The Drugs (Labelling and Packing) Rules, 1986

The Drugs (Labelling and Packing) Rules, 1986

1. Short title and commencement: (1) These rules may be called the Drugs (Labelling and Packing) Rules, 1986.

(2) They shall come into force on the expiration of the period of one year beginning with their publication in the official Gazette.

2. Definitions: In these rules, unless there is anything repugnant in the subject. or context;
(a) "international non-proprietary name" means the name of a drug as recommended by the World Health Organization or such other name as may be notified by the Federal Government in the Official Gazette;
(b) "pharmacopoeia" means a publication mentioned in sub-clause (ii) of clause (z) of Section 3 of the Drugs Act, 1976 (XXXI of 1976);
(c) "pharmacopoeial name" means the name of a drug as mentioned in the pharmacopoeia;
(d) "Schedule" means a schedule to these rules; and
(e) "registered medical practitioner" means a medical practitioner registered or provisionally registered under the Medical and Dental Council Ordinance, 1962 (XXXII of 1962).

3. Manner of labelling: The following particulars shall appear either in print or in writing in inedible ink in a conspicuous manner on the label of the innermost container of a drug and also on the covering in which such container is packed, namely :--

(a) the registered name of the drug;

(b) if the registered name is a proprietary name, then immediately following the registered name, the generic name or other name, if any, approved by the Registration Board, for this purpose small be printed within breakets with at least equal prominence as that of the brand name;

(c) the international non-proprietary name or the pharmacopoeial name or the generic name, and if no such name is known, the chemical name, of each active ingredient of a drug with weight or measure in metric system, or the number of units of activity, as the case may be, expressed,--

(i) in the case of oral liquid preparations, in terms of contents per specified volume,, the volume being indicated in millilitres;

(ii) in the case of liquid parenteral preparations ready for administration, in terms of millilitres or percentage by volume or dose:

Provided that in the case of a preparation contained in ampoule, it, shall be sufficient if the ingredients are shown on the label or warpper affixed to any package in which such ampoule is issued for sale:

(iii) in the case of drugs in solid form intended for parenteral administration, in terms of weight or unitage, per milligram or gram or per container;

(iv) in the case of tablets, capsules, pills and the like, in terms of the contents per tablets, capsule, pill or other unit, as the case may be; and

(v) in the case of other preparations, in terms of percentage by weigh or volume or unitage, per gram or millilitre, as the case may be;

(d) the name and principle place of business of the manufacturer;
(e) the drug manufacturing licence number;
(f) the drug registration number;
(g) the date of expiry;
(h) Urdu version of the following namely:-
(i) registered name of drug.
(ii) dosage (numerals in English shall be sufficient): and
(iii) Instructions.

(i) the distinctive batch number, date of manufacture, and the maximum retail price:

Provided that in the case of a drug packed in a strip of paper, or blister or foil, or contained in an ampoule of a capacity of not more than two millilitres or in an ampoule containing a sterile suture or ligature, and such strip, foil. blister, or ampoule is placed in another package, and also in the case of printed collapsible tubes, it shall be sufficient to give the information on the outer packing containing such strip, foil, blister or ampoule:

Provided further that the Registration Board may allow relaxation of any of these conditions.

4. Labelling of drugs for internal use: The label of container of a drug meant for internal use, except a drug contained in a strip or foil or blister or collapsible tube, shall, in addition to the particulars required to be given under rule 3, bear in a conspicuous manner,--

(i) If it contains a substance specified in the Schedule, the words "To be sold on prescriptions of a registered medical practitioner only"; and
(ii) if it contains not less than three per cent by volume an alcohol, a statement giving the quantity of alcohol in terms of average percentage by volume of absolute alcohol in the finished product.

5. Labelling of drugs for external use only: The label of a container of ointment, cream, liniment, lotion, liquid, antiseptic or any other drug for external application shall, in addition to the particulars required to be given under rule 3, bear in a conspicuous manner,--
(i) the words "For external use only"; and
(ii) if the drug contains a substance specified in the Schedule, the words "Poison; for external use only".

6. Labelling of physician's samples: The label of a container of every drug intended for distribution to the medical profession as free sample shall, in addition to the particulars required to be given under these rules, bear the words "Physician's sample: Not for sale" which shall be overprinted or stamped: Provided that if the drug is packed in a strip of paper or blister or foil or contained in an ampoule of a capacity of not more than three millilitres or in a collapsible tube, it shall be sufficient to label the outer packing only with the said words.

7. Labelling of drugs for Government supply: The label of a container of every drug intended for the supply to any Government agency including an autonomous body or a semi-Government Agency shall, while complying with the other labelling requirements of these rules, bear the words or mark reading "Government Supply" or such other words or mark as may be required by the agency concerned.

8. Labelling of drugs for veterinary use: The label of a container of drug for veterinary use

shall bear in a conspicuous manner, preferably in red ink the words for veterinary use only.

9. Outer transparent wrapper not to require labelling: Nothing in these rules shall be deemed to require the labelling of any transport cover, wrapper, case or other covering used solely for the purpose of packing, transport or delivery of a drug.

10. Labelling of non-sterile surgical ligature and suture: Every container of, and every wrapper enclosing a surgical ligature or suture, other than a ligature or suture certified to be sterile and fit for surgical use without further sterilization, shall bear a label on which shall be printed or written in a conspicuous manner in indelible red ink the word "Non-sterile surgical ligature/suture: Not to be used for operation upon human body unless properly sterilized".

11. Use of letter to indicate specifications: If a drug is included in the recent edition of any publication specified in the rules, the name of relevant publication in conventional abbreviations (B.P., U.S.P., etc.) shall be printed in indelible ink, on the label to indicate that the drug conforms to the specifications set out in that publication.

12. Packing of finished drugs: Each finished drug ready of use-shall be packed in containers intended for retail sale to a hospital, .dispensary, clinic or any other such institution.

13. Labelling of drugs manufactured for export or experimental purposes: (1) Nothing contained in rules 3 to 12 shall apply to a drug manufactured for experimental purposes which shall be labelled in accordance with rule 23 of the Drugs (Licensing, Registering and Advertising) Rules. 1976.

(2) Labelling of drugs manufactured for export shall, in addition to meeting specific requirements of the importers, bear following particulars printed in indelible ink, on the inner most container and other packings of such drugs,--

(i) name of drugs ;
(ii) name and address of manufacturer; and
(iii) batch number and dates of manufacture and expiry date of the drug:

Provided that in case of a drug packed in a strip of paper, foil or blister or contained in an ampoule of a capacity of not more than two millilitres or in a printed collapsible tube or in an ampoule containing a sterile suture or ligature and that such strip, foil, blister or ampoule is placed in another package, then it shall be sufficient to give name, date of expiry and batch number of the drug, name and address of the manufacturer on the inner-most container or its label, while full particulars shall be given on outer packing containing such strip, foil, blister, ampoule or tube.

14. Exemption: These rules shall not be applicable in respect of a drug made up ready for treatment, whether after or without dilution and is supplied by a person licensed to sell drugs on the prescription of a registered medical practitioner.

Provided that the label bears the following particulars, namely :--
(i) the ham e and address of the suppliers of the drug;
(ii) the name of the patient ;
(iii) the number representing the serial number of the entries in the prescription register;
(iv) if the drug is for internal use, the dosage;
(v) if the drug is for external use, and does not contain a substance specified in the Schedule' the words "For external use only"; and
(vi) if the drug is for external use and contains a substance specified in the Schedule, the words "Poison: for external use only".
THE SCHEDULE

TO BE SOLD BY A RETAILER ON THE PRESCRIPTION OF REGISTERED MEDICAL PRACTITIONER
1. C.N.S. stimulants.
2. Drugs affecting uterine motility.
3, Drugs inhibiting hormonal production.
3. Hormones and other steroidal preparation excluding preparations for external and topical use.
5. Narcotic drugs as per Single Convention on Narcotic Drugs, 1961.
6. Psychotropic substances mentioned as per Convention on Psychotropic Substances, 1971.

DRUGS (LICENSING, REGISTERING AND ADVERTISING) RULES, 1976

S.R.O. 145 (I)/76 dated 12th February 1976:- In exercise of the powers conferred by Section 41 of the Drugs Ordinance, 1976 (IV of 1976), the Federal Government is pleased to make the following rules, namely :--

CHAPTER I - PRELIMINARY

1. Short title and commencement: .(1) These rules may be called the Drugs (Licensing, Registering and Advertising) Rules, 1976.
(2) They shall come into force at once.

2. Definitions.-- In these rules, unless there is anything repugnant in the subject or context:--

(a) "active pharmaceutical ingredient" means a substance or compound that is intended to be used in the manufacture of a pharmaceutical product as a pharmacologically active compound (ingredient);

(b) "airlock" means an enclosed space with two or more doors, which is interposed between two or more rooms of differing classes of cleanliness for the purpose of controlling the airflow between those rooms when they need to be entered and an airlock is designed for and used by either people or goods;

(c) "authorized person" means a person responsible for the release of batches of product for sale;

(d) "basic manufacture" means manufacture of a drug from basic raw material to a product which is ready for use as a starting material for the formulation of a finished drug or for repacking and such manufacture may involve chemical, bio-chemical, photochemical, microbial or such other processes or a combination of any of such processes;

(e) "batch (or lot)" means a defined quantity of starting material, packaging material, or finish product processed in a single process or series of processes so that it could be expected to be homogeneous in the case of continuous manufacture the batch must correspond to a defined fraction of the production, characterized by its intended homogeneity, and to complete certain stages of manufacture it may sometimes be necessary to divide a batch into a number of sub-batches, which are later brought together to from a final homogeneous batch;

(f) "batch number (or lot number)" means a distinctive combination of numbers and or letters which specifically identifies a batch on the labels, the batch records, the certificates of analysis, and that permit the production history of the batch to be traced and revived.

(g) "batch numbering system" means a standard operating procedure describing the details of the batch numbering;

(h) "batch records" means all documents associated with the manufacture of a batch of bulk product or finished product showing a history of each batch of product and of all circumstances pertinent to the quality of the final product;

(i) "biological agents" means micro-organisms, including genetically engineered micro-organisms, cell cultures and endoparasites, whether pathogenic or not;

(j) "bulk product" means any product that has completed all processing stages up to, but not including, final packaging;

(k) "calibration" means the set of operations that establish, under specified conditions, the relationship between values indicated by a instrument or measuring system for especially weighing, recording and controlling, or the values represented by a material measure and the corresponding known values of a reference standard and the limits for acceptance of the results of measuring;

(l) "clean area" means an area with defined environmental control of particulate and microbial contamination, constructed and used in such a way as to reduce and or eliminate introduction, generation and retention of contaminants within the area;

(m) "compounding" means scientific combination of two or more ingredients with a view to make a finished drug;

(n) "consignment or delivery" means the quantity of starting material or of a drug product, made by one manufacturer and supplied one time in response to a particular request or order, a consignment may comprise one or more packages or containers and may include material belonging to more than one batch;

(o) "critical process" means a process that may cause variation in the quality of the pharmaceutical product;

(p) "cross-contamination" means contamination of a staring material intermediate product, or finished product with another starting material or drug during production;

(q) "finished product" means a product that has undergone all stages of production, including packaging in its final container and labeling;

(r) "Form" means a form set forth in Schedule A;

(s) "formulation" means all operations involved in converting a drug into a final pharmaceutical dosage form ready for use as a finished drug including compounding, processing, formulating, filling, packing, finishing, labelling and other like processes;

(t) "good manufacturing practices for pharmaceutical products" means part of quality assurance which:--
(i) ensure that products are consistently produced and controlled to the quality standards appropriate to their intended use are as required by the marketing authorization or product specification; and
(ii) diminish the risks, inherent in any pharmaceutical production, including contamination, cross contamination and mix ups (confusion) that cannot be detected completely through the testing of final products;

(u) "half-finished product" means any material or mixture of materials that has to undergo further manufacture;

(v) "in-process control" means checks performed during production in order to monitor and if necessary to adjust the process to ensure that the product conforms to its specifications and control of the environment or equipment may also be regarded as a part of in-process control;

(w) "intermediate product" means partly processed material that must undergo further manufacturing steps before it becomes a bulk product;

(x) "large-volume parenterals" means sterile solutions intended for parenteral application with a volume of more than 100ml in one container of the finished dosage form;

(y) "manufacture" means all operations of production, quality control, release, storage and the related controls;

(z) "manufacturer" means a company that carries out at least one step of manufacture;

(aa) "marketing authorization" means a document, issued by the Drug Registration Board set up under the Drugs Act, 1976, as a certificate of drug registration;

(ab) "master formula" means a document or set of documents specifying the starting materials with their quantities and the packaging materials, together with a description of the procedure and precautions required to produce a specified quantity of a finished product as well as the processing instructions, including the in-process controls;

(ac) "master record" means a document or set of documents that serve as a basis for the batch documentation (blank batch record);

(ad) "new drug" means a drug that has not been commonly sold or distributed to the public in Pakistan and is introduced for the first time;

(ae) "Ordinance" means the Drugs Ordinance, 1976 (IV of 1976);

(af) "packaging" means all operations, including filling and labelling which a bulk drug has to undergo in order to become a finished product;

Note: Sterile filling would not normally be regarded as part of packaging, the bulk product being the filled, but not the finally packaged, primary container.

(ag) "packaging material" means any material, including printed material, employed in the packaging of a pharmaceutical product, excluding any outer packaging used for transportation or shipment and packaging materials are referred to as primary or secondary according to whether or not they are intended to be in direct contact with the product;

(ah) "pharmaceutical product" means any drug intended for human use or veterinary use presented in its finished dosage form or as a starting material for use in such a dosage form;

(ai) "processing instructions or procedures" means a defined in clause (ab) of this section;

(aj) "production" means all operations involved in the preparation of a pharmaceutical product, from receipt of materials, through processing and packaging, to its completion as the finished product;

(ak) "purity" means the degree to which other chemical or biological entities are present in any substance;

(al) "quality assurance" means the totality of the arrangements made with the object of ensuring that pharmaceutical products are of the quality required for their intended use and so incorporates good manufacturing practices, Quality Control and other factors including product design and development and good laboratory practices;

(am) "quality control" means the part of good manufacturing practices concerned with sampling, specifications, and testing as well as the organization, documentation, and release procedures which ensure that the necessary and relevant tests are actually carried out and that materials are not released for use, nor finished products released for sale or supply until their quality has been judged to be satisfactory and it is involved in all decisions concerning the quality of the product;

(an) "quarantine" means status of starting or packaging materials intermediate, or bulk or finished products isolated physically or by other effective means while a decision is awaited on their release, rejection, or reprocessing;

(ao) "reconciliation" means a comparison, making due allowance for normal variation between the amount of product or materials theoretically produced or used and the amount actually produced or used;

(ap) "recovery or blending" means the introduction of all or part of previous batches, or of redistilled solvents and similar products, of the required quality into another batch at a defined stage of manufacture;

(aq) "repacking" means all operations involved in the transfer of a drug from a larger container or packing into smaller containers or packings including filling, packing and labeling with a view to make it ready for retail sale or wholesale, but does not includes any compounding, or processing with a view to formulate it in any dosage form;

(ar) "retail sale" means a sale other than wholesale;

(as) "reprocessing" means the reworking of all or part of a batch of product of an unacceptable quality from a refined stage of production so that its quality may be rendered acceptable by one or more additional operations;

(at) "returned product" means finished product sent back to the manufacturer or distributor;

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

(av) "semi-basic manufacture" means manufacture from an intermediate substance of a drug to be used as a starting material for the formulation of a finished drug or to be used for repacking;

(aw) "specification" means the requirements with which the products or materials used or obtained during manufacture must conform as specified in the Drugs (Specification) Rules, 1978;

(ax) "standard operating procedure" means an authorized written procedure indicating instructions for performing operations not necessarily specific to a given product or material but of a more general nature such as equipment operation, maintenance and cleaning validation, cleaning of premises and environmental control sampling and inspection, and certain standard operating procedures may be used to supplement product specific master and batch production documentation;

(ay) "starting material" means any substance used in the production of a pharmaceutical product but excluding packaging materials;

(az) "system" means a regulated pattern of interacting activities and techniques which are united to form an organized whole;

(ba) "validation" means the documented act of proving that any procedure, process, equipment, material, activity or system works correctly and actually leads to the expected result; and

(bb) "wholesale" means sale to a person who purchases for the purpose of selling again and includes sale to a hospital or dispensary, or to medical, educational or research institute.

CHAPTER II
MANUFACTURE OF DRUGS FOR SALE
3. Types of licences to manufacture drugs: Licences to manufacture drugs shall be of the following types, namely :--
(i) licence to manufacture by way of basic manufacture.
(ii) licence to manufacture by way of semi-basic manufacture;
(iii) licence to manufacture by way of formulation;
(iv) licence to manufacture by way of repacking; and
(v) licence to manufacture for experimental purposes.

4. Manufacture on more than one set of premises: If drugs are manufactured on more than one set of premises, a separate application shall be made and a separate licence shall be issued in respect of each such set of premises.

5. Application for licence to manufacture drugs and fee therefor: (1) An application for the grant or renewal of a licence referred to in clauses (i) to (iv) of rule 3 shall be made in Form 1 or l-A to the Central Licensing Board addressed to its Secretary.

(2) An application under sub-rule (1) shall be accompanied by the proper fee as specified in Schedule F.

Proviso: Added vide S.R.O. 536(1)/93 dated 23rd June 1993. Omitted vide S.R.O. 277 (1)/96 dated 2 lst April 1996.

(3) If the application for renewal of the licence is made after the expiry of the period of the validity of the licence, it shall be treated as a fresh application for the grant of a licence.

(4) A fee of rupees one hundred shall be paid for a duplicate copy of the licence if the original is defaced, damaged or lost. Such copy of the licence shall bear the words "DUPLICATE COPY".

(5) Any fee deposited under sub-rule (2) Shall in no case be refunded.

6. Duration of a licence to manufacture drugs: A licence issued under this Chapter shall, unless earlier suspended or cancelled, be inforce for a period of five years from the date of issue and may thereafter be renewed for periods of five years at a time:

Provided that an application for renewal shall not be entertained unless it has been made within sixty days after the expiry of the licence and when an application has been made as aforesaid the licence shall subject to the orders passed on the application for renewal continue in force for the next period of two years.

Provided further that duration of a licence issued under rule 21 shall be two years unless earlier suspended or cancelled.

7. Certificate of licence to manufacture drugs: A licence to manufacture by way of basic manufacture, semi-basic manufacture, formulation or repacking, as the case may be, shall be issued in Form 2.

. 8. Central Licensing Board: (1) The Central Licensing Board shall consist of the following members, namely :--

(a) the Director-General Health, Government of Pakistan, who shall be its ex-officio Chairman;
(b) the Director, Health Services of, each Provincial Government;
(c) two pharmacologists, to be nominated by the Federal Government.
(d) one pharmacist, to be nominated by the Federal Government;
(e) one medical specialist from the Army Medical Corps. to be nominated by the Federal Government.
(f) one pharmaceutical chemist or expert in quality control, to be nominated by the Federal Government;
(g) the Drugs Controller, Ministry of Health, Government of Pakistan who shall be its ex-officio Secretary;
(h) one representative, not below the status of an officer of BPS- 19 [.....], of each of the Ministries of Commerce Industries & Justice to be nominated by the Federal Government; and
(i) one representative of the Central Board of Revenue, not below the status of an officer of B-20, to be nominated by the Federal Government;
(j) Cost Accountant of the Ministry of Health;
(k) One physician, to be nominated by the Federal Government;
(j) One Surgeon, to be nominated by the Federal Government. or an officer of the Provincial Health Department not below the status of Additional Secretary, to be nominated by the Secretary, Health Department of that Province. and
(m) one expert in veterinary medicine to be nominated by the Federal Government.

(2) No person who is a member of the Appellate Board shall be nominated to the Central Licensing Board.

(3) The members of the Central licensing Board, other than its ex officio members, shall hold office for three years and shall be eligible for renomination.

(4) The Central Licensing Board may co-opt any other person who is expert in the pharmaceutical or medical profession for advice on any particular matter under consideration.

(5) The meetings of the Central Licensing Board may be held at such time as the Board may deem fit and, on the request of any of its members, the Chairman may at any time call a meeting if there is any important matter for its consideration.

(6) In the absence of the Chairman, the Board may elect one of its members to preside over a meeting.

(6-A) The quorum to constitute a meeting of the Board shall be one third of its total membership.

(7) The Central Licensing Board may authorise the Chairman to any of its members to perform any specific function of the Board for a specified period.

(8) The Central Licensing Board shall follow such policy directing as the Federal Government may issue from time to time.

(9) No act or proceeding of the Central Licensing Board shall be invalid merely on the ground of the existence of any vacancy in, or any defect in the constitution of the Board.

(10) The chairman and the Secretary of the Central Licensing Board shall, after the Board has approved the issuance of a licence sign the licence.

(11) Subject to rule 14, the Central Licensing Board may appoint a licensing authority or authorities for such purpose as it may deem fit.

9. Powers of the Central Licensing Board: (1) The members of the Central Licensing Board shall exercise all the powers of an Inspector without restriction as to area, and shall have the powers of a Provincial Inspector in relation to Section 30.

(2) In the exercise of their powers the members of the Central Licensing Board shall follow the procedure prescribed for the Federal Inspector -

Provided that member nominated by a Provincial Government may follow the procedure as laid down for a Provincial Inspector.

10. Procedure of Central Licensing Board: (1) The Central Licensing Board may, before issuing a licence, cause the premises in which the manufacture is proposed to be conducted to be inspected by itself or by its sub-committee or by a panel of Inspector or experts appointed by it for the purpose, which may examine all portions of the premises and the plant and appliances, inspect the process of manufacture intended to be employed and the means to be employed for standarizing, if necessary, and analysing substances to be manufactured and enquire into the professional qualifications of the technical staff employed.

(2) Where inspection under sub-rule (1) is carried out by a sub-commmittee or panel of experts of Inspectors appointed under the said sub-rule it shall forward to the Central Licensing Board a detailed report of the result of the inspection.

(3) If the Central Licensing Board, after' such further enquiry, if any, as it may consider necessary, is satisfied that the requirements of the rules have been complied with, it may issue a licence in Form 2.

(4) If the Central Licensing Board is not so satisfied, it shall reject the application and shall inform the applicant of the reasons for such rejection and of the conditions which must be satisfied before a licence may be issued.

(5) No application shall be entertained within three months of the rejection of an application under sub-rule (4).

(6) If after the expiry of three months but within six months of the rejection of an application under sub-rule (4), the applicant informs the Central Licensing Board that the requirements of the rules have been fulfilled, the Board may if after causing a further inspection to be made, is satisfied that the conditions for the grant of a licence have been complied with, issue a licence and no further fee shall be required to be deposited for such an application.

(7) In case an application for licence to manufacture is made after the expiry of six months from the date of rejection of an application under sub-rule (1), such application shall be treated as a fresh application and full fee shall have to be deposited.

11. Special provisions regarding grant of a licence: (1) Where a manufacturer intends to manufacture a drug a part of the process of which is of specialised nature and would be uneconomical for him to conduct it, the Central Licensing Board may permit such process to be

undertaken at another licensed premises specialised for this purpose, subject to such conditions, if any, as may be specified in this behalf.

(2) If a person is conducting a part of the process of the manufacture on behalf of another manufacturer in accordance with the permission granted under sub-rule (1), and he is not responsible for the quality of the final product, the Central Licensing Board may not require him to establish an independent quality control laboratory for such products.

(3) If a person possesses, or applies for, more than one type of licences to manufacture drugs in the same premises, he may establish one Quality Control Department for the purpose of both the licences.

12. Cancellation or suspension of licences: (1) If licensee does not comply with any of the conditions of a licence or violates any of the provisions of the Ordinance or the rules, or fails to deposit the requisite amount of the Central Research Fund due from him, the Central Licensing Board may, by an order in writing stating the reasons thereof, cancel a licence or suspend it for such period as it thinks fit, either wholly or in respect of some of the drugs to which it relates.

(2) The Central Licensing Board shall, before cancelling or suspending a licence under sub-rule (1), provide an opportunity of being heard to the licensee.

(3) When a licence is cancelled or suspended, an entry to that effect shall be recorded on the licence.

(4) A licensee whose licence has been cancelled or suspended may appeal to the Appellate Board within sixty days of the date of receipt of the decision of the Central Licensing Board by the licensee and until the Appellate Board has given its order, the licence shall remain cancelled or suspended, as the case may be.

13. Renewal of a licence: On application being made for renewal, the Central Licensing Board may cause an inspection to be made, and if satisfied that the conditions of the licence and the rules are and will continue to be observed, shall issue a certificate of renewal or otherwise reject the application and inform the licencee accordingly.

14. Licensing authority: For the purpose of Section 18 of the Ordinance the Secretary to the Government of Province in the Health Department shall be the licensing authority for that Province.

15. Conditions for grant or renewal of a licence to manufacture drugs by way of basic or semi-basic manufacture: (1) Before a licence to manufacture by way of basic or semi-basic manufacture is granted or rehewed, the Central Licensing Board shall satisfy itself that the following conditions are complied with by the applicant, namely :--

(a) The applicant shall provide premises which shall be suitable for intended use, in size and construction and shall be located in an area free from offensive and obnoxious odours and other possible sources of contamination.

(b) The applicant shall provide adequate space, plant and equipment for the manufacturing operations;

(c) The manufacture shall be conducted under the active directions and personal supervision of competent technical staff consisting of. at least one person holding a degree in pharmacy, medicine, science with chemistry or chemical engineering from a university in Pakistan or any other institution, recognised by the Federal Government for the purposes of the Ordinance,

and shall possess qualifications and experience which, in the opinion of the Central Licensing Board, is appropriate and adequate for the manufacture and handling of the drug to be, or being, manufactured.

(d) The applicant shall establish an independent Quality Control Department and maintain separate staff, premises and adequate laboratory equipment for carrying out tests of the strength, potency, quality and purity of the substances being or to be used in the manufacture.

(e) The Quality Control Department shall be independent of the manufacturing units and its incharge shall be a whole-time employee of the manufacturer and shall possess a degree in pharmacy, or a degree in science with chemistry, or a degree in medicine, microbiology, pharmacology, or bacteriology from a university in Pakistan or any other institution recognised by the Federal Government for the purposes of Ordinance, as the Central Licensing Board may deem fit for any particular unit; and shall be independent of the incharge of the manufacture (Production Units).

(f) the applicant shall ensure that--

(i) the manufacturing premises shall be maintained properly and shall, as far as possible, be orderly , clean and free from accumulated waste and vermin;
(ii) unhygienic practices eating and smoking shall not take place in any production or quality control area;
(ii) sufficiently clean, appropriately ventilated toilet facilities, including facilities for washing and room for changing clothes, shall be available for the use of manufacturing personnel where required;
(iv) hygienic garments shall be worn by all staff in processing and packaging areas;
(v) high standard of personnel hygiene shall be observed by all persons concerned with production processes, and
(vi) no person known to be suffering from communicable disease or to be a carrier of such a disease and no person with. open lesions or skin infection shall be engaged in production areas.

(g) The applicant shall provide--
(i) adequate facilities for first aid;
(ii) medical inspection of workers at the time of employment and periodical check up thereafter at least once a year;
(iii) facilities for vaccination and inoculation against the enteric or any other epidemic group of diseases; and
(iv) adequate precautions for safe-guarding the health of the workers, including measures to avoid industrial accidents or diseases.

Provided that where a person possess or applies for a licence to manufacture by way of basic and he also intends to conduct semi-basic manufacture of drugs, he may conduct such manufacture under the same license, subject to the approval of, and under such conditions as, the Central Licensing Board may specify, and

16. Conditions for the grant or renewal of licence to manufacture drugs by way of formulation: Before a licence to manufacture drugs by way of formulation is granted or renewed, the Central Licensing Board shall satisfy itself that the following conditions are being complied with by the applicant namely :--

(a) The factory premises shall comply with the conditions specified in Schedule B.
(b) The applicant shall provide adequate space, plant and equipment for the manufacturing operations, the minimum space, plant and equipment for various operations are specified in Schedule B-1.

(bb) An applicant for registration of insecticides, pesticides and household disinfectants shall, in addition to the conditions specified in Schedule B and Schedule B-I, comply with the conditions specified in Schedule B-I, A.

(c) The manufacture shall be conducted under the 'active directions and personal supervisions of competent technical staff conisting of at least one person who is a whole-time employee and who has--

(i) a degree in Pharmacy from a university in Pakistan or any other institution recognised by the Federal Government for the purpose of the Ordinance and has at least twelve months of practical experience in the manufacture of drugs; or

(ii) a degree in science with chemistry or pharmaceutical chemistry as the principal subject who, for the time being is working as incharge of a licensed pharmaceutical manufacturing unit, has not less than ten years practical experience in the manufacture of drugs intended to be manufactured knowledge of pharmacy which, in the opinion of the Central Licensing Board is adequate for the purposes; or

(iii) any foreign qualification the quality and content of the training of which are comparable with those described in sub-clause (i) or sub-clause (ii) and is approved for the purposes, of this sub-rule by the Central Licensing Board: Provided that the Central Licensing Board may, in the case of manufacture of drugs included in Schedule C, permit the manufacture of such drugs under the active direction and personal supervision or a person holding a degree in medicine or veterinary sciences of a university in Pakistan or any other institution recognised by the Federal Government, with at least three years experience in the manufacture, testing and analysis of biological products which are intended to be produced:

Provided further that the Central Licensing Board, may, in the case of anufacture of disinfectant fluids, insecticides liquid paraffin, medicinal gases, non-chemical contraceptives, plaster of paris, surgical dressing or chemicals for the manufacture of which the knowledge of pharmacy or pharmaceutical chemistry is not essential, permit manufacture of the drug under the active direction and personal supervision of competent staff who, [.....] has in the opinion of the Central Licensing Board, adequate knowledge and experience in the manufacture of the drug (s) to be produced.

(d) The applicant shall establish an independent Quality Control Department and maintain separate staff, premises and adequate laboratory equipment for carrying out tests of strength, quality and purity of the substances being or to be used in the manufacture.

Provided further that a person already approved by the Central Licensing Board as the production incharge of a pharmaceutical firm shall continue to be the technical supervisor of that firm for the purposes of this rule.

(e) The Quality Control Department shall be independent of the manufacturing unit and its incharge shall be whole time employee of the manufacturer and shall possess a degree in pharmacy, or a degree in science with chemistry or a degree in medicine or pharmacology (for pharmacological testing) or a degree in microbiology (for microbiological testing) and has sufficient experience in testing of drugs:

Provided that in the case of drugs specified in Schedule C, the Central Licensing Board may allow the applicant to make arrangements with some other institution approved by the Central Licensing Board for such tests to be regularly carried out on his behalf by that institution.

17. Licence to manufacture drugs by way of repacking: (1) A licence to manufacture drugs by way of repacking is required for the repacking of such drugs, and under such conditions, as are specified in Schedule D.

(2) Where a person possesses or applies for a licence to manufacture by way of formulation and he also intends to conduct repacking of drugs, he may conduct such repacking under the same licence subject to the approval of, and under such conditions as, the Central Licensing Board may specify.

18. Condition for the grant or renewal of a licence to manufacture drugs by way of repacking: Before a licence to manufacture drugs by way of repacking is granted or renewed, the Central Licensing Board shall satisfy itself that the following conditions are complied with by the applicant, namely :--

(a) adequate space and equipment shall be provided;
(b) repacking operation shall be carried out under hygienic conditions and under supervision of technical staff provided for in clause (c) of rule 16;
(c) adequate arrangements shall be provided for carrying out the tests for strength potency, quality and purity of the drugs to be repacked.

19. Conditions of licence to manufacture, by way of basic manufacture, semi-basic manufacture formulation and repacking of drugs: (1) A licence to manufacture by way of basic, semi-basic manufacture, formulation or repacking of drugs shall be subject to the conditions stated herein, if any, and to the further condition that the licensee shall continue to maintain conditions on the basis of which he was granted a licence.

(2) The licence shall be kept on the licenced premises and shall be p roduced at the request of any member of the Central Licensing Board or of Provincial Quality Control Board or an Inspector.

(3) Any change in the expert staff or significant alteration in the licensed premises or equipment shall be immediately notified to the Central Licensing Board.

(4) The licensee shall maintain in the inspection book provided by the Central Licensing Board at the time of the issuance of the licence on which a member of the said Board or of a Provincial Quality Control Board or an Inspector shall record proceedings of each of his visits, his impressions and the defect or irregularities noticed, if any, by him and such inspection book shall be signed by him as well as the licensee or his authorised agent.

(5) If any defects or irregularities are recorded in the inspection book under sub-rule (4) the manufacturer shall take steps to remove such defects or irregularities.
(6) A licensee who for any purpose is engaged in the culture or manipulation of pathogenic spore bearing micro-organisms shall provide, to the satisfaction of the Central Licensing Board, separate laboratories, utensils and apparatus required for the culture or manipulation of such .micro-organisms, and they shall not be used for the manufacture of any other substance.

(7) The licensee shall comply with the provisions of the Ordinance and the rules and with such further requirements, if any, as may be specified in any rule subsequently made-in this behalf or any other condition that may be imposed at the time of grant of a licence in the special circumstances of each case.

(8) The licensee shall allow any member of the Central Licensing Board or of a Provincial Quality Control Board or an Inspector to enter, with or without prior notice, any premises and to inspect the plant and the process of manufacture & the means employed in standardising and testing the drugs and to take samples for test and analysis.

(9) The licensee shall allow any member of the Central Licensing "Board or of a Provincial Quality Control Board of an Inspector to inspect all registers and records maintained under these rules and to take samples of the manufactured drugs and shall supply to such member

or Inspector such information as he may require for the purpose of ascertaining whether the provisions of the Ordinance and the rules have been observed.

(10) The Licensee shall, on demand, furnish to the Central Licensing Board or the Provincial Quality Control Board or to such authority as the Central Licensing Board may direct, from every batch of a drug, or from such batch or batches of drugs as it may from time to time specify, a sample for examination and, if required, furnish full Protocols of the tests which have been applied.

(11) If the Central Licensing Board or a Provincial Quality Control Board so directs, the licensee shall not sell or offer for sale any batch of a drug in respect of which a sample is, or protocols are, furnished under clause (10) until a certificate authorising the sale of the batch of such drug has been issued to him by or on behalf of the Central Licensing Board or the Provincial Quality Control Board, as the case may be.

(12) The licensee shall on being informed by the Central Licensing Board or a Provincial Quality Control Board that any part of any batch of a drug has been found not to conform with the requirements of the Ordinance or the rules and on being directed so to do, withdraw the remainder of the batch of such drug from sale and, so far as may in the particular circumstances of the case be practicable, recall all issues already made from that batch and dispose it of in such manner as may be directed by the said Board.

(13) No drug manufactured under licence shall be sold unless the precautions necessary for preserving its properties have been observed throughout the period after manufacture.
(13-A) The licensee or his authorised agent shall issue a warranty in Form 2-A For any drug sold by him for the purpose of re-sale or distribution.

(14) The Licensee shall , by the 30th June and the 31st December each year, Whichever is immediately after the annual financial closing of the company. contribute one per cent of his gross profit before deduction of income-tax towards the Central Research Fund to be maintained by the Federal Government and utilised by it in accordance with the Drugs (Research) Rules, 1978:

Provided that the Central Licensing Board may allow a portion of such contribution to be spent by the firm itself for research and development of new drugs or for establishing research laboratories when it is fully satisfied that such expenditure will be utilised for the said purpose effectively and properly.
Explanation: In this sub-rule, "profit" means gross profit before payment of income tax or other tax.

(14-A) The contributions made towards the Central 'Research Fund under sub-rule (14) shall be kept in such bank as the Federal Government may specify and shall be utilised in accordance with the Drugs (Research) Rules, 1978.
(15) The licensee shall, on or before the 31st July each year, submit a duly Signed profit and loss statement as per "PROFORMA" given in FORM-1 of SCHEDULE-A alongwith an evidence of deposit of 1 per cent of profit towards the Central Research Fund;

20. Additional conditions of licence to manufacture drugs by way of formulation: A licence to manufacture drugs by way of formulation shall, in addition to the conditions laid down in rule 19, be subject to the following further conditions, namely :--

(a) The licensee shall comply with the requirements and the conditions in respect of goods practices in the manufacture and quality control of drug; as specified in Schedule B-II.

(b) The licensee shall record in Schedule B-Ill the particulars of manufacture of each batch of drugs manufactured by him and shall retain such records, in the case of a substance for which

expiry date is fixed for a period of two years from the expiry of such date and, in the case of other substances, for a period of five years from the date of manufacture.

(c) The licensee shall either in his own laboratory or, where so authorised u nder the proviso to clause (e) of rule 16, in any other laboratory approved by the Central Licensing Board, test each batch of the raw materials used by him for the manufacture of drugs and also each batch of the final drug, shall maintain records showing the particulars in respect of such tests as specified in Schedule B-III and shall retain such records, in the case of a substance for which expiry date is fixed for a period of two years from the expiry of such date and, in the case of other substances, for a period of five years from the date of manufacture.

20A. Contract Manufacture.-- Manufacture or analysis on contract is permissible on behalf of a licensee or of a pharmaceutical company whose products are registered in Pakistan for sale subject to the conditions laid down in Schedule G," as a special case and for genuine reasons as approved by the Registration Board.

SCHEDULE ‘G’

1. Contract production and analysis

1.1 Contract of manufacture shall be undertaken only by a manufacturer who hold a valid d rug manufacturing license, and the contract acceptor shall/have adequate facilities, knowledge, experience and competent personnel to satisfactorily carry out the work ordered by the contract giver.

1.2 General.-- Contract production and analysis shall be correctly defined, agreed and controlled in order to avoid misunderstandings that could result in a drug or work or analysis of unsatisfactory quality. A written contract between the contract giver and the contract acceptor shall clearly establish the duties of each party had state the way in which the authorized person shall exercise his full responsibility in releasing each batch of product for sale or issuing the certificate of analysis and a copy of such a contract shall be supplied to the Central Licensing Board also.

1.3 All arrangements for contract manufacture and analysis, including any proposed changes in technical or other arrangements, shall be in accordance with the registration of the drug concerned.

1.4 There shall be a written contract covering the manufacture and or analysis arranged, under contract and any technical arrangements made in connection with it.

1.5 The contract shall permit the contract giver to audit the facilities of the contract acceptor.

1.6 In the case of contract analysis, the final approval for release must be given by the authorised person(s).

2. Contract Giver

2.1 The contract giver shall be responsible for assessing the competence of the contract acceptor in successfully carrying out the work or tests required and for ensuring by means of the contract that the principles of good manufacturing practices are followed.

2.2 The contract giver shall provide the contract acceptor with all the information necessary to carry out the contracted operations correctly in accordance w ith the registration and any other legal requirements and the contract giver shall ensure that the contract acceptor is fully aware of any problem associated with the product, work, or tests that might pose a hazard to premises, equipment , personnel, other materials or other products.

2.3 The contract giver shall ensure that all processed products and materials delivered by the contract acceptor to comply with their specifications or that the product has been released by the authorised person(s).

3. Contract acceptor
3.1 The contract acceptor shall not pass to a third party any of the work entrusted to him or her under the contract without the written consent of the contract giver and prior evaluation and approval by the arrangements of the Central Licensing Board, and arrangements made between the contract acceptor and any third party shall ensure that the manufacturing and analytical information is made available in the same way as between the original contract giver and contract acceptor.

3.2 The contract acceptor shall refrain from any activity that may adversely affect the quality of the product manufactured and or analyzed for the contract giver.

4. The contract
4.1 A contract shall be drawn up between the contract giver and contract acceptor that specifies their respective responsibilities relating to the manufacture and control of the product, and technical aspects of the contract shall be drawn up by competent persons suitably knowledgeable in pharmaceutical technology, analysis, and good manufacturing practices. All arrangements for production and analysis must be in accordance with the registration and agreed by both parties.

4.2 The contract shall specify the way in which the authorized person releasing the batch for sale ensures that each batch has been manufactured in, and checked for, compliance with the requirements of the marketing authorization.

4.3 The contract shall be describe clearly who is responsible for purchasing, testing and releasing materials and for undertaking production and quality controls, including in-process controls, and who has responsibility for sampling and analysis, and in the case of contract analysis, the contract shall state whether or not the contract acceptor shall take samples at the premises of the manufacturer.

4.4 Manufacturing, analytical and distribution records and reference samples shall be kept by, or be available to, the contract giver, and any records relevant to assessing the quality of a product in the event of complaints or a suspected defect shall be accessible and specified in the defect or recall procedures of the contract giver.

4.5 The contract shall describe the handling of starting materials, intermediate and bulk products and finished products if they are rejected and it shall also describe the processing of information if the contract analysis shows that the tested product must be rejected.

21. Licence to manufacture drugs for experimental purposes: (1) If a person intending to manufacture a drug for experimental purposes does not hold a licence to manufacture drugs, he shall before commencing such manufacture, apply in Form 3 for the grant or renewal of a licence to the Central Licensing Board addressed to its Secretary.

(2) An application under sub-rule (1) shall be countersigned by the head of the institution in which,. or the director or manager of the firm or company by which, the drug will be manufactured.

(3) The licence for the manufacture of drugs for experimental purposes shall be in Form 4.

22. Conditions of licence to manufacture drugs for experimental proposes: A licence issuing under rule 21 shall be subject to the following conditions, namely :--

(a) That licensee shall use the drugs manufactured under the licence exclusively for experimental purposes and shall carry on the manufacture and experimental work at the place specified in the licence.

(b) The licensee shall allow a member of the Central Licensing Board or of a Provincial Quality Control Board or an Inspector to enter, with or without notice, the premises where the drugs are manufactured and to satisfy himself that the manufacture is being conducted for experimental purposes.

(C) The licensee shall comply with such further requirements, if any, as may be specified under any rule subsequently made.

23. Labeling of drugs manufactured for experimental purposes: (l) Any d -rug manufactured for experimental purposes shall be kept in containers bearing labels indicating the purpose for which it has been manufactured.

(2) If any drug manufactured for experimental purposes is supplied by the manufacturer to any other person, the container shall bear a label on which shall be stated the name and address of the manufacturer, the accepted scientific name of the drug, if known, or, if not known, a reference which will enable the drug to be identified and the purpose for which it has been manufactured.

CHAPTER 3
REGISTRATION OF DRUGS

24. Registration Board: (1) The Registration Board shall consist of such members, including the
Chairman and the Secretary, and its members-shall hold office for such term, as is prescribed for the Central Licensing Board set up under rule 8.

(2) The Registration Board may refer any case for detailed .examination to the committee of experts on the Drugs Evaluation constituted under Section 10 of the Act.

(3) The Registration Board may appoint a sub-committee consisting of at least one Clinical Professor, one pharmacologist and one pharmacist to make a detailed examination of each case and to submit a report for the consideration of the Board.

(4) The Registration Board may appoint a panel of experts or inspectors to inspect on behalf of the Board the premises of a manufacturer of drugs and to submit its report to the Board.

(5) The Chairman and the Secretary of the Registration Board shall, after the Board has approved the registration of a drug, sign the certificate of registration.

(6) For the manner and conduct of the meetings of the Registration Board, the provisions of sub-rules (3), (4), (5), (6), (7), (8), and (9) of rule 8 shall mutatis mutandis apply.

25. Powers of Registration Board: The members of the Registration Board shall exercise all the powers of Inspector without restriction as the area, and shall have the powers of a Provincial Inspector in relation to Section 30.

26. Application for registration of d rugs and fees thereof: (1) An application for registration of a drug shall be made in Form 5 or 5-A in duplicate to the Registration Board addressed to its Secretary, and separate application shall be made for each drug.

(2) The applicant shall furnish such further information and material as may be required by the Registration Board for the proper evaluation of the drug.

(3) An application under sub-rule (1) shall be accompanied by fee or--
(a) rupees one thousand for the registration of new drug;
(b) rupees five hundred for the registration of any other drug; and
(c) rupees two hundred and fifty for the renewal of the registration of a new or any other drug:

Provided that the application for the renewal of registration is made before the expiry of the validity of the certificate of registration.

(3-A) Application for renewal of registration of a drug shall be made in Form 5-B.
(3-B) Any application under sub-rule (1) or sub-rule (3) shall be accompanied by the proper fee specified in Schedule F.
(4) If the application for renewal of registration is made after the expiry of the period of the validity of the certificate or registration, it shall be treated as a fresh application for the registration of drug.
(5) A fee of rupees fifty shall be paid for a duplicate copy of the certificate of registration if the original is defaced, damaged or lost, and such copy of the certificate shall bear the words "Duplicate Copy".
(6) Any fee deposited under sub-rule (3)shall in no case be refunded.

27. Duration of certificate of registration: A certificate of registration under this chapter, shall, unless earlier suspended or cancelled, be. in force for a period of five years from the date of Registration of the drug and may thereafter be renewed for periods not exceeding 5 years at a time.

Provided that an application for the renewal of registration shall not be entertained unless it has been made within sixty days after the expiry of the registration and when an application has been made as aforesaid the registration shall subject to the orders passed on the application for the renewal continue in force for the next period of five years :

Provided further that, if in the opinion of the Registration Board it is necessary so to do in the Public interest, it may provisionally register a [....] drug for period of two years.

28. Certificate of registration: A certificate of registration of drug shall be issued in Form 6.

29. Procedure for registration: (1) The Registration Board may, if it considers necessary, cause the application for registration and the information and material supplied to it under rule 26 to be evaluated by a Committee on Drugs Evaluation consisting of experts related to the aspect of the drug to be evaluated and obtain its report.

(2) The Registration (2) The Registration Board may, before issuing a registration], cause the premises in which the manufacture is proposed to be conducted to be inspected by itself or by its sub-committee or by a panel of Inspectors or experts appointed by it for the purpose, which may examine all portions of the premises and the plant and appliances, inspect the process of manufacture intended to be employed and the means to be employed for standardising, if necessary, and testing the substances to be manufactured and enquire into the professional qualifications of the technical staff employed.

(3) Where inspection under sub-rule (2) is carried out by a Sub-Committee or panel of experts or Inspectors appointed under the said sub-rule, it shall forward to the Registration Board a detailed report of ;he result of the inspection.

(4) If the Registration Board, after such further enquiry, if any, as it may consider necessary, is satisfied of its safety, efficacy, quality and economical value or where the public interest so requires, it may register the drug and issue a certificate of registration in Form 6, subject to such specific conditions as it may specify.'

(5) The Registration Board may, while registering a drug under sub-rule (4), approve the details as supplied by the applicant or approve them with amendments as it may deem fit in respect of the following particulars, namely :--

(a) the name under which the drug may be sold;
(b) the labelling;
(c) the statement of all the representations to be made for the promotion of the drug in respect of--
(i) the claims to be made for the drug;
(ii) the route of administration;
(iii) the dosage;
(iv) the contra-indications, the side effects and precautions if any; and

(d) Omitted by S.R.O. 551(1)//93, dated 3. 7. 1993.

(5-A) Where the Registration Board registers a new drug, it may recommend to the Federal Government for fixation of maximum price of such drug.

(6) The Registration Board shall, before registering a new drug for which the research work has been conducted in other countries and itsefficacy, safety and quality has been established therein, require the investigation on such pharmaceutical, pharmacological and other aspects, to be conducted and clinical trials to be made as are necessary to establish its quality and, where applicable, the biological, availability, and its safety and efficacy to be established under the local conditions:

Provided that under special circumstances to be recorded in writing, the Registration Board may register a drug and require such investigations and clinical trials to be conducted after its registration.

(7) A new drug, where new method of manufacture is contemplated or a change is proposed in source, standard or specification of the active ingredient or the finished product, may not require full investigations and clinical trials except in so far as they are necessary for the purpose of establishing bio-equivalence, absorption, acceptability or other such features.

(8) Where it is necessary in the public interest so to do, the Registration Board may register a drug on its own motion without having received any application for registration.

(9) If the Registration Board is not satisfied as to the safety, efficacy, quality or economic value of a drug, or where the public interest so requires it may, [.]..., reject the application for registration and inform the applicant of the reasons for such rejection in writing.

(10) Rejection of an application for the registration of a drug shall not debar an applicant from submitting a fresh application under rule 26.

30. Conditions or registration of drug: (1) The relevant provisions of the Ordinance and the rules in respect of the registered drug, shall be complied with.

(2) The import, manufacture and sale of drugs shall be in accordance with the information contained in the applications in respect of those drugs or in any supplementary information or, where such information was amended by the Registration Board, in accordance with such amended information on the basis of which such drugs were registered:

Provided that deviations from any such information may be made only after obtaining prior approval of the Registration Board.

(3) The indications, contra-indication, side effects, the dosage and cautions, if any, as have been approved for the purpose of registration of a drug shall be clearly specified in the labelling and promotion.

(4) Every drug shall be produced in sufficient quantity so as to ensure its regular and adequate supply in the market.

(5) The manufacture of any drug shall not, without the prior approval of the Registration Board, be discontinued for period which may result in its shortage:

Provided that in the circumstances beyond the control of a manufacturer,, of a drug which may lead to reduction in the production of that drug, the circumstances may be intimated to the Registration Board.

(6) A record of quarterly production and disposal of a drug shall be maintained and supplied to the Chairman of the Registration Board in Form 7 in the months of January, April, July and October each year.

(7) In case of an imported drug, the indenter or any other approved representative in Pakistan of the foreign firm shall ensure regular and adequate supply of tee drug in Pakistan.

(7-A) The indenter, importer or manufacturer's authorised agent shall issue a warranty in Form 2-A for any drug indented or sold by him for the purpose of re-sale or distribution; and

(8) In respect of new drug, records, including adequately organised and indexed files, shall be maintained containing full information regarding--

(a) animal or clinical investigations and tests conducted by the manufacturer or reported to him by any person concerning
that drug;
(b) reports from the scientific literature or the bibliography therefrom that are available to him concerning that drug;
(c) experiences, investigations, studies and tests involving the chemical or physical properties or any other properties of that drug;
(d) any substitution of another substance for that drug or any mixing of another substance with that drug;
(e) any error in the labelling of that drug;
(f) any bacteriological or any significant chemical or physical or other change or deterioration in any batch of that drug;
(g) any failure of one or more distributed batches of that drug to meet the required specifications;
(h) any unexpected side effects, injury, toxicity or sensitivity reaction associated with the clinical uses, studies, investigations and tests respecting that drug; and
(i) any unusual failure of that drug to product it expected pharmacological activity.

(9) The following information shall be supplied to the Registration Board--
(a) on request, report in duplicate of all records respecting the information contemplated by paragraphs (d), (e), and (f) of
sub-rule (8); and
(b) immediately upon receipt by him, reports in duplicate of all records respecting the information contemplated by paragraphs (d), (e) and (f) of sub-rule (8); and
(c) as soon as possible and in any event within fifteen working days of their receipt by him, reports in duplicate of all records respecting the information contemplated by paragraphs (g), (h) and (i) of sub-rule (8).

(10) If a drug or any of its ingredients, which is imported or manufactured by a company in Pakistan is also approved for registration and free sale by its subsidiary, sister concern, associate or parent company in the country where it was originally developed or in any of the countries namely, USA, European Union Countries, Canada, Japan, Australia, and--

(a) if that drug at any time, for safety reasons is withdrawn or banned or certain restrictions are imposed in any of the said countries, then it shall be the responsibility of the manufacturer in Pakistan or as the case may be, the indentor, to immediately withdraw the drug from the market in Pakistan or, as the case may be to impose similar restriction and to inform the registration Board within fourteen days of such an information having come to his knowledge and having taken the necessary action. The Registration Board after getting the said intimation shall take similar action for the same drug available from other sources within the shortest possible time;

(b) if a clinical information for a drug is approved by the Drug Regulatory Authority in any of the said countries, the same clinical information shall be considered as approved for drug registration in Pakistan unless modified by the Registration Board on the basis of scientific data available to it, and such clinical information may include indication, contra-indications, side effects, precautions, dosage, etc;

(c) if any adverse drug reaction not otherwise included in the application for registration, is registration, is registered in any of the said countries, it shall be the responsibility of the concerned manufacturer or in case of imported drugs the indentor or manufacturer's agent in Pakistan, to be aware of such adverse action and to report to the Registration Board within thirty days of becoming so aware.

(11) The manufacturer or as the case may be, the indentor shall follow the ethical criteria for medical drug promotion as given in Schedule G.

(12) The manufacturer or, as the case may be, the indentor shall supply the information in relation to safety, efficacy, production, quality, or availability of the drugs as and when required by the Registration Board with a view to ensure safety, efficacy or quality of the drug, and

CHAPTER IV
ADVERTISING OF DRUGS, Etc.

31. Conditions for Advertising: (1) The Federal Government may, after seeking advice of the Committee on Advertising, allow the advertisement of a drug, or any substance or a remedy as specified in Schedule D-1 or a treatment or offer of a treatment for any disease. approve the contents of such advertisement and specify conditions subject to which such advertisement shall be made:

Provided that the Federal Government may, if in its opinion the public interest so required, withdraw the approval granted to any advertisement or modify or alter any condition subject to which the advertisement was approved.

(1-A) An application for advertisement of any drug, substance, remedy, treatment or offer of treatment for any disease shall be made it Form-8, addressed to the Secretary of the Commissioner on Advertising and there shall be made a separate application for each advertisement.

(l-B) An application under sub-rule (l-A) shall be accompanied by the proper fee specified in Schedule F : and

(1-C) The approval of the advertisement, granted under sub-rule (1), shall be valid for a period of two years only.

(2) A drug or any substance referred to in clause (ii) of Sec. 24 may be advertised to the medical, pharmaceutical and allied professions, without referring to the Federal Government, through medical representatives or through professional journals and publication which are meant for circulation exclusively amongst the members of the medical, pharmaceutical and allied professions •

Provided that:
(i)one copy of each issue of such journal or publication is sent to the Drug Administration of the Health Division; and
(ii) the Federal Government may, after giving an opportunity of being heard, prohibit the publication of any advertisement in any such journal as it is found to violate any of the conditions specified under sub-rule (1).

(3) Advertisements under sub-rule (2) shall be subjected to the following conditions, namely :--
(i)All claims shall be made in accordance with these approved for registration of that drug.
(ii) Where the usual information on indications and dosage is provided, that advertisement material shall contain information on contra-indications, side effects and other necessary precautions as may be applicable.

(4) A drug or any substance referred to in clause (ii) of Section 24, may be advertised through Press without reference to the Federal Government if it is merely intended to inform the public of the availability or the price of such drug or any substance referred to in clause (ii) of Section 24 subject to the condition that the Federal Government may prohibit such advertisement if, in its opinion, the public interest so requires.

(5) A drug or any substance referred to in clause (ii) of Section 24, may be advertised to the medical, pharmaceutical and allied professions through a documentary film.

(6) No advertisement under this rule shall contain any direct or indirect comparison in any way with any other drug or substance or remedy for any disease for the purpose of attracting customers or with a view to discredit other such product.

(7) Advertisement material shall be presented with courtesy and good taste and words and phrases implying urgency, uniqueness or such expressions which are absolute in character, such as "the most potent", "the most rapid", "the most efficacious", or which make exaggerated claims or to general claims, such as "effective in all cases" or "effective against all complaints" or superlatives shall be avoided.

(8) Advertisement of a drug or any substance referred to in clause (ii) of Section 24 shall include such information or any risks and other precautions as may be necessary for the protection of public health, and in the case of drug also its maximum retail price fixed under Section 12.

(9) No drug or any other substance shall be advertised in a manner which encourages self-medication or use to the extent that it endangers health.

(10) No drug or any remedy, treatment or after treatment of any disease specified in Schedule 'E' shall be advertised except as provided in sub-rule (2).

(11) Reminder publications for the medical, pharmaceutical and allied professions shall include the name of the drug and its exact composition, the price, the name and address of the manufacturer and a statement to the effect that "Full information is available on request".

32. Sampling of drugs: Samples of drugs may be provided to the physicians or dentists or Pharmacists or Veterinarians or a medical institution in a reasonable quantity and in reduced packings marked with the words "Physicians Sample Not for Sale".

33. Expenditure on advertisement: No person shall spend more than five per cent of his turnover on advertisement, sampling and other promotional activities in respect of drugs,

Explanation: The expenditure on pay and allowances of the field force connected with the promotional activities shall not be included in expenditure for the purpose of this rule.

34. Substances required to be prescribed under Section 24: Any substance or a mixture of substances offered for sale which is injurious, or likely to become hazardous, to the health of a person shall be deemed to be a substance for the purpose of Section 24 of the Ordinance.

35. Retailer's discount: The retailers discount shall be 15% of the maximum retail price.

SCHEDULE A
[See rule 2 (e)]
Form 1
[See rule 5 (/)]
APPLICATION FORM GRANT OF A LICENCE TO MANUFACTURE BY WAY OF FORMULATION/BASIC MANUFACTURE/SEMI-BASIC MANUFACTURE/REPACKING
I/We .....of .....hereby apply for the grant of a licence to manufacture by way of.....on premises situated at .....

2. The drug(s) or class(es) of drugs intended to be manufactured :-
(1) Class(es) of drugs.
(2) Dosage form(s) of drugs.
(3) Name of the drug(s).

3. I enclose :-

(i) Particulars regarding the legal status of the applicant (i.e. in case of proprietorship the names) of proprietors and their address (es), in the case of firm the name and names and addresses of its partners and in the case of company the name and address of the company and its directors).

(ii) Details of the premises including layout plan of the factory.

(iii) Details of the section-wise equipment and machinery for manufacture and quality control.

(iv) Names and qualifications of the Production Incharge and Quality Control Incharge for supervising manufacturing processes and Quality Control Department, and other technical staff working in these departments.

4. The premises and plan will be ready for inspectionon or are ready for inspection.
Dated..... Signed.....
Place..... Name, designation and address .....

PROFORMA
DETAILS OF THE FIRM
Name of the Company .....Type of ownership (Partnership, Proprietorship, Public limited, Private limited, etc.)
Name(s) of Proprietor(s)/Director(s)/Partner(s).
Date of Establishment.

Initial investment (and details of equity shares).
Present investment (and details of equity shares).
Profit and loss statement as per audited accounts for the last five years :
Year
Investment Turnover Profit before tax Percentage 1% before tax for Central Research Fund percentage of Profit
Calculated Paid investment Turnover

Note: Copies of balance sheets to be enclosed with the application for renewal only"; and

(6) in. Schedule B, in paragraph (2), in clause (k), for the semi colon and word"; and" a colon shall be substituted and thereafter the following proviso shall be inserted, namely:

Provided that the conditions of location may be relaxed by the Board in suitable cases for grant or renewal or a licence subject to such conditions as it may deem fit, if the surroundings and the premises, in the opinion of the Board, are satisfactory for the intended manufacture.

FORM 1-A
[See rule (5(I)]
APPLICATION FORM FOR RENEWAL OF A LICENCE TO MANUFACTURE DURGS BY WAY OF FORMULATION/BASIC MANUFACTURE/SEMI-BA SIC MANUFACTURE/REPACKING
I/We ..... of ..... hereby apply for the renewal of a licence to manufacture by way of on premises situated at .....

2. The drug(s) or class(es)of drugs intended to be continued to be manufactured:-
(i) Class(es) of drugs.
(ii) Dossage form(s) of drugs.
(iii) Name of the drug(s) registered/approved.

3. There have been/have not been any change in respect of
(i) Name of the proprietor/directors/partner(s)
(ii) Details of the premises including layout plan of the factory.
(iii) Details of the section-wise equipment and machinery for manufacture and quality control.
(iv) Names and qualifications of the Production Incharge and Quality Control Incharge for supervision of manufacturing processes and Quality Control Departments, and other technical staff working in these departments

4. Statement of the Central Research Fund.

Attested copies of the last two income tax assessment orders of the Income Tax Department attached.
Following statement, as per audited accounts/based on Income Tax Return for the last five years:-
Year Investment Turn-over
CRF due C R F paid as per Col. 41 2 3 4 5
Date Signed…….
Place Name, designation and address of the signatory .....
Note:-Strike off which is not applicable

FORM 2
[See rule 7] GOVERNMENT OF PAKISTAN
Licence to Manufacture
is/are hereby licensed to manufacture by way of Basic Manufacture/Semi Basic manufacture/Formulation/Repacking at the following premises:-

2. This licence permits the manufacture of

3. This licence shall, in addition to the conditions specified in the rules made under the Drugs Ordinance/Act, 1976, be subject to the following conditions namely:-

(i) The licence will be in force for a period of five years from the date of issue unless earlier suspended or cancelled.

(ii) The licence authorises the sale by way of wholesale dealing and storage for sale by the licensee of the products manufactured under this licence, subject to the conditions applicable to licences for sale.

(iii) Name of the approved expert staff.
.....
....
.....
Date of issue .....
Secretary, Central Licensing Board. (Seal) Chairman, Central Licensing Board.

FORM 2A
(See rules 19 and 30)
Warranty under Section 23(I)(i) of the Drugs Act, 1976
I.....being a person resident in Pakistan, carrying on business at (full address) ..... under the name of.....(and being an importer/indenter/authorised agent of .....), do hereby give this warranty that the drugs here-under described as sold/indented by me/specified and contained in the bill of sale, invoice, bill of lading or other document describing the goods referred to herein do not contravene in any way the provisions of section 23 of the Drugs Act, 19.76.
Dated (Signed)
1. Name(s)• of the drug(s):
(i)
(ii) Batch number(s)

2. Description of bill of sale, invoice, bill of lading or other document (if any).
Signed .....

FORM 3
[See rule 21(I)]
APPLICATION FOR LICENCE TO MANUFACTURE DRUG(S) FOR EXPERIMENTAL PURPOSES.
I/We ..... of ..... hereby apply for a licence to manufacture drug(s) specified below for experimental purposes at ..... and I/We undertake to comply with the conditions applicable to the licence under rule 22 of the Drugs (Licensing, Registering and Advertising) Rules, 1976.

1. Name and quantity of drug(s) to be manufactured for the said purposes:.
Signature.....
Name .....
Address .....
Countersigned by .....

FORM 4
[See rule 21(3)]
LICENCE TO MANUFACTURE DRUG(S)
FOR EXPERIMENTAL PURPOSES
Mr./Messrs ..... of ..... is/are hereby licensed to manufacture the drug(s) specified below for experimental purposes at ..... :. or at such other place(s) at the. Central Licensing Board may from time to time permit.

2. The licence is subject to the conditions prescribed in rule 22 of the Drugs (Licensing, Registering and Advertising) Rules, 1976, and such other conditions as n3ay be subsequently prescribed or Specified by the Central Licensing Board in this behalf.

3. This licence shall unless previously suspended or cancelled be in force for a period of two years from the date specified below:-

Name of drugs with quantity to be manufactured.
Date:.....
Place:..... Licensing Authority.

FORM 5
[See rule 26(I)]
APPLICATION FORM FOR REGISTRATION OF A DRUG FOR LOCAL MANUFACTURE
I/we.....of .....hereby apply for registration of the drug namely .....details of which are enclosed.
Date .....
Place .....
ENCLOSURE OF THE APPLICATION FOR REGISTRATION OF A DRUG
1. Name and address of the manufacturer •

2, Name of drug •
(a) Generic/international non-proprietary name:
(b) Proprietory name, if any:

3 Name under which drug is proposed to be sold

4. Dosage from of the drug:

5. Composition of the drug, stating quantity of each active and non-active ingredient(s) per unit or as a percent age of total formulation :

6. Proposed dosage :
(a) for adults.
(b) children by age group.
(c) infant
(d) special groups.

7. Main Pharmacological group to which the drug belongs:

8. Pharmacological and clinical data :
(a) recommended clinical use and the claims to be made for the drug.
(b) contra-indications.
(c) toxicity or the side-effects.
(d) any directions for the use to be included in the labelling, warning and precautions in use : symptoms of over dosage should be given alongwith the treatment including antidotes, where required.

9. Proposed route of administration.

10. Description of the method of manufacture and quality control with details of the equipment.

11. Specifications, with details of analytical procedure for each ingredient and the finished drugs (not required in case of a drug for which pharmacopocial standards recognised under the Drugs Act, 1976, are claimed).

12. Bio-availability, Bio-equivalence and Pharmacokinetics Analysis (For Dosage Form Introducing first time in Pakistan).

13. Stability Summary :
(a) A complete description of and date derived from studies on the stability of new drug, including information pertaining to the suitability of the analytical methods used

(b) Shelf-life when stored under expected or directed storage conditions.

(c) Recommended storage conditions and expiration date to be assigned to the specific formulation and package..

(d) Extreme Temperature Fluctuations Study for all liquid and semi-solid preparations. (Such observations should be utilized for appropriate labelled storage conditions or warning statements).

(e) Type of container/package, with the nature of material, package testing (chemical, mechanical, environmental).

14. Labelling : Specimen or draft with colour scheme, alongwith the undertaking to refrain from counterfeiting shall also be submitted.

15. Pack size (s) and proposed maximum retail price with the following details:-
(i) Cost per retail pack of each active and non-active. Ingredients :
(ii) Cost of each packing material.
(iii) Cost of direct labour,

16. Justification : (Only in case of a new entity).

17. Patent number, if any, with date and its date of expiry.

18. In case of a new drug (entity) not yet registered in Pakistan :
(i) enclose certificate of registration and Free Sale from any of the following countries: Japan, USA and European Company Member countries.

(ii) Any other relevant information that may be required by the Board for consideration of this application.

FORM -5(A)

[See rule 26 (1)]

APPLICATION FORM FOR REGISTRATION OF AN IMPORTED DRUG

I/We .....of .....hereby apply for registration of the drug, namely.....details of which are enclosed.

Date .....

Place ..... Signed.....

ENCLOSURES OF THE APPLICATION FOR REGISTRATION OF A DRUG

1. Name, address and status of the applicant:
2. Name and address of the manufacturer:
3. Name of the drug:
(a) Generic international non-proprietory name:
(b) Proprietory name, if any:

4. Name of drug, under which it is proposed to be sod:
5. Dosage form of the drug:
6. Composition of the drug stating quantity of each active and non-active ingredients per unit dose or percentage of total formulation:
7. Proposed dosage:
(a) for adults.
(b) children by age group.
(c) infants.
(d) special groups,

8. Main Pharmacological group to which the drug belongs:

9. Proposed route of administration:

10. Pharmacological and clinical data :
(a) recommended clinical use and the claim to be made for the drug.
(b) contra-indications.
(c) toxicity or the side-effects.
(d) any directions for. use to be included in the labelling warnings and precautions in use: symptoms of overdosage should be given alongwith the treatment including antidotes where required.

11. Specifications with details of analytical procedure (not required in case of a drug for which the pharmacopocial standards recognised under the Drugs Act, 1976 are claimed):

12. Bio-availability studies:

13. Stability studies :

14. Proposed shelf life with storage conditions, if any :

15 Type of container :

16. Labelling : (Specimen to be enclosed alongwith a .sample and undertaking to refrain from counterfeiting shall also be submitted) :

17. Proposed C and F and maximum retail price (in case of imported drug) :

18. Justification :

19. Certificate regarding sale and G.M.P. in the country of origin (in English and in Form 5 (c) :

20. Certificate of registration by F.D.A. of USA. Committee on Safety of Medicines of U.K. or corresponding agencies of France, West Germany, Japan, Sweden. and Denmark.

21. Patent number, if any, with date and its date of expiry :

22. Undertaking to manufacture drug locally within two years. If it is not possible, the reasons therefor.

FORM-5B

[See rule 26(3A)]

APPLICATION FORM FOR RENEWAL OF REGISTRATION OF ALL KINDS OF DRUGS

I/We ..... of ..... hereby apply for renewal of registration of the drug, namely .....details of which are as follows •

1. Name and address of the manufacturer:
2. Name and address of the agent or indentor in case of imported drug -
3. Whether the drug is registered for local manufacture or import •
4. Name of the registered drug, with its registration number and date or initial ,registration and last renewal '
5. Changes, if any, in information furnished at the time of initial registration or last renewal
6. If withdrawn from the market anywhere •
(i) Country.
(ii) Reasons thereof.
Place..... Signature .....
Date..... Name, and address of the signatory .....

FORM-5C

TO WHOM IT MAY CONCERN CERTIFICATE OF DRUGS REGISTERED UNDER THE DRUGS ACT, 1976

Name and dosage form of product .....
Name and amount of each active ingredient
.....

Manufacturer and or when applicable the person responsible for Placing the Product on the market ..... Address(es).....

It is certified :
* This product has been authorised to be place of the market for use in this country.
*Number of Registration and date of issue if plicable.
*This product has not been authorised to be placed on the market for use in this country for the following reason-
.....
.....
.....
.....

It is also certified that (a) the manufacturing plant in which the product is produced is subject in inspections at suitable intervals, and (b) the manufacturer conforms to requirements for good practices in the manufacture and quality control, in respect of products to be sold or distributed within the country of origin or to be exported.
(Signature of designated authority (Place and date)

FORM 6

[See rules 28 and 29(4)]

GOVERNMENT OF PAKISTAN

CERTIFICATE OF REGISTRATION

Certified that following drug(s) are hereby registered under the Drugs Ordinance/Act, 1976:-
Name of Drug(s).
Name of Manufacturer.
Name of Indenter/Manufacturer's agent/Importer (in case of imported drugs only).

2. This registration shall be valid for a period of five years unless earlier suspended or cancelled.

3. This registration is subject to the conditions specified in the Drugs Ordinance/Act, 1976, and .the rules thereunder and to the conditions specified in the enclosure.
Date of Registration Secretary Registration Board (Seal) Chairman. Registration Board

FORM 7

[See rule 30(6)]

STATEMENT SHOWING QUARTERLY PRODUCTION TO BE SUBMITTED IN DUPLICATE
Name of drug. _____
Pharmacological group _____

Name of the Firm. _____
Address. _____
For the quarter ending. _____
Pack size. No. of Pack Total quantity in terms of individual units e.g., total No. of tablets, injections tubes litres etc.
1 2 3
VALUE (in Rs.) Details of Disposal
On trade price On retail price Indicate whether supplied through normal distribution, channels or exported or supplied to any specific institution. Value of raw materials used (Active & inactive) (in Rs.)
4 5 6 7
Total.

SCHEDULE B

CONDITIONS FOR GRANT OF A LICENSE TO MANUFACTURE BY WAY OF FORMULATION

SECTION-I
PREMISES
1. Location and Surroundings .
1.1 Location
1.2 Surroundings
2. Building Layout And Its Pre-Approval3. Building Design And Construction (General)
3.1 General
3.2 Services
3.3 Protection Against Insects etc.
3.4 Surfaces
4. Storage Areas
4.1 Capacity
4.2 Design
4.3 Bays
4.4 Quarantine
4.5 Sampling
4.6 Rejected Materials
4.7 Special Materials
4.8 Packaging Materials
4.9 Weighing Area
5. Production Department
5.1 General Facilities
5.2 Dedicated Facilities for Production
5.3 General Requirements for Production Areas
(i) Layout
(ii) Adequacy
(iii) Surfaces
(iv) Services
(v) Drains
(vi) Environmental Controls
(vii) Packaging
(viii) Light
6. Ancillary Areas
6.1 Rest Rooms
6.2 Changing Rooms
6.3 Workshops
6.4 Animal House

SECTION--2
EQUIPMENT FOR PRODUCTION
2.1 General

2.2 Layout
2.3 Construction
2.4 Piping
2.5 Tanks
2.6 Filters
2.7 Cleaning Equipment
2.8 Defective Equipment

SECTION--3
QUALITY CONTROL DEPARTMENT
3.1 General
3.2 Laboratories
3.3 Areas
3.4 Facilities
(i) Equipment
(ii) Others
(iii) Written Procedures
(iv) Validation
(v) Storage

SECTION--4
DOCUMENTATION
4.1 General
4.2 Specification & Testing Procedures
(i) Reference Books
(ii) Testing Procedures
(iii) Specifications
4.3 Specifications for Starting and Packaging Materials
4.4 Specifications for Finished Products
4.5 Master Formula
4.6 Packaging Instructions
4.7 Standard Operating Procedures (SOPs) and Records
4.8 S.O.Ps for Testing
4.9 S.O.Ps for Sanitation
4.10 S.O.Ps Miscellaneous
4.11 Labels
4.12 Batch processing records

SECTION--5
SANITATION AND HYGIENE
5.1 Sanitation
5.2 Hygiene

SCHEDULE B-I
[See rule 16 (6) (b)]

REQUIREMENTS OF PLANT AND EQUIPMENT
(A) The following equipment is required for the manufacture of drugs for external appliances or suspense:
(1) Mixing tanks where applicable:
(2) Kettles, steam, gas or electrically heated.
(3) A suitable power driven mixer.
(4) Storage tanks or pots.
(5) A calloid mill or a suitable emulsifier or homogeniser, where applicable.
(6) A triple-roller mill or an ointment mill, where applicable.
(7) Liquid filling equipment.
(8) Jar or tube filling equipment, where applicable.
Area of minimum of 200 square feet is required for the basic installation.

(B) The following equipment is required for manufacture of Syrups, Exlixirs and Solutions :--
(1) Mixing and storage tanks.
(2) Mixer.
(3) Filter press or other suitable filtering equipment such as metafilter or sparklet filter or Also-pad filter.
(4) Water still or Deioniser.
(5) Various liquid measures and weighing scale.
An area of maximum 300 square feet is required for the basic installations.

(C) Equipment for the manufacture of Pills and Compressed Tablets including Hypodermic Tablets. For efficient operation, the tablet production department shall be divided into the following three distinct and separate sections situated in different rooms,
(i) Granulating Section;
(ii) Tableting Section;
(iii) Coating Section.
The following equipment is required in each of the three sections :-

1. Granulating Section: (1) Disintegrator, where applicable.
(2) Power Mixer or granulation mixer with stainless steel cabinet
(3} Granular
(4) Oven thermostatically controlled.

2. Tableting Section:
(1) Tablet machine, single punch or rotary.
(2) Pill machine, where applicable.
(3) Punch and dyes storages cabinet.

The Tableting Section shall be free from dust and floating particles. For this purpose, it is desirable that each tablet machine is connected either to an exhaust system or isolated into cubicles.

3. Coating Section:
(1) Jacketed kettle, or equivalent steam, gas or dect£1cally heated for preparing solution.
(2) Coating pan.
(3) Polishing pan, where applicable,
{4) Heater and exhaust system, where applicable.

The coating section shall be made dust-free and suitable exhaust provided to remove excess powder and the fumes resulting from solvent evaporation.

A total area of not less than 900 square feet for the three Sections is required for basic installations.

The manufacture of Hypodermic Tablets shall be conducted under aseptic conditions in a separate air-conditioned room, the walls of which shall be smooth and washable. The granulation, tableting and packing shall be done in this room.

(D) The following equipment is required for the manufacture of Powders :--
(1) Disintegrator, where applicable.
(2) Mixer.
(3) Sifter or sieve.
(4) Stainless steel vessels and scoops of suitable material,
(5) Filling equipment,

In the case of operations involving floating particles of fine powder or dust a suitable exhaust system shall be provided, Workers shall be provided with suitable marks during operation.

If a manufacturer has e tablet section where the powder of the granules can be manufactured, provided that such granules or powder or non toxic, no separate equipment will be required for manufacture of such powder as granules.

(E) The following equipment is required for filling of Hard Gelatin Capsules:-

(1) Mixing and blending equipment.

(2) Capsule filling units.
An area of minimum of 200 square feet is required for the basic installations. The room shall be air-conditioned and also dehumidified wherever necessary.

(F) The following equipment is required for ,the manufacture of Surgical Dressings other than Absorbent Cotton Wool
(1) Rolling machine.
(2) Trimming machine.
(3) Cutting equipment.
(4) Folding and pressing machine for gauze.
(5) Mixing tanks for processing medicated dressings.
(6) Hot air drying ovens.
(7) Steam steriliser or dry heat steriliser.

An area of minimum of 300 square feet is required for the basic installations. In case medicated dressings are to be manufactured, room with an area of minimum of 300 square feet shall be provided.

(G) The following equipment is required for the manufacture under aseptic conditions of Eye-Ointments, Eye-Drops, Eye-Lotions and other use :-

(1) Hot air oven electrically heated with thermostatic control.
(2) Kettle, gas or electrically heated with suitable mixing arrangement.
(3) Colloid mill or homogeniser.
(4) Tube filling equipment.
(5) Mixing and storage tanks of stainless steel or of other suitable material.
(6) Sintered glass funnel, seitz filter or filter candle.
(7) Liquid filling equipment.
(8) Autoclave.

An area of minimum of 250 square feet is required for the basic installation. The manufacture and filling shall be carried out in art air-conditioned room under aseptic conditions. The room shall be further dehumidified if preparations containing antibiotics are manufactured.

(H) The following equipment is required for the manufacture of Pessaries and Suppositories :-
(1) Mixing and pouring equipment.
(2) Moulding equipment.
An area of minimum of 200, square feet required far the basic installation,

In case of pessaries manufactured by granulation compression, if the licence does not have a tablet section, a separate area of minimum of 300 squared feet and the following equipment is necessary :--
(1) Mixer.
(2) Granulator.
(3) Drier.
(4) Compressing machine.
(5) Pessary and tablet counter.

(I) The following equipment is required for the manufacture of inhalers end Vitrallae:
(1) Mixing equipment.
(2) Graduated delivery equipment for measurement of the medicament.
(3) Sealing equipment,
An area of minimum of 200 square feet is required for the basic installations.

(J) The following equipment is required for the repacking installation of drugs and Pharmaceutical Chemicals
(1) Sifter.
(2) Stainless steel scoops end vessels.
(3) Weighing and measuring equipment.
(4) Filling equipment.
An area of minimum of 300 square feet is required for basic packing operations. In the case of operations involving floating particles of fine powder or dust, a suitable exhaust system should be provided.

(K) Requirements for the manufacture of Parenteral Preparations: The whole process of the manufacture of parenteral preparations may be divided into the following separate operations:

(a) Preparations of the container: This includes, cutting. washing, drying sterilisation of ampoules or vials prior to
(b) Preparation of solution: This includes preparation and filteration of solution.
(c) Filling and sealing: This includes filling and sealing of ampoules or filling and capping of vials.
(d) Sterilisation.
(e) Testing,
The following basic hygienic requirement shall be complied with

(1) Strict sanitation shall be maintained throughout the entire plant in order to prevent contamination and to keep out pyrogens, Masks end overalls shall be worn wherever necessary.

(2) The preparation room w here the solution ate prepared shall be of such a nature that may be kept scrupulously clean. This room shall be air-conditioned.

(3) The filling and sealing rooms shall likewise be air-conditioned under positive pressure with air locks provided to. prevent, the entry of air from outside. The walls and floor shall be such as may permit their being sprayed and washed with an antiseptic solution. The benches shall preferably have stainless steel or laminated plastic tops capable of being washed.

(4) In the room provided for aseptic filling and sealing, necessary measures for maintaining sterility and to preventing contamination shall be adopted.

(5) A separate room shall be provided .for sterilisation, testing (for leaks and floating particles) and dryin

(6) Finished products shall be stored in a suitable separate place.

The following equipment required :-

Manufacturing Area :
(1) Storage equipment for ampoules and vials
(2) Ampoule washing and drying equipment.
(3) Dust proof storage Cabinets.
(4) Water still.
(5) Mixing and preparation tanks or other containers. The tanks or containers shall be made of

either glass or such material which will not react with the liquid
(6) Filtering equipments such as filter press or sintered glass funnel.
(7) Autoclave,
(8) Hot Air Steriliser,

Filling and Sealing Room:
(9) Benches for filling and sealing.
(10) Filling and sealing unit

Aseptic Filling and sealing room:
(11) Bacteriological filters such as Seitz filter, candles or sintered glass filters,
(12} Filling and. sealing unit,

General Room:
(13) Inspection table with draft and light background
(14) Leak tasting equipment.
(15) Labelling and packing benches,
(16) Storage equipment including cold storage and refrigerators, if necessary

Note /: The above requirements of this schedule are subject to modifications, at the discretion of the Central Licensing Board if it is of the opinion that having regard to the nature and extent of the manufacturing operations it is necessary to relax or alter in the circumstances of a particular case:

Provided that such variation shall be recorded in writing with reasons therefor and also communicated in writing to the manufacturer for his record,

Note//: This Schedule gives equipment and space required for certain categories of drugs only. There are, in addition, other categories such as drugs miscellaneous pharmaceuticals such as Ferries Ammonii Citras. Potassium Citras, Glycerin, Paraffin, Oxygen gas, Disinfectant fluids, mechanical contraceptives, surgical cotton and tinctures which are not listed in this Schedule. The Central Licensing Board shall, in respect of such categories of drugs, have the discretion to examine the adequacy or otherwise of factory premises, space, plant, machinery and other requirements having regard to the nature and extent of the manufacture to carry out necessary modifications in them and, on the modification. having been made, approve of the manufacture of such categories of drugs. Any drug so permitted to be manufactured by the Central Licensing. Board shall be deemed to be an additional category of drug for the purpose of this Schedule.

SCHEDULE B I-A.
[See rule 16 (bb)-7]
CONDITIONS OF FACTORY PREMISES
1. Location and surrounding: The premises should be away from drinking water sources and an area liable to flooding.

2. (a) Building: Building should be provided with both good general ventilation and protection against direct sunlight, with easy access for fire-fighting equipment including fire-extinguishers, fire-blankets, .hose, reels and fire-alarm, etc. Sufficient water must be available for fire-fighting.
(b) Wells: Walls as far as possible should be protected by non-flammable or slow burning material.
(c) Doors; Doors must be fire resistant preferably with self-closing system,
(d) Floors: Floors should be impermeable to liquids, smooth and free from cracks. There should be no drains at all in plants and in warehouse. If drains are absolutely necessary they must not contract directly with waterways or public sewers,
(e) Signs: Signs indicating smoking restrictions, location of emergency kits, fire-fighting

equipment, telephone end escape routes must be prominently displayed. Local exhaust system must be effective,.

3. Personnel: To void intoxication by skin contact, inhalation of fumes, vapours and dust, accidental ingestion, the protected clothing and equipments, e.g., protective helmet or cloth cap, eye protection (safety spectacles, goggles or face shield) dust or light fume masks, one piece worksuit with closely fitting trouser bottoms, rubber or plastic gloves Or gauntlets, rubber or plastic apron, and workboots with protective toecaps, must be provided.

Staff must not be allowed to go home wearing the same clothing they wore at work; emergency showers and eye washing facilities must be provided in the premises. Safety instructions should be strategically displayed in local language. All emergency and safety equipment must be frequently and regularly checked and maintained to ensure its conditions satisfactory.

4. Medical Services: There must be pre-employment medical; , examination for all staff members whether working permanently or on contract basis. When organophosphates or carbamates are handled, pre-exposure baseline blood cholinesterase level must be determined for all operational staff. Staff regularly engaged in formulation and packing procedures and maintenances must have their cholinesterase levels checked regularly and detailed records must be kept. The checks should be carried .out by a properly equipped hospital or laboratory under qualified expert.

"Levels of cholinesterase activity should be interpreted by a doctor, but the following guide might be helpful :--

(i) A decease of more than 20% in blood cholinesterase activity,. from the pre-exposure value indicates that the cause should be investigated.

(ii) A decrease of more than 40% in blood cholinesterase activity from the pre-exposure value indicates that the worker concerned should be removed from further exposure to organophosphates or carbamates.

Workers should not be exposed again to cholinesterase inhibiting compounds until further tests show a blood cholinesterase activity within 20% of the pre-exposure value.

SCHEDULE B-II
GOOD MANUFACTURING PRACTICES (GMPs) FOR LICENCE TO MANUFACTURE BY WAY OF FORMULATION

CONTENTS

3.3 Control procedures
3.3.1 General
3.3.2 Sampling
3.3.3 Test requirement for starting and packaging materials
3.3.4 Test requirement for in-process controls
3.3.5 Test Requirement for Finished Products
3.3.6 Production record/batch review
3.3.7 Stability studies
3.4 Self inspection
3.4.1 General
3.4.2 Items for self inspection
3.4.3 Self inspection team
3.4.4 Frequency of self inspection
3.4.5 Self inspection report
3.4.6 Follow-up Action
3.5 Quality Audit
3.5.1 Audit by independent specialist
3.5.2 Supplier's audits
3.6 Complaints
3.6.1 Review of complaints
3.6.2 Person authorized
3.6.3 Written procedures
3.6.4 Recording defects and investigation
3.6.5 Investigations
3.6.6 Follow-up action
3.6.7 Recording measures
3.6.8 Review for Reviewing Problem
3.7 Product recalls
3.7.1 System
3.7.2 Authorized procedures
3.7.3 Written procedures
3.7.4 Recall with promptness
3.7.5 Distribution records
3.7.6 Recording and progress
3.7.7 Evaluation
3.7.8 Storage of recalled drugs
3.7.9 All concerned to be informed

SECTION--4
4. Personnel
4.1 General
4.2 Written duties
4.3 GMP awareness
4.4 Prohibition of unauthorized person
4.5 Duties of Heads of Departments
4.6 Duties of Production Incharges
4.7 Duties of Quality Control Incharges
4.8 Training
4.8.1 Written programme
4.8.2 Training appropriate to duties
4.8.3 Specific training
4.8.4 Understanding concepts
4.8.5 Visitor and untrained personnel discouraged
4.9 Personal hygiene
4.9.1 Health examination
4.9.2 Practices in personal hygiene
4.9.3 Illness
4.9.4 Reporting health problems
4.9.5 Avoiding direct contact with materials

7.1.3 Avoiding deviation
7.1.4 Yield checks
7.1.5 Avoiding mix-ups
7.1.6 Labelling
7.1.7 Unauthorized entry prohibited
7.1.8 In price controls
7.2 Prevention of cross-contamination and bacterial contamination in production
7.2.1 Precautions against dust
7.2.2 Measures against contamination
7.2.3 Cross contamination checks
7.2.4 Microbiological monitory
7.3 Processing operations intermediate and bulk products
7.3.1 Pre-Processing cleanliness checks
7.3.2 In-process controls
7.3.3 Defective equipment
7.3.4 Cleaning containers
7.3.5 Yield deviations
7.3.6 Product pipelines
7.3.7 Water pipes
7.3.8 Equipment calibration
7.3.9 Repair or maintenance
7.4 Packaging operations
7.4.1 Avoiding mix-ups
7.4.2 Pre-packaging checks
7.4.3 Labeling packaging line
7.4.4 Process continuity
7.4.5 Printing operation checks
7.4.6 Label verification
7.4.7 Resistant printing on labels
7.4.8 On-line packaging checks
7.4.9 Product re-introduction on packaging line
7.4.10 Discrepancies to be investigated
7.4.11 Destruction of un-used packaging materials

SECTION -- 8
8. Sanitation and hygiene

SECTION -- 9
9. Validation
9.1 General
9.2 Process validation
9.2.1 Validation of critical processes
9.2.2 Validation of new master formula
9.2.3 Validation of equipment if materials

SECTION -- 10
10.1 Documents
10.1.1 Maintenance of documents
10.1.2 Recording actions
10.1.3 Documentation system
10.1.4 Status identification
10.1.5 Product labelling
10.1.6 Reference standards identification
10.1.7 Specification approvals
10.1.8 Revision of specification
10.1.9 Packaging material specification
10.1.10 Starting material re-assay
10.2 Specification for intermediate and bulk products
10.3 Batch processing records

10.3.1 General
10.3.2 Checking work station
10.3.3 Recording process operation
10.4 Batch packaging records
10.4.1 General
10.4.2 Pre-packaging line checks
10.4.3 Recording packaging operation
10.4.4 Recording batch numbers
10.4.5 Analytical records
10.4.6 Finished product release procedure
10.4.7 Recording batch distribution
10.4.8 Standard operating procedures
10.4.9 Equipment logbooks
10.4.10 Equipment utilization record

PART-II

ADDITIONAL CONDITIONS FOR MANUFACTURE OF STERILE PRODUCT
SECTION -1
1. General
Air Classification system for manufacture of sterile products
2. Manufacture of sterile preparations
2.1 Manufacturing operations
2.2 Terminally sterilized products
2.3 Products sterilized by filtration
2.4 Products manufactured under aseptic conditions
3. Personnel
General
Personnel training
Entry restricted
Hygiene and cleanliness
Use of protective garments
Clothing requirements
Protective garments in grade B room
Washing of clothing
Prohibitions

SECTION--2
4. Maintenance of clean area
General
Airlock system
Air supply system
Maintenance of equipment
Water supply

SECTION -- 3
5. Equipment maintenance
Documentation

SECTION -- 4
6. Sanitation
Procedure
Use of disinfectants and detergents
Fumigation
Monitoring of clean areas

SECTION -- 5
7. Processing

Precautions against contamination
Preparation of live organisms
Simulation of aseptic operations validation
Monitoring water supply of sources
Activities in clean areas kept minimum
Care of starting materials
Care against fibers
Care after final cleaning of materials
Interval between operations to be minimal
Sterilization of gases used
Bioburden to be minimal
Asepsis of articles in clean areas
New processes to be validated

SECTION -- 6
8. Sterilization
General
Validation
Suitability of process
Care for biological indicators
Sterilized non-sterilizer products differentiation
9. Sterilization by heat
Recording sterilization cycle
Sufficient time allowed to reach required temperature
Precautions during cooling
10. Sterilization by moist heat
General
Wrapping materials
11. Sterilization by dry heat
12. Sterilization by radiation
General
Outside contractor
Measurement of radiation
Validation
Handling procedures
13. Sterilization by ethylene oxide
General
Ensure contact between gas and microbial cells
Equilibrium with humidity and temperature
Monitoring each cycle
Biological indicators
Record maintenance
Validation
14. Filtration of pharmaceutical products that cannot be sterilized in the final container
General
Using double filter layer
Eliminate fibers
Checking integrity of filters
Frequency of use of filter
Filter safety
15. Finishing of sterile products
General
Use of vacuum
Inspection of containers

SECTION -- 7
16. Quality control
Sterility testing
Sterility test as the last measures

Monitoring endotoxin

SCHEDULE B-III
[See rule 20 (b)]
PARTICULARS TO BE SHOWN IN MANUFACTURING RECORDS
A. Substances Parenteral preparation in general:
1. Serial Number.
2. Name of the drug.
3, Batch Size,
4. Batch number.
5. Date of commencement of manufacture and date when manufecture was completed,
6. Name of all ingredients, quantities required for the batch size, quantities actually used. (All weighings and measurements shall be checked initiated b¥ the competent person in the section).
7. Control reference numbers in respect of raw materials used in formulation.
8. Date of mixing in case of dry products, e.g., powder, powder mixture for capsule products, etc.
9. Date of granulation wherever applicable.
10. Weight of granules.
11. Date of compression in case of tablets/date of filling in case of capsules.
12. Dates of coating wherever applicable.
13. Records of test to be carried out in case of tablets as under
(a) Average weight every thirty minutes.
(b) Disintegration time as often as practicable.
14. Records of readings taken to check weight variation in case of capsules,
15. Reference to Analytical Report number stating whether of standard quality or otherwise.
16, Records on the disposal of rejected batches and batches with-drawn from the market.
17, Actual production and packing particulars indicating the size and quantity of finished packings,
18. Date of release of finished packings for distribution or sale,
19. in case of Hypodermic tablets and ophthalmic preparations which are required to be manufactured under aseptic conditions, records shall be maintained indicating the precautions taken during the process of manufacture to ensure that aseptic conditions are maintained,
20. Signature of the expert staff responsible for the manufacture,

B. Parenteral preparation:
1. Serial Number,
2. Name of the drug,
3. Batch Size,
4. Batch number (if bulk lot is divided into various batches and processed separately, a batch number distinctly different from that of the bulk lot should be assigned to each of the processed batch),

5. Date of commencement of manufacture and date of completion.

6. Name of all ingredients, quantities required for the lot size, quantities actually used. (All weighings and measurements shall be checked and initialled by the competent person in the section).

7. Control reference numbers in respect of raw materials used.
8. PH of the solution wherever applicable.
9. Date and methods of filtration.
10. Sterility test reference on bulk batch wherever applicable. (If bulk lot is divided into various batches and processed separately, a batch number distinctly different from that of the bulk lot should be assigned to each of the processed batch.
11. Date of filling.
12. Records of tests employed :--

(a) To ensure that sealed ampules are leak-proof,
(b) To check the presence of foreign particles.
(c) For pyrogens wherever applicable.

13. Records of sterilisation in case of parenteral preparation which are heat sterilised including particulars of time temperature and pressure employed.
14. Number and size of containers filed and number rejected.
15, Reference to Analytical Report numbers stating whether of standard quality or otherwise.
16. Records of the disposal of rejected batch and batches with-drawn from the market.
17. Actual production and packing particulars.
18. Date of release finished packings for distribution or sale.
19. Particulars regarding the precautions taken during manufacture to ensure that aseptic conditions are maintained.
20. Control reference numbers in respect of the lot of glass containers used for filling.
21. Signature of the expert staff responsible for manufacture.

II. RECORDS OF RAW MATERIALS

Records in respect of each raw material shall be maintained indicating the quantity received, control reference numbers, the quantities issued from time to time, the names and batch Nos. of the products for the manufacture of which the quantities have been issued and the particulars relating to the proper disposal of the stocks.

III. PARTICULARS TO BE RECORDED IN THE ANALYTICAL RECORDS

A. Tablets and capsules:
1. Analytical report number.
2. Name of the sample.
3. Date of receipt of sample,
4. Batch number.
5. Protocols of tests applied:
(a) Description.
(b) Identification.
(c) Uniformity of weight.
(d) Uniformity of diameter (if applicable).
(e) Disintegration test (time in minutes).
(f) Any other tests.
(g) Results of assay.

Note: Records racer, cling various tests applied (including reading and calculation) should be maintained and necessary reference to these records should .be entered in serial No. 5 whenever necessary.
6. Signature of the Analyst.
7. Opinion and signature of the approved Analyst.

B. Parenteral Preparations
1. Analytical report number.
2. Name of the sample.
3. Batch number.
4, Date of receipt of sample.
5. Number of containers filled.
6. Number of container packed
7. Protocols of tests applied
(a) Clarity,
(b) PH wherever applicable,
(c) Identification.
(d) Volume in container,
(e) Sterility--(/) Bulk sample wherever applicable (ii) container sample.
(f) Pyrogen test, wherever applicable.

(g) Toxicity test, wherever applicable.
(h) Any other teats.
(i) Results of assay.

Note: Records regarding various tests applied (including readings and calculations)should be maintained and necessary reference to these records should be entered in Serial No.7. wherever necessary
8. Signature of the Analyst.
9, Opinion and signature of the approved Analyst Pyrogen Tests:-
1. Test Report number.
2. Name of the sample.
3. Batch number.
4. Number of rabbits used.
5. Weight of each rabbit.
6. Normal temperature of each rabbit.
7. Mean initial temperature of each rabbit,
8. Dose and volume of solution injected into each rabbit and time of injection.
9. Temperature of each rabbit noted at suitable intervals,
10. Maximum temperature.
11. Response.
12. Summed response,
13. Signature of the Analyst,
14. Opinion and signature of the approved Analyst

Toxicity Test:
1. Test Report number.
2. Name of the Sample
3, Batch number
4. Number of mice used and weight of each mouse, Strength and volume of the drug injected,
6, Date of injection,
7. Results and remarks,
8. Signature of Analyst,
9. Opinion and signature of the approved Analyst.

C. For other drugs:
1.Analytical report number
2. Name of the sample
3. Batch number.
4, Date of receipt of sample
5. Protocols of tests applied:
(a) Description.
(b) Identification.
(c) Any other tests
(d). Results of assay.

Note: Particulars regarding various tests applied (including reading and calculations) shall be maintained and necessary reference to these records shall be entered in s erial No. 5 wherever necessary.

6. Signature of the Analyst.
7. Opinion and signature of the approved Analyst.

D. Raw materials:
1. Serial number
2. Name of the material
3. Name of the manufacturer/supplier.
4. Quantity received.

5. Invoice/Challan number and date.
6. Protocols of tests applied.
Note: Particular regarding various tests applied (including reading and calculations) shall be maintained and necessary reference these records shall be entered in serial No. 6 wherever necessary.
E. Container, packing material, etc.:
1. Serial number.
2. Name of the item.
3. Name of the manufacturer/supplier.
4. Quantity received.
5. Invoice/Challan number and date.
6, Results of tests applied.

Note: Particulars regarding various tests applied shall be maintained and necessary reference to these records shall be entered serial No. 6 wherever necessary.

7. Remarks.
8. Signature of the examiner.

Note I: The foregoing provisions represent the minimum requirements to be complied with by the licensee. The Central Licensing Board may, however, direct the nature of records to be maintained by the licensee for such drugs as are not covered by the categories described in this Schedule.

Note 2: The Central Licensing Board may permit the licensee to maintain records in such manner as are considered satisfactory, provided the basic requirements laid down in the Schedule are complied with.

Note 3: The Central Licensing Board may as its discretion direct the licensee to maintain records for such additional particulars as it may consider necessary in the circumstances of a particular case.

SCHEDULE C
[See rule 16(c) (iii) and (e)]
1. Sera.
2. Solution of serum proteins intended for injunction.
3. Vaccines.
4. Toxins.
5. Antigen.
6. Antitoxins.
7. Insulin.
8. Pituitary (Posterior Lobe) Extract.
9. Sterilized surgical lignature and sterilized surgical suture.
10. Bacteriophages.

SCHEDULE D
[See rule 17(1)]
DRUGS FOR REPACKING
1. Alniminium Hydroxide Gel Dried.
2. Ammonium Bicarbonate.
3. Ammonium Chloride.
4. Ammonium Carbonate.
5. Benzoic Acid.
6. Bismuth Carbonate.
7. Bismuth Subnitrate.
8. Boric Acid.

9. Borax.
10. Caffein and its Salts.
11. Calamine.
12. Calcium Carbonate.
13. Calcium Lactate.
14. Calcium Gluconate.
15. Calcium Hydroxide.
16. Castor Oil.
17. Cetrimide Powder.
18. Chloral Hydrate.
19. Ephedrine Hadrochloride.
20. Ephedrine Sulphate.
21. Ferrous Sulphate.
22. Ferric Ammonium Citrate.
23. Gentian Violet.
24. Glycerin.
25. Iodine.
26. Ichthammol.
27. Kaolin.
28. Liquid Paraffin Heavy.
29. Magnesium Carbonate.
30. Magnesium Hydroxide.
31. Magnesium Sulphate.
32. Methylene Blue.
33. Magnesium Trisilicate.
34. Methyl Salicylate.
35. Phenothlazine (B. VET. C.).
36. Pix Carb.
37. Potassium Acetate.
38. Potassium Bromide.
39. Potassium Bicarb.
40. Potassium Chloride.
41. Potassium Citrate.
42. Potassium Iodine.
43. Potassium Permanganate.
44. Procaine Hydro-Chloride.
45. Pulv Gentian.
46. Resorcin.
47. Salicylic Acid.
48. Sentonin.
49. Sena.
50. Sodium Benzoate.
51. Sodium Bicarbonate.
52. Sodium Chloride.
53. Sodium Bromide.
54. Sodium Carbonate.
55. Sodium Citrate.
56. Sodium Iodide.
57. Sodium Metabisuphite.
58. Sodium Potassium Tartrate.
59. Sodium Salicylate.
60. Sodium Sulphate.
61. Sodium Thiosulphate.
62. Soft yellow Paraffin.
63. Sulphonilamide Powder (B. VET. C).
64. Sulphur Precipitated.
65. Sulphur Sublime.
66. Tannic Acid.
67. Zinc Oxide.

68. Zinc Sulphate.

SCHEDULE D-I

[See rule (31)1]

Household remedies including--

Analgesics:

Aspirin and Paracetamol in tablets and liquid forms.

(2) Analgesic Balms/Plasters.

(3) Antiseptics and disinfectants for household use, excluding those containing hormone and antiniotics.

(4) Antidandruff preparations.

(5) Dental preparations.

(6) Antacid and carminatives:

Compound Effervescent Salts, [--] , Milk of Magnesia.

(7)

(8) Contraceptives.

(9) Miscellaneous.

Fish Liver Oil and its equivalents.

SCHEDULE E

[See rule 31 (10)]

DISEASES, ADVERTISEMENT FOR TREATMENT OF
WHICH IS PROHIBITED

1. [Omitted vide S.R.O. 871(I)/78, dated 8th July, 1978.]

2. [Omitted vide S.R.O. 871(I)/78, dated 8th July, 1978.]

3. Venereal diseases.

4. Sexual importance.

5. Amenorrhoea metrorrhagia, memorthagia, metrosalpingitis, ovaritis, fibromas, cysts.

6. Bright's disease, cataract, glaucoma, epilepsy, [...] lacomotive ataxia, multiple sclerosis, lupus, paralysis, blindness.

7. Complaints requiring surgical operation (e.g., appendicitis, stomach ulcers, prostatic disorders, hernias, sinusitis, mastodities.

8. Serious illness liable to endanger the life of the patient (e.g., pneumonai, pleurisy, abscess of the lungs).

9. Gripe Waters.

10. Cough Preparations.

SCHEDULE F

[See rule 5 (2)]

1. DRUG MANUFACTURING LICENCE FEE

(a) For the grant of licence:

Type of licence Fee

By way of basic Rs. 10,000By way of semi-basic Rs. 10,000

By way of formulation Rs. 25,000

By way of repacking Rs. 15,000

(b) For the renewal of licence

(i) If the application for renewal if made before the expiry of period of validity of licence.

Type of licence Fee

By way of basic Rs. 5000By way of semi-basic Rs. 5,000

By way of formulation Rs. 12,500

By way of repacking Rs. 7,500

(ii) If the application for renewal is made after the expiry of the period of validity of licence but within sixty days after expiry of the period validity:

Type of licence Fee

By way of basic Rs. 10,000By way of semi-basic Rs. 10,000

By way of formulation Rs. 25,000

By way of repacking Rs. 15,000

II. DRUG REGISTRATION FEE
[See rule 26 (3)]
(A) For the grant of Registration Rs. 5,000
(B) For the renewal of Registration
(i) if the application for renewal is made before the expiry of the validity of a certificate Rs. 2,500
(ii) if the application for renewal is made within thirty days after the expiry of the period of validity of a certificate
Rs. 5,000
III. FEE FOR ADVERTISEMENT
[See rule 31 (1A) and (1B)]
Application fee for Advertisement. Rs. 1,000 per advertisement

SCHEDULE G
[See rule 30 (11)]
ETHICAL CRITERIA FOR MEDICINAL DRUG PROMOTION
1. Promotion of drugs.- (1) For the purposes of this Schedule, "promotion" means all informational and persuasive activities by manufacturer and distributors, the effect of which is to induce the prescription, supply, purchase and/or use of medicinal drugs.

(2) All claims concerning a drug for the purposes of promotion shall be reliable, accurate, truthful; informative, balanced, up to date, capable of substantiation and in good taste. Such claims shall not contain misleading, unverifiable statements, omissions likely to induce medically unjustifiable use of a drug or to give rise to under risks. The word "safe" shall not be used with respect to promotion unless properly qualified. Comparison of products shall be factual, fair and capable of substantiation. Promotional material shall not be designed so as to disguise its real nature.

(3) Scientific data in the public domain shall be made available, on request, to prescribers and any other person entitled to receive it as appropriate to their requirements. Promotion in the form of financial or material benefits shall not be offered to or sought by health care practitioners to influence them in the prescription of drugs.

2. Advertisements in any form made to physicians and health-related professionals.-(1) The wording and illustrations in advertisements to physicians and related health professionals shall be fully consistent with the approved scientific data sheet for the drug concerned or other source of information with similar content. The text shall be fully legible.

(2). While introducing the drug to the physician for the first time in shall contain full product information, on the basis of the approved scientific data sheet or similar document and shall contain, among others, the following information:-
(a) The generic name(s) of the active ingredient(s);
(b) the content of active ingredient(s) per dosage form or regimen;
(c) the generic name(s) of other ingredient(s) known to cause problem(s)
(d) the approved therapeutic uses;
(e) dosage form or regimen;
(f) side-effects and major adverse drug reactions;
(g) precautions, contra-indications and warnings;
(h) major interactions;
(i) the name and address of manufacturer or distributor; [--]
(j) reference to appropriate scientific literature ; and
(k) Price of the drug, ; and

(3) Reminder advertisements shall include, amongst others, at least the international non-proprietary name or generic name , the name of each active ingredient and the price of drug

and the name and address for the manufacturer or distributor for the purpose of receiving further information.

3. Advertisements in any form to the general public.- (1) Advertisements to the general public, where permissible, shall help people to make rational decisions on the use of drugs determined to be legally available without a prescription. While advertisements shall take account of people's legitimate desire for information regarding their health they shall not take undue advantage of people's concern about their own health. Advertisement shall not generally be permitted for prescription drugs or to promote drugs for certain serious conditions that can be treated only by qualified health practitioners. The scheduled narcotic and psychotropic drugs shall not be advertised to the general public in connection with fight against drug addiction and dependency. Although health education aimed at children is highly desirable, drug advertisements shall not be directed at children. Promotional material shall be factual and claims for cure, prevention or relieve of an ailment shall be made only if this can be substantiated. Advertisements shall also indicate, where applicable, appropriate limitations to the use of the drug.

(2) When lay language is used the information shall be consistent with the approved scientific data or other legally determined scientific basis for approval. Language which brings about fear or distress shall not be used.

(3) Taking into account the media employed, advertisements to the general public may amongst others, contain, he following information:-
(a) The generic name(s) of the active ingredient(s);
(b) major indication(s) for use; (S.R.O. 1362(I)/96-28.11.96).
(c) major precautions, contra-indications and warnings, if any; and
(d) name of manufacturer or distributor.

4. Information on price to the consumer shall be accurately and honestly portrayed.

4. Medical Representatives.- (1) Medical representatives shall have an appropriate educational background. They shall be adequately trained so as to posses sufficient medical and technical knowledge and integrity to present information on products and carry out other promotional activities in an accurate and responsible manner. Employers shall be responsible for the basic and continuing training of their representatives. The training shall include instructions regarding appropriate ethical conduct taking into consideration the W.H.O. criteria.

(2) Medical representatives shall make available to prescribers and dispensers complete and unbiased information for each product discussed, such as an approved scientific data or other source of information with similar contents.

(3) Employers shall be responsible for the statements and activities of their medical, representatives. Medical representative shall not offer inducements to prescribers and dispensers. Prescribers and dispenses shall not solicit such inducements. In order to avoid over-promotion, the main part of the volume of sales they generate.

5. Free samples of prescription drugs for promotional purposes.- Free samples of drugs may be provided in modest quantities to prescribers, preferably on request.

6. Free samples of non-prescription drugs to the general public for promotional purposes.- There shall be no free sampling of non-prescription drug to the general public for promotional purposes.

7. Symposia and other scientific meetings.- The intimation regarding scientific symposia, seminars, conferences and such meetings where sponsored by a pharmaceutical manufacturer or distributor shall be clearly communicated in advance. The invitation letter should accurately

reflect the presentations and discussions to be held. Entertainment or other hospitality, offered to members of the medical and allied professions shall be secondary to the main purpose of the meeting and shall be kept to a modest level.

8. Post-marketing scientific studies, surveilance and disseminaion of information.- (1) The Registration Board shall be made aware of any post-marketing clinical trials for drugs that are conducted and the results thereafter as soon as possible.

(2) Post-marketing scientific studies and surveillance shall not be misused as a disguised form of promotion.

(3) Substantiated information on hazards associated with the drug shall be reported to the Registration Board as a priority.

9. Packaging and labelling.- Appropriate information being important to ensure the rational use of drugs, all packaging and labelling material shall provide information consistent with that approved by the Registration Board and if no such approval is available it shall be, consistent with that approved by the drug regulatory authority of the country from which the drug is imported or other reliable sources of information with similar content. Any wording and illustration on the package and label shall conform to the principles of ethical criteria enunciated in this Schedule.

10. Information for patients contained in package inserts, leaflets and booklets.- (1) Adequate information on the use of drugs shall be made available to the patients where it is necessary for rational use of a drug. In package inserts or leaflets the manufacturers or distributors shall ensure that the information reflected is correct. If package inserts or leaflets are used for promotional purposes, they shall comply with the ethical criteria enunciated in this Schedule. The wording of the pcakge inserts or leaflets, if prepared specially for patients, shall be in lay language subject to the condition that the medical and scientific content is properly reflected.

(2) In addition to approved package inserts and leaflets wherever available the preparation and distribution of booklets and other information material for patients and consumer shall also comply with the ethical criteria enunciated in this schedule.

[No. F. 8-1/90--AU (Vol-11.)]
DR. F.R.Y. FAZLI,
Deputy Director General (Pharmacy)/Drugs Controller.
(S.R.O. 1362(I)/96 28.11.1997)

The Drugs (Appellate Board) Rules, 1976

S. R. O. 595 (1)/76, dated 2lst June, 1976: In exercise of the powers conferred by Section 43 of the Drugs Act, 1976 (XXXI of 1976), the Federal Government is pleased to make the following rules, the same having been previously published as required by sub-section (3) of the said section, namely :--

1. Short title and commencements: (1) These rules may be called the Drugs (Appellate Board) Rules, 1976.
(2) They shall come into force at once.

2. The Appellate Board: (1) The Appellate Board shall consist of the following members, namely :--
(a) Secretary, Health Division, Government of Pakistan, who shall be its ex-officio Chairman.
(b) Secretary, Health Department, Government of the Punjab, ex-officio or his representative, not below the rank of an officer in BPS 19, who is an expert in machine, pharmacology or pharmacy.

(c) Secretary, Health Department, Government of Sind, ex-officio or his representative, not below the rank of an officer in BPS 19, who is an expert in machine, pharmacology or pharmacy.
(d) Secretary, Health Department, Government of Baluchistan, ex-officio or his representative, not below the rank of an officer in BPS 19, who is an expert in machine, pharmacology or pharmacy.
(e) Secretary, Health Department, Government of the North-West Frontier Province, ex-officio or his representative, not below the rank of an officer in BPS 19, who is an expert in machine, pharmacology or pharmacy.
(f) One Professor of medicine, to be nominated by the Federal Government.
(g) One Professor of Pharmacology, pharmacology or medicine to be nominated by the Federal Government.
(h) One representative of the Law Division, Government of Pakistan.
(i) Chairman, Quality Control Authority, Health Division, Government of Pakistan, who shall be its ex-officio Secretary,
(j) One representative of the Ministry of Law and Parliamentary Affairs, Government of Pakistan,
(k) Chief Cost Accounts Officer of the Ministry of Finance.

(2) The members, other than ex-officio members, of the Appellate Board shall hold office for a period of three years and shall be eligible for renominations.

(3) The Appellate Board shall meet as and when required to perform its functions.

(4) The Appellate Board shall have powers to appoint a Committee of Experts for detailed investigation of any matter and report to the Board.

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

3. Powers of the Appellate Board: The members of the Appellate Board shall exercise all the powers of an Inspector without restriction as to area, and such other powers as may be necessary to perform their functions.

4. Procedure of Appeal: (1) Any person aggrieved by a decision of the Registration Board, the Central Licensing Board or a licensing authority may, within sixty days of receipt Of such decision, submit an appeal to the Appellate Board.

(2) An application for appeal under sub-rule (1) shall be in triplicate and be accompanied by a copy of the decision appealed against, and shall contain all material statements and arguments relied on by the appellant.

(3) The Appellate Board shall transmit a copy of the application for appeal referred to in sub-rule (2) to the Registration Board or the Central Licensing Board or the licensing authority against whose decision

the appeal has been made. and such Board or authority shall. on demand, produce before the Appellate Board the record of the case leading to the decision.

(4) The Appellate Board shall, after giving the appellant an opportunity of being heard, pass such orders as it thinks tit and such orders shall be final.

5. Revision: The Appellate Board may, of its own motion at any time, call for the record of any case for the purpose of satisfying itself as to the correctness, legality or propriety of such order and may pass such order in relation thereto as it thinks fit.

RESEARCH

S.R.O. 1047(I)/78, dated 15th July, 1978: In exercise of the powers conferred by Section 43 of the Drugs Act, 1976 (XXXI of 1976), the Federal Government is pleased to make the following rules, the same having been previously published as required by sub-section (3) of the said section, namely :-

1. Short title and commencement:
(1) These rules may be called the Drugs (Research) Rules, 1978.
(2) They shall come into force at once,

2. Definitions: In these rules, unless there is anything repugnant in the subject or context,-
(a) "Committee" means the Committee of Experts constituted under rule 8;
(aa) "form" means form appended to these rules;
(b) "Fund" means the Central Research Fund maintained by the Federal Government under sub-rule (14) of rule 19 of the Drugs (Licensing, Registering and Advertising), Rules, 1976;
(c) "investigator" means a person engaged in the investigation, research, development or evaluation of a drug on his own initiative or under the sponsorship of any other person or an institution;
(d) "recipient" means a person or an institution who or which receives aid from the Fund; and
(e) "sponsor" means a person, firm, an establishment or institution promoting research on a drug.

3. Utilisation of Fund: The Federal Government may utilise the Fund for conducting research, development or evaluation of a drug either itself or through a research institution working under its control or disburse it among investigators or institutions for such purposes subject to such conditions as may be specified and for that matter, it may also utilize the fund to upgrade and establish Drugs Research and testing laboratories and a unit in the Drugs Control Section, Ministry of Health, for evaluation and monitoring of the research proposals and projects and management of the fund.

4. Research in drugs: The research in drugs shall be conducted at such place or places and by such person or persons as may be approved by the Federal Government and shall be categorised as under :--
(i) other than clinical trials; and
(ii) clinical trials.

5. Application for grant of aid: (1) An application for the grant of aid from the Fund for conducting research on a drug on aspects other than the clinical trials and for clinical trials shall be made in Form 'A' and Form 'B', respectively, and addressed to the Secretary of the Committee.
(2) The Federal Government may, before granting any aid from the Fund, cause inspection of the premises concerned end technical evaluation of the project by the Committee or any expert appointed by it for this purpose.
(3) The Federal Government may, after obtaining the advice of the Committee and subject to such conditions as it may specify in this behalf, grant such aid from the Fund to a person or an institution as it may deem fit.

6. Conditions for conducting research on aspects of other than clinical trials: (1) The research on any aspect of drugs other than clinical trial shall be conducted under the supervision of an investigator who possesses post-graduate qualification and experience in the relevant field and has sufficient background knowledge to conduct scientific investigation.
(2) The recipient shall, at regular intervals not exceeding six months, submit the progress report to the Federal Government in respect of the investigation being conducted.
(3) No change of an investigator or in the plan for investigation shall be made without prior approval of the Federal Government.
(4) The recipient shall allow an expert or a panel of experts authorised by the Federal Government to visit the premises at which the research is being conducted and to see that the

Fund is being utilised in accordance with the approved plan.

7. Conditions for research in clinical trials: (1) In addition to the conditions laid down in rule 6, research in drugs on aspect of clinical trials shall be conducted in the following stages:-
(i) Stage 1 of investigation on human beings shall consist of studies to determine single and short term multiple dosing for tolerance, side effects, toxicity, metabolism, preferred routes of administration, safe dosage range and other pharmacological actions of the drug:
Provided that these studies shall be conducted under carefully controlled circumstances on comparatively small number of subjects to prevent any serious deleterious effect on health.
(ii) Stage II of investigation shall consist of studies to determine safety and effectiveness including an effective dose range, the common side effects of the drug on both clinical and laboratory parameters and where possible the level of drug in biological fluids in relation to therapeutic response:
Provided that these studies shall be undertaken if studies in Stage I of investigation demonstrate satisfactory results and shall involve initial and limited use of the drug in the treatment or prevention of the disease for which the drug is intended and shall be administered to carefully supervised patients:
Provided further that the Federal Government may require additional pharmacological studies to be conducted concurrently on animals to indicate safety for stage II of the investigation.
(iii) Stage III of investigation shall consist of studies under controlled conditions in order to expand knowledge of potential use and hazards and shall be undertaken if the data obtained in stages I and II provide reasonable assurance of safety and effectiveness or suggest that the drug may have a potential value of conducting several trials outweighing its hazards:
Provided that these studies shall be carefully monitored and all possible precautions shall be taken to prevent unnecessary exposure of the patient to the risk.
(2) If at any stage there appears to be an unwarranted hazard in the continuation of the ongoing clinical trials, the sponsor and recipient may be asked by the Federal Government to modify or discontinue clinical trials until further pre-clinical work has been done and the investigator conducting such research shall discontinue further tests under intimation to the sponsor and the recipient in writing, a copy of which be sent to the Federal Government.
(3) Studies on children shall not be undertaken unless there is a possibility of benefit to them and adequate studies of safety and efficacy are available in adults.
(4) When any dangerous or adverse effects are observed, emergency reports shall be sent immediately by the recipient to the Federal Government so that the other investigators are informed and the studies are stopped if the hazard so warrants.
(5) The consent for use of all investigational new drugs in clinical trials for stages I and II shall be obtained in writing by the investigator but for stage III it is the responsibility of the investigator to take into consideration the physical and mental state of the patient to decide when it is necessary or preferable to obtain consent other than in writing and if written consent is not obtained, the investigator, must obtain oral consent and record the fact in the medical record of the person receiving the drug.
(6) The recipient shall keep the record of his studies carefully in respect of every drug, retain it for at least ten years after registration of that drug and produce it before the Federal Government whenever required.

8. Committee of Experts on Drug Research: (1) The Federal. Government shall set up a Committee of Experts on Drug Research to determine the priorities, to give directions in drug research, to evaluate the applications received for the grant and make allocations from the .Fund and to take or propose such actions and measures as may be necessary for ensuring effective and proper use of the Fund:
(1) The Federal Government shall constitute a Committee of Experts to advise it on the utilisation of the Fund and for such other purposes as may be necessary for the proper utilisation of the Fund.
(2) The Committee shall consist of the following members namely :-
(a) Director-General Health who shall be its ex-officio Chairman.
(b) Executive Director, National Institute of Health, Islamabad.
(c) Chairman of the Pharmacy Department who shall hold office for three years by rotation. Chairman, Pharmacy Department, Peshawar University shall be the member for the first term.
(d) Chairman of the Pakistan Council of Scientific and industrial Research or his nominee who

may be directly responsible for drugs research activities in the Council.
(e) Chairman of the Pakistan Medical Research Council, or his. nominee who may be directly responsible for drugs research activities in the Council.
(f) A Dean of the Pharmacy Faculty who shall hold office for three years by rotation. Dean of the Pharmacy Faculty, University of Karachi, shall be the member for the first term.
(g) A Professor of Pharmacology who shall hold office for three years by rotation. Professor of Pharmacology Allama Iqbal Medical College, Lahore, shall be the member for the first term.
(h) One representative of the Pakistan Pharmaceutical Manufacturers' Association (PPMA) who may be well-versed with the subject and actively engaged in the planning or conducting of research on drugs.
(i) Drugs Controller, Ministry of Health, Islamabad.
(j) Deputy Director General Health (Research and Development), Ministry of Health, Islamabad, who shall be its ex-officio Secretary.
(3) The Federal Government may appoint a Secretary of the Committee from amongst its members.
9. Withdrawal of Fund and termination of an investigation: (1) The Federal Government may, at any stage of an investigation, withdraw the aid from the recipient and direct him and the sponsor to terminate a clinical trial under any of the following conditions, namely :-
(i) evidence of significant hazard;
(ii) convincing evidence that the drug is ineffective;
(iii) submission of false data;
(iv} omission of material information pertaining to safety or efficiency of the drug;
(v) unsatisfactory manufacturing practices;
(vi) failure to conduct the investigation in accordance with plan submitted and approved by the Federal Government;
(vii) commercialization of the drug before completing clinical trial;
(viii) failure to report serious or potentially serious adverse reaction;
(ix) failure to meet the requirement of patient's consent; and
(x) evidence of misuse of the Fund:
Provided that the Federal Government may, before withdrawing the aid, require the recipient and the sponsor of any drug to comply with any of the above conditions which he has failed to comply within a specified period and may, after it is satisfied that the said conditions have been compiled with, allow resumption of the investigation.

FORM 'A'
[See rule 5 (1)]
Application for grant of aid for conducting research in drugs other than clinical trials

1. Name and address of the applicant.
2. Name and address of the sponsor if he is other than the applicant.
3. Title of Research project.
4. Financial implications of the project.
(i) Total Financial implications.
(ii) Present investment.
(iii) Other sources of finance. if any
(iv) Amount required from the Drugs Research Fund and details of its proposed utilisation.
5. Details of the Research project as follows :--
(i) Purpose.
(ii) Outline.
(iii) Progress already made (if any).
(iv) Comprehensive future Plan.
(v) Benefits.
6. Bio-data of all investigators including Incharge of the Research project giving the name. qualifications with years and experience.

FORM 'B'
[See rule S (I)]
Application for grant of aid for conducting clinical trials

1. Name and address of the applicant.
2. Name and address of the sponsor if he is other than applicant.
3. Title of Research project.
4. Financial implications of the project:
(i) Total Financial implications.
(ii) Present Investment.
(iii) Other sources of finance, if any.
(iv) Amount required from the Central Research Fund and details of its proposed utilisation.
5. Enclose herewith--
(i) outline of the Research Project, its purpose, benefits, description of the comprehensive plans. and progress already made, if any :
(ii) information and data about the drug to be investigated including its exact composition, chemistry. pharmacology, toxicity, conditions for use in man, and pharmacy with special reference to the method of manufacture and quality control to show that adequate standards exist and a meaningful assessment can be made of the safety of the material for use in man (copies of all informational material to be supplied to the investigator should be enclosed);
(iii) results of pre.clinical investigation including animal studies directed towards defining its safety and efficacy; and
(iv) an agreement from the sponsor and the applicant that they shall notify the Federal Government and all investigators if they become aware of any adverse effect arising during the course of investigation.
Note: When an investigator himself wishes to act as sponsor conducting an investigation, the amount of information required under item 4 (ii) and (iii) may vary but should be sufficient to identify the compound under investigation together with the facts which satisfy that the substance may be justifiably administered to human beings with reasonable margin o f safety.
6. Bio-data of all investigators including Incharge of the Research project giving the name,

THE DRUGS (FEDERAL INSPECTORS, FEDERAL DRUG LABORATORY AND FEDERAL GOVERNMENT ANALYSTS) RULES, 1976

S. R. O. 793 (1)176: In exercise of the powers conferred by Sec. 43 of the Drugs Act, 1976 (XXXI of 1976), the Federal Government is pleased to make the following rules, the same having been previously published as required by sub-section (3) of the said section, namely

1 Short title and Commencement : (I) These rules may be called 'the Drugs (Federal Inspectors, Federal Drug Laboratory and Federal Government Analysts) Rules, 1976.

(2) They shall come into force at once.
2. Definitions: In these rules, unless there is anything repugnant in the subject or context,--
(a) "Act" means the Drugs Act, 1976 (XXX1 of 1976);
(b) "Section" means a section of the Act; and
{c) "form" means a form set forth in the Schedule.

3. Qualification of Federal Inspectors: (1) A Federal Inspector shall be a person who-

(a) has a degree in Pharmacy from a Pakistani University or any other institution recognised for this purpose by the Federal Government; and

(b) has for a period of, or for periods: aggregating, not less than ten years' practical experience in, (i) the manufacture, testing or analysis of drugs, or (ii) in drug administration:

Provided that the condition of experience may be relaxed in exceptionally deserving cases or for persons with higher qualifications or where the candidate; with requisite experience are not readily available:

Provided further that the Federal Government may, by notification in the official Gazette, for the exercise of such powers as may be specified in such notification, appoint as ex officio Inspector any officer of medical or public health department who is a registered medical practitioner or any officer who is working in the drugs administration of a Government who has a degree in Medicine or Science or Pharmacy or any person having similar qualifications working as a teacher in any pharmaceutical or medical educational institution

(2) The Federal Inspector shall be under the control of the licensing authority referred to in Section 18.

Explanation: For the purposes of this sub-rule and rule 4, "licensing authority" means the Director General Health, Government of Pakistan, or an officer authorised by him in this behalf.

4. Duties of Federal Inspectors: (1) Subject to the instructions of the licensing authority, it shall be the duty of an inspector, within the local limits for which he is. appointed--

(a) to inspect not less than twice a year, all premises licensed for the manufacture of drugs including the plant and the process of manufacture, the means employed for standardising and testing the drugs,, the methods and places of storage, the location, construction and administration of the establishment likely to affect the potency for purity of the product, records and registers and to satisfy himself that the conditions of the licence and the provisions of the Act and the rules made thereunder, are being observed ;

(b) to inspect from time to time establishment licensed for the import, export or sale of drugs and to satisfy himself that the conditions of the licence are being observed;

(c) to send forthwith to the licensing authority after each inspection a detailed-report indicating the conditions of the licence and provisions of the Act and the rules made thereunder which are being observed and the conditions and provisions, if any, which are not being observed;

(d) to take samples of any drug which he has reason to suspect that it is being manufactured, stocked, sold or exhibited for sale in contravention of the provisions of the Act or the rules made thereunder. and send them for test or analysis;

(e) to investigate any complaint in writing which may be made to him; [.....]

(f) to institute, if necessary, prosecutions in respect of breaches of the Act and the rules made thereunder. and

(g) to give advice to pharmaceutical industry on technical matters pertaining to the manufacture of drugs in accordance with good manufacturing practices with a view to improve the standard of industry and quality control of drugs;

(h) to conduct surveillance of the marketed drugs for ensuring quality control and compliance of the various provisions of the Act and these rules, and

(i) to assist in organizing and conducting the programme for monitoring of the adverse reactions of drugs.

(2) A Federal Inspector shall, for the purpose of clause (i) of sub-section(l) of Section 18 take the approval of, and for the purpose of clause (ii) of sub-section (3) and sub-section (5) of Section 19, send the sample to, or, as the case may be, inform. the Registration Board in the case of registered Drugs and the Central Licensing Board in all other cases.

5. Form of orders not to dispose of storks: An order in writing by an Inspector under clause (i) of sub section (I) of Section 18 requiring a person not to dispose of any stock in his possession shall Form 1.

6. Form of receipt for seized drag: A receipt by an inspector for the stock of any drug seized under clause (f) of sub-section (.1) of Section 18 shall be in Form 2.

7. Form of Intimation of purpose of taking samples: Where an Inspector takes a sample of a drug for the purpose of test or analysis, he shall intimate such purpose in writing in Form 3 to the person from whom he takes it.

8. Procedure for despatch of sample to Government Analyst: (1) The portion of sample or the container sent by an Inspector to the Government Analyst for test or analysis under sub-section (3} of Section shall be sent by registered post or by hand in a sealed packet enclosed together with a memorandum in Form 4 in an outer cover addressed to the Government Analyst.

(2) A Copy of the memorandum and a specimen impression of the seal used to seal the packet shall be sent to the Government Analyst.

9. Confiscation of drugs: When any person has been convicted under the Act for contravening the provisions of clauses (a) to (e), (g) and (h) of Section 23, the stock of the drug or a substance in respect of which the contravention has been made may be confiscated if the Drug Court so directs.

10. Prohibition of disclosure of Information: Except for the purpose of official business or when required by a Court of Law, an Inspector shall not, without the sanction in writing of his official superior, disclose to any person any information acquired by him in the course of his official duties.

11. The Federal Drug Laboratory: This Federal Drug Laboratory shall have the following functions, namely :--
(i) to test and analyse such samples of drugs as may be sent to it under sub-section (5) of Section 22;
(ii) to test or analyses such samples as may be sent to it by the Federal Government:
(iii) to carry out such other functions as may be entrusted to it by the Federal Government or, with the prior approval of the Federal Government, by & Provincial Government.

12. The Regional Drugs Testing Laboratory. The Regional Drugs Testing Laboratories established by the Federal Government shall perform the following functions, namely :--

(i) to test and analyse such samples of drug as may be sent to it under sub-section (2) of Section 33;

(ii) to analyse such samples as may be sent to it by the Registration Board,. the Central Licensing Board or a Federal Inspector;

(iii) to carry out such other functions as may be entrusted to it by the Federal Government or, with the prior approval of the Federal Government, by the Provincial Government.

13. Qualifications of Federal Government Analysis: A Federal Government Analyst shall be a person who has a degree in Pharmacy or Pharmaceutical Chemistry or Medicine of a Pakistani University or of any other institution recognised by the Federal Government for this purpose and has pot less than three years post-graduate experience in the test a nd analysis of drugs or experience of the Drugs Control Administration or Drugs Quality Control Administration or of both for a period aggregating not less than five years.

14. Despatch of samples for teat or analysis: (1) Samples for test or analysis shall be sent to the officer for the time being incharge of the Federal Laboratory by registered post in a sealed packet, together with a memorandum in Form 5, in case the sample is being sent under sub-section (5) of Section 22.

(2) The packet, as well as the outer cover shall be marked with a distinguishing number.

(3) In the case of submission of samples under sub-section (5) of Section 22, a copy of the memorandum in Form 5 and a specimen impression of the seal used to seal the packet and a sample of the cloth and thread, if used, shall be sent to the officer for the time being incharge of the Federal Laboratory.

15. Recording of condition of seals: (1) On receipt of the packet, it shall be opened by the officer for the time being incharge of the Laboratory, a Government Analyst or any responsible officer authorised in writing by any of them in this behalf who shall record the conditions of the seals on the packet, on the form accompanying the sample, and on a register maintained for the purpose.

(2) Immediately on receipt of the sample, the officer opening the packet containing the sample shall examine the sample for any contravention of provisions of the Act in respect of labelling.

16. Report of result of test or analysis: (1) After test or analysis the result thereof together with full protocols of the test applied, shall be supplied forthwith to the sender in Form 6.

(2) The Government Analyst shall, for the purpose of sub-section (1) of Section 22, forward a copy of the report to the Registration Board in the case of a registered drug and to the Central Licensing Board in all other cases.

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

17. Signature on certificate: Certificates issued under these rules by the Laboratory, or a Government Analyst shall be signed by the officer-in-charge of the Laboratory or by an officer authorised by the Federal Government by notification in the official Gazette to sign such certificates or by a Government Analyst, as the case may be.

18. Fees: The fees for test or analysis of any drug shall be those specified in Schedule II.

SCHEDULE 1

FORM 1

(See rule 5)

ORDER UNDER SECTION 18 (1) OF THE DRUGS ACT 1976, REQUIRING A PERSON NOT TO DISPOSE OF STOCK IN HIS POSSESSION.

Whereas I have reason to believe that the stock of drugs in your possession detailed below contravenes the provisions of the Drug. Act, 1976 or rules made thereunder; and whereas I have reported the: facts to tee Board concerned or the authority and have been authorised by it to take action under clause (i) of Section 18 of the said Act;

I hereby require you not to dispose of the said stock for a period of .....days from this date.
Date..... Inspector .....
Details of stock of drugs
Inspector .....
FORM 2
(See rule 6)
RECEIPT FOR STOCK OF DRUGS SEIZED UNDER SECTION 8 (f) OF THE DRUGS ACT, 1976
The stock of drugs/materials/articles detailed below has this day been seized by me under the provision of clause (f) of Section 19 of the Drugs Act, 1976, from the premises of..... situated.....
Date ..... Inspector .....
Details of drugs seized
Inspector.....
FORM 3
(See rule 7)
INTIMATION TO PERSON FROM WHOM SAMPLE IS TAKEN.
I have this day taken from the premises of .....situated at .....samples of the drugs specified below for the purposes of test or analysis.
Inspector ..... Date .....
Details of sample taken
Inspector .....
FORM 4
(See rule 8)
MEMORANDUM TO GOVERNMENT ANALYST
Serial No .....
From .....

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

The portion of sample or container has been marked by me with the following mark :-

Details of portion of sample or container with name of drug which it purports to contain :-
Date..... Inspector .....
FORM 5
(See rule 14)
MEMORANDUM TO THE FEDERAL LABORATORY
Serial No .....
From .....

To the Officer. in-charge, Federal Drugs Laboratory.
I send herewith, under the provisions of section .....of the Drugs Act, 1976, sample (s) of a drug purporting to be .....for test or analysis and request that a report of the result of the test or analysis may be supplied.
2. The distinguishing number on the packet is .....
3. Particulars of offence alleged .....
4. Matter on which opinion is required.....
Date .....Drug Court.
FORM 6
(See rule 16)

CERTIFICATE OF TEST OR ANALYSIS BY THE FEDERAL 'DRUGS LABORATORY/GOVERNMENT ANALYST
Certified that the samples, bearing number.....purporting to be a sample

of.....received on .....with memorandum No .....Dated.....from.....has been tested/analysed and that the result of such test/analysis is as stated below :-

2. The condition of the seals on the packet of receipt was follows .....
3. In the opinion of the undersigned the sample is not/is .adulterated/ sub standard/misbranded/spurious, as defined in the Drugs Act, 1976 for the reasons given below :-

Details of results of test or analysis: (with protocols of tests applied}.
Director, Federal Drugs Laboratory
or other authorised officer/Government Analyst.
Secretary

DRUGS (IMPORT & EXPORT) RULES, 1976

S R O. 890 (I)/76. In exercise of the powers conferred by Section 43 of the Drugs Act, 1976 (XXX! of 1976), the Federal Government is pleased to make the following rules, the same having been previously published as required by sub-section (3) of the said. section) namely :--

CHAPTER I

1. Short title and commencement. (1) These rules may be called the Drugs (import and Export) Rules, 1976.
(2) They shall come into force at once.
2. Definitions. In these rules unless there is anything repugnant in the subject or context :-
(a) "Act" means the Drugs Act, 1976 ('XXXI of 1976); and
(b) "form" means form appended to these rules.

CHAPTER 11

IMPORT OF DRUGS

3. Import of finished drugs. Finished drugs may be imported subject to the following conditions, namely :-

(i) the importer possesses a licence to sell by way of retail wholesale, the drug intended to be imported and has adequate facilities for proper storage to preserve its properties

(ii) the importer shall, within fifteen days of establishing the letter of credit, intimate such action on Form I to an officer authorised by the Federal Government in this behalf;

(iii) the drug shall be imported in containers intended for retail sale or supply to hospitals, dispensaries or such other institutions; and

(iv) the drugs shall be imported against indents issued by the authorised indentors or local agents of the manufacturers.]

Provided that such drug may be imported in bulk containers by any person who possesses a licence for re-packing and has obtained permission in writing to such import from an officer authorised by the Federal Government in this behalf.

4. Types of licences to import drugs. Licences to import drugs shall be of the following types, namely :--
(i) licence to import drug other than the finished drugs; and
(ii) licence to Import small quantities of drugs for the purpose of clinical trial, examination, test or analysis.

5. Licences for import of drugs manufactured by one manufacturer. A single application shall be made, and a single licence shall be required, in respect of the import of more than one drug or class of drugs manufactured by the same manufacturer:

Provided that if a manufacturer front whom the drugs are to be imported has two or more premises manufacturing the same or different drugs. a separate application shall be made,. and a separate licence shall be required, in respect of the. drugs manufactured in each such premises.

6. Application for licence to import drugs. (1) An application for licence to import drugs other than finished drugs shall be made to the licensing authority in Form 2 and shall be accompanied by a fee of fifty rupees and by an undertaking in Form 3, signed by or on behalf of the manufacturer:

Provided that in the case of a subsequent application by the same importer for addition to the import licence of any drug manufactured by the same manufacturer, the fee to accompany each such application shall be twenty-five rupees.

(2) A fee of twenty. five rupees shall be paid for a duplicate copy of licence issued under this Chapter if the original is defaced, damaged or lost.

(3) An application for a licence to import small quantity of drugs for the purpose of clinical trial, examination, test or analysis shall be made to the licensing authority in Form 4; and the licensing authority may require such other particulars to be supplied as it may consider necessary.

(4) Any fee deposited under sub rule (1) or sub rule (2) shall in no case be refunded.

7. Licence to import drugs. A licence to import drugs other than finished drugs shall be issued in Form 5 and for the import of small quantity of drugs for clinical trial, examination, test or analysis shall be issued in Form 6.

8. Duration of licence to import drugs. Licence to import drugs, unless earlier suspended or cancelled, shall be valid for two years.

9. Licensing authority. For the purpose of this Chapter, "licensing authority" means the authority appointed by the Federal Government to issue licences to import drugs and includes any person subordinate to it to whom such authority may, with the approval of the Federal Government by an order in writing, delegate the power to sign licences and such other powers as may be specified in the order.

10. Grant of licence to import drugs. On receipt of an application fern licence to import drugs the licensing authority shall. on being satisfied that, if granted, she conditions of the licence will be observed issue an import licence.

11. Conditions of licence to import drugs other than finished drugs: A licence to import drugs other than finished drugs shall bc subject to the following conditions, namely :--
(i) the manufacturer shall at all times observe the under-taking given by him or on his behalf in Form 3;

(ii) the license shall allow the licensing authority or any person authorised by it in this behalf to enter, with or without prior notice. any premises where the imported drug is stocked to inspect the means, if any, employed for testing the drug and to take samples;

(iii) the licensee shall on request furnish to the licensing authority from every batch of each drug or from such batch or batches as the licensing authority may from time to time specify as sample in such quantity as the licensing authority may consider adequate for any examination, test or analysis required to be made, and the license shall, if so required furnish full protocols of the tests, if any which have been applied;

(iv) the licensee shall ensure proper storage facilities for preserving the properties of the imported drug;

(v) the licensee shall maintain a complete record of utilization of the imported drug, showing particulars of the substance manufactured from it and such further particulars, if any as the licensing authority may specify and such record shall be open to the inspection of licensing authority or any person authorised in this behalf by the licensing authority

(vi) the licensee shall comply with such further requirements, if any applicable to the holders of import licences, as may be specified in any rules subsequently made under the Act in this behalf and of which the licensing authority has given to him not less than three months notice.

12. Conditions of licence to import small quantities of drugs for clinical trial, etc : A licence to import small quantities of drugs including drugs the import of which is otherwise prohibited under the Act for the purposes of clinical trial, examination, test or analysis shall be subject to the following conditions, namely:-

(a) the licensee shall exclusively use the drug for the purpose for which it has been imported and at the place specified in the licence, or at such other plate as the licensing authority may from time to time authorise;

(b) the licensee shall allow the licensing authority or any person authorised by it in this behalf to enter, with or without prior notice, the premises where the drugs are kept and to inspect the premises and investigate the manner in which the drugs are being used and to take samples thereof;

(c) the licensee shall keep record of, and shall report to the. licensing authority, the drugs imported under the licence, together with the quantities imported, the date of importation and the name of the manufacturer;

(d) the licensee shall comply with such further requirements if any, applicable to the holders of licences for clinical trial, examination, test or analysis as may be specified in any rules subsequently made under the Act and of which the licensing authority has given to him not less than .one month's notice.

13. Import of drugs for personal use: Small quantities. of drugs including drugs the import. of which is otherwise prohibited tinder the Act may be imported for personal use subject to the following conditions. namely :--

(a) the drugs shall form part or a passenger's bona fide baggage and shall be intended for the exclusive .personal use. of the passenger;

(b) the quantity of any single drug so imported shall not exceed one hundred average doses:

Provided that any drug imported for personal use but not forming part of bona fide personal baggage may be allowed to be imported subject to the following conditions, namely :-

(i) the licensing authority on an application being made to it prior to the import, and. being satisfied that the drug is for bona tide personal use has granted permission for the import of the said drug; and

(ii) the quantity to be imported is, in the opinion of the licensing authority, reasonable and is covered by a prescription from a registered medical practitioner.

14. General provisions regarding import: An importer of drugs. except where such import is for personal use, shall comply with the following general provisions, namely :--

(a) the importer shall allow any person authorised in. this behalf to enter, with or without prior notice, any premises where the imported drugs are stocked, to inspect the storage facilities and to take samples for testing ;

(b) the importer shall, on being informed by the Registration Board or the licensing authority or an officer authorised by it in this behalf or the Chairman .of the Provincial Quality Control Board that any part of any batches of a drug has been found to be in contravention of the provisions. of the Act or the rules made thereunder and on being directed so to do, withdraw the remainder of that batch from sale and, so far as practicable, recall the issues already made from that batch and dispose of in such manner as the Board or, as the case may be, the authority, may direct;

(c) the importer shall maintain a record of all sales by way of wholesale made by him of the imported drugs, and such record shall be open to the inspection by any person authorised in this behalf;

(d) the importer shall ensure that the import of each batch of a drug is accompanied by--

(i) a batch certificate in Form 7 from the competent health authority or any other such agency of the country of export or from the manufacturer;
(ii) a copy of the test report of the drug from the competent health authority or any other such agency of the country of export or from the manufacturer;

(e) the importer shall maintain an inspection book on which a member of the Registration Board or of the licensing authority or an Inspector shall record proceedings of each of his visits, his impressions and the defects notified by him and such inspection book shall be signed by him as well as the. licensee or his authorised agent;

(f) the importer, shall on receipt of information of arrival of the consignment of drugs at the port of importation report in Form 8 alongwith three copies of the invoice to the officer authorised by the Federal Government to grant clearance under rule 15.

15. Procedure at customs-ports: (1) No drug shall be released from the customs unless a clearance certificates has been obtained by the importer from an officer authorised in this behalf by the Federal Government.

(2) If the Collector of Customs or an officer authorised by him has reason to suspect that any drug does not comply with the provisions of the Actor the rules made thereunder, he may, or if requested by as officer authorised in this behalf by the Federal Government shall, take samples of any drugs from the consignment and forward them to the officer-in charge of the laboratory appointed for the purpose by the Federal Government and may detain the drugs from the consignment of which samples have been taken until the report of the officer-in charge of the said laboratory on such samples is received:

Provided that if the importer gives an undertaking in writing not to dispose of the drugs without the consent of the Collector of Customs and to return the consignment or such portion thereof as may be required, the Collector of Customs shall make over the consignment to the importer.

(3) If an importer who has given an undertaking under the proviso to sub-rule (2} is required by the Collector of Customs to return the consignment or any portion thereof. he shall return the consignment or portion thereof within ten days of receipt of the notice.

(4) If the officer-in-charge of the laboratory appointed for the-purpose by the Federal Government reports to the Collector of Customs that the samples of any drug in a consignment do not conform to the specification or that the drug contravenes in any other respect the provisions of the Act or the rules made thereunder and that the contravention is such it cannot be remedied by the importer, the Collector of Customs shall communicate the report forthwith to the importer who shall within two months of his receiving the communication, either export all the drugs of that description in the consignment to the country from which they were imported or surrender them to the Federal Government for disposal in such manner as it may deem fit:

Provided that the importer may, within fifteen days of the receipt of the report make a representation against the report to the Collector of Customs who shall forward the representation with a further sample to the licensing authority or, as the case may be, the Registration Board which after obtaining, ff necessary, the report of the .officer-in-charge of the Federal Drugs Laboratory, shall pass orders thereon which shall be final.

(5) If he officer-in- charge of the laboratory appointed for the purpose by the Federal Government reports to the Collector of Customs that the samples of any drug contravene in any respect the provisions of the Act or the rules made thereunder and that the contravention is such that it can be remedied by the importer, the Collector of Customs shall communicate the report forthwith to the importer and permit him to import the drug on his giving an undertaking in writing not to dispose of that drug without remedying the said contravention.

(6) A Federal a provincial Inspector Inspector or a person authorised in this behalf by the Federal Government may physically inspect the consignment and draw samples from each batch for test and analysis as may be necessary and, if the consignment has been released by the customs, may order the importer not to sell or offer for sale or dispose of the drug for a reasonable period not exceeding one month with a view to obtain a test report:

Provided that the Federal a provincial Inspector Inspector or such authorised officer may prohibit the disposal of a drug for a longer. period if he has sufficient reason to believe that the import, in any way, is in contravention of any or the provision of the Act or these rules in which case. the importer shall not dispose of that drug until a certificate authorising the sale of the batch has been issued to him.

16. Suspension and cancellation of licence to import drugs: If the manufacturer or licensee fails to comply with any of the conditions of a licence to import drugs or violates any of the provisions of the Act or the rules made thereunder, the licensing authority may, after giving the licensee an opportunity of being heard, by an order in writing stating the reason therefor, suspend or cancel the licence for such period as it thinks tit or cancel for all times. either wholly or in respect of some of the drugs. to which it relates or, if the nature of offence is so serious that it is likely to endanger the public health, .may prohibit the import of all other drugs of the said manufacturer:

Provided that a person who is aggrieved by the suspension or cancellation of his licence, may. within sixty days of the receipt of such order, appeal to the Appellate Board.

CHAPTER III

EXPORT OF DRUGS

17. Export of finished drugs: Finished drugs may be exported subject to the condition that the exporter possesses a licence to manufacture or sell by way of retail sale or wholesale.

18. Licences for export drugs: A licence to export drugs shall be required in Form 9 for the export of drugs other than the finished drugs.

19. Licences for export of drugs manufactured by one manufacturer: A Single application shall be made, and a single licence shall be required in respect of the export of more than one drugs or class of drugs manufactured by the same manufacturer:
Provided that if a manufacturer has two or more premises manufacturing the same or different drugs, a separate application shall be made, and a separate licence shall bc required, in respect of the drugs manufactured in each such premises.

20. Application for licence to export drugs: (1) An application for licence to export drugs shall be made to the licensing authority in Form 10 alongwith an undertaking on Form 11 signed by the manufacturer and shall be accompanied by a fee of fifty rupees:

Provided that in the case of a subsequent application by the same exporter for addition to the export licence of any drug manufactured by the same manufacturer, the fee to accompany each such application shall be twenty-five rupees.

(2) A fee of twenty-five rupees shall be paid for a duplicate copy of licence issued under this Chapter if the original is defaced, damaged or lost.

(3) An application for a licence to export small quantity of drugs, including drugs the export of which is otherwise prohibited under the Act, for the purpose of clinical trial, examination, teat or analysis shall be made to the licensing authority in Form 12; and the licensing authority may require such other particulars to be supplied as it may consider necessary.

(4) Any fee deposited under sub-rule (I) or sub-rule (2) shall in no case be refunded.

21. Duration of a licence to export drugs: A licence to export drugs, unless earlier suspended or cancelled, shall be valid for two years:

Provided that if application for a fresh licence, is made three month, before the expiry of the existing licence, the current licence shall continue to be in force until orders are passed on the application

22. Licensing Authority: For the purpose of this Chapter. "licensing authority" means the authority appointed by the Federal Government to issue export licences and includes any person subordinate to it to with such authority may, with the approval of the Federal Government by an order in writing, delegate the power to sign licences and such other powers as may be prescribed in the order.

23. Grant of export licence: On receipt of on application for an export licence, the licensing authority shall, on being satisfied that, if granted, the conditions of the licences will be observed, issue an export licence.

24. Conditions of licence to export drugs: A licence to export drugs other than finished drugs shall be subject to the following conditions, namely :-

(i) the licensee shall allow any person authorised by the licensing authority in this behalf to enter, with or without prior notice, any premises where the drug to be exported is stocked to inspect the means, if any employed for testing the drug and to take samples;

(ii) the licensee shall on request furnish to the licensing authority from every batch of each drug or from such batch or batches as the licensing authority may from time to time specify samples in such quantity as the licensing authority may consider adequate for any examination, test or analysis required to be made and the licensee shall, if so required furnish full protocols of the tests, if any, which have been applied;

(iii) if the licensing authority so directs, the licensee shall not export or offer for export any batch in respect of which a sample is, or protocols are, furnished under clause (ii) until a certificate authorising the export of the batch has been issued to him by or on behalf of the licensing authority:

(iv) the licensee shall, on being informed by the licensing authority that any part of any batch of a drug has been found by the licensing authority not to conform to the required specifications and on being directed so to do, withdraw the remainder of that batch from export and, so far as may, in the particular circumstances of the case, be practicable, recall the issues already made from that batch;

(v) the licensee shall maintain a record of all exports made by him of each drug showing particulars of the drug and of the person to whom exported and such further particulars, if any, as the licensing authority may specify, and such record shall be open to the inspection of any inspector authorised in that behalf by the licensing authority and such records shall be preserved for three years from the date of the export of the drug;

(vi) the licensee shall cause the drugs to be packed and labelled in conformity with the requirements of the consignee;

(vii) the licensee shall ensure proper storage facilities for preserving the properties of the drugs to be exported during storage;

(viii) the licensee shall comply with such further requirements, if any, applicable to the holders of export licenses, as may be specified in any rules subsequently made under the Act in this behalf and of which the licensing authority has given to him not less than three months' notice.

25. Export of drugs for the purposes of clinical trial, examination, test analysis or personal use: Small quantities of drugs, including drugs the export of which is otherwise prohibited under the Act, may be exported for the purposes of clinical trial examination, test, analysis or personal use with the written permission of the licensing authority.

26. Statement to accompany drugs for export: All consignments of drugs sought to be exported shall be accompanied by an invoice or other statement showing the name and address of the manufacturer and the names and quantities of the drugs.

27. General provisions regarding export: An exporter of drugs, except where such export is for personal use, shall comply with the following general provisions, namely:-

(a) The exporter shall allow any person authorised in this behalf to enter with or without prior notice, any premises where the drugs to be exported are stocked, in inspect the storage facilities and take samples for testing.

(b) The exporter shall, on being informed by the Registration Board or the licensing authority or an officer authorised by it in this behalf or the Chairman of the Provincial Quality Control board that any part of any batch of a drug has been found in contravention of any of the provisions of the Act or the rules made thereunder and on being directed so to do, withdraw the remainder of that batch from export and so far as practicable, recall the issues already

made from that batch and dispose of it in such manner as the Board, or, as the case may be, the licensing authority, may direct.

(c) The exporter shall maintain a record of all exports of drugs made by him and such record shall be open to inspection by any person authorised in this behalf.

(d) the exporter shall maintain an inspection book on which a me mber of the Registration board or the licensing authority or an Inspector shall record proceedings of each of his visits, his impressions, and the defects noticed by him and such inspection book shall be signed by him as well as the licensee or his authorised agent.

28. Procedure at customs port: (1) If the Collector of Customs or an officer authorised by him has reason to suspect that any drug does not comply with the provisions of the Act or the rules make thereunder, he may, and if requested by an officer appointed for this purpose by the Federal Government shall, take samples of any drugs from the consignment and forward them to the officer-in-charge of the laboratory appointed for the purpose by the Federal Government and may detain the drugs from the consignment of which samples have been taken until the report of the officer-in-charge of the said laboratory on such samples is received:

Provided that if the exporter gives an undertaking in writing not to export or dispose of the drugs without the consent of the Collector of Customs and to return the consignment or such portion thereof as may be required, the Collector of Customs shall make over the consignment to the exporter.

(2) If an exporter who has given an undertaking under the proviso to sub-rule (I) is required by the Collector of Customs to return the consignment or any portion thereof, he shall return the consignment or portion thereof within ten days of the receipt of the notice.

(3) If the officer in-charge of the laboratory appointed for the purpose by the Federal Government reports to the Collector of Customs that the samples of any dug in a consignment do not conform to the specifications or that the drug contravenes in any other respect the provisions of the Act or the rules made thereunder and that the contravention is such that it cannot be remedied by the exporter, the Collector of Customs shall communicate the report forthwith to the exporter who shall cause them to be destroyed or surrender them to the Federal Government for disposal in such manner as it may deem fit:

Provided that the exporter may, within fifteen days of the receipt of the report, make a representation against the report to the Collector of Customs who shall forward the representation with a further sample to the licensing authority or, as the case may be, the Registration Board which after obtaining, if necessary, the report of the officer-in-charge of the Federal Drugs Laboratory, shall pass orders thereon which shall be final.

(4) If the officer-in-charge of the laboratory appointed for the purpose by the Federal Government reports to the Collector of Customs that the samples of any drug contravene in any respect the provisions of the Act or the rules made thereunder and that the contravention is such that it can be remedied by the exporter, the Collector of Customs shall communicate the report forthwith to the exporter and permit him to withdraw the drug on his giving an undertaking in writing not to export that drug without remedying the said contravention.

29. Suspension and cancellation of license to export drugs: If the manufacturer or licensee fails to comply with any of the conditions of license to export drugs or violates any of the provisions of the Act or the rules made thereunder, the licensing authority may, after giving the licensee an opportunity of being heard, by an order in writing stating the reasons therefor, suspend or cancel it for such period as it thinks fit or cancel for all times, either wholly or in respect of some of the drugs, to which it relates or, if the nature of offense is so serious that it

is likely to endanger the public health, may prohibit the export of all other drugs of the said manufacturer:

Provided that a person who is aggrieved by the suspension or cancellation of his license, may within sixty days of the receipt of such order, appeal to the Appellate Board.

FORM 1

[See rule 3 (ii)]

INTIMATION REGARDING IMPORT

I/We.....of.....have established the letter of credit to conduct import of drug(s) details of which are as follows:--

(i) Name of the drug(s) ----------

(ii) Drug Registration number(s) ----------

(iii) Name and address of Manufacturer ----------

(iv) Name and address of exporter ----------

(v) Date of establishing L/C ----------

(vi) Quantity to be imported ----------

(vii) Rate per unit ----------

(viii) Total C & F value ----------

(xi) Mode of shipment ----------

(x) Expected date of arrival ----------

(xi) Nature of Drugs Sale License ----------

Date---------- Signed----------

FORM 2

[See rule 6 (1)]

APPLICATION FOR LICENSE TO IMPORT DRUG(S)

I/We ----------hereby apply for import of drug(s) specified below manufactured by---------- of----------.

NAME OF DRUG(S)

I/We----------enclose herewith an undertaking in Form 3 signed by or on behalf of the manufacturer as required by the rule under the Drugs Act, 1976.

FORM 3

[See rule 5 (1)]

FORM OF UNDERTAKING TO ACCOMPANY AN APPLICATION FOR LICENSE TO IMPORT DRUGS

Whereas----------of----------intends to apply for a license under the Drugs (Import and Export) Rules, 1976, for the import into Pakistan of the drug(s) specified below manufactured by us. We----------of----------hereby give this undertaking that:

(1) the said applicant has made a contract with us for import of drug(s) mentioned in the undertaking;

(2) we declare that we are bonafide licensed manufacturer of the drugs covered under this undertaking at the premises specified below and we shall report change, if any, in the said premises;

(3) we shall comply with the conditions imposed on a license by the rules under the Drugs Act, 1976 and such other requirements as may the laid down by the Government of Pakistan in this behalf;

(4) the drug(s) mentioned below conform(s) to the provisions or the Drugs Act, 1976, and the rules made thereunder.

NAME OF THE DRUG(S)

Particulars of the premises where manufacture is carried on.

Date---------- Signature of Manufacturer----------

FORM 4

[See rule 6 (3)]

APPLICATION FOR LICENSE TO IMPORT DRUGS FOR THE PURPOSE OF CLINICAL TRIAL, EXAMINATION, TEST OR ANALYSIS

I/We----------of----------by occupation----------hereby apply for a license to import the drug(s) analysis at----------and I/We undertake to comply with

the conditions applicable to the license under rule 12 of the Drugs (Import and Export) Rules, 1976.
Name of drug(s)---------- Quantities----------
Manufactured by----------
Date---------- Signature----------
Name and address of applicant
FORM 5
(See rule 7)
LICENSE TO IMPORT DRUG(S)
Number of license----------M/s---------- of----------is/are hereby licensed to import into Pakistan during the period for which this license is in force the drug(s) specified below, manufactured by----------of----------.

2. This license is subject to the conditions prescribed in the Drugs Act, 1976 and shall be in force for a period of two years from the date stated below unless it is sooner suspended or cancelled under the said Rules:

Name of Drug(s) to which this license applied:
(1) ----------
(2) ----------
(3) ----------
Date---------- Licensing Authority----------
FORM 6
[See rule 7]
LICENSE TO IMPORT DRUG(S) FOR CLINICAL TRIAL, EXAMINATION, TEST OR ANALYSIS
No. of license----------M/s----------of---------- is/are hereby licensed to import from----------the drug(s) specified below for the purpose of clinical trial, examination test or analysis at----------or in such other place as the licensing authority may from time to time authorise.

2. This license is subject to the condition prescribed in rule 12 of the Drugs (Import and Export) Rules, 1976, and such other conditions as may be prescribed by the Federal Government in this behalf.

3. This license shall, unless, previously suspended or cancelled, be in force for a period of two years from the date specified below:
Name(s) of drug(s) with quantities which may be imported
Date---------- Licensing Authority----------
FORM 7
[See rule 14 (d) (I)]
BATCH CERTIFICATION
Name and Registration No. of drug ----------
Batch number of drug ----------
Name and address of the Manufacturer ----------
Date of Manufacture ----------
Date of expiry, if any ----------
It is hereby certified that the above-mentioned drug (s) has/have been manufactured and labelled in conformity with the provisions of the Drugs Act, 1976, and the rules made thereunder.

It is further certified that this/these drug (s) has/have been manufactured under a valid permit/license issued by the competent Health or any other authority to manufacture this/these drug(s).
Signed ----------
Name, designation and official seal of the Signatory ----------
Place and date ----------
FORM 8

[See rule 14 (f)]
Intimation of arrival of consignment (s) of imported drug (s) other than those imported for personal use.
Name and address of importer.
Status (whether commercial importer or industrial consumer).
Drugs Manufacturing License No (in case of industrial consumer).
Drug Import License No. (in case of industrial consumer).
C.C.I., &E License No. with date and value of the License.
Import Policy Order applicable.
Name and address of exporter/manufacturer.
Name of drug (with dosage form for finished drug) Drug Registration No. finished drug Rate (for C & F/F.O.B.) Packing Quantity Total Value
FORM 9
(See rule 18)
LICENCE TO EXPORT DRUG (S)
Number of licence.....M/s.....of.....is/are hereby licensed to export during the period for which this licence is in force the drug specified below manufactured.....

(2) This licence is subject to the conditions prescribed in the rules under the Drugs Act, 1976, and shall be in force for a period of two years from the date stated below unless it is sooner suspended or cancelled under the said rules.
Name (s) of drug (s) to which the licence applied:
Dated..... Licensing Authority
FORM 10
[See rule 20 (1)]
APPLICATION FOR A LICENCE TO EXPORT DRUG
l/We ..... of ..... hereby apply for licence to export the drugs specified below manufactured by.....

Name (s) of drugs

l/We .....enclose herewith an undertaking in form 11 signed by the manufacturer/exporter as required by rule under Drugs Act, 1976.
Date ..... Exporter .....
FORM 11
See rule 20 (2)]
FORM OF UNDERTAKING TO ACCOMPANY AN APPLICATION FOR AN EXPORT LICENCE
Whereas .....of .....intends to apply for licence under the Drugs (Import and Export) Rules, 1976 for the export of the drug (s) specified below manufactured by .....

(1) the said applicant has made a contract with use for thc purchase of drug (s) mentioned in the undertaking;

(2) we shall comply with the conditions imposed on a licensee made the Drugs Act, 1976;

(3) we declare that we arc carrying on the manufacture of drug (s) mentioned in this undertaking at the premises specified below and we shall from time to time, report any change of premises on which the manufacture will be carried on and, in cases where manufacture is carried on in more than one factory, any change in the distributions between the factories;

(4) every drug manufactured by us for export under licence shall conform with the provisions of the Drugs Act, 1976 and the Rules made thereunder;

(5) we shall comply with such further requirements if any, as may be specified by rules made by the Federal Government under the Act and of which the licensing authority has given to the licensee not less than three months notice.
List of drug (s)

Particulars of premises where manufacture is carried on.
Date ..... Signed by the manufacturer.
FORM 12
[See rule 20 (3)]
APPLICATION FOR EXPORT OF SMALL QUANTITIES OF DRUG (s) FOR THE PURPOSE OF CLINICAL TRIALS, EXAMINATION, TEST OR ANALYSIS OR FOR PERSONAL USE
I/We ..... of ..... hereby apply for permission to export the drug (s) specified below manufactured by of ..... for the purpose of ..... clinical trials, examination, test or 2analysis or for personal use

Name (s) of drug (s)
Date..... Exporter .....

Drugs (Specifications) Rules, 1978

Notification S.R.O. 1080 (1)/78: In exercise of the powers conferred by Section 43 of the Drugs Act, 1976 (XXXI of 1976), the Federal Govern moist is pleased to make the following rules, the same having been previously published as required by sub-section (3) of the said section, .namely :--

1. Short title and commencement: (1) These rules may bc called the Drugs (Specifications) Rules, 1978.

(2) They shall come into force at once.

2. Specifications: The specifications for the classes of drugs specified in column 1 of the schedule shall be those specified against those drugs in column 2 of the schedule.
SCHEDULE
Specifications for Drugs

SCHEDULE
Specifications for Drugs

Class of drug	Specifications to be compiled with
1. Drugs bearing reference on the lebelling to any of the publications specified under sub-clause t (ii) of clause (z) of Section 3.	Specifications given in the publication referred to on the labelling.
2. Drugs included in the recent editions of any of the following publications but not bearing any reference to such publication :- (a) the international Pharmacopoeia or such other specifications as published by the World Health Organisation, (b) the European Pharmacopoeia, (c) the United States Pharmacopoeia, (d) the British Pharmacopoeia, (e) the British Pharmaceutical Codex. (f) the United States .National Formulary.	Specifications as approved by the Registration Board for this purpose and if no such approval is available the specifications given in the said publications in the same order of preference as given in column 1.
3. Veterinary drugs	Specifications as approved by the Registration

	Board for this purpose and if no such approval is available, the specification given in the current edition of British Veterinary Codex and, if a drug is not included in the current edition and is included in an earlier edition the specification proscribed in that edition.
4. Drugs other than those falling under serial number 1, 2 or 3 above.	Specifications as approved by the Registration Board for specification are available the ingredients and their quantities displayed in the labelling which shall be tested and analysed by the Government Analyst or the Federal Drug Laboratory or such other laboratory as may have been specified to be the laboratory for the purpose of sub-section (5) of section 22.
5. Ophthalmic preparations	In addition to the requirements, if any, set out above, ophthalmic preparations shall meet the following requirement:- A-Ophthalmic Solutions and Suspensions; Ophthalmic solutions and suspensions shall-- (a) be sterile except in case of those ophthalmic solutions and suspensions which are not specifically required to comply with the test for 'Sterility' in the Pharmacopocia; (b) contain one or more suitable substances as preservatives to prevent the growth of micro-organisms Provided that solutions in used surgery shall not have any preservative and be packed in single dose containers; (c). be free from foreign matter: (d) be contained in bottles made of either neutral glass or soda glass specially treated to reduce the amount of alkali released when in contact with aqueous liquids or in suitable plastic containers which would not in any way be incompatible with the solution and the droppers to be supplied with the containers shall be made of neutral glass or of suitable plastic material and when supplied separately shall be packed in sterile cellophane or other suitable packings; and B-- Ophthalmic Ointment Ophthalmic Ointment shall-- (a) be sterile; (b) be free from foreign matter

NOTIFICATION
Islamabad, the 27th October, 1996

S.R.O. 1214(I)/96.- In exercise of the powers conferred by sub-section (1) of section 44 of the Drugs Act, 1975 (XXXI of 1976), the Chief Executive, Northern Areas is pleased to make the following Drugs Rules, namely:-

The Northern Areas Drugs Rules, 1996.

PART I.-PRELIMINARY

1. Short title and commencement.- (1) These rules may be called the Northern Areas Drugs Rules, 1996.

(2) They shall come into force at once.

2. Definitions.- In these rules, unless there is anything repugnant in the subject or context:-

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

(b) "Board" means the Northern Areas Quality Control Board;

(c) "Form" means form prescribed in Schedule "A".

(d) "Government" means the Kashmir Affairs and Northern Affairs Division and Northern Areas Administration;

(e) "Narcotic and other controlled drugs" means the drug specified in Schedule "B".

(f) "Pharmacy" means a shop, store or place where drugs are compounded or prepared on prescription, it shall include a place which bears the words. Pharmacy, Pharmacist or dispensing chemist and shall conform to requirement laid down in Schedule "F".

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

(h) "Schedule" means a schedule to these rules;

(i) "section" means section of the Act; and

(j) "Whole Sales" sale by way of whole sale dealing, means, sale to a person who buys for the purpose of selling again.

PART II.-NORTHERN AREAS QUALITY CONTROL BOARD GOVERNMENT ANALYST AND DRUG INSPECTOR.

3. Northern Areas Quality Control Board.-

(1) The Board shall consist of the following members, namely:-

(a) Director Health Services, Northern Areas, Gilgit Chairman

(b) Medical Superintendent, District Health Officer, Hospital Gilgit Member

(c) Deputy Commissioner, Gilgit Member

(d) Drug Inspector, Directorate of Health Services Norther Areas, Gilgit. Secretary

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

(3) The quorum to constitute a meeting of the Board shall be three including its Chairman.

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

4. Functions of the Board.-(1) The Inspector and the Government Analyst shall submit monthly returns in Form-1 and Form-2 respectively, to the Board and a summary on the over all situation of quality control in the area under their respective jurisdiction and the Board shall maintain such information so as to monitor the quality of all the drugs sold and to keep watch on the performance of all manufacturers and the drugs sale licence holder.

(2) The Board shall, as far as possible, meet at least once in a month and review the situation of the quality control of drugs on whole including consideration of any specific point arising during the period on the working of various Firms. Drug Testing Laboratories and Inspectors.

(3). The Board shall examine the cases referred to it by any Inspector under the Act before directing him to prosecute such accused or recommending to the Licensing Authority for cancellation or suspension of the licence, provided that no such action shall be taken without a show cause notice to the accused.

(4) Before referring any case to the Drug Court, the Board shall ascertain the name of the Directors, Partners and e mployees of the Company, Corporation, Firms or institutions who are

prima facie responsible for the commission of the offence under the Act or the rules and allow an Inspector to institute prosecution only against such persons.

(5) The Board may in view of minor contravention of offences in its discretion, advise the accused to make improvement, or if considered necessary, issue a warning to the accused.

5. Qualifications of Inspectors and Analyst.- (1) No person shall be appointed as a Inspector unless he posses a Degree in Pharmacy from a Pakistani University or any other Institution recognised for this purpose by the Pharmacy Council of Pakistan and has at least one year experience in the manufacture, retail sale testing or analysis of drug or in the Drug Control Administration or in a Hospital Pharmacy:

Provided that for dealing with specific cases, the Government may appoint as ex-officio inspector any Gazetted Officer of Medical or Public Health Department, who is a Registered Medical Practitioner, or any officer working in the Health Administration, who has a degree in medicine or pharmacy or any other person having similar qualification and is working as a teacher in Pharmacy or Medical Education:

Provided further that the ex-officio Inspector shall be appointed for the purpose of conducting inspection of:-
(i) any premises wherein any drug is sold or is stocked or exhibited for sale or distribution;
(ii) the storage arrangements and all relevant records registers; and
(iii) taking samples of any drug which is being sold or is stocked or exhibited for sale or is being distributed.

(2) No person shall be appointed as an Analyst unless he possesses a Degree in Pharmacy from a Pakistani University or any other Institution recognized for this purpose by the Pharmacy Council of Pakistan and has at least five years experience preferably in the manufacture, testing or analysis of drugs or in the Drugs Control Administration;

Provided that the provisions of these rules shall not apply to the Analysts who were appointed as such on regular basis before the coming into force of these rules.

6. Duties of Drug Inspector.- Subject to the instructions of the Licensing Authority, it shall be the duty of Drug Inspector:-

(a) to inspect not less than twice a year all establishments of drugs licenced for sale and all establishments licenced for manufacture of drugs within the area assigned to him and to keep record of such inspections;

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

(c) to take and send for test or analysis if necessary, samples of any drug which he has reason to suspect is being manufactured, sold, stocked or exhibited for sale in contravention of any of the provisions of the act;

(d) to investigate any complaint in writing which may be made to him and furnish the report in respect thereof to the Licensing Authority;

(e) to institute prosecution in respect of contravention of the Act and these rules; and

(f) to maintain record of all inspections made and actions taken by him in the performance of his duties, including the taking of samples and seizure of stocks, and submit report of such record as may be required by the Quality Control Board.

7. Prohibition of Disclosure of Information.- Except for the purpose of official business or when required by the Court of Law, an Inspector or any Analyst shall not disclose to any unauthorised person any information acquired, by him in the course of his official duties.

8. Form of order not to dispose off stock.- An order in writing by an Inspector under clause (I) of sub-section (1) of section 18 of the Act, requiring a person not to dispose of any stock in his possession shall be in Form-3.

9. Form of intimation for the purpose of taking samples.- (1) Where an Inspector takes a sample of drugs under clause (c) of sub-section (1) of section-18 of the Act, for the purpose of test or analysis, he shall intimate such purpose in writing in Form-4, to the person from whom he takes it and where he seizes stock of drug or other material under clause (f) of section 18 of the Act, the receipt for such drugs and material shall be in Form-5.

(2) The Inspector shall send a portion of the sample or the container to the Analyst for test and analysis under clause (I) of sub-section (3) of section 19 of the Act, through a memorandum in Form-6.

(3) The Inspector shall send a specimen impression of his seal to the Analyst and shall inform him of any change.

10. Powers to transfer cases.- Where an offence is found to have been committed in an area outside the jurisdiction of an Inspector, he shall transfer the case with all details and material to the concerned Inspector for conducting investigation and prosecution as may be considered necessary.

11. Duties of Government Analyst.- (1) An Analyst shall cause to be analysed or tested such samples of drugs as may be sent to him under the Act and shall furnish report, the result of test and analysis on Form-7, in accordance with these rules.

(2) An Analyst shall cause to be tested and analysed such samples of drugs as may be sent to him in writing from a Government Department or any other public institution and shall furnish the report of the result of test and analysts to the Government Department or the public institution concerned.

(3) An Analyst shall forward monthly report giving results of samples tested and analysed during the period under report for publication at the discretion of the Federal Government and furnish such other information as may be required by that Government.

12. Procedure on receipt of samples from Inspector.- On receipt of a package from an Inspector containing a sample for test and analysis, the Analyst shall compare the seals on the packet with the specimen impression received separately and shall note the condition of the seal on the package and after the test or analysis has been completed, he shall forwith supply to the Inspector a report of the result of the test and analysis.

13. Fee for test and analysis of drugs.- The fee for test and analysis of drugs in respect of samples sent by a person other than an Inspector or a Government Institution shall be determined by the Government Analyst or the person Incharge of the Government Laboratory in accordance with the fees specified in Schedule "C".

PART III.-SALES OF DRUGS

14. Licensing Authority.- (1) The Chief Inspector of Drugs or Secretary Quality Control Board will be the drugs licensing authority for all type of drug sale licence within the area of his jurisdiction.

15. Type of Licences to sell Drugs.- The licences under these rules shall be of the following types, namely:-

(i) licence for drugs by way of retails sale;
(ii) licence for drugs by way of whole sale;
(iii) licence for narcotics and other controlled drug; and
(iv) licence for drug in a Pharmacy.

16. Application for licence to sell Drug and fees thereof.- (1) Application for the grant or renewal of a licence referred to in clause (I) to (iv) of rule 15 shall be made in Form-8, to the licensing authority. The fee shall be charged as under:-

(a) one thousand rupees for the grant of a licence to sell either the drugs specified in the clause (I) to (iv) of rules 15; and
(b) five hundred rupees in case of renewal of such licence subject to the condition that the provisions of these rules have been complied with.

(2) A fee of five hundred rupees shall be paid for a change of a qualified person and a duplicate copy of the licence referred to in clause (I) to (iv) of rule 15, if the original is defaced, damaged or lost and such copy of the licence shall bear the words "duplicate copy."

(3) The fees so collected will be utilised as under:-

(i) fifty per cent of the fee shall be deposited into Government Treasury under the relevant Head of Accounts; and

(ii) remaining fifty per cent of the fee shall be utilised on day to day expenses for collection of samples, packing and parceling of the samples to the Government Testing Laboratories, besides other petty expenditure in the Chief Drug. Inspectors office, proper Accounts of the same will be maintained accordingly.

17. Forms of Licences to sell Drugs.-(1) A licence to sell, store exhibit for sale or distribute drugs by way of retail sale shall be issued in Form-9.

(2) A licence to sell, store exhibit for sale or distribute drugs by way of whole sale shall be issued in Form-10.

(3). A licence to sell, store, exhibit for sale or distribute narcotics, and other controlled drugs shall be in Form-II.

(4). A licence to sell drugs in a Pharmacy shall be in Form-12.

18. Sale at more than one place.- If drugs are sold, stored, exhibited for sale or distributed or more than one place, a separate licence shall be required in respect of each such place.

19. Duration of licences.- (1) A licence issued under these rules shall unless suspended or cancelled earlier, remain in force for two years-from the date of issue, and if an application for renewal of such licence is not made within one month of its expiry of the licence shall stand cancelled.

Provided that if an application for renewal of a licence is made before the expiry of the period of its validity or where it is not done so far, reasons beyond the control of the licence and the application is made within one month of the expiry of the licence shall continue to be in force, until orders are passed on the application.

(2) An application for renewal shall be disposed of within three months of the receipt of such application after receiving inspection report from the Inspector concerned.

20. Pre-conditions for the issue of licence.- (1) The licensing Authority shall not issue:-

(a) Licences in Form-9 and Form-12, unless;-

(I) the premises have proper and adequate facilities for storage of drugs and for their protection from direct sunlight, dust or dirt including refrigeration facilities;

(ii) the premises are-clean and in hygienic and tidy condition; and

(iii) in the case of Pharmacy, the requirements laid down in Schedule "F" are complied with.

(b) Licences in Form-10 unless the appoint is an indentor, importer, manufacturer or distributor of drugs and fulfills the conditions laid down in sub-clause (a); and

(c) licence in Form-II, unless:-

(i) the applicant posses a licence in Form-9, Form-10 or Form-12; and

(ii) the applicant has never been convicted of any offence under the Act.

(2) The sale of drugs in Forms 9, 10, 11 and 12 shall be supervised by a persons who is registered under clause (a) and (b) of sub-section (1) of section 24 of the Pharmacy Act, 1967 (XI of 1967).

(3). In the case of renewal of already licenced premises, the licence shall not be renewed unless they employ on wholetime basis a qualified person as mentioned in sub-rule (2).

21. Conditions of licences.- (1) Licences in Forms 9, 10, 11 and 12 shall be issued subject to the conditions stated therein and to the following general conditions, namely:-

(a) the supply by way of retail sale of any drug shall be recorded suitably and such records, bills or counterfoils shall be preserved for a period of at least three years from the date of such sale, and

(b) drugs specified in Schedule "B" and "D" and preparations containing such drugs shall not be sold by retail sale, except on, and in accordance, with the prescription of a registered medical practitioner with the Pakistan Medical and Dental Council. A prescription shall be dispensed only once, unless or otherwise specifically directed by the prescriber to repeat it:

Provided that no such prescription shall be required for sale of these drugs to a registered medical practitioner, hospital, dispensary or any other institution approved by an order of the Licensing Authority for such sale.

(c) The sale of any drug specified in Schedule "B" and "D" by way of retail sale shall be recorded at the time of supply in a register specially maintained for the purpose and the serial number of the entry in the register shall be entered in the prescription, and the following particulars shall be entered in the register, namely:-
(i) serial number.

(ii) date of sale.

(iii) name of the prescriber.

(iv) name of the patient or purchaser.

(v) name of the drug.

(vi) name of the manufacturer.

(vii) quantity.

(viii) batch No.

(ix) signature of the qualified person;

Provided that if the drugs-specified in Schedule "D" is sold on a prescription on which the drug has been sold on a previous occasion, it shall be sufficient if the entry in the register includes serial number, the date of sale, the quantity sold and a sufficient reference to an entry in the register recording the dispensing of the drug on a previous occasion.

(2) For the purpose of this rule, a prescription shall:-
(a) be in writing and signed by the person giving it with his usual signature and be dated by him;

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

(c) indicate the total quantities of drugs to be supplied and the doses to be taken.

(3) All invoices and bills of purchase of drugs shall be reserved for a period of at least three years.

(4) In case of sale of drugs by way of whole sale by manufacturer of their authorised dealers, they must invariably ensure that the purchaser holds a valid Drug Sale Licence, and shall issue an invoice and warranty at the time of sale of drug;

(5) The whole seller while selling drugs to a retailer must also invariably ensure that the retailer holds a valid Drug Sale Licence as required under the Act and these rules and shall issue an invoice and warranty at the time of sale of drugs.

(6). The invoice and warranty must bear the full name and address of the purchaser and shall be signed by the warrantor clearly indicating his name and must be dated.

(7) Records shall be maintained of all purchases and sale of drugs by way of whole sale and such records shall be preserved for three years and shall include the following particulars, namely:-

(a) the date of purchase and sale;

(b) The name and address of the concern from which purchased and the concerns to whom sold;

(c) the name of the drugs, their batch number, their dates of expiry where applicable and the quantities; and

(d) the name of the manufacturer.

(8) Except as otherwise provided in these rules, all registers and records maintained under these rules shall be preserved for a period of not less than five years from the date of last entry.

(9) The licence shall produce for inspection on demand by an Inspector all registers and records maintained under these rules, and shall supply to the Inspector such information as he may require.

(10) Substances specified in Schedule ‘E’ and falling under the list of poisons and those specified in Schedule ‘B’ shall be stored in the retail shop:-

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

(b) in an almarah, cupboard or drawer locked and reserved solely for the storage of such drugs.

(11) Substance falling under the list of poisons in Schedule ‘E’ shall be stored in containers, impervious to the poison, and sufficient stout to prevent leakage arising from the ordinary risks of handling and transport.

(12) A substance falling in the list of poisons under Schedule ‘E’ when compounded and dispensed, shall be labelled with the word "Poison."

22. Cancellation and suspension of licences.- (1) The Licensing Authority may, on the report an Inspector or the Board, after giving the licencee an opportunity to show cause by an order in writing stating the reasons therefore, cancel a licence issued under these rules or suspend it for such period as it thinks fit, if in its opinion the licencee has failed to comply with any of the conditions of the licence or with any of the provisions of the Act or these rules.

(2) A licensee whose licence has been cancelled or suspended may appeal to the Appellate Board within sixty days of the date of such order.

[No. 10/5/96-NA.I.]