UNIT II

Drugs and Cosmetics Act, 1940 and its rules 1945.

Detailed study of Schedule G, H, M, N, P,T,U, V, X, Y, Part XII B, Sch F & DMR (OA)

Sale of Drugs – Wholesale, Retail sale and Restricted license. Offences and penalties

Labeling & Packing of drugs- General labeling requirements and specimen labels for drugs and cosmetics, List of permitted colors. Offences and penalties.

Administration of the Act and Rules – Drugs Technical Advisory Board, Central drugs Laboratory, Drugs Consultative Committee, Government drug analysts, Licensing authorities, controlling authorities, Drugs Inspectors

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2.1 DETAILED STUDY OF THE SCHEDULES

Schedule G:

Most of these drugs are hormonal preparations. The drug label must display the text. *"Caution: It is dangerous to take this preparation except under medical supervision"* prominently. Examples: Testolactone, Hydroxyurea, Carbutamide, Primidone, Mercaptopurine, Methsuximide, Thiotepa etc.

Schedule H:

The drug label must display the texts *"Rx"* on the left top corner of the label and *"Schedule H drug. Warning : To be sold by retail on the prescription of a Registered Medical practitioner only"* prominently. It can only be supplied to licensed parties. It cannot be sold without a prescription and only the amount specified in the prescription should be sold. The time and date of prescription must be noted. Examples: Androgenic, anabolic, oestrogenic and progestational substances; Alprazolam, Hepatitis B vaccine, Adrenocorticotrophic hormone, Ibuprofen, Vasopressin etc.

If a Schedule H drug also comes under the purview of Narcotic Drugs and Psychotropic Substances Act, 1985, it must carry the texts *"NRx"* in red on the left top corner of the lable and *"Schedule H drug. Warning: To be sold by retail on the prescription of a Registered Medical Practitioner only."* on the label prominently.

Schedule M (GMP-GOOD MANUFACTURING PRACTICES):

It is defined as “the part of quality assurance which is aimed to ensure that the product are consistently manufactured to the quality appropriate to their intended use”.

It prescribes the requirements of premises, plant and equipment needed for setting up manufacturing unit. Also documents every stage of manufacture, packing, storage, transportation checking and testing of medicinal product, maintenance or keeping records.

Part-1: Requirements for Premises and Materials

1. **Locations and Surroundings:** The factory building shall be situated and constructed to avoid contamination from open sewerage, drain, disagreeable or obnoxious odour, dust and smoke etc.

2. **Buildings and Premises:** A building for manufacturing unit shall permit work under hygienic conditions. It should be free from any insects/rodents. Light and ventilation facility should be adequate. Walls and floor should be free from cracks and damp. Premises should also be confirmed with provisions of factory act. It shall be located so as to be:

(i) Building should be compatible of other manufacturing operations carried out in same premises.

(ii) Space should be adequate for placement of equipment and materials to avoid mix- up/contamination risk of different drugs and components.

(iii) Designed, constructed and maintained to prevent entry of insects and rodents. Interior surface (walls, floors and ceilings) shall be smooth and free from cracks and permit easy cleaning and disinfection. The walls of the room in which the manufacturing operations are carried out shall be impervious to and be capable of being kept clean.

(iv) The flooring shall be smooth and even and shall be such as not to permit retention or accumulation of dust or waste products.

(v) Building should have a proper drainage system. Sanitary fitting and electric fixtures shall be proper and safe.

(vi) Proper fire safety measures and proper exists should be there.

(vii) Drying space for raw material, in process medicines should be separate and measures should be done to prevent it from flies/insects/dust etc.

3. Water Supply: Water supply should be pure and of potable quality. Adequate provision of water for wasting the premises shall be made.

4. Disposable of Waste:

(i) Disposal of sewage and effluents from the factory should be as per "Environment Pollution Control Board''.

(ii) All bio-medical wastes should be destroyed as per "Biomedical Waste management rules-1996".

(iii) Hazardous, toxic and inflammable substances should be stored in suitably designed and segregated in enclosed areas, as prescribed by Central and State legislations.

5. Stores: Store should have adequate space for independently and separately store raw material, packaging material and finished products.

6. Working Space: Manufacturing area should be adequate for orderly placement of equipment, machinery and material used during manufacturing operations and quality control to facilitate easy and safe working and to minimize or eliminate any risk of mix-up between different drugs, raw materials and to prevent the cross contamination during manufacturing, storage and handling operations.

7. Sterile Products: For the manufacture of sterile products separate enclosed areas shall be provided with the air lock system for the entry and shall be essentially dust free and ventilated with an air supply for all areas where aseptic manufacturing has to be carried out.

Air supply shall be filtered through bacteria proof filter (HEPA filter) and shall be at a pressure higher than in the adjacent area. The filter shall be checked for performance an installation and periodically there after, and records there of shall be maintained.

The entire surface in the manufacturing area shall be designed to facilitate cleaning and dis-infections. Routine microbial counts to facilitate cleaning and dis-infections. Routine microbial counts of all sterile area shall be carried out during manufacturing operation.

The resultant of each shall be checked against established house standards and record maintained. Access to manufacturing area shall be restricted to minimum number of authorized personal. Special procedure to be followed for entering and leaving the manufacturing area shall be written down and displayed.

8. Container's Cleaning: Washing, cleaning and drying section of containers such as bottles, vials and jars should have adequate arrangement and should be separated from manufacturing operations.

9. Machinery: To carry out manufacturing process, adequate machinery and equipment require. These machinery could be manually operated or semi-automatic or fully automatic based upon your need and investment.

10. Raw-Materials: The licensee shall keep on inventory of all raw material to be used at any stage of manufacture of drugs and maintain the record as per schedule U. All such raw material be:

(a) Identified and their container examined for damage and assigned control number.

(b) Stored at optimum temperature and relative humidity.

(c) Conspicuously labelled indicating the number of materials, control numbers, name of manufacture and be labelled 'under test' or 'approved' or 'rejected'.

(d) Systematically sampled by quality control personnel.

(e) Tested for compliance with required standard of quality.

(f) Released from quarantine by quality control personal through written instruction.

(g) The stock rotation is so organized that, it is on the basis of **first come first out**.

(h) The all rejected material are conspicuously identified and are destroyed or returned to the supplier as soon as possible and record maintained there of.

11. Equipment: Equipment used for the manufacturing of drugs shall be constructed designed, installed and maintained to

(i) Achieve operational efficiency to attain desired quality.

(ii) Prevent physical, chemical and physico-chemical change through surface contact.

(iii) Prevent contact of any substance required for operation of the equipment like lubricant etc.

(iv) Facilitate through cleaning wherever necessary.

(v) Minimize any contamination of drug and their container during manufacture.

(vi) Equipment used for critical steps in progress shall be maintained by device capable of recording the parameter or with drawn systems to indicate malfunction. These devices shall be calibrated and tested and recorded there of shall be maintained.

12. Batch Manufacturing Record: Each batch record should be maintained irrespective of product manufactured (classical preparations or patent or proprietary medicines).

(i) Manufacturing records are required to provide an account of the list of raw materials and their quantities obtained from the store, tests conducted during the various stages of manufacture like taste, colour, physical characteristics and chemical tests as may be necessary or indicated in the Drugs and Cosmetics Act.

(ii) These tests may include any in-house or pharmacopoeial test adopted by the manufacturer in the raw material or in the process material and in the finished product.

(iii) Manufacturing Batch record should be signed by production chemist and analytical chemist. Stock should be transferred to finished goods store along with record of testing with date and quantity of drug.

(iv) Only after the manufactured drugs have been verified and accepted quality shall be allowed to be cleared for sale.

(v) It should be essential to maintain the record of date, manpower, machine and equipments used.

Master Formula Records:

The licensee shall maintain MFR relating to all manufacturing procedure for each product which will be prepared and endorsed by the competent technical staff that is head of production and quality control. The master formula record should have:

(a) The patent or propriatory name of the product along with generic name, if any, strength and the dosage form.

(b) A description of identification of the final container packing material label and closer to be used.

(c) The identity and quality of the raw material to be used irrespective of whether or not it appear in the finished product, the permissible averages that may be included in formulation batch, should be indicated.

(d) Description of all vessel and equipment and the size used in the progresses.

(e) Manufacturing and control instruction along with parameter for critical steps such as mixing, drying, blending, sieving and sterilizing the product etc.

(f) The theoretical yield to be expected from the formulation at different stage of manufacture and permissible yield limit.

(g) Detail instruction on precaution to be taken in manufacture and storage of drug and of semi-finished product.

The requirement of in processes quality control test and analysis to be carried out during each step of manufacture including designation of person or department responsible for execution of such test and analysis.

13. Health Clothing, Sanitation and Hygiene of Workers:

(i) All workers should be healthy and should be free from any contagious diseases.

(ii) Proper uniform should be provided to workers according to nature of work and the climates.

(iii) A uniform may include cloth or synthetic covering for hands, feet and head wherever required.

(iv) Adequate facilities for personnel use should be provided like clean towel, soap etc. Lavatories for men and women should be separate and should be away from processing and manufacturing area.

(v) Changing room facility should also be provided for changing their clothes and to keep their personal belongings.

14. Medical Services: Adequate facility for first aids should be provided by manufacturer. Medical examination of workers at the time of employment and periodical check-up should be conducted at least once in a year and proper record should be maintained.

15. Distribution Record: Distribution record (Dispatch register) should be maintained to facilitate process of prompt and complete recall of the batch. Distribution record should be maintained till expiry of batch.

16. Record of Market Complaints: A complain register should maintain to record all reports of market complaints received regarding the products sold in the market. The manufacturer shall enter all data received on such market complaints, investigations carried out by the manufacturers regarding the complaint as well as any corrective action initiated to prevent recurrence of such market complaints shall also be recorded. Once in a period of six months the manufacturer shall submit the record of such complaints to the licensing authority. The Register shall also be available for inspection during any inspection of the premises.

Reports of any adverse reaction resulting from the use of drugs shall also be maintained in a separate register by each manufacturer. The manufacturer shall investigate any of the adverse reaction to find if the same is due to any defect in the product, and whether such reactions are already reported in the literature or it is a new observation.

17. Quality Control: A manufacturer can set-up own quality control section or testing could be done through government approved testing laboratory.

Part-2: Requirements for Plant and Equipments

1. **Area:**
   (i) Basic installation - Requires minimum of 30 sq. mt. (for tablets manufacturing, upto 60 sq. mt.)
   (ii) Ancillary area: 10 sq. mt. (for tablets manufacturing, upto 20 sq. mt.)
2. **Equipment:** Colloidal mill, mixing and storage tanks, stainless steel containers, Planetary mixer, Triple roller, tube filling equipments, filter proof cap sealing machine, water distillation unit, clarity testing inspection unit, disintegrator and sifter, granulator, tray or fluidized bed driers, weighing machine, tablet compression machine (single-multi-rotary punch), tablet inspection unit, dissolution test apparatus, hardness tester, friability tester, disintegration test apparatus, air conditioners, polishing pan, jacketed kettle, leakage test apparatus, capsule filling unit, hot air ovens, Laminar air flow unit, bottle washing machines, autoclave, transfer pumps, trimming machine, cutting machine etc.

Parts of Schedule M

Part 1: Describes Good Manufacturing Practices For Premises and Material.

Part 1A: Describes the specific requirement for manufacture of sterile products. Parenteral preparations (Small Volume Injections and Large Volume Parentrals) and Sterile Ophthalmic Preparations.

Part 1B: Describes the specific requirements for manufacture of oral solid forms (Capsule and Tablets)

Part 1C: Describes the specific requirements for manufacture of oral liquids (syrups, elixirs, emulsions and suspensions).

Part 1D: Describes the specific requirements for manufacture of topical products i.e. External Preparations (Cream, Ointments, Pastes, Emulsions, Lotions, Solutions, Dusting Powders and Identical Products)

Part 1E: Describes the specific requirements for manufacture of Metered Dose Inhalers (MDI).
The other associated codes such as those of Good laboratory practice (GLP) and Good clinical practice (GCP).

Schedule N:

Describes the facilities and equipments for efficient running of a Pharmacy.

1. **Entrance:** Front of a pharmacy shall bear an inscription "Pharmacy" in front.
2. **Premises:**
   - (i) Separated from rooms, well built, dry, well lit and ventilated with sufficient dimensions for stock of medicaments.
   - (ii) Poisons to be kept in a clearly visible and appropriate manner.
   - (iii) Dispensing department shall be not less than 6 sq. m. for one pharmacist working therein with additional 2 sq. m. for each additional pharmacist.
   - (iv) Height of the premises shall be at least 2.5 metres.
   - (v) Floor of the pharmacy shall be smooth and washable.
   - (vi) Walls shall be plastered or tiled or oil painted so as to maintain smooth, durable and washable surface devoid of holes, cracks and crevices.
   - (vii) A pharmacy shall be provided with ample supply of good quality water.
   - (viii) The dispensing department shall be separated by a barrier to prevent the admission of the public.
3. **Furniture and Apparatus:**
   - (i) A pharmacy shall contain furniture and apparatus, drawers, containers, glasses of suitable sizes and designed to prevent dust entry.
   - (ii) Every container shall bear a labels, easily readable with names of medicaments as given in the Pharmacopoeias.
   - (iii) Shall be provided with a dispensing bench, washable top etc.
   - (iv) Separate cupboards with lock and key for Poisons, and shall be marked in red letters as ''POISON'' on a white background.
   - (v) All concentrated solutions shall be labelled as ''To be diluted''.
   - (vi) Pharmacy shall bear all the prescribed apparatus and books for official preparations and prescriptions.
     - (a) Balance
     - (b) Beakers, bottles, funnels
     - (c) Filter and litmus papers
     - (d) Mortar and pestle, other glasswares
     - (e) Spatula, scissors, stands
     - (f) Spirit lamp, thermometer
     - (g) Water bath, distillation apparatus
     - (h) Watch glasses, pill machines, suppository mould etc.
     - (i) Books: The Pharmacopoeia (current edition), National Formulary of India, The Drugs and Cosmetic Act 1940 and rules 1945, The Pharmacy Act, Narcotic and Psychotropic substances Act, 1985 etc.
4. **General provisions:** Pharamcist shall always wear a clean white overalls, records and registers shall be maintained as per the law, medicaments must bear labels when supplied as per the law.

Schedule P:

Schedule P describes the life period of drugs in months (unless otherwise specified) between date of

manufacture and date of expiry which the labelled potency period of the drug shall not exceed under the conditions of storage specified.

Sr. No.	Drug	Life period in months	Storage conditions
1.	Ampicillin	36	Cool place
2.	Bacitracin	18	Cool place
3.	Carbanicillin sodium injection	24	At temp. not exceeding 5°C.
4.	Colistin sulphate	60	Protected from light
5.	Erythromycin stearate	36	Cool place

Note: Cool place means, a temperature of 10-25°c

Schedule P_1:

Pack sizes of drugs

Sr. No.	Drug	Dosage form	Pack size
1.	Albendazole	Suspension	10 ml
2.	Atenolol	Tablets	14
3.	Piperazine	Granules	5 gm

Schedule T:

Contains various regulations and requirements for manufacture of Ayurvedic, Siddha and Unani products.

Part 1: Describes the Good Manufacturing Practice of Ayurvedic, Sidha and Unani Medicines.

A Manufacturing Premises should have adequate space for all daily activity like:

1. Receiving and Storage of Herbs, Packaging material and other raw material.
2. Production and Manufacturing Activity Area.
3. Quality Control Section.
4. Finished Goods Store.
5. Office and Administration.
6. Rejected Products/Drugs Store.
7. Minimum area required for setting up Ayurveda, Sidha and Unani Medicine manufacturing unit is 1200 sq. ft. covered with separate cabins and partitions for each activity. If unani medicines/ayurvedic medicines are manufactured along with ayurvedic medicines/unani medicines additional 400 sq. ft. area is required.

General Requirements:

1. Location and Surroundings: The factory building shall be situated and constructed to avoid contamination from open sewerage, drain, disagreeable or obnoxious odour, dust and smoke etc.

2. Buildings: A building for manufacturing unit shall permit work under hygienic conditions. It should be free from any insects/rodents. Light and ventilation facility should be adequate. Walls and floor should be free from cracks and damp. Premises should also be conformed with provisions of factory act. It shall be located so as to be:

(i) Building should be compatible of other manufacturing operations carried out in same premises.

(ii) Space should be adequate for placement of equipment and materials to avoid mix-up/contamination risk of different drugs and components.

(iii) Designed, constructed and maintained to prevent entry of insects and rodents. Interior surface (walls, floors and ceilings) shall be smooth and free from cracks and permit easy cleaning and disinfection. The walls of the room in which the manufacturing operations are carried out shall be impervious to and be capable of being kept clean.

(iv) The flooring shall be smooth and even and shall be such as not to permit retention or accumulation of dust or waste products.

(v) Building should have a proper drainage system. Sanitary fitting and electric fixtures shall be proper and safe.

(vi) Burner/Bhatti section could be covered with tin roof and proper ventilation, but care should be done to prevent flies and dust.

(vii) Proper fire safety measures and proper exists should be there.

(viii) Drying space for raw material, in process medicines should be separate and measures should be done to prevent it from flies/insects/dust etc.

3. Water Supply: Water supply should be pure and of potable quality. Adequate provision of water for wasting the premises shall be made.

4. Disposable of Waste: Proper waste management care should be done.

5. Container's Cleaning: Washing, cleaning and drying section of containers such as bottles, vials and jars should have adequate arrangement and should be separated from manufacturing operations.

6. Stores: Store should have adequate space for independently and separately store raw material, packaging material and finished products.

7. Working Space: Manufacturing area should be adequate for orderly placement of equipment, machinery and material used during manufacturing operations and quality control to facilitate easy and safe working and to minimize or eliminate any risk of mix-up between different drugs, raw materials and to prevent the cross-contamination during manufacturing, storage and handling operations.

8. Health Clothing, Sanitation and Hygiene of Workers:

(i) All workers should be healthy and should be free from any contagious diseases.

(ii) Proper uniform should be provided to workers according to nature of work and the climates.

(iii) A uniform may include cloth or synthetic covering for hands, feet and head wherever required.

(iv) Adequate facilities for personnel use should be provided like clean towel, soap etc. Lavatories for men and women should be separate and should be away from processing and manufacturing area.

(v) Changing room facility should also be provided for changing their clothes and to keep their personal belongings.

9. Medical Services: Adequate facility for first aids should be provided by manufacturer. Medical examination of workers at the time of employment and periodical check-up should be conducted at least once in a year and proper record should be maintained.

10. Machinery and Equipment: To carry out manufacturing process, adequate machinery and equipment require. These machinery could be manually operated or semi- automatic or fully automatic based upon your need and investment.

11. Batch Manufacturing Record: Each batch record should be maintained irrespective of product manufactured (classical preparations or patent or proprietary medicines).

(i) Manufacturing records are required to provide an account of the list of raw materials and their quantities obtained from the store, tests conducted during the various stages of manufacture like taste, colour, physical characteristics and chemical tests as may be necessary or indicated in the approved books of Ayurveda, Siddha and Unani mentioned in the First Schedule of the Drugs and Cosmetics Act.

(ii) These tests may include any in-house or pharmacopoeial test adopted by the manufacturer in the raw material or in the process material and in the finished product.

(iii) Manufacturing batch record should be signed by production chemist and analytical chemist. Stock should be transferred to finished goods stored along with record of testing with date and quantity of drug.

(iv) Only after the manufactured drugs have been verified and accepted, quality shall be allowed to be cleared for sale.

(v) It should be essential to maintain the record of date, manpower, machine and equipments used and to keep

in process record of various shodhana, bhavana, burning and fire and specific grindings in terms of internal use.

12. Distribution Record: Distribution record (Dispatch register) should be maintained to facilitate process of prompt and complete recall of the batch. Distribution record should be maintained till expiry of batch. For drugs who do not have expiry date like Bhasma, Rasa, Asava-arishtha etc. record should be maintained upto five years of the exhausting of stock.

13. Record of Market Complaints: A complaint register should be maintained to record all reports of market complaints received regarding the products sold in the market. The manufacturer shall enter all data received on such market complaints, investigations carried out by the manufacturers regarding the complaint as well as any corrective action initiated to prevent recurrence of such market complaints shall also be recorded. Once in a period of six months the manufacturer shall submit the record of such complaints to the licensing authority. The Register shall also be available for inspection during any inspection of the premises.

Reports of any adverse reaction resulting from the use of Ayurvedic, Siddha and Unani drugs shall also be maintained in a separate register by each manufacturer. The manufacturer shall investigate any of the adverse reaction to find if the same is due to any defect in the product, and whether such reactions are already reported in the literature or it is a new observation.

14. Quality Control: A manufacturer can set-up own quality control section or testing could be done through government approved testing laboratory read in detail about Ayurvedic, Sidha and Unani manufacturing unit quality control section.

Part 2: Describes list of recommended machinery, equipment and manufacturing premises required for the manufacture of various categories of Ayurvedic, Siddha system of medicines.

Anjana/Pisti: End runner/Ball-Mill, Sieves/Shifter.

Churna/Nasya/Manjan/Lepa: Grinder/disintegrator, Pulveriser, Powder mixer, Sieves/ shifter.

Pills/Vati/Gutika Matirai and Tablets: Ball Mill, Mass mixer/powder mixer, Granulator, Drier, Tablet compressing machine, Pill/vati cutting machine, trays/container for storage and sugar coating, Polishing pan in case of sugar-coated tablets, Mechanised chattoo (for mixing guggulu).

Kupi pakava/Ksara/Parpati/Lavana/Bhasma/Satva/Sindura Karpu/Uppu/Param: Bhatti, Karahi/Vessels/Patila Flask, Multani Matti/Plaster of Paris.

Copper rod, Earthen container, Gaj Put Bhatti, Muffle furnace (Electrically operated), End/Edge runner, Exhaust fan, Wooden/Steel spatula.

Kajal: Filling/ packing and manufacturing room should be provided with exhaust fan and ultra violet lamps, Earthern lamps for collection of Kajal, Triple roller mill, End runner, Sieves.

Capsules: Air conditioner, De-humidifier, Hygrometer, Thermometer, Capsule filling machine and chemical balance.

Ointment/Marham Pasai: Tube filling machine, Crimping Machine/Ointment Mixer, End Runner/ Mill, Storage Container.

Pak/Avaleh/Khand/Modak/Lakayam: Bhatti section fitted with exhaust fan and should be fly proof, Iron Kadahi, Storage container.

Panak, Syrup/Pravahi Kwath Manapaku: Tincture press, Exhaust fan fitted and fly proof, Bhatti section, Bottle washing machine, Filter press / Gravity filter, Liquid filling machine, Capping machine.

Asava-Aristha: Fermentation tanks, Containers and distillation plant where necessary, Filter press.

Sura: Distillation plant, Transfer pump.

Ark Tinir: Maceration tank, Distillation plant, Liquid filling tank with tap, Gravity filter/Filter press, Visual inspection box.

Tail/Ghrit Ney: Bhatti, Kadahi/Patila, Storage containers, Filtration equipment, Filling tank with tap, Liquid filling machine.

Aschyotan/Netra Malham Panir/Karn Bindu/Nasa-bindu: Hot air oven electrically heated with thermostatic control, Kettle gas or electrically heated with suitable mixing arrangements, Collation mill or ointment mill, Tube

filling equipment, Mixing and storage tanks of stainless steel or of other suitable material sintered glass funnel, Seitz filter or filter candle, Liquid filling equipment, Autoclave.

Each manufacturing unit will have a separate area for Bhatti, furnace boilers, puta etc. This will have proper ventilation, removal of smoke, prevention of flies, insets, dust etc. The furnace section could have tin roof.

Schedule U:

Schedule U describes the particulars to be shown in manufacturing record, records of raw materials and analytical drugs.

Following details are included in Schedule U:

1. Manufacturing Records:

   (i) Substances other than Parenteral Preparation: Serial number, Product name, Reference of Master formula records, Batch size and number, Date-time-duration conditions of the process for manufacture, Name of all the ingredients, Specifications, Quantity required, References to analytical report number,theoretical yield and actual production yield of finished product, specimen of label, date of release of finishes packagings etc.

   (ii) Parenteral Preparations: All the above including, Sterility tests such as Leakage, Pyrogen, Clarity and Toxicity tests; records of sterilization etc.

2. Records of Raw Materials: Date of receipt, Invoice number, Name and address of the manufacturer/supplier, Batch number, Quantities received, Pack size, Dates of manufacture and expiry, Date of analysis and release/rejection by quality control, Analytical report number with special remarks, quantity and date of issue etc.

3. Particulars to be recorded in the Analytical Records.

   (i) Tablet, Capsules and for other drugs: Analytical report number, Sample name, Date of receipt, Batch number, Protocols of test applied, Signature of analyst etc.

   (ii) Parenteral Preparations: All the above including, sterility tests.

   (iii) Raw Materials: Serial number, Number of materials, Name of manufacturer/ supplier, Quantity received, Challan/invoice number and date, Protocols for test applied.

   (iv) Container and Packing Material: All the above including, Results of tests, Remarks, Signature of examiner etc.

Schedule U_I:

Schedule U_I describes the particulars to be shown in the manufacturing record for cosmetics:

1. Manufacturing Records: Serial number, Product name, Reference of Master formula records, Batch size and number, Date-time-duration conditions of the process for manufacture, Name of all the ingredients, specifications, quantity required, references to analytical report number, theoretical yield and actual production yield of finished product, specimen of label, date of release of finishes packagings, etc,.
2. Records of Raw Materials: Date of receipt, invoice number, name and address of the manufacturer/supplier, batch number, quantities received, pack size, dates of manufacture and expiry, date of analysis and release/rejection by quality control, analytical report number with special remarks, quantity and date of issue etc.

Schedule V:

Schedule V describes the standards for patent or proprietary medicines.

Patent or Proprietary medicines containing vitamins for prophylactic, therapeutic or paediatric use shall contain the vitamins in quantities not less than and not more than those specified in single or in two divided daily doses.

Sr. No.	Drug	Unit	Adult (daily dose)
1.	Vitamin A	I.U.	NLT 5,000 and NMT 10,000

2.	Vitamin D	I.U.	NLT 400 and NMT 1,000
3.	Vitamin B_1	Mg	NLT 4.5 and NMT 10
4.	Vitamin B_6	Mg	NLT 1.5 and NMT 3

NLT - Not less than; NMT - Not more than; I.U. - International units

Schedule X:

Drugs which are habit forming, psychotropic and other drugs likely to be misused for addictive purposes. Hence import, manufacture, sale and distribution of these are regulated under special provisions.

All the regulations of Schedule H apply. The retailer must keep a copy of the prescription for two years. The drugs must be kept under lock and key. Examples: Amphetamine, Secobarbital, Glutethimide, Cyclobarbital, Phencyclidine, Phenobarbital etc.

Schedule Y:

Describes requirements and guidelines on Clinical trials for import and manufacture of new drugs.

1. Clinical Trials

(i) Permission of trials: One must apply for Form 12 for test license (TL). The application shall comprise-data for various phases, protocol for proposed trials, case report forms to be used, names of Investigators and Institutions.

(ii) Responsibility of Sponsor/ Investigator: Sponsors must submit the annual status report of each clinical trial, to the licensing authority. Any termination, unusual, unexpected or serious adverse drug reactions (ADR) detected during trial must be communicated to the authority.

(iii) In all trials, informal, written, voluntary consent must be obtained from each volunteer in the prescribed forms.

2. Data required to be submitted with the application for permission to market New Drug

(i) Clinical and Pharmaceutical Informations.

(ii) Animal toxicology: Acute, chronic, reproduction status (fertility, teratogenic and prenatal studies, local toxicology, mutagenicity, carcinogenicity).

(iii) Animal pharmacology.

(iv) Phase - 1,2,3 trials.

(v) Special studies (bioavailability and dissolution studies).

Phase 1 trials (Human/Clinical Pharmacology): Determines the maximum tolerated dose in humans; pharmacodynamics effects, adverse effects etc.

Phase 2 trials (Exploratory Trials): Determines the therapeutic doses, effective dose range, safety and pharmacokinetics.

Phase 3 trials (Confirmatory Trials): To obtain sufficient evidences about the efficacy and safety of the drugs. The reports of the complete trials shall be submitted by the applicant duly signed by the investigator within a specified period of time. It should include description, actions, indications, dosage precautions, drug interactions, warning and adverse reactions.

Schedule F:

This contains regulations and standards for running a blood bank.

Schedule F_1:

This contains regulations and standards for bacterial vaccines, viral vaccines, antisera and diagnostic agents.

Schedule F_2:

This contains regulations and standards for surgical dressing.

Schedule F_3:

This contains regulations and standards for umbilical tapes (polyester and cotton tapes).

Schedule FF:

This contains regulations and standards for ophthalmic preparations (solutions, suspensions and

ointments). The label must bear:

(i) The statement “use the solution within one month after opening the container”.
(ii) Name and concentration of the preservative used.
(iii) ‘’Not for Injection’’.
(iv) Storage instructions.
(v) Warning
  (a) If irritation persists or increases, discontinue the use and consult physician.
  (b) Do not touch the dropper tip or the other dispensing tip to any surface since this may contaminate the solution.

Part XII-B:

Requirements for the premises, personnel, equipments and organizations and operation of a Blood Bank and/or for preparation of Blood components. It’s a part under Schedule F.

I. Blood Banks/Blood Components:

(i) General
(ii) Accommodation for a Blood Bank
(iii) Personnel
(iv) Maintenance
(v) Equipments and instruments
  (a) BP apparatus
  (b) Stethoscope
  (c) Blood bags (single, double, triple, quadrapole)
  (d) Donor questionnaire
  (e) Weighing device for donors
  (f) Weighing device for blood bags
  (g) Artery forceps, scissors
  (h) Stripper for blood tubing
  (i) Bed sheets, blankets/mattress
  (j) Lancets, swab stick/tooth picks
  (k) Glass slides
  (l) Portable Hb meter/copper sulphate 337
  (m) Test tube (big) and 12 □ 100 mm (small)
  (n) Test tube stand
  (o) Anti-A, Anti-B and Anti-AB, Antisera and Anti-D
  (p) Medicated adhesive tape
  (q) Plastic waste basket
  (r) Donor cards and refreshment for donors
  (s) Emergency medical kit
  (t) Insulated blood bag containers with provisions for storing between 2°C to 10°C.
  (u) Dielectric sealer or portable tube sealer
  (v) Needle destroyer (wherever necessary)
(vi) Supplies and Reagents
(vii) Good Manufacturing Practices (GMPs)/ Standard Operating Procedures (SOPs)

(viii) Criteria For Blood Donation

(ix) Special Reagents

(x) Testing of whole blood

(xi) Records

(xii) Labels

II. Blood Donation Camps:

(i) Premises, personnel etc.

(ii) Personnel for Out-door Blood Donation Camp.

(a) One Medical Officer and two nurses or phlebotomists for managing 6-8 donor tables.

(b) Two medico social workers.

(c) Three blood bank technicians.

(d) Two attendants.

(e) Vehicle having a capacity to seat 8-10 persons, with provision for carriage of donation goods including facilities to conduct a blood donation camp.

(iii) Equipments.

III. Processing of Blood Components from Whole Blood by a Blood Bank:

(i) Accommodation

(ii) Equipment

(iii) Personnel

(iv) Testing Facilities

(v) Categories of Blood Components

(a) Concentrated Human Red Blood Corpuscles

(b) Platelets Concentration

(c) Granulocyte Concentration

(d) Fresh Frozen Plasma

(e) Cryoprecipitate

Drug and Magic Remedies (Objectionable Advertisements):

The act defines "magic remedy" as any talisman, mantra, kavachas or any other object which is claimed to have miraculous powers to cure, diagnose, prevent or mitigate a disease in humans or animal. It also includes such devices that are claimed to have power to influence structure or function of an organ in humans or animals.

The law prohibits advertising of drugs and remedies for −

(i) Inducing miscarriage or preventing conception in women.

(ii) Improving or maintaining the capacity for sexual pleasure.

(iii) Correction of menstrual disorders.

(iv) Curing, diagnosing or preventing any disease or condition mentioned in an included schedule.

(v)

2.2.1 Wholesale, Retail and Restricted Sale Licenses

1. **Wholesale:** From stockists to shopkeepers.
2. **Retail sale:** From shopkeepers (drug store, chemists and druggists, pharmacy or dispensing chemist) to patients.

Drug control organization issues two type of license, out of which one is Retail Drug License (RDL) to run a chemist shop, and it is issued to only those persons who possess degree or diploma in pharmacy from a recognized

university on the payment of the requisite fees and other is Wholesale Drug License (WDL) which is issued to a person who is engaged in the business of wholesale of drugs and medicines.

Sr. No.	Type of License	Forms		
		Other than Schedule-C, C_1 and X drugs	Schedule-C and C_1 Drugs	Schedule-X drugs
1.	Retail	20	21	20-F
2.	Restricted	20-A	21-A	--
3.	Wholesale	20-B	21-B	20-G
4.	Wholesale or distribution from motor vehicle	20-BB	21-BB	--

Conditions of Whole Sale License:

1. **Area:** Shall not be less than 10 sq. m.
2. **Storage:** It is necessary to have a refrigerator and air conditioner on the premises because certain drugs such as vaccines, insulin injections etc. are needed to be stored in the fridge.
3. **Competent Staff:** The sale can be made either by a **registered pharmacist** or another competent person who must be a graduate with one year experience in drugs or in the presence of any one who has passed S.S.L.C having experience of four years in drugs, specially approved by drug control department.
4. License shall be displayed in a prominent place.
5. The drugs shall be purchased from a duly licensed dealer or a manufacturer.
6. Supply of drugs shall be made against a cash memo. Carbon copies of the same shall be preserved for 3 years from the date of last entry.
7. Shall maintain the records of purchase, and produce all the registers and records during inspection. Records must be preserved for 2 years from the last entry.
8. An Inspection book shall be maintained in Form 35.
9. The drugs after expiry, Physician's sample and the drugs meant for Government supply, shall not be stocked or sold.
10. A separate record shall be maintained for the supply of Schedule X drugs, the copies of invoices of sale of such drugs to the retailer, shall be forwarded to the Licensing authority.
11. No sale of any drug should be made for the purpose of resale to a person not holding the license to sell or distribute the drugs.

Conditions of Restricted License:

These are issued for the retail sale of the drugs. Restricted licences in Forms 20A and 21A.

(a) Dealers or persons in respect of drugs whose sale **does not require the supervision of a qualified person**.

(b) Licenses to itinerant vendors shall be issued only in exceptional cases for bonafide travelling agents of firms dealing in drugs.

(c) The licensing authority may issue a license in Form 21A to a travelling agent of a firm but to no other class of itinerant vendors for the specific purpose of distribution to medical practitioners or dealers samples of biological and other special products specified in Schedule C.

(d) The licensee must have adequate premises equipped with facilities for the proper storage of which the license applies, provided that, this condition does not apply to the vendors.

(e) License should be displayed in a prominent place in a part of the premises open to the public or must be kept on the person of vendor who shall produce the same on demand by authorized government officers.

(f) Licensee must comply with the provisions of D and C act.

(g) Drugs should be purchased only from a duly licensed dealer or manufacturer.

(h) The licensee can deal only with such drugs, which can be sold without the supervision of a qualified person.

(i) Drugs must be sold in their original container.

Required Documents for Obtaining Drug License:

1. Application Form.
2. Cover letter with the name and designation of the applicant.
3. Copy of challan achieved by depositing fees for obtaining drug license.
4. Declaration in a prescribed manner.
5. Kite plan and site plan for the premises.
6. The basis of possession of premises.
7. In the case of rented property, ownership proof.
8. Document related to the constitution of business such as Incorporation certificate/ MOA (Memorandum of association)/AOA (Articles of association)/Partnership Deed.
9. Affidavit related to non-conviction of director/partner/proprietor.
10. Testimony of registered pharmacist or competent person and their appointment letter in case of an employed person.

2.2.2 Offences and Penalties

Offences and penalties relating to the Sale of drugs:

Sr. No.	**Offence**	**Penalties**	
		First conviction	**Subsequent conviction**
1.	Sale or distribution of:		
	(i) Any adulterated or spurious drugs or drug not of standard quality	Imprisonment upto 5 years and extending upto lifetime and fine of not less than ` 10,000.	Imprisonment upto 10 years or fine upto ` 20,000 or both.
	(ii) Any adulterated but not containing toxic or harmful substances injurious to health	Imprisonment from 1-3 and fine of not less than ` 5,000	Imprisonment for 2-4 years or fine upto ` 10,000.
	(iii) Without a license	Imprisonment of less than a year and a lesser fine.	Imprisonment for not less than 2 years or fine upto ` 10,000.
	(iv) Spurious drugs but not manufactured under the name of any other drug	Imprisonment for 3-5 years and fine of not less than ` 5,000.	Imprisonment for not less than 6-10 years or fine upto ` 10,000.
	(v) Any other	Imprisonment for 1 year.	Imprisonment for 2-4 years or fine upto ` 5,000 or both.
	(vi) Contravention of this act	Imprisonment from 1-2 years and fine.	

2.	Not keeping records of sale in the specified manner.	Imprisonment upto 3 years or fine upto ` 1000 or both.	Same as first conviction
3.	Using the report of Government analyst for advertising any drug.	Fine upto ` 500	Imprisonment upto 10 years or with fine or both.

2.3 LABELLING AND PACKING OF DRUGS AND COSMETICS

2.3.1 General Labelling Requirements

The following particulars shall be either printed or written in indelible ink and shall appear in a conspicuous manner on the label of the innermost container of any drug and on every other covering in which the container is packed:

1. Drug name: the proper name of the drug shall be printed or written in a more conspicuous manner than the trade name, if any.
2. Net content: weight, volume, in metric system or units.
3. Content of Active ingredients:
   (i) Oral liquids: Contents per single dose, i.e. 5 ml or multiple thereof. If dose is below 5 ml, then per ml.
   (ii) Liquid parenterals: Contents per ml or in percentage or per dose.
   (iii) Solid parenterals: Contents per mg or per gm or in terms of units. (iv)Tablets, capsules and pills: Contents per tablet, capsule, pill.
   (v) For other preparations: Contents in terms of percentage by w/w or w/v or units per gm or ml.
4. Name and address of manufacturer.
5. Manufacturing license number: Mfg. Lic. No. or ML No.
6. Batch number: Batch No. or Lot No.
7. Date of manufacturing: Mfg. Date.
8. Date of expiry: Exp. Date
9. Free samples to medical profession: "Physician's Sample - Not To Be Sold".
10. Alcoholic preparations: If alcoholic content exceeds 3% by volume, percentage of alcohol must be mentioned on the lable.
11. Information of handling, use, distribution, storage etc.
12. Maximum Retail Price: M.R.P.
13. Hair dyes containing coal tar colours: on inner and outer label both, in English and local languages: "Caution: The product contains ingredients which may cause skin irritation in certain cases and so preliminary test according to the accompanying directions shall first be made. This product shall not be used for dyeing the eyelashes or eyebrows as such if used, may cause blindness".
14. Toothpaste containing Fluoride: Fluoride content in ppm (NMT 1000 ppm); Date of expiry.

2.3.2 Special Labelling Requirements

1. Schedule C_1 : Date of manufacture and expiry, Import license number.
2. Schedule G : "It is dangerous to take this preparation except under medical supervision".
3. Schedule H: Symbol R_X conspicuously on the left top corner of the label; "To be sold by retail on the prescription of a registered medical practitioner only"; For Narcotic and Psychotropic drugs, symbol NR_X conspicuously on the left top corner of the label in red ink and "To be sold by retail on the prescription of a registered medical practitioner only".
4. Schedule X: Symbol XR_X in red ink, conspicuously on the left top corner of the label; "To be sold by retail

on the prescription of a registered medical practitioner only''.

5. Preparations for External use: FOR EXTERNAL USE ONLY; eg: lotion, liniment, ointment, liquid antiseptics.
6. Pharmacopoeial preparations: 'I.P.', 'B.P.', 'B.P.C', 'U.S.P', 'N.F.' etc.
7. Patents and Proprietary medicines: Quantities of active ingredients.
8. Ophthalmic preparations (solutions, suspensions and ointments): Schedule FF
   (i) The statement "use the solution within one month after opening the container".
   (ii) Name and concentration of the preservative used.
   (iii) ''Not for Injection''.
   (iv) Storage instructions.
   (v) Warning:
      (a) If irritation persists or increases, discontinue the use and consult physician.
      (b) Do not touch the dropper tip or the other dispensing tip to any surface since this may contaminate the solution.
9. Medicines for Animals: ''NOT FOR HUMAN USE, FOR ANIMAL TREATMENT ONLY"; Symbol depicting the head of a domestic animals.

2.3.3 Specimen Labels

Schedule H drug

Rx **ERYTHROMYCIN ESTOLATE TABLETS IP 500 MG**

Each uncoated tablet contains:
Erythromycin Estolate IP
equivalent to Erythromycin…….500 mg
Dosage: As directed by the Physician
Store in a cool, dark and dry place

Schedule H Drug
Warning: To be sold by retail on the prescription of a Registered Medical Practitioner only.

Mfg Lic. No. 2/20 M.R.P not to exceed `…….
Batch No. 2019 inclusive of all taxes
Mfg. Date
Exp. Date

Manufactured by: XYZ Pharmaceuticals, India.

External use

15 gm

POVIDONE IODINE OINTMENT USP

Composition:
Povidone-Iodine USP ..... 5% w/w
(0.5% w/w available Iodine)
Water-soluble ointment base q.s.
Store in a cool place

FOR EXTERNAL USE ONLY

Mfg Lic. No. 2/20 M.R.P not to exceed `…….
Batch No. 2019 inclusive of all taxes

Schedule X Drug

XR_x **PENTOBARBITONE SODIUM INJECTION USP**

Each ml contains:
Pentobarbitone Sodium USP.....50 mg

For Intramuscular Injection only

Dosage: As directed by the Physician

Schedule X Drug
Warning: To be sold by retail on the prescription of a Registered Medical Practitioner only.

The Injection must be discarded if any precipitate is observed

Mfg Lic. No. 2/20 M.R.P not to exceed `…….
Batch No. 2019 inclusive of all taxes
Mfg. Date
Exp. Date

Manufactured by: XYZ Pharmaceuticals, India.

Schedule G drug

PHENIRAMINE TABLETS IP

Each uncoated tablet contains:
Pheniramine maleate IP..... 25 mg
Dosage: 1 tablet 2-3 times daily or as directed by the Physician.
Store protected from light

Caution: It is dangerous to take this preparation except under medical supervision.

Mfg Lic. No. 2/20 M.R.P not to exceed `…….
Batch No. 2019 inclusive of all taxes
Mfg. Date
Exp. Date

Manufactured by: XYZ Pharmaceuticals, India.

2.4 LIST OF PERMITTED COLOURS

No drug shall contain a colour other than that specified below:

(1) Natural Colours: Annatto, Carotene, Chlorophyll, Cochineal, Curcumin, Red oxide of iron, Yellow oxide of iron, Titanium dioxide, Black oxide of iron.

(2) Artificial Colours: Caramel, Riboflavin.

(3) Coal Tar Colours: Quinazarine Green SS, Alizarin Cyanine Green F, Fast Green FCF, Tartrazine, RED (Erythrosine), Eosin YS or Eosine G, Toney Red or Sudan III, Indigo Carmine, Brilliant Blue FCF, Orange G, Resorcin Brown, Naphthol Blue-Black.

(4) Lakes the aluminium or calcium salts (lakes) of any of the water-soluble colours listed above.

(5) The label on the container of a drug containing a permitted colour shall indicate the common name of the colour.

2.5 OFFENCES AND PENALTIES

Same as offences and penalties under sale of drugs.

2.6 ADMINISTRATION OF THE ACT AND RULES

2.6.1 The Drugs Technical Advisory Board (DTAB)

The Central Government constituted this Board, so as to advise the Central Government and the State Governments on technical matters arising out the administration of this Act and to carry out the other functions assigned to it by this Act.

The Board shall consist of the following members, namely:

1. Ex-Officio memebers:
   - (i) The Director General of Health Services, who shall be Chairman.
   - (ii) The Drugs Controller, India.
   - (iii) The Director of the Central Drugs Laboratory, Calcutta.
   - (iv) The Director of the Central Research Institute, Kasauli.
   - (v) The Director of the Indian Veterinary Research Institute, Izatnagar.
   - (vi) The President of the Medical Council of India.
   - (vii) The President of the Pharmacy Council of India.
   - (viii) The Director of the Central Drug Research Institute, Lucknow.
2. Nominated members:
   - (i) Two persons to be nominated by the Central Government from among persons who are in charge of drugs control in the States.
   - (ii) One person nominated by the Central Government from the Pharmaceutical Industry.
   - (iii) Two persons holding the appointment of Government analyst, nominated by the Central Government.
3. Elected members:
   - (i) One person, to be elected by the Executive Committee of the Pharmacy Council of India, from among teachers in pharmacy or pharmaceutical chemistry or pharmacognosy on the staff of an Indian university or a college affiliated thereto.
   - (ii) One person, to be elected by the Executive Committee of the Medical Council of India, from among teachers in medicine or therapeutics on the staff of an Indian university or a college affiliated thereto.
   - (iii) One pharmacologist to be elected by the Governing Body of the Indian Council of Medical Research.
   - (iv) One person to be elected by the Central Council of the Indian Medical Association.
   - (v) One person to be elected by the Council of the Indian Pharmaceutical Association.

The nominated and elected members of the Board shall hold office for three years, but shall be eligible for re-nomination and re-election.

The Central government shall appoint persons to be secretary of the board and other staffs, if necessary.

Provided that, the person nominated or elected, shall hold office for so long as he holds the appointment of the office by virtue of which he was nominated or elected to the Board.

The Board may constitute sub-committees and may appoint to such sub-committees for such periods, not exceeding three years. As it may decide, or temporarily for the consideration of particular matters, persons who are not members of the Board.

2.6.2 The Central Drugs Laboratory (CDL)

The Central Government established a Central Drugs Laboratory under the control of a Director to be appointed by the Central Government, to carry out the functions entrusted to it by this Act or any rules. This was established in Calcutta to carry out the following functions:

1. To analyse or test, samples of drugs as may be sent to it by the Custom Collectors or Courts.

2. Since, CDL is not equipped for testing of all types of products, some other Government labs and Institutes shall also perform the functions of CDL :
   (i) Central Research Institute, Kasauli; carries out the assigned functions in respect of: Sera, vaccines, toxins, antigens, sterilized surgical sutures and ligatures, Bacteriophage.
   (ii) Pasteur Institute of India, Conoor and Enterovirus Research Centre, Mumbai in respect of Polio vaccine.
   (iii) Indian Veterinary Research Institute, Izatnagar or Mukteshwar in respect of: antisera, toxoids, vaccines, diagnostic agents for veterinary use.
   (iv) Central Indian Pharmacopoeia Laboratory, Ghaziabad in respect of Condoms.
   (v) Laboratory of the Serologist and Chemist examiner to the Government of India, Calcutta in respect of VDRL antigen.
   (vi) Department of Biomedical engineering of the Indian Institute of Technology, New Delhi in respect of Intra Uterine Devices.
   (vii) Homeopathic Pharmacopoeia Laboratory, Ghaziabad in respect of Homeopathic medicines.
3. All samples sent to the laboratories are required to be sent by registered post in a sealed packet enclosed together with a memorandum in the prescribed form, addressed to the Director.
4. On receipt of the packet, it must be opened by an authorized officer, in this behalf by the Director.
5. After test, the results with complete protocols of the tests applied, should be sent to the sender.
6. Certificates issued by the Laboratory under the rules should be signed by the Director or any other Central Government authorized officer.

2.6.3 The Drugs Consultative Committee (DCC)

This is also an advisory body constituted by the Central government for the purpose of advising the Central government the State government and the DTAB, on any matter tending to secure uniformity throughout India in the administration of this Act.

1. The Drugs Consultative Committee shall consist of two representatives nominated by the Central Government and one representative nominated by each State Government.
2. The Drugs Consultative Committee shall meet when required to do so by the Central Government and shall have power to regulate its own procedure.

2.6.4 Government Drug Analysts

1. The Central and State Government both, by notification in the Official Gazette, appoint such persons, having the prescribed qualifications, to be Government Analysts for such areas in the State and in respect of such drugs or classes of drugs or such cosmetics or classes of cosmetics as may be specified in the notification.
2. A person to be appointed as Government analyst should not have any financial interest in the import, manufacture or sale of drugs or cosmetics.

Qualifications of Government Analyst

1. A graduate in medicine or science or pharmacy or pharmaceutical chemistry of a recognized university, with not less than 5 years post graduate experience in the testing of drugs; or
2. A post graduate degree in medicine or science or pharmacy or pharmaceutical chemistry of a recognized university, with not less than 3 years experience; or
3. Associateship Diploma of the institution of chemists with 'Analysis of Drugs and Pharmaceuticals' as one of the subjects with not less than 3 years experience in the testing of drugs in the laboratory under the control of: A government analyst; or Head of the institution or testing laboratories approved by the government authorities.

Duties of Government Analysts:

1. On receipt of a package of a sample from Drug Inspector, the analyst compares the seals on packages with the specimen impression of the seal received separately and notes the condition of seals.
2. Thereafter, analyse or test the samples of drugs and cosmetics sent to him by Drug Inspectors or other persons and to furnish the reports.
3. On completion of analysis, he furnishes the reports of analytical and research work to the Inspector in Form

13, along with test protocols applied.

Note: If purchaser want to analyse the drug or cosmetic, he has to make an application for analysis in Form 14-A, with a prescribed fee. The reports of such drugs will be furnished in Form 14-B, by Government analyst.

2.7 LICENSING AUTHORITIES

1. These are appointed by the Central and State governments for the grant and the renewal of a licence for the import, manufacture, sale, distribution etc. of any drug or cosmetic.
2. The licenses once issued, shall remain valid forever, unless suspended or cancelled by the licensing authority.
3. The licensing authorities are mostly designated as Drug Controller.
4. The Drug Controller, India has recently been notified as the Central License Approving Authority.

Qualification of a Licensing Authority:

1. He must be a graduate in Pharmacy or Pharmaceutical chemistry or medicine with specialization in Clinical Pharmacology or Microbiology, from a recognized university.
2. He must be experienced in manufacture or testing of drugs for a minimum period of 5 years.

2.8 **CONTROLLING AUTHORITIES**

All Drug Inspectors appointed by the Central Government or the State Government act are under the control of an officer appointed by respective governments referred to as Controlling authority.

Qualification of a Controlling Authority:

1. He must be a graduate in Pharmacy or Pharmaceutical chemistry or medicine with specialization in Clinical Pharmacology or Microbiology, from a recognized university.

2. He must be experienced in manufacture or testing of drugs for a minimum period of 5 years.

The Drug Control Department (DCD): The department is vested with the licenseing of manufacturing and sales premises of drugs and cosmetics in the state. It primarily strives to ensure the supply of quality drugs. It comprises 3 wings: Enforcement wing, Educational wing and Drugs Testing Laboratory (DTL).

The Central Drugs Standard Control Organisation (CDSCO) under Directorate General of Health Services, Ministry of Health and Family Welfare, Government of India is the National Regulatory Authority (NRA) of India. Its headquarter is located at FDA Bhawan, Kotla Road, New Delhi and also has six zonal offices, four sub zonal offices, thirteen Port offices and seven laboratories spread across the country.

The Drugs and Cosmetics Act, 1940 and rules 1945 have entrusted various responsibilities to central and state regulators for regulation of drugs and cosmetics.

1. It envisages uniform implementation of the provisions of the Act and Rules made there under for ensuring the safety, rights and wellbeing of the patients by regulating the drugs and cosmetics.
2. CDSCO is constantly thriving upon to bring out transparency, accountability and uniformity in its services in order to ensure safety, efficacy and quality of the medical product manufactured, imported and distributed in the country.
3. Under the Drugs and Cosmetics Act, CDSCO is responsible for approval of Drugs, Conduct of Clinical Trials, laying down the standards for Drugs, control over the quality of imported Drugs in the country and co-ordination of the activities of State Drug Control Organizations by providing expert advice with a view of bring about the uniformity in the enforcement of the Drugs and Cosmetics Act.
4. Further CDSCO along with state regulators, is jointly responsible for grant of licenses of certain specialized categories of critical Drugs such as blood and blood products,
   I. V. Fluids, Vaccine and Sera.

2.9 DRUG INSPECTORS

The Central Government or a State Government appoints such persons, having the prescribed qualifications, to be Inspectors.

1. Who have not less than 18 months experience in the manufacture of atleast one of the substances specified in Schedule C; or

2. Who have not less than 18 months experience in testing of atleast one of the substances specified in Schedule C in a laboratory approved for this purpose by the licensing authority; or
3. Who have gained experience of not less than 3 years in the inspection of firms manufacturing any of the substances specified in Schedule C during the tenure of their services as Drug Inspectors.

Duties of Drug Inspector:

1. **To inspect:**
   (i) Any premises wherein any drug or cosmetic is being manufactured and the means employed for standardizing and testing the drug or cosmetic;
   (ii) Any premises wherein any drug or cosmetic is being sold, or stocked or exhibited or offered for sale or distributed;

2. **Take samples of any drug or cosmetic:**
   (i) Which is being manufactured or being sold or is stocked or exhibited or offered for sale, or is being distributed;
   (ii) From any person who is in the course of conveying, delivering or preparing to deliver such drug or cosmetic to a purchaser or a consignee;
3. **For entering and searching any place, person or vehicle etc.** in which he has reason to believe that an offence has been, or is being, committed; or Stop and search any vehicle, vessel or other conveyance which, he has reason to believe, is being used for carrying any drug or cosmetic in respect of an offence been or being committed;
4. **For seizure of stocks:**
   (i) Not to dispose off any stock of such drug or cosmetic for a specified period not exceeding twenty days, or, unless the alleged offence is such that the defect may be removed by the possessor of the drug or cosmetic, seize the stock of such drug or cosmetic and any substance or article by means of which the offence has been or being committed.
   (ii) Examine any record, register, document or any other material object found with any person, or in any place, vehicle, vessel or other conveyance, and seize the same if he has reason to believe that it may furnish evidence of the commission of an offence punishable under this Act or the rules made thereunder;
   (iii) Require any person to produce any record, register, or other document relating to the manufacture for sale or for distribution, stocking, exhibition for sale, offer for sale or distribution of any drug or cosmetic in respect of which he has reason to believe that an offence under this Chapter has been, or is being, committed;

The provisions of the Code of Criminal Procedure, 1973, shall, so far may be, apply to any search or seizure under this Chapter as they apply to any search or seizure made under the authority of a warrant issued under section 94 of the said Code.

If any person willfully obstructs an Inspector in the exercise of the powers conferred upon him by or under this Chapter or refuses to produce any record, register or other document when so required, shall be punishable with imprisonment which may extend to three years, or with fine, or with both.