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PART II

Statutory Notifications (S.R.O.)

GOVERNMENT OF GILGIT-BALTISTAN
LAW AND PROSECUTION DEPARTMENT
GILGIT-BALTISTAN SECRETARIAT

NOTIFICATION

Gilgit, the 15th October, 2026

THE GILGIT-BALTISTAN THERAPEUTIC GOODS SALE RULES, 2025

S.R.O. 1867(I)/26.—In exercise of the powers conferred upon it under section 44 of the Drugs Act, 1976 (XXXI of I976), which is part of Schedule-VI of the Drug Regulatory Authority of Pakistan Act 2012 (XXI of 2012), the Provincial Government of the Gilgit-Baltistan is pleased to make the following rules, namely, —

CHAPTER I
PRELIMINARY

1. **Short title and commencement.**—(1) These rules may be called the Gilgit-Baltistan Therapeutic Goods Sale Rules, 2025.

2587(1—57)

Price: Rs.80.00

[11952(2026)/Ex. Gaz.]

(2) These rules shall come into force at once.

2. **Definitions**.—(I) In these rules, unless there is anything repugnant in the subject or context:

(a) "Act" means the Drugs Act, I976 (XXXI of 1976);

(b) "Alternative Medicine" means alternative medicines as defined in the DRAP Act and rules framed thereunder;

(c) "Committee" means a committee of the Board and the words and phrases "District Quality Control Board" may be construed accordingly, if so required;

(d) "Compounding" means a drug 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 as prescribed in Schedule-F;

(e) "Distributor" means supplier or seller of therapeutic goods who stores, sells or distributes therapeutic goods to a pharmacy, medical store or health institution as authorized agent on behalf of pharmaceutical manufacturer or importer, and the word "Distribution" may be construed accordingly but shall not include medical device distribution store;

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

(g) "Form" means a form mentioned in Schedule-A;

(h) "Government" means Government of Gilgit-Baltistan.;

(i) "Health Product" means a health product as defined under the DRAP Act and rules framed thereunder;

(j) "Inspector" means a Provincial Inspector appointed under section 17 of the Act and vested with the powers under Schedule-V of the DRAP Act;

(k) "Licensing Authority" means the Chief Drug Controller or Chief Inspector of Drugs/ Directorate of Drugs Control Gilgit-Baltistan an officer of the Government/Directorate of Drugs Control. Gilgit-Baltistan duly authorized by notification in official gazette;

(l) "Licensee" means a person, a company or a firm to whom license has been issued under these rules;

(m) "Medical Device" means medical devices as defined in the DRAP Act and rules framed thereunder;

(n) "Medical Devices Distribution Store" means a premises where medical devices are stored, sold, distributed or exhibited for sale to hospitals/ institutions/ healthcare facilities, or consumers on behalf of medical devices manufacturer or importer as authorized agent;

(o) "Medical store" means premises where therapeutic goods, excluding the drugs specified in Schedule G, are stored, sold, exhibited, or offered for only retail sale;

(p) "Manufacturer' means a manufacturer of a therapeutic goods;

(q) "Narcotic, psychotropic or controlled drug" means a therapeutic good as placed under Schedule-B;

(r) "Online sale" sale of a therapeutic good by a licensee under these rules through E-Commerce including internet or any online medium in accordance with the conditions prescribed by in the rules;

(s) "Pharmacist" means a pharmacist as defined under the Pharmacy Act, 1967 (XI of 1967);

(t) "Pharmacy" means licensed premises for retail sale where therapeutic goods are compounded or dispensed and sold on prescription or stored, offered for sale;

(u) "Pharmacy Services" means pharmacy services as defined in the DRAP Act and rules framed thereunder;

(v) Drug Control Administration/ Directorate of Drugs Control Gilgit-Baltistan.

(w) "Prescriber" means the person who is registered under the Act of the relevant Council and is authorized to prescribe respective therapeutic goods;

(x) "Provincial Board" means the Provincial Quality Control Board as defined under Section 11 of the Act and constituted in rule 3;

(y) "Qualified person" means a person defined under rule 15 of these rules;

(z) "Recall" means removal of specific batch / batches or the part of thereof of a therapeutic good from the market or where supplied for reasons relating to quality, safety or efficacy, as may be provided in the DRAP Guidelines;

(aa) "Retail sale" means sale of therapeutic goods to consumers or patients;

(ab) "Schedule" means Schedule to these rules;

(ac) "Sell" means sell, offer for sale, exhibit for sale, have in possession for sale and distribution and "to sell", "sold" or "sale" shall be construed accordingly;

(ad) "Seller" means person who sell, sale or hawk the therapeutic goods;

(ae) "Secretary" means a person who has been appointed as a Secretary Provincial Quality Control Board of Gilgit-Baltistan.

(af) "Substitute or alternate or replacement qualified person" means a person having same or equal qualification or registration to fulfill the legal requirement of license premises and authorized by the qualified person. One qualified person shall be engaged for one licensed premises only;

(ag) "Therapeutic goods" mean therapeutic goods as defined in the DRAP Act; and

(ah) "Wholesale" means a facility of stock of therapeutic goods for sale to a pharmacy, medical store, hospital or institute.

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

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

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

(a) Secretary to the Government, Health Department/Drug Control Administration GB, *ex-officio* member and Chairperson;

(b) Additional Secretary concerned to the Health Department/Drug Control Administration *ex-officio* member, who shall also act as Vice-Chairperson;

(c) Chief Drug Controller/Chief Inspector of Drugs, Drug Control Administration, Gilgit-Baltistan *ex-officio* member;

(d) One expert of Pharmaceutics preferably a professor of pharmaceutics,

appointed as a private member from Al Hayat Institute Gilgit or any other recognized institute of Pharmacy Technician from Central Pharmacy Council Pakistan for a term of five years;

(e) One pharmacologist preferably a professor of pharmacology and has more than ten years of professional experience, appointed as a private member by the Provincial Headquarter Hospital for a term of five years;

(f) One expert of pharmaceutical chemistry preferably a professor of pharmaceutical chemistry and has more than ten years of professional experience, appointed as a private member by the Karakarum International University, Gilgit for a term of five years;

(g) One expert of analytical chemistry preferably a professor of analytical chemistry and have more than ten years of professional experience, appointed as a private member by the University of Baltistan for a term of five years;

(h) One physician preferably a professor of medicine and has more than ten years of professional experience, appointed as a private member by the RHQ Hospital Gilgit for a term of five years;

(i) One expert of Alternative medicines; having at least ten years' experience in the relevant field from the public sector, appointed as a private member by the University for a term of five years;

(j) One expert in Veterinary medicines; having a qualification of Doctor of Veterinary medicines with at least ten years' experience in the relevant field from the public sector, appointed as a private member by the Directorate of Livestock & Animal Husbandry Gilgit for a term of five years;

(k) One expert of Biotechnology; with at least ten years' experience in the relevant field from the public sector, appointed as a private member by the Health Department for a term of five years;

(l) One law expert to be nominated by the prosecution or law department; who shall not be below BPS-18 having experience in the relevant field from the public sector, appointed as a private member by the Law Department Gilgit-Baltistan for a term of five years;

(m) One representative of Drugs Regulatory Authority of Pakistan not below the rank of Additional Director or Deputy Director/Federal Inspector of drugs nominated by the CEO, DRAP who shall be *ex-officio* member.

(n) Secretary of Board who shall be the *ex-officio* secretary cum member.

(o) any co-opted member with the permission of the Chairperson.

(2) In the absence of the Chairperson, the Additional Secretary Health or Chief Drug Controller as Vice-Chairperson shall preside over a meeting.

(3) The Secretary of the Board or any officer authorized by the Board may sign and

issue the show cause notice, personal hearing letter or orders or any other correspondence on behalf of the Board.

(4) The quorum for a meeting of the Provincial Board shall be half of the total members, including the Chairperson or Vice-Chairperson.

(5) No act or proceeding of the Provincial Board shall be invalid merely on the ground of the existence of any vacancy or any defect in the constitution of the said Board.

(6) The Health Department on the recommendations of the Board may approve or revise the analysis fee for the test /analysis of therapeutic goods in Drug Testing Laboratory Gilgit-Baltistan as mentioned in Schedule-C.

(7) The Board may permit the analysis of any sample from one drug testing Laboratory to another Laboratory due to any reason of non-availability of testing in that laboratory.

4. District Quality Control Board– (1) The Board may, if so required, constitute a committee in a district to be known as the District Quality Control Board comprising of the following members:

(a) Deputy Commissioner of the district, *ex-officio* member and convener;

(b) An expert in the field of Pharmacy in a district appointed by the department as member;

(c) An expert of medicine in the district appointed by the concerned Health Department Gilgit under rule 3 (6), private as member; and

(d) The Drug Inspector /Deputy Drug Controller who shall be the Secretary/ member of the Committee to be nominated by the Provincial Quality Control Board.

(2) The quorum for the meeting of a District Board shall be two third.

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

(4) The Board may issue direction or/ and issue instruction to a District Board.

5. Procedure for the Board– (1) An Inspector or a Government Analyst shall submit, manually or electronically, monthly reports on Form 1 and Form 2, to the District Board, if required and the Provincial Board. The Provincial Board and the District Board shall maintain the information in order to monitor the quality of all the therapeutic goods.

(2) The Provincial and the District Board, as the case may be, shall meet preferably once in a month to review the situation of the quality control of therapeutic goods on the whole including consideration of any specific point arising during the period on the working of pharmacies, medical stores, distributors, manufacturers, importers, indenters, drug testing laboratories and inspectors.

(3) The Provincial or the District Board, as the case may be, shall examine a case

referred to it by an Inspector and shall, if an action is proposed to be taken against a person under the Act, DRAP Act, 2012 or the rules frame thereunder, issue a show cause notice to the person and provide him an opportunity for hearing before taking the action about the prosecution of the person or recommending suspension or cancellation of License to the Licensing Authority or suspension or cancellation of License or registration or enlistment of Therapeutic Goods to the Registration Board or Central Licensing Board or Enlistment Evaluation Committee or Medical Devices Board, as the case may be.

(4) The Provincial or the District Board as the case may be, may grant the permission for registration of FIR in cognizable cases as per the Act, without issuance of any show-cause notice.

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

(6) The Provincial or the District Board may, in case of a contravention, direct the manufacturer or distributor or the seller to bring improvement, issue a warning to him, order the de-sealing and/ take any other action.

(7) The Provincial or the District Board, as the case may decide the fate of case property or direct the drug inspector or secretary of the concerned Board or constitute a committee for disposal of case property or recovered or seized therapeutic goods of the cases which are not referred for prosecution by the Board.

(8) The Provincial and the District Board, as the case may, forbid a person, for a further period not exceeding three months, from removing or disposing of a Therapeutic Good, article or other thing, on the request of an Inspector. The Board may allow safe custody of the seized stock of therapeutic goods or any other article till decision by the Court of Competent jurisdiction if said material is required to be used as evidence in prosecution.

(9) A retired Secretary of the Provincial Board or District Board or Drug Inspector, while attending the Drug Court for recording of his evidence, shall be entitled to TA/DA and accommodation as admissible to the serving, officers of equivalent grade, as the case may be and same shall be paid by the respective government.

6. Qualifications for appointment of 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 an 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 an institution, recognized by the Pharmacy Council of Pakistan and has at least three years' experience in the testing or analysis of drugs.

(3) Provided that more than one Government analysts may be appointed for test and analysis of various therapeutic goods as deems appropriate.

(4) No person shall be appointed as pharmaceutical expert / member in drug court unless he holds a degree in Pharmacy from a University, or an institution, by the Pharmacy

Council of Pakistan and working in public sector preferably has at least 10 years' professional experience in the manufacturing, testing or analysis of drugs or drug control administration or pharmacy services.

(5) No person shall be appointed as medical expert / member in drug court unless he holds a MBBS degree or equivalent from a University or medical institution recognized by the Pakistan Medical & Dental Council and working in public sector preferably has at least 10 years' professional experience in the hospital or medical or health institute or health services or health administration.

7. Duties of Inspectors– Subject to the instructions of the licensing authority and section 18 of the Drugs Act, 1976, an Inspector may-

(a) inspect a medical store, a pharmacy, distributor of a therapeutic goods manufacturing premises at least once in six months at his own or schedule notified by the licensing authority and maintain record of the inspections and to satisfy himself that the conditions of the license are being observed;

(b) if he has reasons to believe that the therapeutic goods are being manufactured, distributed, sold, stocked or exhibited for sale in contravention of a provision of the Act, DRAP Act, 2012 or the rules framed thereunder, he may take samples of the therapeutic goods on Form 4 and send it for test or analysis and may seize the therapeutic goods or any equipment Form 5;

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

(d) initiate prosecution on the direction of the Provincial or the District Board within 90 days from the date of receipt of order and to pursue cases in the Court;

Provided that the inspector may seek extension for further 90 days with cogent reasons if he fails to submit prosecution with stipulated time period.

(e) maintain record of actions taken by him in the performance of his duties, including the taking of samples and seizure of therapeutic goods or equipment's, and submit reports of such record to the Provincial and the District Board;

(f) stop sale of therapeutic goods being carried in contravention of the Act, DRAP Act and these rules;

(g) inspect a place licensed under the Act, DRAP Act, 2012 or the rules for the purpose of issuance or renewal of the therapeutic goods sale license;

(h) submit the investigation report, in case of non-cognizable offenses or forward the matter to the provincial or district board as the case may be for grant of permission for prosecution or necessary action within 120 days. The inspector has to seek permission in writing for extension of time for completion of investigation if he fails to complete investigation in 120 days; and

(i) seek information, documents and data or the names of person prima facie involved in the commission of offenses.

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

9. Form of order not to dispose of stock– An Inspector, requiring a person not to dispose of a therapeutic goods or other material, shall make the order under section 18(1)(i) of the Act in on Form 3.

10. Form of intimation of purpose of taking samples– (1) An Inspector who takes sample of a therapeutic goods for the purposes of test or analysis, shall intimate the purpose of taking the sample to the person from whom he takes the sample in on Form 4 and if he seizes a therapeutic goods or drug or other material, shall issue receipt of the seizure in on Form 5.

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

(3) The Inspector shall send a specimen impression of his seal to the Government Analyst concerned within 30 days of his appointment as an inspector.

11. Duties of Government Analyst. – (1) A Government Analyst shall cause test and analysis of the sample of a therapeutic goods sent to him under the Act or the rules shall furnish report, the result of test and analysis in on Form 7.

(2) A Government Analyst shall cause test and analysis of the sample of a therapeutic good sent to him in writing by an Inspector, 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 one from whom the sample was received.

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

12. Procedure on receipt of samples from Inspectors. – On receipt of a sample of a therapeutic good from an Inspector or a person or Government institution or hospital, the Government Analyst shall compare the seals on the packet of the sample or the sample as the case may be, with the specimen impression received and shall note the condition of the seal on the packet of the sample or the sample as the case may be and after the test and analysis has been completed, he shall forthwith supply to the Inspector and the Board, a report of the result of the test and analysis within prescribed period.

13. Fee for test and analysis of therapeutic goods. – (1) The Government Analyst may receive sample of a therapeutic goods from a person other than Inspector, the Government Department or a governmental Institution or hospital.

(2) If the sample of a therapeutic good is received from the person or Government Institution or hospital, the Government Analyst shall charge fee for the test and analysis of the sample at the rate specified in the Schedule-C.

(3) The fee of test / analysis specified in the Schedule C shall be revised from time to time by the Provincial Quality Control Board.

CHAPTER III
SALE OF THERAPEUTIC GOODS

14. Licenses under the rules. – (1) The licensing authority may issue a license of pharmacy/Narcotic medicines on Form 9 or medical store on Form 10 or distributor on Form 11 or alternative medicines on Form 12 or medical devices on Form 13.

Provided that the license holder on Form 9 for the sale of therapeutic goods may adopt the online sale modality while adhering to all prescribed conditions relating to the records and traceability.

15. Application and fee for license. – (1) A person may apply manually or through web generated Form to the licensing authority for the grant / issuance of new or renewal of a license referred to in rule 14 in Form 8(A) or Form 8(B) or Form 8(C) or Form 8(D) or Form 8(E).

(2) The licensing authority may issue guidelines regarding all the matters for the grant or renewal of licenses.

(3) The applicant shall deposit the fee for the grant or renewal of a license in the Head of Account of government treasury as specified by licensing authority, at the following rates:

(a) Thirty two thousand rupees for a license of a pharmacy or online sale;

(b) Twenty thousand rupees for a license of a medical store;

(c) Thirty Six thousand rupees for a license of a distributor or Alternative medicines or a medical device; and

(d) Fifty percent of the original fee shall be applicable for renewal or duplicate license or addition of go-down or extension in size of premises or change / addition of qualified person or licensee or firm or change of proprietorship of license of government hospital acquired pharmacy.

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

16. Qualification of qualified person to supervise licensed premises. (1) A person who is pharmacist having degree in pharmacy from a University or an institution recognized by the Pharmacy Council and registered in Register 'A' under clause (a) of sub-section (1) of section 24 of the Pharmacy Act, 1967 (XI of 1967) shall be approved as qualified person to supervise pharmacy, distribution, established for the purposes of sale of therapeutic goods or go-down, used only for storage of therapeutic goods.

(2) A person registered in Registers 'A' or 'B' under clauses (a) and (b) of sub-section (1) of section 24 of the said Act shall be approved as qualified person to supervise medical store.

Provided that a person who is not pharmacist and has been previously approved as qualified person shall continue on same premises as qualified person till he resigns or proprietor terminates his agreement for continuation of service.

(3) A person having degree in Bio medical engineering from a University or an institution recognized by the Pakistan Engineering Council or pharmacist having degree in pharmacy from a University or an institution recognized by the Pharmacy Council and registered in Register 'A' under clause (a) of sub-section (1) of section 24 of the said Act shall be approved as qualified person to supervise pharmacy, distribution, medical store established for the exclusive purpose of sale of medical devices.

(4) A person having degree in pharmacy from a University or an institution recognized by the Pharmacy Council and registered in Register 'A' under clause (a) of sub-section (1) of section 24 of the said Act shall be approved as qualified person to supervise pharmacy, distribution, medical store established for the exclusive purpose of sale of Homoeopathic medicines or Unani, Ayurvedic system of remedy or product.

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

(2) The stockiest of chain pharmacy may obtain a license on Form 11 to distribute therapeutic goods to its own pharmacy either owned or franchise located anywhere subject the condition specified in Schedule-H.

18. Duration of Licenses. – (1) A license issued or renewed under these rules shall unless suspended or cancelled earlier, remain in force for the period of five years from the date of issue.

(2) If a person fails to apply for the renewal of a license within sixty days after the expiry of the license shall stand canceled. 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.

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

(4) The licensing authority shall dispose of an application for a license or renewal of a license within 45 days of the receipt of the application after fulfillment of codal formalities.

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

(6) If in the opinion of the licensing authority, it is not expedient in public interest to grant a license, it may reject the application in writing after affording an opportunity of a personal hearing and recording reasons thereof.

(7) The licensing authority shall not issue or renew a license without an inspection report by of the Inspector. The inspector shall generate a report on the prescribed form.

19. Conditions for issuance of licenses. – (1) The licensing authority shall not issue a license on Forms 9, 10, 11, 12 and 13 unless-

(a) the premises have proper and adequate facility for storage of 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) in the case of a license of a pharmacy in which preparation or compounding of therapeutic goods is undertaken, the premises has fulfilled the requirements contained in the Schedule-F;

(d) the covered horizontal/vertical area of the premises of a pharmacy shall not be less than 150 squares feet with minimum width of 10 feet, for a medical store 96 square feet with minimum width of 8 feet, for distributor 500 square feet minimum for the warehouse, for medical store for alternate medicines 96 square feet with minimum width of 8 feet and for medical store for medical devices 200 square feet with minimum width of 10 feet;

(e) in case of maintenance of an online sale by the licensee, the license number of the licensee shall be available on the domain of licensee as well as shall be verifiable from the website of the licensing authority.

(2) The licensing authority shall not issue or renew a license to a distributor without verification of the computerized facility ensuring maintenance of a proper computerized system of inventory control for the sale and purchase of therapeutic goods and requirements of Schedule-H.

(3) The licensing Authority shall not issue license if either the applicant or qualified person has been convicted under sub-section (1) of Section 27 of the Act or paragraph (1) of Schedule-III of the DRAP Act.

20. Conditions of licenses. – (1) The licensing authority shall issue a license in Forms 9, 10, 11, 12 and 13 subject to the conditions stated in the Act or rules and to the following general conditions:

(a) All therapeutic goods sale licensees shall display a signboard in front of their premises having minimum dimensions of 2.6 feet and 5 feet length with following specifications:

(i) Red colour background with white colour writing for medical store;

(ii) Green colour background with white colour writing for Pharmacy;

(iii) Yellow colour background with black colour for distribution;

(iv) Blue colour background with white colour writing for Alternative medicines store; and

(v) Purple colour background with white colour writing for Medical Devices Store.

Provided that if a Pharmacy, medical store, good -own, or distribution, as the case may be, is operating more than one shift of 8 hours, the number of qualified persons shall be appointed accordingly to allow supervision of sale of therapeutic goods throughout the working hours. The licensee is bound to keep a record of attendance and leave of qualified persons and hours of duty.

(b) a licensee of a medical store (Form 10) shall not sell or store therapeutic goods mentioned in the Schedule G;

(c) the supply of a therapeutic goods shall be recorded suitably and the records, the warranty, the bills or the counterfoils shall be preserved for a period of at least three years from the date of the sale;

(d) a therapeutic goods specified in the Schedules B, D and E and a preparation containing such therapeutic goods shall not be sold except on and in accordance with the prescription of a registered medical practitioner;

(e) the sale of therapeutic goods specified in the Schedule-I is permitted without prescription of a registered medical practitioner;

(f) an invoice or a bill for the purchase of therapeutic goods shall be preserved for a period of at least three years.

(2) A manufacturer, importer or distributor of therapeutic goods shall sell the therapeutic goods only to a holder of a valid therapeutic goods sale licensee or to a registered medical practitioner and shall issue an invoice and warranty at the time of sale of the therapeutic goods.

Provided that the sale of therapeutic goods to a registered medical practitioner shall be exclusively for the purpose of emergency use.

(3) In case of sale of therapeutic goods to a registered medical practitioner; the manufacturer, importer, distributor, or seller of therapeutic goods shall maintain the copies of the record in duplicate including the invoices and warranties, and produced to the Inspector when required. The Electronic record must also be maintained.

(4) The invoice and warranty shall bear the full name and address of the purchaser and shall be signed by the warrantor (stamp signature or system generated signature) clearly indicating his name and CNIC and shall be dated.

(5) The manufacturer, importer, or seller of therapeutic goods shall maintain a record of the purchase or sale of therapeutic goods and shall preserve the record for at least one year after the expiry of therapeutic goods containing the following particulars:

(a) the date of purchase and sale;

(b) the name and address of the concern from which the therapeutic goods are purchased or the concern to whom the therapeutic goods are sold;

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

(d) the name of the manufacturer; and

(e) The record pertaining to the warranty of the therapeutic good purchased or sold, as the case may be, shall be maintained till one year after the expiry of the therapeutic good.

Except as otherwise provided in these rules, a record required to be maintained under these rules shall be preserved for a period of not less than one year after the date of expiry of therapeutic good.

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

(7) A substance specified in the Schedule E and that falls under the list of poisons and the therapeutic goods specified in the Schedule B shall be stored in a locked almirah, cupboard or drawer, reserved solely for the storage of the substance or the therapeutic goods.

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

(9) A substance that falls in the list of poisons under the Schedule-E when compounded and dispensed shall be labeled with the word 'Poison'.

(10) The qualified person of any license shall inform the licensing authority or area drug inspector in writing within one month in case of death of proprietor and the proprietor shall inform vice-versa; but in case of death of qualified person, immediately sale will be stopped till the appointment of new qualified person, if only one qualified person is approved.

(11) A manufacturer, importer or the distributor of a drug/therapeutic good shall sell the drug/therapeutic good only to a holder of a valid drug/therapeutic good sale license and shall issue an invoice/warranty at the time of sale of such drug/therapeutic good.

(12) The licensee having license in Forms 9, 10, 11 and 12 shall ensure that warranty in the Form for every batch of drug so procured is obtained in accordance with the provisions of the clause (i) of sub-section (1) of section 23 of the Act.

(13) The licensee holding license on Forms 9, 10, 11 and 12 shall be required to ensure storage of the allopathic drugs completely segregated from other items, if so stored.

(14) The licensee holding license on Forms 9, 10, 11 and 12 shall ensure storage of expired drugs in a shelf/cupboard reserved for that purpose and labelled accordingly with red ink as 'Expired Drugs' conspicuously.

(15) The registration certificate from pharmacy council of the qualified person, to whom a drug sale license is issued, shall be displayed in original along with drug sale license in a conspicuous place in part of the premises at appropriate level, open and visible to the

public.

(16) The licensee holding a license issued under these rules shall in no case store, sell or exhibit for sale any item, including but not limited to tobacco products, which are injurious to health.

(17) A manufacturer, importer or the distributor of a drug/therapeutic good shall sell the drug/therapeutic good only to a holder of a valid drug/therapeutic good sale license and shall issue an invoice/warranty at the time of sale of such drug/therapeutic good.

(18) The licensee having license in Forms 9, 10, 11 and 12 shall ensure that warranty in the Form for every batch of drug so procured is obtained in accordance with the provisions of the clause (i) of sub-section (1) of section 23 of the Act.

(19) The licensee holding license on Forms 9, 10, 11, and 12 shall be required to ensure storage of the allopathic drugs completely segregated from other items, if so stored.

(20) The licensee holding license on Forms 9, 10, 11, and 12 shall ensure storage of expired drugs in a shelf/cupboard reserved for that purpose and labeled accordingly with red ink as 'Expired Drugs' conspicuously.

(21) The registration certificate from the pharmacy council of the qualified person, to whom a drug sale license is issued shall be displayed in original along with drug sale license in a conspicuous place in part of the premises at an appropriate level, open and visible to the public.

(22) The licensee holding a license issued under these rules shall in no case store, sell or exhibit for sale any item, including but not limited to tobacco products, which are injurious to health.

21. Cancellation or suspension of licenses.– The licensing authority may, on the report of an Inspector or the Provincial or the District Board, if in its opinion the licensee has failed to comply with any of the conditions of the license or with any of the provisions of the Act or these rules, after giving the licensee an opportunity to show cause and personal hearing and by an order in writing stating the reasons, cancel a license issued under these rules or suspend it for such period as it may deem fit.

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

(2) The Secretary to the Government,Healthcare Department shall be the Provincial Appellate Authority for the purpose of hearing appeals against an order of the licensing authority.

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

(4) The Provincial Appellate Authority shall, after giving the appellant an opportunity of hearing, pass such order as it deems fit and the order of the Authority shall be final and cannot be called in question before any forum.

23. Good storage and distribution practices. – A Licensee under these rules, a public sector institution or a private organization dealing in distribution and storage of therapeutic goods shall comply with the good storage and distribution practices contained in Schedule-H in accordance with the Guidelines on Good Distribution Practices for Pharmaceutical and Biological Drug Product and Guidelines on Good Cold Chain Management Practices for Time and Temperature- Sensitive Drug Products.

24. Recall of Therapeutic goods- (1) to assure the availability of quality, safe and efficacious therapeutic goods, the process of the recall of therapeutic goods shall follow the Guidelines on Recalls and Rapid Alerts of Defective Therapeutic Goods and monitoring of the effectiveness of Recall from the market, pharmacy, medical store, distribution, manufacturer site, health institutes or hospital is responsibility of the area drug inspector, who shall prepare an investigation report of recall of therapeutic goods.

(2) The Board shall initiate the process of regulatory recall on complaint or news or on failure of recall by the manufacturer to protect the public health or risk of health hazards, injury or otherwise defective and share the information to the Drug Regulatory Authority of Pakistan for an effective Recall at National Level.

(3) The licensee is primarily responsible for not selling or distributing any recalled product when notified by the provincial or district quality control boards.

(4) The manufacturer or importer or distributor is responsible for the complete recall / total recall of the therapeutic good voluntarily or statuary, and submit the detail report of recall to concerned drug inspector or provincial or district quality control boards.

25. **Pharmacovigilance.-** A licensee on Form 9 under these rules shall comply with the pharmacovigilance activities to fulfill the legal obligations as defined in the Pharmacovigilance Rules, 2022 under the DRAP Act and the relevant guidelines issued from time to time. The licensee shall collect, prepare, and maintain the record of pharmacovigilance reports. The pharmacovigilance data shall be submitted to provincial or national centers through the website.

26. Pharmacy Services.– (1) Qualified person shall render pharmacy services on licenses issued under the DRAP Act and rules framed thereunder and the relevant guidelines issued from time to time.

(2) The licensee shall extend all possible support to a qualified person rendering applicable pharmacy services at the licensed premises.

27. Track and traceability of therapeutic goods.- The Provincial Government shall implement a track-and-trace system of therapeutic goods under the DRAP Act and rules framed thereunder and guidelines issued by the Drug Regulatory Authority of Pakistan from time to time.

28. Power to amend Forms and Schedules.– The Provincial Quality Control Board may amend Forms and Schedules of these rules from time to time so as to omit any entry therefrom, add any entry thereto or amend any entry therein.

SCHEDULE A

FORM 1

[See rule 5(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 + adulterated**	**No. of DQCB 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 5(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 field force	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	20	21
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 PQCB approved method	No. of Samples analyzed by official methods	No. of Samples analyzed by official methods with deviation as per SOP	Total pending samples at the end of month

Government Analyst _____, QMS Manager _____ Area _____

Director DTL _____

Book No._____
Serial No._____

FORM 3
[See rule 9]
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, DRAP Act, 2012 and rules framed thereunder. Now, therefore I hereby direct you not to dispose of the stock for a period of ..... days from this date.

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

Details of stock of therapeutic goods

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

Book No._____
Serial No._____

FORM 4

[See rule 10(1)]

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

To,

_____

_____

_____

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

Date.....Time..... Inspector.....

Temp.....Humidity.....

Details of samples of therapeutic good taken

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

Any Specific Test (mention here) _____

Date.....

Inspector.....

Book No._____

Serial No._____

FORM 4-A

[See Rule 8(2)]

SEALING ORDER

In exercise of powers conferred upon me under section 18(1)(h) of the Drugs Act, 1976 and Schedule-V 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 he (owner of premises) also 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 5
[See rule 10(1)]
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, read with schedule V of the DRAP Act, 2012 and rules framed thereunder from the premises of.....
Situated at .....

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

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

Sr. No	Brand Name of therapeutic goods	Generic Name	Batch/Lot No.	Name of manufacturer/Importer/Marketer	Quantity	Reason for seizure

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

Inspector.....

FORM 6
[See rule 10(2)]
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, read with Schedule V of the DRAP Act, 2012 and rules framed thereunder
The portion of sample/container has been marked by me with the following marks.

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

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

Brand Name of Therapeutic Goods	Generic Name	Name of Manufacturer	Registration/ Enlistment No.	Batch / Lot No.	Mfg. date	Exp. date	Quantity

Dated .....

Inspector.....

FORM 7

[see rule (11) (1)]

Report of test/analysis by Government Analyst, Gilgit-Baltistan

1. Name of Inspector of Drugs 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 of Drugs .....

2. The Chairman Provincial Quality Control Board, Government of Gilgit-Baltistan, Health Department.

Government Analyst _____

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

FORM 8(A)

{See rule 15 (1)}

Application for the license to sell, store and exhibit for sale of therapeutic goods by way of pharmacy / Online Pharmacy.

1. I / We _____
of M/S _____
situated at _____along with **Godown (s)**_____
hereby apply for New / Renewal of License of Pharmacy/Online Pharmacy:

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). (name, registration No, CNIC No & address with qualification).
i- _____
ii _____

3. I / We/ am are submitting herewith the following documents;
A) Testimonials of the Qualified person / 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 9 (pharmacy / Online Pharmacy) .
i) Original and one copy of Certificate of registration "A" issued by a pharmacy council.
ii) Copies of CNIC of Pharmacist
iii) Affidavit of the Pharmacist will remain present during the sale of therapeutic goods, duly verified by Magistrate 1st Class, to the effect that they: -
a) shall comply with the provision of the *Drugs Act 1976 and DRAP Act 2012* and rules framed there under;
(b) **Pharmacist shall present in the pharmacy/Online Pharmacy as per specific schedule and display his / her with name and registration on counter** of pharmacy.
c) **Pharmacist may change the brand of therapeutic good having same generic name but not change the generic class or therapeutic class or chemical name** with the consent of customer.
(d) **shall inform the Licensing Authority for any change in Pharmacist staff or any replacement pharmacist for the specific period etc.**
d)have not been convicted of any offence from any Court of law. [See rule 19 (1) (e)];
d) are not working or employee or civil servant of in any government / semi government / autonomous organization.
f) shall not sell / stock any expired, spurious, substandard, unregistered misbranded, counterfeit or any therapeutic good in violation to the drugs laws in force.

B) Testimonials of the proprietor (s).
ii) Copies of CNIC of the proprietor (s)
iii) Affidavit of the proprietor (s) that the Pharmacist **(or substitute Pharmacist)** of pharmacy/Online Pharmacy will remain present

iii) Proprietor is duty bond to close the pharmacy or stop the sale if pharmacist is not present on pharmacy.

C) Site Plan indicating the exact location and dully attested rent deed of the premises including vertical covered area not less than 140 square feet, dimensions, signboard, air conditioning and refrigeration facilities.

D) **Pharmacy must fulfill the requirements of Schedule "F" in case of dispensing.**

E) **Online Pharmacy, fulfill following requirements**

i) The information of each prescription transaction will be intimated to concerned area drug inspector through online message/email and whole record of online sale in system and audit trail will be available at least for one year.

F) 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
proprietor(s)
{Name and address}

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

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

FORM 8(B)

{See rule 15 (1)}

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

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

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), registered under section 24(1)(b) of the Pharmacy Act 1967 (register in Register "B" only), who has agreed to remain present during the sale of therapeutic goods for license in Form 10 (Medical Store).

i) Original and one copy of Certificate of registration 'A' or 'B" issued by [name of Province] pharmacy council only.

ii) Copies of CNIC of Qualified Person

iii) Affidavit of the *Qualified Person* will remain present during the sale of therapeutic goods, duly verified by magistrate 1st Class, to the effect that they:-

a) shall comply with the provision of the *Drugs Act 1976 and DRAP Act 2012* and rules framed there under;

(b) Qualified Person shall present in the Medical store as per specific schedule mentioned his/her name and registration on counter of Medical store.

c) shall inform the Licensing Authority for any change in *Qualified Person* or any replacement of *Qualified Person* for the specific period etc.

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

e) are not working or employee or civil servant in any government / semi government / autonomous organization.

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

B) Testimonials of the proprietor (s).

i) Copies of CNIC of the proprietor (s)

ii) Affidavit of the proprietor (s) that the *Qualified Person* **(or substitute** Pharmacist or ***Pharmacy Technician / Pharmacy assistant*** **of Medical** store will remain present.

iii) ***Proprietor is duty bond to close the pharmacy or stop the sale if Qualified Person is not present on Medical store.***

C) Site Plan indicating the exact location and dully attested rent deed of the premises including vertical covered area not less than 96 square feet, dimensions, signboard, air conditioning and refrigeration facilities.

D) 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
Qualified Person

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

FORM 8(C)

{See rule 15 (1)}

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

1. I / We _____
of M/S _____

situated at _____
along with **Godown (s)** _____
hereby apply for New / Renewal of License of Distributor;

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) Affidavit of the Qualified Person (s) duly verified by Judicial Magistrate to the effect that they:-

(a) shall remain present during the sale of therapeutic goods,

(b) shall comply with the provision of the *Drugs Act 1976 and DRAP Act 2012* and rules framed there under;

(c) ***Qualified Person* shall present in the Distribution as per specific schedule and display his / her with name and registration.**

(d) shall inform the Licensing Authority for any change in Pharmacist staff or any replacement pharmacist for the specific period etc.

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

(f) are not working or employee or civil servant of in any government / semi government / autonomous organization.

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

B) Testimonials of the proprietor (s).

i) Copies of CNIC of the proprietor (s)

ii) Affidavit of the proprietor (s) that the Pharmacist **(or substitute Pharmacist)** of pharmacy will remain present.

iii) Proprietor is duty bond to close the distribution setup or stop the sale if pharmacist is not present on Distribution.

C) Site Plan indicating the exact location and dully attested rent deed of the premises including covered area not less than 500 square feet (Premises plus go-downs), dimensions, signboard, air conditioning and refrigeration facilities.
D) Distribution setup must fulfill the requirements of Schedule "H".
E) The Distributor (Form 11) shall sell the selected therapeutic goods on retail sale on the direction of area drug inspector or manufacturer or importer.
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
proprietor(s)
{Name and address}

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

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

FORM 8(D)
{See rule 15 (1)}
Application for the license to sell, store and exhibit for sale of Alternative Medicines/ Nutraceutical/ Homeo / Herbal Medicine by way of Store / stockist / Distributor

1. I / We _____
of M/S _____

situated at _____
hereby apply for **License of Alternative Medicines / Neutraceuticals / Homeo / Herbal Medicine Store /Stockist /Distributor;**

2. The sale of Therapeutic Goods will be under the personal supervision of Pharmacist or Homeo Doctor / Fazel-e-Tibb; (name, registration No, CNIC No & address with qualification).
i- _____
ii _____

4. I / We/ am are submitting herewith the following documents;
Testimonials of the person (s), Registered Unani, Ayurvedic or Homeopathic Practitioner council, who has agreed to personally supervise the sale of alternative medicine/health-OTC product for license in Form 12.
i) three attested copies of registration certificate issued by a pharmacy council and/or Pakistan Engineering Council
ii) four attested copies of CNIC & passport size photographs of the proprietor (s) and person (s) incharge who has agreed to personally supervise the sale of the alternative medicine/health product.
iii) Affidavit of the person who will supervise the sale of alternative medicine/health product and the proprietor, duly verified from the Judicial Magistrate, to the effect that they:-
a) shall comply with the provision of the Gilgit Baltistan Drugs Amendments Act, 2017 and rules framed there under;
b) have not been convicted of any offence from any Court of law. [See rule 19 (1) (e)];
c) shall inform the Licensing Authority for any change in supervisory staff etc.
d) are not working in any government / semi government / autonomous organization.
e) shall not sell / stock any expired, spurious, substandard, unregistered misbranded, counterfeit or any therapeutic good in violation to the drugs laws in force.
B) Site Plan indicating the exact location and specification of the premises including covered area, dimensions, signboard, air conditioning and refrigeration facilities and addresses of godown with site plan (if any).
C) Website address for online transactions
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 of
proprietor(s)
{Name and address}

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

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

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

FORM 8(E)
{See rule 15 (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 **License of Medical Device Store;**

2. The sale of Therapeutic Goods will be under the personal supervision of person register with Engineering council; (name, registration No. CNIC No & address with qualification)._____

3. I / We/ am are submitting herewith the following documents;
A) **Testimonials of the person (s),** Pharmacist or **Biomedical Engineer registered with Pakistan Engineering Council who has agreed to personally supervise the sale of alternative medicine/health product for license in Form 13.**
i) three attested copies of registration certificate issued by a pharmacy council and/or Pakistan Engineering Council
ii) four attested copies of CNIC & passport size photographs of the proprietor (s) and person (s) incharge who has agreed to personally supervise the sale of medical devices
iii) Affidavit of the person who will supervise the sale of medical devices and the proprietor, duly verified, to the effect that they:-
a) shall comply with the provision of the Drugs Act, 1976/DRAP Act, 2012 and rules framed there under;
b) have not been convicted of any offence from any Court of law. [See rule 19 (1) (e)];
c) shall inform the Licensing Authority for any change in supervisory staff etc.
d) are not working in any government / semi government / autonomous organization.
e) shall not sell / stock any expired, spurious, substandard, unregistered misbranded, counterfeit or any therapeutic good in violation to the drugs laws in force.
4. Site Plan indicating the exact location and specification of the premises including vertical covered area, dimensions, signboard, air conditioning and refrigeration facilities and addresses of godown with site plan (if any).
5. Website address for online transactions
6.Treasury receipt / challan No & dated ------- amounting to Rs. ------- in the Account as prescribed by the Licensing Authority.
Date of Submission:_____

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

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

FORM 9
{See rule 16}
License to sell Therapeutic Goods (Biologicals, Drugs, Alternative Medicines/Health Products and Medical Devices) in a Pharmacy

License No:_____
Valid up to:_____

2D QR CODE

1. M/S._____
Along with address(s) of go-down(s) _____
is hereby licensed to sell on prescription, exhibit for sale / compound or dispense or prepare on prescription the therapeutic goods (Biologicals, Drugs, Alternative Medicines/Health Products and Disposable Medical Devices) and sell all types of registered therapeutic goods on the premises situated at _____

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)

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

Photograph of Qualified Person (s)

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.
_____

Google Map of Premises

Drug Sale License History

Dated_____ **Licensing Authority**

(This License is Computer-generated, no need of signature)

FORM 10

{See rule 16}

License to sell Therapeutic Goods (Biologicals, Drugs, Alternative Medicines/Health Products and Medical Devices) by way of retail sale in a Medical Store

License No:_____

Valid up to:_____

2D QR CODE

1. M/S._____

Along with address(s) of go-down(s) _____.

is hereby licensed to sell on prescription, stock and exhibit for sale the specified therapeutic goods (Biologicals, Drugs, Alternative Medicines/Health Products and Disposable Medical Devices) and sell the registered therapeutic goods on the premises situated at

_____

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)	2. Name of proprietor(s) along with residential address and CNIC. _____
Photograph of Qualified Person (s)	3. Name(s) of the pharmacy Technician /Pharmacy assistant who will remain present and supervise the sale of therapeutic goods along with registration number, residential address and CNIC. _____

Google Map of Premises

Drug Sale License History

Dated_____

Licensing Authority

(This License is Computer-generated, no need of signature)

FORM 11

{See rule 16}

License to sell Therapeutic Goods (Biologicals, Drugs, Alternative Medicines/Health Products and Disposable Medical Devices) as Distributor

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 and distribute the therapeutic goods (Biologicals, Drugs, Alternative Medicines/Health Products and Disposable Medical Devices) and sell all the registered therapeutic goods on the premises situated at:

_____

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

Google Map of Premises

Drug Sale License History

Dated_____

Licensing Authority

(This License is Computer-generated, no need of signature)

FORM 12

{See rule 16}

License to sell, Stock, Exhibit for Sale and Distribute Alternative Medicines and Health Products as an Alternative Medicine

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, distribute and sell online the Alternative Medicines and Health Products/Nutraceuticals and sale on the premises situated at

_____

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

Google Map of Premises

Drug Sale License History

Dated_____

Licensing Authority

(This License is Computer-generated, no need of signature)

FORM 13

{See rule 16}

License to sell Therapeutic Goods (Biologicals, Drugs, Alternative Medicines/Health Products and Medical Devices) as a Medical Device Store.

License No:_____
Valid up to:_____

2D QR CODE

1. M/S._____
Along with address(s) of go-down(s) _____.
is hereby licensed to sell on prescription the therapeutic goods (Biologicals, Drugs, Alternative Medicines / Health Products and Disposable Medical Devices) and sell all types of registered therapeutic goods on the premises situated at:

_____

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)	2. Name of proprietor(s) along with residential address and CNIC.
Photograph of Qualified person (s)	3. Name(s) of the Qualified person (registered with Pakistan Engineering Council as bio-medical engineer/ Electrical Engineer/ Electronic Engineer who will remain present and supervise the sale of therapeutic goods along with registration number, residential address and CNIC.

Google Map of Premises

Drug Sale License History

Dated_____

Licensing Authority

(This License is Computer-generated, no need of signature)

SCHEDULE B
[See Rule 20]

THERAPEUTIC GOODS CONTAINING NARCOTIC DRUGS, PSYCHOTROPIC SUBSTANCES, ANTIDEPRESSANT AND OTHERS CONTROLLED DRUGS (Strictly sold on prescription of Registered Medical Practioner Practitioner and maintain separate inventory record on register or on computer system under control)

1. Benzodizepine
2. Pentazocine
3. Dextropropxyphene
4. Phenobarbital
5. Tramadol
6. Pholcodine
7. Methylphenidate
8. Cannabis compounds
9. Desmorphine
10. Dihydromorphine
11. Heroin
12. Morphine M - oxide.
13. Noracynethadol
14. Normorphine
15. Oxycodone
16. Pethidine intermediate A
17. Phenadoxone
18. Phenomorphan
19. Piritrameide
20. Racemorphan
21. Thebacon
22. Trimeperidine
23. Nicocodiene
24. Propyiyam
25. Nicomorphine
26. Normathadone
27. Opium
28. Pethidine
29. Pethidine Intermediate C
30. Phenazocine
31. Piminodine
32. Properidine
33. Recomoramide
34. Steroids drugs except topical preparations
35. Tramadol
36. Ethlmorphine
37. Lysergide

38. Psilicocybine
39. Amphetamine
40. Methamphetamine
41. Methylphenidate
42. Phencyclidine
43. Phenmetrazine
44. Amobarbital
45. Cyclobarbital
46. Glutithimide
47. Pentobarbital
48. Secobarbital
49. Ampetramone
50. Barbital
51. EthchloroVinyol
52. Ethinamate
53. Meprobamate
54. Methaqualone
55. Methyl Phenobarbital
56. Methyprylon
57. Pipradrol
58. Ketamine

Morphine, Morphine Met horbromide and other pentavalent nitrogen morphine derivatives include in particular the morphine-N-oxide derivatives, one of which is Codeine-N-oxideand the Drugs listed in schedule to CNS Act 1997.

SCHEDULE C
[See Rule 20]

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	Dosage Forms; i.e., Tablets, Capsules, Syrup, Dry syrup/ Powder, Suspension, Linctus, Suppositories, Cream, Ointment, Eye / Ear /Nasal Drops, antiseptics, Disinfectants, Tinctures, Lotion, Topical Solutions, aerosol, Inhalers, all other oral, topical preparations etc.	2000	3000
2	Injectable/ Parenteral Preparations; Ampoules, Vials, Infusions, etc.	3000	5000
3	Samples Containing Suspected allopathic ingredient	5000	10000
4	Surgical Dressings; Absorbent cotton Wool, Bandages, Gauze, Plaster of Paris Bandage, Crepe Bandage,	2000	
B	**Fee Schedule for sample received from any other person / institute / export purpose or any other department.**		
1	Dosage Forms; i.e., Tablets, Capsules, Syrup, Dry syrup/ Powder, Suspension, Linctus, Suppositories, Cream, Ointment, Eye / Ear /Nasal Drops, antiseptics, Disinfectants, Tinctures, Lotion, Topical Solutions, aerosol, Inhalers, all other oral, topical preparations etc.	10000	
2	Injectable/ Parenteral Preparations; Ampoules, Vials, Infusions, etc.	15000	
3	Samples Containing Suspected allopathic ingredient	20000	
4	Surgical Dressings; Absorbent cotton Wool, Bandages, Gauze, Plaster of Paris Bandage, Crepe Bandage,	5000	
C	**Fee Schedule for sample received from any other person / company / firm / 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.	Liquid Chromatography / HPLC /UHPLC/ UPLC	10000
3.	GC-MS / LC-MS	10000
4.	TLC / FTIR / Flame Photometery	5000
5.	Atomic absorption Spectroscopy	15000
6.	Refractomotry / 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.	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, saponification value Acetyl value, esters 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 other resources used in testing etc. (if not available in the above table).
(ii). The government analyst will forward the revision of Fee for the test / analysis to the Provincial Quality Control Board for approval (as and when required).

SCHEDULE 'D'
(See rules 20)

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

All registered/ enlisted therapeutic goods or drugs, biologicals, medical devices or Preparations containing the allopathic ingredients substances or mixture of substances, or such dosage forms or preparations intended or used for treatment or mitigation of any disease.

SCHEDULE 'E'
(See rule 20)

Name of Poisonous substances	Percentage of poison content below which the substance or its preparation is exempted from the provision of rule
Aconite, alkaloids	0.20
Apomorphine	0.15
Atropine	0.15
Bellodona, alkoloids calculated as Hyoscyamine	0.15
Brucine	0.20
Calabar beans alkaloids of Cocoa, Alkaloids	0.10
Cocaine?	0.10
Codeine	0.10
Colchicum	0.50 calculated as colchicines
Conine	0.10
Coternine	0.20
Dihydroxy di oxy codein?	0.1
Emetine	1.0
Ephedra Alkaloids?	1.0
Ethylmorphine	0.2
Gelsemium Alkaloids	0.1
Home Atropine	0.15
Hyoscymine	0.15
Daborandi Alkaloids	0.50
Lobellia Alkaloids	0.50
Morphine	0.20 Calculated as anhydrous Morphine
Nicotine	0.20
Papaverine	1.0
Pomegrante Alkaloids	0.15

Sabadilla Alkaloids	1.0
Solananceous Alkaloids not otherwise specified in the list	0.15 Caculated as Hyosimine
Stav sacre, Alkaloids of	0.20
Strychnine	0.20
Thebane	1.0
Veratrum Alkaloids	1.0
Amino alcohol esterified with benzoic acid, phenyl propionic acid or the derivatives of these acids, their salts	1.0
Ammonia	Smelling salts
Antimony, Oxide of Antimony, Ssulphides of Antimony, Organic compounds of antimony	Equivalent of 1.0% of trioxide
Canthridine, Cantharidates	0.10 of canthridine
Chloroform	Substances containing 1% of 10% chloroform
Creosote from wood	Substances containing 50% creosote
Datura herb and seeds, preparation of datura	0.15 calculated as hyoscyamine
Deso morphine, its salts	1.5
Dextrometharphine, its salts	1.50
Formaldehyde Formic acid	Substances containing less than 5% of formaldehyde
Hydrochloric acids	Substances containing 9% of Hcl
Hydro cyanic acid, cyanides	0.15
Mercury, Mercuric chloride, Mercuric aluminium chloride	1.00 of mercuric chloride
Mercuric Iodine	2.0
Mercuric Nitrate	Equivalent of 3% of mercury
Mercury or inorganic compounds of mercury	Equivalent of 2% of mercury
Mercury, Oxides of mercury oxy cyanides of mercuric pot. Iodine	Equivalent of 1% of mercury
Nitric Acid	Substances containing 9% of Nitric acid
Nux Vomica, seeds of nux vomica, preparation of nux vomica	0.20, Calculated as strychnine
Opium	0.20, Calculated as anhydrous morphine

Para aminobenzene sulphonamide, its salts, derivatives of para amino benzene sulphonamide having any of the hydrogen atom of the para amino group of the sulphonamide group substituted by another radical, their salts	Substances intended for topical or external use
Phenampromide, it salts	Phenformin, its salts
Phenols (Any member of the series of phenol of which the first member is phenol and of which the molecular composition varies by one atom of carbon and two atoms of hydrogen, halogens derivatives of phenol, compounds of phenols with a Metal	Substances containing less than 1a5 of phenol Nasal Sprays, mouth washes, pastilles lozer capsules, ointments less than 2.5%of phenol
Pholcodine, its salts	1.50
Picric acid	Substances containing less than 9% of picric acid
Potassium Flouride	Substances containing less than 1% of Pot fluoride
Procaine, salts of procaine	Combination of procaine with antibiotics
Savin oil of sodium fluoride	Substances containing less than 1% of sodium fluoride
Sodium Hydroxide	Substances containing less than 12% of NaOH
Sulphuric Acid	Substances containing less than 9% of Sulphuric Acid

SCHEDULE F
[See rule 19(1)(c)]

LIST OF MINIMUM REQUIREMENTS FOR A PHARMACY I.

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

AI. Premises; The premises of a pharmacy shall be separated from room for private use. The premises shall be built dry, well lit and ventilated and shall of sufficient dimensions to allow the goods in stock, especially drugs and poison to be kept in a clearly visible and appropriate manner. The area of the section to be used at dispensing department shall not be less than 6 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 drugs and chemicals shall be kept in a room appropriate to their properties and in such special containers as will prevent any deterioration of contents or of contents of containers kept near them. Drawer glasses and other containers used for keeping medicaments shall be of suitable size and capable of being closed tightly to prevent the entry of dust. Every container shall bear label appropriate size, easily readable, with names of medicaments as given in Pharmacopoeias.

A Pharmacy shall be provided with a dispensing bench, the top of which shall be covered with washable and impervious material like stainless steel, laminated or plastics etc. The containers of concentrated solutions shall bear special label or marked with the word "Poison" in red letters on a white background. A Pharmacy shall be provided with the following minimum apparatus and books necessary for masking of official preparation and prescriptions: -

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.

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

Note: The above requirements are subject to modification or the directions of the Licensing Authority, if the Authority is of the opinion that having regards to the nature of drugs dispensed, compounded or prepared by the licensee it is necessary to relax the above requirements in the circumstances of a particular case.

SCHEDULE G

Anti-Leprosy Drugs –

1. Rifampicin Injection
2. Dapsone, NA
3. Clofazimine, NA
4. Prothionemide.NA

Immunological Products, Vaccines, sera /Anti-sera–

1. Anthrax Vaccines
2. BCG vaccines
3. Botulisms Antitoxin
4. Cholera Vaccines
5. Diphtheria vaccines
6. Influenza vaccines
7. Measles vaccines
8. MMR (Measles, Mumps & Rubella) vaccines,
9. Rubella Vaccines
10. Pneumococcal Vaccines
11. Poliomyelitis Vaccines
12. Smallpox Vaccines
13. Typhoid Vaccines
14. Immunoglobulins.
15. Rabies Vaccines
16. Homophiles Influenza Vaccines
17. Antivenom Vaccines
18. Covid Vaccines
19. Coagulation factors (II, VII, IX, X)
20. Protein C & S.
21. Human Serum Albumin
22. Anti-D immunoglobulin

Products /Drugs related with malignant diseases and immunosuppression –

1. Folinic Acid
2. Doxorubicin
3. Mercaptopurine
4. Thioguanine
5. Vincristine
6. Cisplatin
7. Busulphan
8. Carmustine
9. Lomustine
10. Cyclophosphamide
11. Melphalan

12. Fluorouracil
13. Mitoxantrone
14. Methotrexate
15. Vinblastine
16. Carboplatin
17. Bleomycin
18. Dactinomycin
19. Chlorambucil
20. Decarbonize
21. Amsacrine
22. Azathioprine
23. Cyclosporin
24. Etoposide
25. Leucovorin
26. Oxaliplatin
27. Paclitaxel
28. Epirubicin
29. Capecitabine
30. Baricitinib
31. Cobazantinib
32. Olaparib
33. Lapatinib
34. Bortezomib
35. Azacitidine
36. Bendamustine
37. Pemetrexed
38. Sevelamer carbonate
39. Modafinil
40. Letrozole
41. Brigatinib
42. Tofacitinib

Anesthesia and General inhalation anesthetics –

1. Propofol
2. Enflurane
3. Isoflurane
4. Halothane
5. Bupivacaine
6. Thiopentone
7. Benzodiazepine
8. Midazolam,
9. Naloxone,
10. Vancuronium
11. Pancuronium
12. Tubocurarine

13. Suxamethonium
14. Neostigmine

Injection Antibiotics–

1. Spectinomycin
2. Teicoplanin
3. Vancomycin
4. Colistin
5. Sodium Fusidate
6. Imipenum
7. Benzathine Penicillin G
8. Azithromycin
9. Fosfomycin

Inotropics Injections–

1. Primacor, NA
2. Enoximone NA
3. Milrinone

Injection Prostaglandins –

1. Dinoprostone
2. Gemeprost NA
3. Carboprost.NA

Alpha Blocker –

1. Prazocin
2. Indramine NA
3. Doxazosin
4. Alfuzosin

Biotechnological products –

1. Interferon,
2. Erythropoietin

Narcotics, anti-psychotropic and tricyclic anti-depressant Drugs in parenteral dosage Form–

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. Phenelzine
13. Lithium

14. Dextropropoxyphene
15. Clomipramine
16. Mianserin
17. Maprotiline
18. Chlorpromazine
19. Meprobamate
20. Chlordiazepoxide
21. Alprazolam
22. Clonazepam
23. Flurazepam
24. Loprazolam
25. Dothiepin
26. Doxepin
27. Nortriptyline
28. Trimipramine
29. Tranylcypromine
30. Flupenthixol
31. Tryptophan
32. Imipramine
33. Amitriptyline
34. Vortioxetine

Anti-Viral and Anti-Fungal Drugs–

1. Acyclovir
2. Amantadine
3. Famciclovir
4. Inosine Pranobex
5. Zidovudine
6. Ganciclovir
7. Idoxuridine
8. Ribavirin
9. Vidarabrin
10. Trifluridine
11. Methisozone
12. Remdesivir
13. Favipiravir
14. Molnupiravir
15. Voriconazole (antifungal)

Thrombolytic Enzymes and anticoagulant Drugs–

1. Alteplase
2. Streptokinase
3. Anistreplase
4. Urokinase
5. Rivaroxaban Tablet (anticoagulant)
6. Apixaban Tablet (anticoagulant)
7. Ticagrelor Tablet (Platelet aggregation Inhibitor)

Products used for Urinary / GI Tract / dialysis – 1. Hemodialysis hyper tonic solution, 2. Lysine solution (Irrigation Solution) 3. Darifenacin 4. Mirabegron 5. Solifenacin Succinate (Urinary frequency &incontinence) 6. Polyethylene Glycol (Osmatic Laxative) 7. Obeticholic Acid (Bile & Liver Therapy) 8. Ursodeoxycholic acid (Bile acid Derivative)
Steroidal Drugs / Preparations – 1. Methylprednisolone 2. Dexamethasone 3. Hydrocortisone 4. Prednisolone 5. Triamcinolone 6. Beclomethasone 7. Mometasone 8. Flumethasone
Hormones and antagonists – 1. Vasopressin 2. Desmopressin 3. Stanozolol 4. Nandrolone 5. Mesterolone 6. Finasteride 7. Somatropin 8. Testosterone 9. Progestogens 10. Fulvestrant (Estrogen receptor antagonist) 11. Abiraterone acetate
Adrenergic and Dopaminergic Drugs 1. Norepinephrine Injection
Products related to cardiology and Radiological Dyes 1. Cardiac Stents 2. Balloons 3. Heart Valves 4. Peace makers 5. Oxygenators
Products related to Radiological Dyes 1. Iohexol 2. Iopromide 3. Dimeglumine

4. Gadopentetate 5. Gadodiamide 6. Iopamidol 7. Meglumine Diatrizoate 8. Gadobutrol 9. Iodixanol
1. Zonisamide (New NSAIDs) 2. Omarigliptin (New DDP-4 antidiabetic) 3. Vonoprazan (New PPI) 4. Brivaracetam (antiepileptic)

Note: (ii). The Provincial Quality Control Board will revise the list of drugs in this schedule annually or may amend any entry there in, omit any entry there from or add any entry there to or whenever required.

SCHEDULE H

[See rule 23]

GOOD STORAGE AND DISTRIBUTION PRACTICE TO BE FOLLOWED BY THE LICENSEE AND A PUBLIC SECTOR INSTITUTION OR A PRIVATE ORGANIZATION

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

1. At each sale or storage site i.e. a distributor, wholesaler, retailer and community or hospital pharmacy, there shall be an adequate number of qualified personnel available at all working hours to monitor pharmaceutical quality assurance.
2. There shall be adequate segregation of pharmaceuticals, veterinary, food products, cosmetics, chemicals, disinfectants and cleaning materials to eliminate the risk of cross contamination.
3. There shall be proper cleanliness and hygiene. The humidity and temperature shall be maintained within acceptable limits of respective products.
4. Goods and materials shall be stored off the floor, suitably spaced to permit ventilation, cleaning and inspection.
5. The dispensing equipment of pharmacy including temperature and humidity monitoring devices and scales shall be validated.
6. The vehicles deployed to distribute, store or handle drugs shall be properly designed and equipped to ensure protection from different environmental and weather conditions.
7. Narcotics, psychotropic drugs and radioactive substances shall be stored separately with proper record keeping.
8. The starting material and products used in the dispensing pharmacy shall be isolated and be properly labelled in a way which prevents mix-up and cross contamination.
9. It will be ensured that pharmaceuticals products due to expire first are sold and/or distributed first (FEFO).
10. Adequate controls shall be in place to prevent the sale/distribution of expired products.
11. Expired, broken or damaged items shall be kept/ stored separately, properly labelled and marked I the medical store/pharmacy or warehouse.
12. Thermo labile products shall be kept in refrigerator with proper temperature recording like thermometer, and its temperature shall be monitored to ensure its consistency within the required limits.
13. Storage conditions for products and materials shall be in compliance with the labelling instructions and requirements.]
14. All the medicines must be kept on racks and shelves to allow access for cleaning and to avoid harboring pests. The stores may be arranged in the store room and shelves as per following general guidelines, pallets are being used stake the carton:
    - at least ten cm (4inches) of the floor;
    - at least thirty cm (1 foot) away from the walls and other stakes;
    - not more than 2.5 meter (8 feet) high.
15. Products shall be protected from excessive climatic conditions during storage and transport such as heat frost, moisture and direct sunlight.
16. Buildings shall be kept free of vermin, insects, birds and other pests.
17. Temperature above 40 degree and relative humidity above 70 percent are considered to be the extremes of temperature and humidity respectively.
18. Drugs products that must be stored under defined conditions require appropriate storage instructions. Unless otherwise specifically stated, deviation may be tolerated only during short terms interruptions or during local transportation.
19. It is important to follow manufacturers recommend storage conditions printed on label of products:

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

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

    Keep Cool: Store between 8°-15° C (45°-59° F)

    Store at room temperature:

    Store at ambient temperature:

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

    Protect from Moisture no more than 60° relative humidity. In normal storage condition; to be provided to the patients in a light-resistant container.
20. There shall not be any leaks from roofs of storage sites.
21. The storage facility shall be clean and free from litter, dust and pests.
22. Adequate precautions shall be taken against spillage and breakage, attack by microorganisms and cross contamination.
23. The manufacturer, importers shall ensure the deliveries only to authorized retailers, wholesalers or distributors under a valid warranty under the law.
24. For all supplies a document shall be enclosed making it possible to identify the stocks to ascertain the date, the name and pharmaceutical firm of the medical product, quantity supplied, the name and address of the supplier and addressee.
25. The medicinal products shall be transported in such a way that:
    a) their identification is not lost;
    b) adequate precautions are taken against spillage, breakage or theft; and
    c) they are secure and not subjected to unacceptable degree of heat, cold, light, moisture and such like other factors.
26. Medicinal products requiring controlled temperature storage shall be transported by appropriately specialized means.
27. Defective medicinal products which have been returned shall be kept apart from saleable stock to prevent sale/ redistribution until a decision has been reached regarding the disposal.

SCHEDULE-I

To be sold on Pharmacy and Medical store without prescription

1.	Chloroxylenol	Topical antiseptic solutions
2.	Paracetamol tablets	Dispense up to 20 tablets
3.	Mefenamic acid tablets	Dispense up to 20 tablets
4.	Disprin Tablets	Dispense up to 20 tablets
5.	Saniplast	Topical adhesive plaster
6.	Mospel lotion	All Topical mosquito repellant lotion and cream
7.	Milk of Magnesia or magnesium hydroxide or aluminium hydroxide	Oral antacid tablet and suspension or syrup
8.	2,4-dichlorobenzyl alcohol, amyl metacresol, Vitamin C.	Strepsils like oral lozenges
9.	Ammonium chloride syrup (single ingredient)	
10.	Saline nasal drops	
11.	Soda glycerin ear drops	
12.	Gripe water liquid	
13.	Kaolin pectin Syrup	
14.	health products & alternative medicines	
15.	Homeo medicines	

SCHEDULE J

AUTHORITY LETTER BY MANUFACTURER OR IMPORTOR OR INDENTOR

No._____

Date of Issuance: _____

Valid up-to_____

I/We, Mr./Ms. _____ S/D/o _____ being market authorization holder and carrying out business at _____ (complete name and address) as a Manufacturer / Importer / indenter and holding license No. _____ Valid up-to _____ issued by _____ do hereby appoint Mr./Ms._____ who will carry out business under the name & title of M/s _____ at _____ (complete address) or carrying on business at _____ (complete name and address) under the license bearing No. _____ (issued by _____ and valid upto _____) as authorized agent for the sale of our registered drugs (list of drugs enclosed) as distributor or wholesaler and **issue warranties on behalf of M/s _____ in Form 2A (as prescribed under the Drugs (Labeling, Packaging & Advertising) Rules, 1976) in his area of distribution or wholesale i.e.** _____.

Specimen Signature of Authorized Agent: _____.

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 drugs only to the licensed retail outlets, as well as public and private institutions or hospitals.

UBAID KHAN,
Chief Inspector of Drug/
Secretary Quality Control Drugs
Gildit-Baltistan.

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