>)
    ii. Endotoxin testing (USP <85>)
    iii. Osmolality & particulate testing for injectable products
8. For non-sterile products, define minimum assay/shelf-life tests based on risk.

Documentation:

All compounding facilities must have and maintain documentation (written or electronic) to demonstrate compliance with the requirements in this guideline. The important documentation includes, but is not limited to, the following:

1. Personnel training, competency assessments, and qualification records including corrective actions for any failures.
2. Equipment certification reports, including corrective actions for any failures.
3. Quality control test procedures and results, including corrective actions for any failures.
4. Electronic and non-editable temperature and humidity control record
5. Equipment records (e.g., calibration, verification, and maintenance reports etc. as applicable).
6. Compounding procedure or Master Formulation Records (as applicable).
7. Compounding records; It must include at least the following information:
    i. Name, strength, and dosage form of the compounded product.
    ii. Details of patient for whom compounded and details of prescriber;

iii. Date and time of preparation;
iv. A method to identify the individuals involved in the preparation and checking of compounded product.
v. Name of each component/ingredient
vi. Quantity, weight or volume of each component.
vii. Lot/batch number, and expiration date for each component
viii. Total quantity of compounded product
ix. Assigned BUD/expiry date.
x. Results of QC test procedures (e.g., release assessment such as visual inspection, final filtration, pH testing etc. as applicable).

8. Material safety data sheet (MSDS) for all chemicals used in compounding facility.
9. Spill kit procedure and spill kit / bag contents
10. Standard operating procedures/work instructions/SOPs etc.
11. Information related to recalls, complaints and adverse events.
12. Results of investigations and corrective actions.
13. The compounding must document the implementation of the recall procedures.
14. Cleaning and disinfection record as applicable (LFHs, BSC, room/area, equipment etc.)
15. Quality assurance tests results

Retention of record:

1. All required compounding records (e.g., Master Formulation Record, Compounding Record, and final check before dispensing etc.) must be readily retrievable for at least 1 year after preparation or as required by laws and regulations.
2. Temperature and humidity record should be retrievable for not less than 3 months.
3. Certification, calibrations and validation records of PEC/SEC and all other quality testing for CSPs e.g. product sterility tests, finger dab test etc. record should be available for at least 1 year.

1. STERILE COMPOUNDING:

Sterile compounding is defined as combining, admixing, reconstituting, diluting, pooling, reconstituting, repackaging a drug to create a sterile medication.

Scope:

Sterile preparations include but not limited to:

i. **Injections** (any route) and **infusions**
ii. **Irrigations** for internal body cavities (note: Irrigations for the mouth, rectal cavity, and sinus cavity is not required to be sterile. While other types are required to be sterile).
iii. **Ophthalmic** dosage forms (any route, any dosage form)
iv. **Inhalation drugs**: (note: Nasal dosage forms intended for local application are not required to be sterile).
v. **Baths and soaks** for live organs and tissues

Categories of Compounded sterile Preparations (CSPs):

USP categorizes CSP in to: **low, medium and high-risk** products based upon starting ingredients, compounding complexity and storage conditions.

Low risk:	The compounding involves only transfer, measuring, and mixing manipulations using not more than three commercially manufactured sterile products and **not more than two entries** into any one sterile container or package. E.g. repackaging commercial product in to specific doses (unit dose) or smaller volume, reconstituting vancomycin vial with water for injection and then transferring the contents of the vial to a suitable diluent e.g. in normal saline 0.9% bag.
Medium risk:	The compounding process includes complex aseptic manipulations other than the single-volume transfer. The compounding process requires unusually long duration, such as that required to complete dissolution or homogeneous

mixing.
E.g.: Transfer of volumes from multiple ampules or vials into one or more final sterile containers, e.g. total parenteral nutrition (TPN) bag or Cardioplegia solution etc.

High risk:

If any of the following conditions are met; starting products are either contaminated or at a high risk to become contaminated, such as:

- Nonsterile ingredients (e.g. non-sterile chemical/ingredient) or nonsterile device used (e.g. beaker).
- Exposure to air quality worse than ISO 5 for more than 1 hour.
- Improperly garbed personnel.
- Nonsterile water-containing preparations stored for more than 6 hours before being sterilized.

E.g.: Preparation of hypertonic saline 3% (injection or inhalation solution) from commercially available sodium chloride salt and water.

The conditions required to prepared these products and their general recommendation regarding the shelf-life after preparation is described below

Table 1

Type	Conditions required (for preparation)	Recommended Shelf-life* (after preparation)	
Low risk CSPs	Do not require classified area i.e. buffer and Ante room	Room temperature: Cold temperature: Frozen:	48 hrs. 14 days 45 days
Medium risk CSPs	In classified area having Ante room and buffer room	Room temperature: Cold temperature: Frozen:	30 hrs. 9 days 45 days
High risk CSPs	In classified area having Ante room and buffer room	Room temperature: Cold temperature: Frozen:	24hrs. 3days 45 days

****Note: these are general recommendations and may vary for individual products based on their physico-chemical nature. In addition, if any other product specific authentic stability studies are available in literature, it can also be used as a reference***

I: Facilities:

General Requirements

1. Sterile compounding facilities must be designed and maintained properly to minimize the risk of contamination of CSPs.
2. To maintain and facilitate the air quality the design of the facility should take into account optimum flow of:
   i. Personnel and their movements
   ii. Equipment and supplies
   iii. Components
3. Access to sterile area is limited to qualified and authorized persons only.
4. Surfaces **(ceilings, walls, floors, doors, door frames, fixtures, shelving, work surfaces, counters, and cabinets etc.)** in the clean room should be smooth, impervious, free from cracks and crevices, and no shedding so they can be easily cleaned and disinfected and to minimize spaces in which microorganisms and other contaminants can accumulate.
   i. **Floors**: are of wide sheet vinyl, rubber, epoxy or similar, heat welded seams, coved around corners, up to wall material and sealed

ii. **Ceiling** for compounding area: is of heavy gauge polymer or epoxy painted gypsum board, sealed juncture to wall sealed penetrations through walls and ceiling and junctures between surfaces and may have access panel for maintenance.

iii. **Walls:** are smooth, painted, crack and pores free; walls must be constructed of, or may be covered with, durable material (e.g., epoxy painted walls epoxy painted gypsum board or heavy-gauge polymer).-

iv. Any other penetrations through the ceiling or walls must be sealed.

v. **Doors**: are of glass, steel or aluminum material or epoxy coated metal, with hands free operation.

vi. **Surfaces** must be of stainless-steel material, smooth, impervious and easy to clean with no crack that can trap dust or contaminating and it must be non-porous rust proof.

vii. **Surfaces** should be **resistant to damage** by cleaning agents, disinfectants (e.g. alcohol or bleach), sporicidal agents, and tools used to clean

5. All surfaces (wall to ceiling), equipment and supplies must be properly and regularly cleaned, uncluttered, and organized.
6. Equipment such as baskets, trays, trolleys, calculator, bins, stationary etc. must be dedicated and remain within the compounding section (purpose is to segregate the clean and dirty area as well as the items)
7. Area is well-lighted and has comfortable working environment.
8. **Temperature and humidity**
   Room conditions must take into consideration the comfort of fully garbed personnel as sweating due to heat can lead to contamination of products and distraction/discomfort while drug preparation.
   i. Hence the temperature in preparation/buffer room should be 20^{0}C or less. While it should be 20-25^{0}C for adjacent areas within the compounding section.
   ii. Humidity should be not more than 60%.
   iii. Temperature and humidity readings must be documented at least once daily, or stored in the continuous recording device (data logger).
   iv. This data must be readily retrievable for min. of last 3 months.
   v. Actions are taken and documented when temperature and/or humidity is out of range
   vi. Temperature and humidity monitoring devices must be verified for accuracy (calibrated or validated) at least every 12 months or as specified by the manufacturer.
9. The required air quality must be achieved and maintained through **primary engineering control PECs and secondary engineering controls (SECs)** as indicated. *See table 2*
   i. Where indicated, the ante-room, buffer room, and SCA must be separated from areas not directly related to compounding.

Table 2

Type	Recommended ISO class	PEC requirements	SEC requirements	Ante-room	Buffer room
Low risk CSPs	Unclassified	Yes	No	No	No
Medium risk CSPs	Classified	Yes	Yes	Yes	Yes
High risk CSPs	Classified	Yes	Yes	Yes	Yes

Segregated Compounding Area (SCA):

A. Compounding Area - For Low Risk CSPs:

1. PEC may be located within an unclassified area, **without an ante-room or buffer room.**

2. The SCA must be located away from unsealed windows, doors that connect to the outdoors, and traffic flow, all of which may adversely affect the air quality in the PEC.
3. A visible perimeter must establish the boundaries of the SCA.
4. The sink must be accessible but located at least **1 meter away** from the **PEC**. The sink must not be located inside the perimeter of the SCA.
5. **No pressure differential** is required between the SCA and the surrounding areas.

Secondary Engineering Controls (SEC):

SECs comprise of the environments leading to and including the ISO Class 5 primary controls. Ante-areas and buffer areas or cleanrooms are known collectively as secondary engineering controls (SECs) because they provide the controlled environments in which PECs are placed.

B. Compounding Area - for Medium to High Risk CSPs:

1. The **ISO-classified** ante-room and buffer room must be separated from the surrounding unclassified areas of the facility by fixed walls and doors
2. Controls must be in place to minimize the flow of lower-quality air into the more controlled areas.
3. Airlocks and interlocking doors may be used to facilitate better control of air balance between areas of differing ISO classification.
4. **Air** supplied to the cleanroom suite must be introduced through **HEPA filters** that are located in the ceiling of the buffer and ante-rooms.
5. The classified rooms must be equipped with a **pressure-differential monitoring** system.
    i. In a cleanroom suite, a minimum differential **positive pressure** of 0.020-inch water column is required between each ISO classified area (e.g., between the buffer room and ante-room). The pressure differential between the ante-room and the unclassified area must not be less than 0.020-inch water column.
    ii. **Negative pressure** between 0.01 and 0.03 inches of water column relative to adjacent ante room.
    iii. The results from the pressure monitoring device must be reviewed and documented **at least daily** on the days when compounding is occurring.
6. The ante-room must have a line of demarcation to separate the clean side from the dirty side.
7. **Ante-rooms** providing access to **positive pressure** buffer rooms must meet at least **ISO Class 8 classification**.
8. **Ante-rooms** providing access to **negative pressure** buffer rooms must meet at least **ISO Class 7 classification**.
9. **Buffer room** must meet at least **ISO Class 7** air quality.

Primary Engineering Controls (PEC):

PEC is a device or zone that provides an ISO Class 5 air quality environment for sterile compounding. PEC is hooded area found within ISO class & buffer area.

1. Unidirectional airflow must be maintained in PECs.
2. **For non-hazardous sterile preparations:**
    i. Laminar flow work bench (commonly called as hoods).
    ii. Integrated vertical laminar flow zone.
3. **For hazardous drugs (HD) preparations:**

Any drug identified by at least one of the following six criteria: carcinogenicity, teratogenicity or developmental toxicity, reproductive toxicity in humans, organ toxicity at low dose in humans or animals, genotoxicity, or new drugs that mimic existing HDs in structure or toxicity. HDs require careful handling by healthcare personnel and others who come in contact with them to minimize the adverse health effects of exposure and reduce contamination of the workplace e.g. chemotherapeutic or cytotoxic drugs etc.

PEC use for HD's preparations are:

i. Class II biological safety cabinet. Class II BSCs are further divided into types (Type A1, Type A2, Type B1, and Type B2).

4. The Laminar airflow system (LAFS) must be located out of traffic patterns and away from room air currents that could disrupt the intended airflow patterns inside the PEC.
   i. If used to prepare **only low risk CSPs**, the ISO Class 5 PEC may be located in an **unclassified SCA.**
   ii. If used to prepare **medium or high risk CSPs**, the LAFS must be **located within a cleanroom suite** (A classified area that consists of both an ante-room and buffer room).
5. **Other PECs:**
   i. **Restricted-Access Barrier System (RABS):** It allows for the ingress and/or egress of materials through defined openings that have been designed and validated to preclude the transfer of environmental air contamination, and that generally are not to be opened during compounding operations.
   ii. **Pharmaceutical isolator:** A pharmaceutical isolator provides isolation from the surrounding area and maintains ISO Class 5 air quality during dynamic operating conditions.

Certification and Recertification:

1. Before a compounding area is used to compound either low, medium and high risk CSPs, it must be certified for suitability.
2. Certification is the process conducted by a vendor/3rd party who evaluates the primary engineering controls (PECs) and secondary engineering controls (SECs) for compliance with key elements.
3. Certification indicates that the compounding area and PE is meeting its design and air quality specifications. It is important to place special emphasis on certifying the ISO Class 5 areas.
4. Certification of the classified areas including the PEC, must be performed initially, and recertification must be performed at least every 6 months or as per manufacturer recommendation.
5. Following tests are included in certification:
   i. Airflow testing.
   ii. HEPA filter integrity testing.
   iii. Total particle counts.
   iv. Dynamic airflow smoke pattern test.
6. Ensure Microbiological Controls in Sterile Compounding Including;
   i. Media-fill test frequency (e.g., every 6 months per operator).
   ii. Surface disinfection validation for effectiveness (per USP <1072>).
   iii. Bioburden assessments (e.g., nasal/fingertip swabs)
7. All critical systems (e.g., HVAC, PECs, autoclaves, temperature sensors) must undergo:
   i. Installation Qualification (IQ)
   ii. Operational Qualification (OQ)
   iii. Performance Qualification (PQ)

Personnel Preparation for Compounding:

At a minimum, individuals must:

1. Remove personal outer garments (e.g., bandanas, coats, hats, caps, jackets, sweaters, vests etc.).
   i. Note: Religious head cover for females can be an exception. However, it is either covered with a cap, or dedicated scarf/head covers for the sterile area are worn
2. Remove all cosmetics because they shed flakes and particles.
3. Remove all hand, wrist, and other exposed jewelry including piercings that could interfere with the effectiveness of garbing (e.g., the fit of gloves, cuffs of sleeves, and eye protection) or otherwise increase the risk of contamination of the CSP.
4. Cover any jewelry that cannot be removed.
5. Do not wear earbuds or headphones.

6. Do not bring electronic devices that are not necessary for compounding into the compounding area.
7. Keep nails clean and neatly trimmed to minimize particle shedding and avoid glove punctures.
8. Nail products (e.g., polish, artificial nails, and extenders) must not be worn.
9. Wipe eyeglasses with suitable disinfectant e.g. 70% Isopropyl Alcohol (IPA), if worn.

Garbing Requirements:

Garbing is wearing special garments to reduce the particle shedding count from personnel.
The minimum garbing requirements include:

1. Low-lint garment/gown with sleeves that fit snugly around the wrists and that is enclosed at the neck (e.g., gowns or coveralls).
2. Low-lint, disposable covers for shoes.
3. Low-lint, disposable covers for head that cover the hair, ears and religious head cover.
4. If applicable, disposable cover for facial hair (beard/moustache)
5. Face mask
6. Sterile powder-free gloves
   - **i.** Only furniture, equipment, and other materials necessary for performing compounding activities are permitted in a classified area or SCA, and they should be low-shedding and can be easily cleaned and disinfected.
   - ii. Carts used to transport components or equipment into classified areas must be constructed from nonporous materials with cleanable casters and wheels to promote mobility and ensure ease of cleaning and disinfection.
   - iii. Only equipment necessary for performing compounding activities is permitted in the PEC.

Quality control parameters:

QA is a system of procedures, activities, and oversight that ensures that the compounding process consistently meets quality standards. QC is the sampling, testing, and documentation of results that, taken together, ensure that specifications have been met for the CSP. A designated person must ensure that the facility has formal, written QA and QC programs that establish a system of:

- i. Adherence to procedures.
- ii. Prevention and detection of errors and other quality problems.
- iii. Evaluation of complaints and adverse events.
- iv. Appropriate investigations and corrective actions.

1. The SOPs must describe the roles, duties, and training of the personnel responsible for each aspect of the QA program.
2. The QA and QC program and related policies, procedures must be reviewed at regular interval e.g. annually or as agreed, by the designated person(s).
3. If adequate internal resources are not available, the QA/QC tests must be conducted through reliable and authentic external vendors/laboratories
4. The results of the review must be documented and appropriate action must be taken if needed. The actions are documented.

Personnel and microbiological testing Requirements:

Table 3

Test	Frequency	Cut off / Action levels
Visual observation to assess quality of hand hygiene and garbing process by the staff	Every 6 months	----
Gloved fingertip and thumb Sampling for microbiological testing	Every 6 months	Initially: CFU: 0 After 6 months: >3 CFU

Viable air sampling (done through machine) It is done to verify the environment viable and particulate count remains within limits specified for the sections/area Using the sampling device, test at least 1 cubic meter or 1000 liters of air from each location sampled.	Every 6 months	ISO class 5: >1 CFU/cubic meter ISO class 7: >10 CFU/cubic meter ISO class 8: >100 CFU/cubic meter
Surface sampling Surface sampling is done to assess the state of control and to identify potential risks of contamination.	Monthly	ISO class 5: >3 CFU/device or swab ISO class 7: > 5 CFU/device or swab ISO class 8: >50 CFU/device or swab

Visual Inspection:

A visual inspection must be conducted before it is released or dispensed to make sure that the CSP does not exhibit any defects, such as precipitation, cloudiness, or leakage, which could develop during storage. A CSP with such defects must be immediately discarded, or marked and segregated from acceptable units in a manner that prevents it from being released or dispensed. Any defect may indicate sterility or stability problems, which should be investigated to determine the cause.

Recall:

An SOP for recall of out-of-specification dispensed CSPs must contain:

i. Procedures to determine the severity of the problem and the urgency for implementation and completion of the recall.
ii. Procedures to determine the distribution of any affected CSP, including the date and quantity of distribution.
iii. Procedures to identify patients who have received the CSP.
iv. Procedures for disposition and reconciliation of the recalled CSP.
v. Recalls data is maintained for at least 2 years

Cleaning and disinfection in sterile compounding section

1. Environmental contact is a major source of microbial contamination of CSPs. Consequently, scrupulous attention to cleaning and disinfecting the sterile compounding areas is required to minimize this as a source of CSP contamination.
2. The process of **cleaning** involves removing organic and inorganic materials from surfaces, usually with a cleaning agent.
3. The process of **disinfecting** involves destruction of microorganisms, usually with a chemical agent.
4. Cleaning and disinfecting surfaces must occur at the minimum frequencies, if compounding is not performed daily, cleaning and disinfecting must be completed before initiating compounding.
5. Compounding personnel are responsible for ensuring that the frequency of cleaning, type of products used for this purpose, are in accordance with the requirements set by the compounding facility
6. Any organizational policies or external reference guidelines regarding disinfectant selection should be considered by compounding facility. Most commonly used disinfectant is 70% isopropyl alcohol (IPA) solution.
7. Cleaning must be performed in the direction of 'clean' to 'dirty' areas.
   All cleaning materials, such as wipers, sponges, and mops, shall be non-shedding, preferably composed of synthetic micro fibers, and dedicated to use in the buffer or clean area, ante-area, and segregated compounding areas and **shall not be removed** from these areas except for disposal. Floor mops may be used in both the buffer or clean area and ante-area, but only in that order.

Table 4: Cleaning Frequency

Site	Minimum Frequency
ISO Class 5 PEC	Beginning of each shift Before each batch Every 30 minutes when compounding After spills When surface contamination is known or suspected
Counters and easily cleanable work surfaces	Daily
Floors	Daily
Pass through boxes	Daily
Walls	Monthly
Doors	Monthly
Ceiling	Monthly
Storage shelving	Monthly

Before start working in PEC devices, clean and disinfect hood and turn on UV light for at least 30min once daily.

i. Fully close the sash/cover (if any) of BSC and laminar flow hood before turning on the UV lamp in the hood.
ii. For staff protection, avoid working in or around the safety cabinet/hoods when the UV light is on or avoid using the room when UV light is ON.
iii. Control the access to the room while the UV lights are ON to prevent exposure.
iv. If personnel is exposure to UV then stop the work immediately seek medical advice.

PEC & SEC downtime management

Downtime is the time during which a PEC hood machine/ unit is not working or is not able to be used. It can be a schedule/planned downtime activity (e.g. for routine maintenance work) or sudden or unplanned event (equipment fault or power failure etc.).

To avoid the sudden power failure the PECs (hoods) should be linked with backup like Uninterrupted Power Supply (UPS) or auto-start generator, so that equipment remains functional even in power outage.

Scheduled downtime planning: schedule downtime includes but not limited to

i. Activities requiring recertification.
ii. Cleanroom modifications.
iii. New equipment installation.
iv. Replacing fan filter units or air handlers
v. Closing the hoods temporarily when not in use for a long time

In case of schedule downtime

i. Limit the compounding needed
ii. Schedule downtime in slower days /times /shifts.
iii. Divert remaining compounding to an alternate location, that may have another available cleanroom or SCA.

Unscheduled downtime planning:

i. When PEC is not working or does not certify – Do not continue to use PEC.
ii. Divert compounding to alternate PEC or location. e.g.: LAFW down, but BSC available, designate BSC for non-hazardous compounding.
iii. If unable to divert, must limit BUDs (12 hrs at room temperature and 24 hrs fridge temperature).

SEC unplanned downtime:

i. Immediately stop compounding and exit cleanroom, Monitor pressure differentials, temperature, humidity, and particle counts (if available).
ii. Re-enter room when temperature, humidity, pressure differentials are at normal levels and sufficient time has passed to allow air turn over

iii. Understand typical air change rate (ACPH) for the room to determine how long to wait.
iv. Clean and disinfect PEC prior to compounding

Special Circumstances

Conditions that could compromise PPEs or increase shedding must be reported to the area in-charge who will evaluate whether the individual is fit to work in sterile compounding. These conditions include:

i. Active respiratory infections e.g. flu
ii. Oozing sores
iii. Rashes or peeling sunburns
iv. Conjunctivitis
v. Recent tattoos

Such staff can be reinstated when these conditions resolve, or as deemed fit by the area in-charge.

Reproductive risks have been associated with exposure to HDs, alternative duty (work that does not involve handling HDs) can be offered as per scope of services to individuals who are pregnant, breast-feeding, or attempting to conceive or father a child on clinical basis.

2. **NON-STERILE COMPOUNDING:**

Examples of non-sterile compounding:

i. Oral/buccal (e.g. capsules, sachet, solutions, liquids, suspensions, mouth washes etc.).
ii. Rectal (e.g. suppositories, enemas etc.)
iii. Topical (e.g. lotion, cream, ointment, poultice, pastes, solutions, sticks, gels etc.).

I. Facility:

1. Compounding facilities shall have an adequate space that is specifically designated for compounding of prescriptions.
2. Space shall provide for the orderly placement of equipment and materials to prevent mix-ups among ingredients, containers, labels, in-process preparations, and finished preparations.
3. **Potable water** shall be supplied for hand and equipment washing.
4. **Purified Water/Reverse Osmosis (RO) water** shall be used for compounding nonsterile drug preparations when formulations indicate the inclusion of water and it is also used for rinsing equipment and utensils before preparation.
5. Adequate hand and equipment washing facilities shall be easily accessible to the compounding areas. (running water, soap or detergent, an air-drier or single-use towels).
6. Compounding and storage area should be well lighted. Heating, ventilation, and air conditioning systems shall be controlled to avoid decomposition and contamination of chemicals.
7. Appropriate temperature and humidity monitoring should be maintained as required for certain components and compounded dosage forms.
   i. Temperature and humidity readings must be documented at least once daily, or stored in the continuous recording device (data logger).
   ii. This data must be readily retrievable for min. of last 3 months.
   iii. Actions are taken and documented when temperature and/or humidity is out of range
   iv. Temperature and humidity monitoring devices must be verified for accuracy (calibrated or validated) at least every 12 months or as specified by the manufacturer.

II. Stability:

1. The beyond use date (BUD) is the date after which a compounded preparation shall not be used and is determined from the date when the preparation is compounded.

2. BUDs should be assigned conservatively. When assigning a BUD, compounders shall consult and apply drug-specific and general stability documentation and literature when available
3. BUD by Type of Formulations
    i. **For Non aqueous Formulations:** The BUD is not later than the time remaining until the earliest expiration date of any **API or 6 months, whichever is earlier.**
    ii. For **Water-Containing Oral Formulations**—The BUD is not later than **14 days** when stored at controlled cold temperatures.
    iii. **For Water-Containing Topical/Dermal and Mucosal Liquid and Semisolid Formulations**—The BUD is not later than **30 days.**

3. **Hazardous drug compounding:**

Engineering controls are required to protect the preparation from cross-contamination and microbial contamination. These include following:

i. **Containment primary engineering control (C-PEC)** is a ventilated device designed to minimize worker and environmental HD exposure when directly handling HDs. It is a device in which compounds are mixed, including a containment ventilated enclosure (CVE) commonly called powder hoods, a biological safety cabinet (BSC), and a compounding aseptic containment isolator (CACI).
ii. **Containment secondary engineering control (C-SEC)** is the room in which the C-PEC is placed.

Sterile and nonsterile HDs must be compounded within a C-PEC located in a C-SEC and must:

i. Be externally vented.
ii. Be physically separated (i.e., a different room from other preparation areas).
iii. Have an appropriate air exchange (e.g., Air change per hour - ACHP).
iv. Have a negative pressure between 0.01 and 0.03 inches of water column relative to all adjacent areas.
v. Nonsterile HD compounding must be performed in a C-PEC that provides personnel and environmental protection, such as a Class I Biological Safety Cabinet (BSC) or Containment Ventilated Enclosure (CVE). A Class II BSC or a compounding aseptic containment isolator (CACI) may also be used.
vi. If the C-PECs used for sterile and nonsterile compounding are placed in the same room, they must be placed at least 1 meter apart and particle-generating activity (e.g. decartoning of medicines, frequent in/out movements) must not be performed when sterile compounding is in process.
vii. For occasional nonsterile HD compounding, a C-PEC used for sterile compounding (e.g., Class II BSC or CACI) may be used but must be decontaminated, cleaned, and disinfected before resuming sterile compounding in that C-PEC.

Note:

i. A C-PEC is not required if manipulations are limited to handling of final dosage forms (e.g., counting or repackaging of tablets and capsules) that do not produce particles, aerosols, or gasses.
ii. A C-PEC used only for non-sterile compounding does not require unidirectional airflow because the critical environment does not need to be ISO classified (or maintain sterility).

1. **Sink** must be available for hand washing. An eyewash station and/or other emergency or safety supplies must be readily available in case of spill or personnel exposure to HDs.
2. Sterile and nonsterile HDs may be stored together, but HDs used for nonsterile compounding should not be stored in areas designated for sterile compounding to minimize traffic into the sterile compounding area.

3. HDs must be stored in a manner that prevents spillage or breakage if the container falls. Do not store HDs on the floor. In areas prone to specific types of natural disasters (e.g., earthquakes) the manner of storage must meet applicable safety precautions, such as secure shelves with raised front lips.
4. HDs identified by the entity as requiring special HD handling precautions must be clearly labeled at all times during their transport.
5. Personnel must select and use packaging containers and materials that will maintain physical integrity, stability, and sterility (if needed) of the HDs during transport.
6. HDs that need to be transported must be labeled, stored, and handled in safe manner
7. **All the requirements applicable to the PEC and SEC are also applicable to the C-PEC and C-SEC**

III. Medical Surveillance for HD Handlers:

1. Healthcare workers who handle HDs as a regular part of their job assignment should be enrolled in a **medical surveillance program**. The general purpose of surveillance is to minimize adverse health effects in personnel potentially exposed to HDs.
2. Medical surveillance programs involve
    i. Assessment and documentation of symptom complaints
    ii. Physical findings, and
    iii. Laboratory values (such as a blood count) to determine whether there is a deviation from the expected norms.
3. The occurrence of exposure-related health changes should prompt immediate re-evaluation of primary preventive measures (e.g., administrative and engineering controls, PPE, and others). In this manner, medical surveillance acts as a check on the effectiveness of controls already in use.

IV. Hazardous Drug List

A compounding facility must maintain a list of HDs available in that facility, after consulting authentic references such as current NIOSH, OSHA or NIH list or other relevant references etc. This list must be reviewed at a regular interval. Whenever a new agent or dosage form is used, it should be reviewed against the list.

4. **Incident Reporting, Deviation & CAPA System**

Formalize a Deviation Reporting and CAPA System to log and investigate:

i. Labeling errors
ii. Out-of-specification results
iii. Adverse drug events (**Implement a pharmacovigilance/feedback mechanism** for adverse event tracking post-dispensing)
iv. Equipment failure

5. **Audits and Internal Compliance**

1. Schedule biannual internal audits covering premises, documentation, compounding process, and staff qualification.
2. Include third-party audits (minimum every 2 years) to benchmark with international GMP standards.

Acronyms:

AHU	Air Handling Unit
ACPH	Air Change Per Hour
API	Active Pharmaceutical Ingredients
BUD	Beyond Use Date
BSC	Biological safety cabinet
CSP	Compounded Sterile Preparation
CETA	Controlled Environment Testing Association
CFU	Colony-forming units
CoA	Certificate of Analysis

DRAP	Drug Regulatory Authority Pakistan
FDA	Food and Drug Administration
HD	Hazardous Drug
HEPA	High-efficiency particulate air
HVAC	Heating, ventilation, and air conditioning
ISO	International Organization for Standardization
IV	Intravenous
LAFS	Laminar airflow system
MSDS	Material Safety Data Sheet
NIOSH	National Institute for Occupational Safety and Health
PEC	Primary Engineering Control
PPEs	Personal Protective Equipment
SCA	Segregated compounding area
SEC	Secondary engineering control
SOP	Standard operating procedure
TPN	Total Parenteral Nutrition
USP	United States Pharmacopeia

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Schedule-F
See Rule 2 (1) (u)

Anti-Leprosy Drugs

1. Rifampicin Syrup & Injection
2. Dapsone
3. Clofazimine
4. Prothionamide

Biological/Immunological Products, Vaccines, sera /Anti-sera–

1. BCG Vaccine
2. DTP (Diphtheria, Tetanus, Pertussis)
3. Typhoid Vaccine
4. Cholera Vaccine (WC-rBS)
5. Pneumococcal Vaccine (PCV13)
6. Haemophilus influenzae type b (Hib)
7. Meningococcal Vaccine (A, C, W, Y)
8. MR (Measles, Rubella)
9. MMR (Measles, Mumps, Rubella)
10. Polio Vaccine (OPV/ IPV))
11. Smallpox Vaccine
12. Influenza Vaccine
13. Hepatitis A & B Vaccines
14. Human Papillomavirus (HPV) Vaccine
15. Varicella Vaccine
16. Rotavirus Vaccine
17. Botulism Antitoxin
18. Diphtheria Antitoxin
19. Anti-D Immunoglobulin
20. Hepatitis B Immunoglobulin (HBIG)
21. Varicella Zoster Immunoglobulin (VZIG)
22. Human Normal Immunoglobulin (IVIG/SCIG)
23. Erythropoietin (EPO)
24. Filgrastim / Pegfilgrastim (G-CSF)
25. Human Serum Albumin
26. Coagulation Factors (II, VII, IX, X, VIII)
27. Protein C & S
28. Monoclonal & Polyclonal Antibodies mABs

Products /Drugs related to malignant diseases and immunosuppression

General Anesthetic (Inhalation & IV)

Antibiotics

1. Benzylpenicillin (Penicillin G)
2. Procaine Penicillin
3. Amoxicillin + Clavulanic Acid
4. Piperacillin + Tazobactam
5. Cefazolin
6. Cefuroxime
7. Ceftriaxone
8. Cefotaxime
9. Cefepime
10. Gentamicin
11. Amikacin

12. Tobramycin
13. Glycopeptides
14. Vancomycin
15. Teicoplanin
16. Azithromycin (IV form)
17. Erythromycin lactobionate (IV form)
18. Ciprofloxacin IV
19. Levofloxacin
20. Moxifloxacin IV
21. Polymyxin B
22. Clindamycin (IV)
23. Metronidazole (IV)
24. Aztreonam
25. Daptomycin
26. Dalfopristin
27. Quinupristin
28. Faropenem
29. Aminocycline
30. Cefoperazone
31. Cefpirone
32. Uetrapenem
33. Flumequine
34. Gatifloxacin
35. Gemifloxacin
36. Kenamycin
37. Sparfloxacin
38. Lomefolxacin

Reserve Group Antibiotics

39. Ceftazidime,
40. Colistin (IV, Oral)
41. Fosfomycin (IV)
42. Imipenem/cilastatin
43. Lefamulin
44. Linezolid
45. Meropenem
46. Tedizolid
47. Tigecycline
48. Spectinomycin

Inotropic Injections

1. Dopamine
2. Dobutamine
3. Adrenaline
4. Noradrenaline
5. Isoproterenol
6. Milrinone
7. Amrinone
8. Calcium chloride/gluconate
9. Primacor
10. Enoximone

Prostaglandins

1. Gemeprost Injection

2. Carboprost Injection 3. Alprostadil Injection 4. Latanoprost Injection 5. Misoprostol
Alpha Blocker – 1. Prazosin 2. Terazosin 3. Doxazosin 4. Alfuzosin 5. Indramine 6. Tamsulosin
Narcotics, anti-psychotic, and tricyclic anti-depressant Drugs– 1. Morphine 2. Buprenorphine 3. Nalbuphine, 4. Fentanyl, 5. Pethidine, 6. Lorazepam 7. Temazepam 8. Oxazepam 9. Amoxapine, 10. Iprine Dole Codine, 11. Pentazocine, 12. Phenelizine 13. Dextropropoxyphen 14. Clomipramine, 15. Mianserin, 16. Maprotiline, 17. Chlorpromazine 18. Meprobamate 19. Chlordiazepoxide 20. Alprazolam 21. Clonazepam 22. Flurazepam 23. Loprazolam 24. Dothiepin, 25. Doxepin, 26. Nortriptyline, 27. Trimiprammine, 28. Tranycypromine, 29. Flupenthixol, 30. Tryptophan, 31. Imipramine 32. Amipriptyline 33. Vortioxetine 34. Gabapentin 35. Pregabalin
Medical Devices All lifesaving and life sustaining medical devices mentioned in Schedule D of the Medical Devices Rules, 2017.

Anti-Viral and Anti-Fungal Drugs all dosage form except topical –

1. Acyclovir
2. Famciclovir
3. Ganciclovir
4. Trifluridine
5. Entecavir
6. Ribavirin
7. Remdesivir
8. Favipiravir
9. Molnupiravir
10. Zidovudine
11. Amantadine
12. Zidovudine (AZT)
13. Lamivudine
14. Tenofovir disoproxil fumarate
15. Emtricitabine
16. Efavirenz
17. Dolutegravir
18. Atazanavir
19. Lopinavir + Ritonavir
20. Oseltamivir
21. Sofosbuvir
22. Ledipasvir
23. Velpatasvir
24. Amantadine
25. Voriconazole
26. Posaconazole
27. Amphotericin B (conventional and liposomal forms)
28. Caspofungin
29. Terbinafine
30. Griseofulvin

Cardiology Drugs

1. Streptokinase
2. Alteplase
3. Urokinase
4. Enoxaparin
5. Fondaparinux
6. Warfarin
7. Vitamin K antagonist
8. Ticagrelor Tablet
9. Rivaroxaban
10. Apixaban
11. Dabigatran
12. Edoxaban

Products used for Urinary / GI Tract / dialysis–

Peritoneal Dialysis Products

1. Hypertonic Saline Solutions

Urinary Tract Spasmolytics & Overactive Bladder (OAB) Agents

2. Darifenacin
3. Solifenacin Succinate
4. Tolterodine
5. Oxybutynin

6. Mirabegron
7. Obeticholic Acid
8. Ursodeoxycholic Acid
9. S-Adenosyl Methionine (SAMe)
10. Cholestyramine

Steroidal Drugs / Preparations –

1. Methylprednislone
2. Dexamethasone injection & tablet only
3. Flumethasone

Hormones and antagonists –
Posterior Pituitary Hormones & Analogues

1. Vasopressin
2. Desmopressin
3. Argipressin
4. Terlipressin

Vasopressin Antagonists

5. Tolvaptan

Calcium-Regulating Hormones & Analogues

6. Calcitonin
7. Teriparatide
8. Parathyroid Hormone (PTH 1-84)
9. Cinacalcet

Gonadotropins & Related Hormones

10. Clomifene (Selective Estrogen Receptor Modulator – SERM)
11. Gonadorelin (GnRH analogue)
12. Leuprolide *(GnRH agonist)*
13. HCG (Human Chorionic Gonadotropin)

5. Anabolic Steroids & Androgens

14. Stanozolol
15. Nandrolone
16. Mesterolone
17. Testosterone & Esters (Testosterone, etc.)

6Anti-androgens / 5-alpha Reductase Inhibitors

18. Finasteride
19. Dutasteride
20. Cyproterone acetate
21. Flutamide
22. Bicalutamide
23. Abiraterone acetate

Growth Hormone & Related Agents

24. Somatropin

Estrogens, SERMs, and Antagonists

25. Oestrogens & Hormonal Replacement Therapy
26. Fulvestrant (Estrogen receptor antagonist)
27. Raloxifene
28. Tamoxifen

Progestogens

29. Progestogens (Category, multiple examples like Medroxyprogesterone acetate, Norethisterone, etc.)

Thyroid Hormones & Antagonists 30. Levothyroxine 31. Carbimazole *(Antithyroid)* 32. Propylthiouracil (PTU) *(Antithyroid)*
Products related to cardiology and Radiological Dyes* 1. Cardiac Stents 2. Balloons 3. Heart Valves 4. Pece makers 5. Oxygenators *The devices/products regulated as prescription-only (Rx) medical devices and typically requiring installation or use by cardiologists, interventional radiologists, or surgeons in Hospital setting and tied to implant registry and adverse event monitoring. **Products related to Radiological Dyes** Iodinated Contrast Media (For X-ray/CT Imaging) 1. Iopromide 2. Iopamidol High-Osmolar Ionic Agents 3. Meglumine Diatrizoate 4. Gadolinium Oxide-Based Contrast Agents (GBCAs) 5. Gadopentetate Monomeglumine 6. Gadobutrol 7. Iohexol
New / research Molecules (Injectable)

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SCHEDULE-G

Good Storage & Distribution Practices

See rule 23

World Health Organization Latest Guidelines (Technical Report Series) for Good Storage & Distribution Practices applicable to Drugs or Therapeutic Goods.

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Schedule-H

See rule 23

Drugs or Therapeutic Goods may be sold without prescription

Sr.	Condition	Medication
1.	Acute sore throat	Benzydamine 0.15% Mouthwash and Oromucosal spray
		Throat lozenges
		Throat sprays
2.	Infrequent cold sores of the lips	Acyclovir cream 5%
3.	Conjunctivitis	Chloramphenicol 0.5% eye drops Chloramphenicol 1% eye ointment Eye ointment containing polymyxin, bacitracin, neomycin

		Eye drop Ketorolac, triamcinolone Tear drops for dry eye syndrome
4.	Coughs and colds and nasal congestion	All oral preparation of Paracetamol alone
		All oral dosage forms of Ibuprofen alone or combination of Pseudoephedrine
5.	Coughs and colds and nasal congestion continued	Paracetamol 1000mg/Pseudoephedrine HCL 60mg in 30ml oral solution Paracetamol 500mg/ Pseudoephedrine HCL 30mg capsules
6.	Cradle cap (seborrheic dermatitis in infants)	Emulsifying ointment and shampoo
7.	Hemorrhoids	Zinc oxide preparations
8.	Infant colic	Simethicone 40mg/ml
		Dimethicone 42mg/5ml
9.	Mild cystitis	Sodium citrate 4g sachet
		Potassium citrate 1.5g liquid 3g sachet 1.5g tablet (effervescent)
10.	Mild irritant dermatitis	Emollients Crotamiton Steroid-containing topical preparations such as hydrocortisone
11.	Dandruff	Ketoconazole-containing shampoo
		Coal tar shampoo
		Selenium sulphide shampoo
12.	Diarrhoea (Adults only)	Oral rehydration solutions/ sachets
		Loperamide 2mg capsules
13.	Dry eyes/ sore (tired) eyes	Hypromellose 0.3%
		Carbomer
		Yellow soft paraffin BP/ PhEur Anhydrous Lanolin (Wool fat) BP/ PhEur liquid paraffin BP/ PhEur
		Distilled witch hazel
14.	Earwax	Olive oil drops Arachis oil/ chlorobutanol hemihydrate drops Docusate sodium 0.5% drops Acetic acid 2% (not licensed for wax removal, may help if ears itch after wax removal, however, significant itching may indicate infection and this should be confirmed and treated by GP)
15.	Excessive sweating (hyperhidrosis)	Aluminum chloride
16.	Head lice	Dimeticone gel, lotion or spray 4%
		Malathion aqueous lotion 0.5%
		Conditioner head lice combs
17.	Indigestion and heartburn	Sodium alginate Calcium carbonate Sodium bicarbonate
		Esomeprazole 20mg tablets
		Pantoprazole 20mg tablets

		Ranitidine 75mg tablets
18.	Infrequent constipation	Lactulose
		Bisacodyl tablets 5mg
		Senna
		Ispaghula husk Granules
19.	Infrequent migraine	Prochlorperazine maleate
		Paracetamol 500mg tablets and capsules Paracetamol 500mg/ 5ml oral solution Paracetamol 500ng soluble tablets
		Ibuprofen 200mg, 400mg capsules and tablets Ibuprofen 100mg/ 5ml liquid/ suspension sugar free
20.	Infrequent migraine continued	Co-codamol 8/500mg tablets, capsules, effervescent tablets
21.	Insect bites and stings	Mepyramine maleate 2%
		Lidocaine hydrochloride/ zinc sulphate/ cetrimide
		Calamine/ zinc oxide
		Chloroxylenol/ triclosan/ edetic acid
22.	Mild acne	Benzoyl peroxide-containing preparations
23.	Mild dry skin	Emollients, creams and ointments
24.	Sunburn due to excessive sun exposure	After sun products
25.	Sun protection	Sun protection cream/ sprays/ gels
26.	Mild to moderate hay fever/ allergic rhinitis	Chlorphenamine 4mg tablets Chlorphenamine 2mg/5ml solution
		Loratadine 10mg tablets Loratadine 5mg/5ml syrup
		Acrivastine 8mg capsules
27.	Mild to moderate hay fever/ allergic rhinitis continued	Cetirizine 10mg tablets Cetirizine 1mg/ml solution
		Beclomethasone 0.05% nasal spray
		Sodium cromoglycate 2% eye drops
28.	Minor burns and scalds	Antiseptic burn cream cooling burn gel
29.	Minor conditions associated with pain, discomfort and fever, e.g. aches and sprains, headache, period pain, back pain	Paracetamol 500mg tablets and capsules Paracetamol 120mg/5ml suspension (from 6 years old)/ sugar free
		Ibuprofen 200mg, 400mg tablets, capsules, liquid capsules Ibuprofen 100mg/5ml liquid/ suspension sugar free
		Co-codamol 8/500mg tablets, capsules, effervescent tablets
30.	Minor conditions associated with pain, discomfort and fever, e.g. aches and sprains, headache, period pain, back pain	Ibuprofen 5% gel
31.	Mouth ulcers	Lidocaine hydrochloride/ Chlorocresol/ Cetylpyridinium Chloride Choline salicylate/ Cetalkonium chloride
32.	Nappy Rash	Titanium dioxide/ titanium peroxide/ titanium salicylate
		Zinc oxide/ benzyl alcohol/ benzylbenzoate/ lanolin
33.	Oral thrush	Miconazole 2% oral gel 15g

34.	Prevention of dental caries (dental decay)	Mouthwashes such as chlorhexidine gluconate Fluoride toothpaste
35.	Ringworm/ Athletes foot	Miconazole 2% cream Miconazole powder Miconazole 0.16% spray powder
		Terbinafine hydrochloride 1%
36.	Teething/ mild toothache	Paracetamol 500mg tablets, capsules, effervescent tablets Paracetamol 120mg/5ml suspension (from 3 months) sugar free Paracetamol 250mg/ 5ml suspension (from 6 years old) sugar free
		Ibuprofen 200 mg, 400mg capsules and tablets Ibuprofen 100mg/ 5ml liquid sugar free
		Teething gel
37.	Thread-worms	Mebendazole 100mg tablets
38.	Travel sickness	Cinnarizine tablets 15mg
		Hyoscine hydrobromide tablets 150mcg
39.	Warts and verrucae	Verruca gel, such as those containing salicylic acid and lactic acid
		Wart paint/ ointment such as those containing salicylic acid and lactic acid
		Wart freeze treatments containing liquid freezing agents such as dimethyl ether, propane and isobutene
40.	Health and OTC products	All Health & OTC products registered/ enlisted by the DRAP, except those included in Schedule-D
41.	Alternative Medicines	All Alternative Medicines registered/ enlisted by the DRAP, except those included in Schedule-D

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SCHEDULE-I
[See rule 15]
RECALL

Latest Guidelines of the Drug Regulatory Authority of Pakistan issued in connection to Recall of Drugs or Therapeutic Goods.

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SECRETARY
GOVERNMENT OF THE PUNJAB
HEALTH AND POPULATION DEPARTMENT

Dated Lahore, the 12th November, 2026.

Copy is forwarded to Superintendent, Government Printing Press Punjab, Lahore for publication of the above notification in the extraordinary Gazette and supply of 10 copies of the same for record. The publication of this notification expeditiously is required under the Drug Act, 1976.

m. Zubair 12/11/26

SECTION OFFICER (DRUGS CONTROL-I)

Number & Date even:

A copy is forwarded for information:

1. Deputy Director, HISDU, Health and Population Department, with the request to upload this notification on the official website of Health and Population Department.
2. Senior Law Officer, Health and Population Department.
3. P.S.O to Secretary, Health and Population Department.
4. P.S to Special Secretary (Operations), Health and Population Department.
5. P.A to Additional Secretary (Drugs Control), Health and Population Department.
6. P.A to Deputy Secretary (Drugs Control), Health and Population Department.

m. Zubair 12/11/26

SECTION OFFICER (DRUGS CONTROL-I)