Chapter

1

Drugs and Cosmetics Act, 1940 and its Rules, 1945

- The Drugs and Cosmetics Act was passed in **10th April 1940.**
- 1940**—Drugs and Cosmetics Act**
- 1945**—Rules under the Act**

OBJECTIVES

- To regulate the **import, manufacture, distribution** and **sale** of drugs and cosmetics through licensing.
- To regulate the **manufacture** and **sale** of **Ayurvedic, Siddha** and **Unani** drugs.
- **Manufacture, distribution** and **sale** of drugs and cosmetics by **qualified persons** only.
- To prevent **substandard** in drugs.
- To establish **Drugs Technical Advisory Board** (**DTAB)** and **Drugs Consultative Committees (DCC)** for **allopathic** and **allied drugs** and **cosmetics.**

DEFINITIONS UNDER THE ACT

Drugs

- A medicine or other substance which has a physiological effect when **ingested** or otherwise **introduced into the body**.
- All medicines for **internal** or **external** use of **human beings** or **animals** and all substances intended to be used for or in the **diagnosis, treatment, mitigation** or **prevention** of any disease or disorder in human beings or animals, including preparations applied on human body for the purpose of repelling insects like mosquitoes.

Cosmetic: Section 3 (a)

Any article intended to be **rubbed, poured, sprinkled** or **sprayed** on, or introduced into, or otherwise applied to, the human body or any part thereof for **cleansing, beautifying, promoting attractiveness**, or altering the appearance, and includes any article intended for use as a component of cosmetic.

Ayurvedic, Siddha or Unani Drug: Section 3 (aaa)

It includes all medicine intended for **internal** or **external** use for or in the **diagnosis, treatment, mitigation** or **prevention** of disease or disorder in **human beings** or **animals** and manufactured in accordance with the formula described in the authoritative books of **Ayurvedic, Siddha or Unani system** of medicine, specified in first schedule.

Misbranded Drugs: Section 17

- If it is so **coloured, coated, powdered** or **polished** that damage is concealed; or
- If it is made to appear of **better or greater therapeutic value** than it really is; or
- If it is not **labelled** in the **prescribed manner**.

Adulterated Drug: Section 17 (a)

- If it consists, in whole or in part, of any **filthy, putrid** or **decomposed** substance; or
- If it contains any harmful or toxic substance which may render it injurious to health.

Spurious Drugs: Section 17 (b)

- If it is imported under a name which belongs to another drug; or
- Which purport to be the product of a manufacture of which it is not truly a product.

Inspector: Section 3 (e)

- In relation to Ayurvedic, Siddha or Unani drug, an Inspector appointed by central or state government under Section 33 *(g)*.

Government Analyst (Bench Chemist): Section 3 (c)

In relation to Ayurvedic, Siddha and Unani drugs, a person appointed by central government or state government under Section 33 *(f)*.

Manufacture: Section 3 (f)

In relation to any drug or cosmetic, it includes any process or part of a process for **making, altering, or namenting, finishing, packing, labelling,** breaking up or otherwise treating or adopting any drug or cosmetic with a view to its sale or distribution but does not include the **compounding** or **dispensing** of any drug, or the packing of any drug or cosmetic, in the ordinary course of retail business.

Patent or Proprietary Medicine: Section 3 (h-ii)

A drug which is a remedy or prescription presented in a form ready for internal or external administration of human beings or animals and which is not included in the edition of the Indian Pharmacopoeia for the time being or any other pharmacopoeia authorized in this behalf by the central government

APPENDIX

Appendix I: Data to be submitted along with the application for permission to market a new drug.

Appendix II: Format for submission of clinical trial reports.

Appendix III: Requirements for animal clinical trials and marketing a new drug.

Appendix IV: Number of animals for long-term toxicity studies.

Appendix V: Patient consent form for participation in Phase I clinical trial.

Appendix VI: Four groups of fixed dose combinations and their data requirements.

SCHEDULES TO THE ACT

First Schedule

List of Ayurvedic, Siddha and Unani books.

- **Ayurvedic book**
  Example: Charak Samhita, Sushruta Samhita and Arka Prakasha
- **Siddha book**
  Example: Siddha Vaidya Thirattu and Bhogar Pulippani
- **Unani book**
  Example: Karabadin Quadri and Al Karabadin.

Second Schedule

Standards to be complied with imported drug and by drugs manufactured for sale, sold, stocked or exhibited for sale or distributed.

SCHEDULES TO THE RULE	
Schedule A	List of model forms that are to be used under the Rules like making applications for the licenses, issue and retrieval of licenses.
Schedule B	Fees to be paid for test or analysis at the CDL (central drugs laboratory)/state government analyst.
Schedule C	List of **biological products** whose import, sale, distribution and manufacture are governed by special provisions, e.g. insulin, vaccine for parenteral injections, etc.
Schedule C1	List of **other special products** whose **import, sale, distribution and manufacture** are governed by special provisions, e.g. fish liver oil, adrenaline, vitamins, etc.
Schedule D	List of drugs exempted for the provisions of **import of drugs**, e.g. oats, ginger, etc.
Schedule E	List of **poisonous substance** under the **Ayurvedic, Siddha and Unani** systems of medicine, e.g. nux-vomica, etc.
Schedule F (i)	Space, equipment and supplies required for a **Blood Bank.**
Schedule F (ii)	Minimum **requirement for grant of license** to procure blood components from whole human blood.

Schedule F1	Standards for **surgical dressings.**
Schedule F2	Standards for **sterilized dressings**
Schedule F3	Standards for **ophthalmic preparations**
Schedule G	List of substances that are required to be used only under **medical supervision.**
Schedule H	List of **prescription drugs**
Schedule J	Disease or aliments which a drug **may not** purport to prevent or cure.
Schedule K	Drugs exempted from certain provisions relating to the **manufacture of drugs.**
Schedule M	**Good manufacturing practices (GMP**) requirements of factory premises, plants and equipment.
Schedule M1	Requirements of factory premises for **manufacture of homeopathic preparations.**
Schedule M2	Requirements of factory premises for **manufacture of cosmetics**.
Schedule M3	Requirements of factory premises for **manufacture of medical devices.**
Schedule N	List of minimum requirements of **efficient running of pharmacy**.
Schedule O	Standard of **disinfectant fluids**.
Schedule P	**Life period** of drug
Schedule P1	**Pack sizes** of drug
Schedule Q (i)	List of **dyes, colors** and **pigment** permitted in **cosmetics** and **soaps.**
Schedule Q (ii)	List of **colors permitted in soaps.**
Schedule R	Standards for **condoms** made of rubber latex intended for single use and other mechanical **contraceptives.**
Schedule S	Standards of **cosmetics**.
Schedule T	Requirements of factory premises and hygienic conditions for **Ayurvedic** and **Unani** drugs.
Schedule U	Particulars to be shown in manufacturing, raw materials and analytical records of **drug.**

Schedule U1	Particulars to be shown in manufacturing, raw materials and analytical records of **cosmetics**.
Schedule V	Standards for **patent** or **proprietary medicines.**
Schedule W	List of drugs to be marketed under **generic names only**.
Schedule X	List of drugs whose **import, manufacture and sale** are governed by **special provisions**.
Schedule Y	Requirements and guidelines on **clinical trials** for **import and manufacture of new drugs.**

IMPORT OF DRUGS

Bring (goods or services) into a country from abroad for sale.

No any drug, the **manufacture, sale** or **distribution** of which is **prohibited** in the country of origin, shall be imported under the same name or under any other name except for the purpose of **examination**, **test of analysis**.

Prohibition of Import of Certain Classes of Drugs and Cosmetics

Misbranded Drugs and Cosmetics

- If it is not labeled in the prescribed manner.
- If it contains a **color** which is not prescribed
- If it is **not labelled** in the prescribed manner

Adulterated Drugs and Cosmetics

- If it contains any **harmful or toxic substance** which may render it injurious to health.
- If any substance has been mixed therewith so as to reduce its quality or strength.
- If it bears or contains any harmful for purposes of coloring only, a colour other than one which is prescribed.

Spurious Drugs or Cosmetics

- If it is imported under a name which belongs to another drug; or
- Which purport to be the product of a manufacture of which it is not truly a product.

- If it is imported under a name which belonging to another cosmetics.

Drugs of Substandard Quality

No any drug shall be imported unless it complies with the standard of **strength, quality, and purity** if any, and the test prescribed in the rule shall be applicable for determining whether any such imported drug complies with the said standard.

Provided further that the licensing authority shall not allot the import of any drug having **<60%** residual shelf-life period as on the date of import.

Drugs whose manufacture, sale/distribution are prohibited in original country, except for the purpose of test, examination and analysis.

Patent/proprietary medicines whose true formula is not disclosed.

Packing and labeling of imported drug and cosmetic: No drug shall be imported unless it is packed in conformity with rule in Part IX and X and further conform to the standard laid down in Part XII.

Packing and labeling of imported homoeopathic medicine: No homoeopathic medicine shall be imported unless it is packed and labelled in conformity with the rules in Part IX-A.

Specially cosmetics product which contains more than 2 ppm arsenic, 20 ppm lead, 100 ppm heavy metals.

Import of the Biological Drugs (C/C1)

Conditions to be Fulfilled

- Licensee must have **adequate facility** for the **storage**.
- Licensee must maintain a record of the sale.
- Licensee must allow an inspector to inspect premises and to check the records.
- Licensee must furnish the sample to the authority.
- Licensee must not sell drugs from which sample is withdrawn and he is advised not to sale, and recall the batch from the market.

Import of the Schedule X Drugs (Narcotic Drugs and Psychotropic Substances)

Conditions to be Fulfilled

- Licensee must have adequate **storage facility.**
- Applicant must be **reputable** in the occupation, trade or business.
- The license **granted even** before should **not be suspended or cancelled.**
- The licensee has **not been convicted any offence** under the Drugs and Cosmetics Act or Narcotic Drugs and Psychotropic Substances Act.

Drugs Imported for Examination, Test or Analysis

Conditions to be Fulfilled

- License is necessary under Form 11
- Must use imported drugs **only for said purpose** and at the place specified in the license.
- Must keep the **record** with respect to quantities, name of the manufacturer and date of import.
- Must **allow an inspector** to inspect the premises and check records.

Drugs Imported for Personal use

Conditions to be Fulfilled

- Up to 100 average doses may be imported without any permit, provided it is part of passenger's luggage.
- More than 100 doses imported with license. Apply on Form 12 (*a*) and 12 (*b*).
- Drugs must be bonafied personal use.
- Drugs must be declared to the custom collectors if so directed.

Import of Drugs without License

- Substances **not used for medicinal purpose**
- Drugs in Schedule C1 required for manufacturing and not for medicinal use.
- Substances which are **both drugs and foods** such as:
  – Condensed/powdered milk
  – Malt

– Lactose
– Oats
– Predigested foods: Ginger, pepper, cumin, cinnamon.

Import of Drugs under License or Permit

The following classes of drugs can be imported under the license or permit granted by LA

1. Drugs specified in Schedule C and C1 except those specified in Schedule X
2. Drugs specified in Schedule X
3. Small quantities of drugs imported for the purpose of examination, test or analysis.
4. Drugs for personal use covered by the prescription of registered medical practitioner.
5. Any new drug

An application for import license must be made to the proper authority in prescribed form and license remains valid up to **31st December** of the year, following the year it was granted unless it was suspended earlier.

Aggrieved party has the right to appeal in High Court against an order of the Drugs Controller of India canceling the import license granted to him.

- A separate license is necessary in respect of drugs from each manufacturer.
- A separate license is necessary in respect to drug manufactured in each premises when a single manufacturer abroad has more than one factory.
- A single application may be made and single license may be issued in respect of import of more than one drug or class of drugs manufactured by same manufacturer.
- A change in constitution of licensed firm must be informed to the LA.

Conditions of Import License

1. Manufacturer must observe at all times the undertaking given by him or on his behalf on Form 9.
2. The license must allow any authorized inspector to enter any premises where the imported substance is stocked to

inspect the means, if any, employed for testing the substances 7 to take samples.

3. Maintained records of all sales of imported substances showing particulars of substances and persons to whom it is sold and such records must be open for inspection.

Places through which Drugs may be Imported in India

Table 1.1: Places and their sources for importation

Place	*Sources*
Ferozpur cantonment and Amritsar railway station	In respect to drugs imported by rail across the border with Pakistan
Runagate, Bongaon and Mohiassan railway stations	In respect to drugs imported by rail across the border with Bangladesh
Raxaul	In respect to drugs imported by road and rail connecting India and Nepal
Chennai, Kolkata, Mumbai, Cochin and Kandla	In respect to drugs imported by sea into India
Chennai, Kolkata, Mumbai, Delhi, Ahmedabad and Hyderabad	In respect to drugs imported by air into India

Offences and Penalties

Table 1.2: Offences and penalties related to Import

Offences	*Penalties*
Import of spurious OR adulterated drug OR drug which involves risk to human beings or animals OR drug not having therapeutic values	**3 years** imprisonment and **₹ 5000** fine on **first conviction** **5 years** imprisonment OR **₹ 1000** fine OR **both** for **subsequent conviction**
Contravention (an action which offends against a law) of the provision	**6 months** imprisonment OR **₹ 500** fine for **first conviction** **1 year** imprisonment OR **₹ 1000** fine OR **both** for **subsequent offence**

Application of Laws Relating to Sea and Customs

The customs collector and other officers authorized in this behalf by the central government may detain any imported packages which he suspects to contain any drug or cosmetic the import of which is prohibited under this act, and report such detention to the Drugs Controller, India and if necessary forward any package or sample to central drugs laboratory for analysis.

MANUFACTURE OF DRUG

Manufacture in relation to any drug or cosmetic, includes any process or part of process for making, altering, ornamenting, finishing, packing, labeling, braking up or otherwise treating any drug or cosmetic with a view to its sale and distribution but does not include the compounding or dispensing of any drug or packing of any drug in ordinary course of retail business.

Following Licenses are Provided for Manufacture of Drugs under D&C Act

1. License for manufacture of **Schedule C and C1** drugs
2. License for manufacture of **Schedule X** drugs
3. Drugs specified in **Schedule C, C1** and **X**
4. Drugs for the purpose of **examination, test or analysis**
5. **Loan** licenses
6. **Repacking** licenses
7. **Blood** products
   - Repacking is also a manufacturing for the purpose of the Act.
   - If drugs are manufactured in more than one set of premises, a separate application is to be made and separate license shall be issued in respect of each such premises.
   - Licenses for manufacture or sale or distribution of drugs are granted or renewed by **Central License Approving Authority** (CLAA) appointed by the central government.

- CLAA can delegate his power of signing licenses to any other person under his control with approval of the central government.

Prohibition for the Manufacture and Sale of Certain Drugs

From the date notified by the state government, no person shall himself manufacture for sale or distribution or sell or distributed. Any drug which is not of standard quality or is misbranded, adulterated or spurious:

- If any cosmetic which not of standard quality or is misbranded, adulterated or spurious.
- If any patent or proprietary medicine whose formulae are not disclosed on label or the container.
- If any drug which purports to cure, mitigate or prevent any disease specified in Schedule J.
- If any cosmetic containing any ingredient which may render it unsafe or harmful for use.
- If any drug or cosmetic in contravention of this Act or Rules thereunder.
- If any drug or cosmetic which has been imported or manufactured in contravention of the provisions of this Act or Rules thereunder or in contravention of the conditions of a license.
- Every person not being manufacturer of a drug or cosmetic or his agent for the distribution shall if so required disclose to the inspector the name, address and other particulars of the person from whom he procured the drug or cosmetic.

Manufacture of Drugs Specified in Schedule C, C1 and X

- Application for the license of manufacturing drugs specified in Schedule C, C1 excluding those specified in Schedule X should be made to the CLAA in Form 27 and for manufacture of drugs specified in Schedule C, C1 and X in Form 27 (*b*). Respective licenses are issued in Form 28 and 28 (*b*).

- Application for including any additional drug in the license should be accompanied by a fee of ₹ 50 for each drug subject to a maximum of ₹ 500.
- Conditions for the grant of license: Before the grand of license, the following conditions must be complied by the applicant.

The manufacture will be conducted under the active direction of a competent technical staff consisting at least one person who is a full time employee and **who is:**

1. A graduate in pharmacy/pharmaceutical chemistry of a recognized university with at least 18 months practical experience after graduation in manufacture of drugs to which this license applies.
2. A graduate in science of a recognized university who passed in degree with chemistry or microbiology as principal subject and had at least 3 years' experience in the manufacture of drugs to which the license applies.
3. A graduate in medicine of a recognized university with at least 3 years' experience in manufacture of relevant drugs; or
4. A graduate in chemical engineering of a recognized university with at least 3 years' experience in manufacture of relevant drugs.

- The factory conditions must comply with the conditions prescribed in Schedule M and M3.
- Applicant should provide adequate space, plant and equipment for any or all manufacturing operations as prescribed in Schedule M and M3.
- Applicant should provide adequate staff, premises and laboratory equipment for carrying out such tests for strength, quality and purity of substances as required under the Rules.
- Adequate facilities for the storage of manufactured drugs should be provided.
- License in Form 28 and 28 (*b*) remains valid for a period of 5 years on and from the date on which it is issued.
- If application for renewal is made before its expiry, or application made within 6 months of expiry, after

payment of additional fee, the license shall continue to be valid.

- License shall deemed to have expired if the application for its renewal is not made within 6 months of its expiry.
- **Large volume parenteral** means the sterile solutions indented for parenteral administration with a volume of 100 ml or more in one container of the finished dosage form indented for single usage.

Manufacture of Drugs other than those Specified in Schedule C and C1

- Application for the grand or renewal of license for the manufacture of drugs other than those specified in Schedule C, C1 and X for manufacture of Schedule X drugs in Form 24 (*f*). Respective licenses are issued in Form 25 and 25 (*f*).
- Application for grand/renewal of such license shall be made for up to 10 items in each category in Form 24 (*a*) accompanied by fee of ₹ 6000 and an inspection fee of ₹ 1500 and license shall be issued in Form 25 (*a*).
- Additional fee of ₹ 300 per item is payable for each additional item. License in Form 25 or 25 (*f*) remains valid for a period of 5 years on and from the date on which it is issued.
- If application for renewal is made before its expiry, or application made within 6 months of expiry, after payment of additional fee, the license shall continue to be valid.
- License shall deemed to have expired if the application for its renewal is not made within 6 months of its expiry.

Manufacture of Drugs for Examination, Tests or Analysis

- License is necessary for the manufacture of any drug in small quantity for the purpose of examination, test or analysis.
- If a person proposing to manufacture does not hold license (i) to manufacture drugs other than those specified

in Schedule C, C1 and X, or (ii) to manufacture drugs specified in Schedule C, C1 in respect to such drugs; he should obtain license in Form 29.

- If drug is not recognized as safe for use, license in Form 29 is only granted after producing no objection certificate from LA appointed by central government.
- License remains valid for a period of one year time.
- Drugs to be kept in containers bearing labels indicating the purpose for which it has been manufactured.
- If the drugs are to be supplied, it should bear label stating name and address of manufacturer, scientific name of substance and purpose for which it has been manufactured.

Conditions for License

1. Drugs to be used exclusively for the purpose for which they are manufactured
2. Licensee to allow inspector to inspect the premises and satisfy himself that only examination, test or analysis is being conducted.
3. Licensee to keep record of quantity of drugs manufactured and supplied to any person.
4. Licensee to maintain inspection book to enable inspector to record his impression and defects noticed.
5. Licensee must comply with any rules made subsequently and of which the LA has given him NLT one month's notice.

Manufacture of New Drugs

- Defined as a drug the composition of which is such that it is not generally recognized among experts as safe for use under conditions recommended.
- Suggested on the label and includes any drug the composition of which is such that the drug as a result of investigations for determining its safety for use under such conditions, is so recognized but which has not otherwise than during course of such investigations, been used to any large extend for any appreciable length of time under the said conditions.

- Provisions applicable for the manufacture of new drugs whether classifiable under Schedule C and C1 or otherwise.
- No new drug can be manufactured unless prior approval has been taken.
- Applicant to produce all documentary and other evidence relating to the standards of quality, purity, strength and such other information as may be required including the results of therapeutic trials carried out on the new drug.
- While applying for a license to manufacture a new drug, or its preparations an applicant should produce along with his application evidence that the drug has already been approved.

Loan Licenses

Definition

A person (applicant) who does not have his own arrangements (factory) for manufacture but who wish to avail the manufacturing facilities owned by another licensee. Such licenses are called loan licenses

- Issued for the manufacture for sale or distribution of drugs other than those specified in Schedule C, C1 and X.
- Application for license is made in Form 24 (*a*) and the license is issued in Form 25 (*a*).
- Inspector shall check into all the portions of the plant and shall also inquire in professional qualification for the technical staff employed.
- Licensee is required to test each batch of raw materials and finished products and the records must be maintained for a period of 5 years from the date of manufacture. (2 years in case of drugs having expiry date, from the date of expiry.)
- Loan license is deemed to be cancelled or suspended if license owned by loan licensee, whose manufacturing facilities are been availed by licensee is cancelled or suspended.

Repacking Licenses

Definition

Process of breaking up any drug from a bulk container into small packages and labeling with a view to their sale and distribution

- Repacking license are granted for breaking up of any drug other than those specified in Schedule C, and C1, on application to LA in Form 24 (*b*) and license is issued in Form 25 (*b*) subject to satisfying the following conditions:
  - Factory conditions must specify conditions prescribed in Schedule M.
  - Applicant must have in his premises adequate facilities for the testing of drugs which is separate from the repacking unit
  - License must be kept at licensed premises and produced on request of DI.
  - The label on repacked drugs should mention the name and address of the licensee and his license number preceded by the word 'Reg. Lic. No.
  - The license remains valid up to 31st December of the year, following the year in which it is grated.

Offences and Penalties

Table 1.3: Offences and penalties related to manufacturing

Offences	*Penalties*
Manufacture of any spurious drugs	1–3 years imprisonment and ₹ 5000 fine. 2–6 years imprisonment and ₹ 10000 fine on **subsequent** conviction
Manufacture of adulterated drugs	1 year imprisonment and ₹ 2000 fine 2 years imprisonment and ₹ 2000 fine for subsequent conviction
Manufacture of drugs in contravention of the provisions	Imprisonment up to 3 months and ₹ 500 fine Imprisonment up to 6 months and ₹ 1000 fine on **subsequent conviction**

DETAIL STUDY OF SCHEDULE M (M1 AND M2)

- Good manufacturing practices (GMP).
- Guidelines are meant to assure the quality of drugs.
- Draft of GMP was prepared in 1975 and finalized and implemented in 1988.
- **Part I** deals with good manufacturing practices relating to factory premises.
- **Part II** deals with plant and equipment for the manufacture of drugs.

PART I FACTORY PREMISES

GENERAL REQUIREMENTS

- Location of factory and its surroundings should ensure freedom from contamination due to sewage drain, etc. and obnoxious odors or fumes, or large quantity of soot, dust or smoke.
- **Factory building** should be constructed to ensure production of drugs under hygienic conditions.
- Operations such as manufacturing, processing, packing labeling and testing should be carried out in such a way that mix up and cross contamination are prevented.
- Premises should be constructed and maintained as to prevent entry of insects and rodents, interior surface should be smooth and free from cracks and permit easy cleaning disinfection. Adequate lighting, ventilation and humidity must be maintained. Drainage systems should be underground, the sanitary fitting and electrical fixtures in the manufacture area must be concealed. Water used must be free of pathogenic micro-organisms and of drinkable quality. Waste water should be treated before disposal.
- There should be a validated system for the treatment of water so as to produce purified water confirming to IP specification. Water should be stored in tanks and freedom from microbial growth must be ensured. The tanks should be cleaned periodically and the records should be maintained.
- Provisions should be made for the roper storage of the materials awaiting disposal. The disposal of sewage and effluents shall be as required under the Environmental Pollution Control Board while all biomedical waste must be

destroyed as per the rules of Biomedical Waste Management and Handling Rules.

Warehousing Area

- Adequate areas shall be designed and provided with proper bins, racks and platforms for the storage and warehousing of all materials and products, machine and equipment, etc. Warehousing area must be clean, dry and maintained within acceptable temperature limits. Storage areas should have appropriate housekeeping and rodents, pests and vermin control procedures and records should be maintained. Active raw materials and excipients must require separate sampling and warehousing area.
- Regular check should be made to ensure adequate steps taken against spillage, breakage and leakage of containers.

Production Area

- Should be designed to allow the production preferably in uni-flow and with logical sequence of operations.
- The equipment and materials must be placed orderly and the movement of personnel must be restricted to avoid cross-contamination.
- Separate dedicated self-containing facilities should be made available for the production of sensitive pharmaceutical products like penicillin or biological preparations with live microorganisms.
- Pipe works, electrical fittings, ventilations, openings and similar service lines must be designed to avoid creation of recesses.
- Service lines shall preferably identified by colors and nature of supply and direction of flow shall be indicated.

Quality Control Area

- It should be independent of production area and divided into separate sections for physiochemical, biological, microbiological and radioisotope analysis.
- Laboratories shall be designed to avoid mix ups and cross-contamination. Separate instrument room with adequate area shall be provided for sensitive and sophisticated instruments employed for analysis.

- Suitable storage space shall be provided for test samples, retained samples, reference standards, reagents and records.

Personnel

- Manufacture/testing shall be conducted under the direct supervision of competent technical staff and head of quality control laboratory shall be independent of manufacturing unit.
- Personnel in quality control and quality control operations shall be suitably qualified and experienced and appropriate training must be given to them in the duties and responsibilities assigned to them.

Health, Clothing and Sanitation of Workers

- All personnel coming to contact with products and raw materials should be free from contagious diseases and should undergo periodic health checkup. Just before entry to manufacturing area, room with facility for personnel cleanliness should be provided.
- Prior to employment, personnel shall undergo medical examination and shall be free from TB, skin and other communicable/contagious diseases.
- Periodical medical examination at least once a year may be necessary.
- All persons prior to and during the employment shall be trained in practices that ensure personnel hygiene.
- Persons handling β-lactam antibiotics shall be tested for penicillin sensitivity before employment and those handling sex hormones, cytotoxic substances and other potent drugs shall be periodically examined for adverse effects.
- Direct contact shall be avoided between unprotected hands of personnel and raw materials, intermediate, or finished unpacked products.
- All persons should wear clean body coverings.
- Smoking, eating, drinking, chewing or keeping plants or food and personnel medicines shall not be permitted in production, laboratory storage and other areas.

Ancillary Areas

- Rest and refreshment rooms should be separate and should not lead directly to the manufacturing area.

- Facilities for changing, storing of clothes and for washing and toilet purposes should be provided and must be adequate for the number of users.

Sanitation in Manufacturing Premises

- Manufacturing area should not be utilized for any other purposes and should be maintained clear and in orderly manner free from accumulated waste, dust, debris, etc. A routine sanitation program must be exercised.
- Production areas shall be well lit, particularly where visual online controls are carried out.

Raw Materials

All raw materials must be:

- Purchased from approved sources under valid purchase vouchers, possibly from producers directly.
- Identified and their containers examined for damage and assigned control number.
- There shall be separate areas for materials under test, approved and rejected.
- All incoming materials shall be quarantined immediately after receipt or processing.
- Materials must be stored in such a way that first in/first expiry, first out principle can be applied.
- Only raw materials released by QC department and which are within their shelf-life shall be used.

Sterile Products

- Separate enclosed areas provided with air locks, dust free, ventilated with air supply through HEPA filters are recommended.
- Routine microbial counts of area are necessary during manufacturing operation.
- Design of area must avoid possibility of mix-up between sterile and nonsterile products.
- Access to manufacturing area must be restricted to authorized personnel only.

Working Space

- Adequate working space and adequate room for orderly placement of equipment and materials should be provided

to eliminate mix-up between different drugs and cross contamination.
- Separate space should be provided in storage area for "under test", "approved", and "rejected", materials.

Medical Services

Manufacturer must provide facilities for:
- Adequate facilities for first aid.
- Medical examination of workers at time of employment and periodic checkup there after once in a year.
- Facilities for vaccination or other exigencies.

Equipment

Equipment used for manufacture must be constructed, designed, installed and maintained to:
- Achieve operational efficiency to attain the desired quality.
- Prevent physical, chemical or physiochemical change through surface contact.
- Prevent contact of any substances required for operation of equipment such as lubricants.
- Facilitate thorough cleaning whenever necessary.
- Minimize any contamination of any drugs and their containers during manufacture.

Master Formula Records

- The licensee has to maintain master formula records.
- Relating to all manufacturing procedures for each product, the master formula record must have:
  - Patent or proprietary name of product along with generic name, strength and dosage form, description or identification of final containers, packaging materials.
  - Labels and closures to be used.
  - Identity, quality and quantity of each raw material to be used.
  - Description of all equipment and vessels and the size used in the process.
  - Manufacturing and control instructions along with parameters for critical steps such as mixing, drying, blending, sieving, and sterilizing the product.

- Theoretical yield to be expected from the formulation
- Detailed instructions and precautions to be taken in manufacture, storage of drugs and of semi-finished products and the requirements in process quality control tests and analysis to be carried out during each stage of manufacture.

Batch Manufacturing Records

Licensee has maintain batch manufacturing records for each batch of drugs as per Schedule U. It has provide complete account of manufacturing history of each batch showing that it has been manufactured, tested and analyzed in accordance with manufacturing procedures and written instructions as per master formulae.

Manufacturing Operations and Control

All manufacturing operations must be carried out under the supervision of competent technical staff. Critical steps in the process related to selection, weighing and measuring of raw materials must be done under the direct supervision of competent technical staff.

Product Containers and Closures

Has complied with pharmacopoeial requirements. Suitable test methods, cleaning and sterilization procedures should be used to assure that components, closures and other component part of drug packages are suitable and they are not reactive, additive, absorptive or leach to an extent that significantly affects the quality or purity of the drug.

Labels and other Printed Materials

Printed labels and packaging materials including leaflets have be handles and accounted to ensure that they do not become intermixed. Prior to issue, they should be examined and released as satisfactory for use by quality control personnel.

Distribution of Records

Records for the distribution of each batch of drug should be maintained in order to facilitate prompt and complete recall of the batch if necessary.

Quality Control System

Principal duties of quality control department are:

- Prepared detailed instruction for carrying out each tests and analysis.
- To release or reject (i) each batch of raw material, (ii) semi-finished products if necessary, (iii) packaging and labeling materials and final containers, (iv) each batch of finished products ready for distribution.
- Evaluate adequacy of conditions under which raw materials, semifinished products and finished products are stored.
- Evaluate quality and stability of finished products.
- To establish, and when necessary revise, control procedures and specifications.
- To examine returned products as to whether such products be released, reprocessed or destroyed.

PART IA

Specific requirements for manufacture of sterile products. parenteral preparations (small volume injectables and large volume parenterals) and sterile ophthalmic preparations.

Introduction

- Following implementation of these WHO good manufacturing practices (GMP) guidelines within the context of the WHO Prequalification of Medicines Programme, clarifying, editorial modifications have been proposed.
- These changes were adopted for maintenance purposes. In order to ease reading the full guideline has been reproduced again as an Annex to the current report of the WHO Expert Committee on specifications for pharmaceutical preparations.

WHO Good Manufacturing Practices for Sterile Pharmaceutical Products

1. General considerations
2. Quality control
3. Sanitation
4. Manufacture of sterile preparations
5. Sterilization

6. Terminal sterilization
7. Aseptic processing and sterilization by filtration
8. Isolator technology
9. Blow/fill/seal technology
10. Personnel
11. Premises
12. Equipment
13. Finishing of sterile products

General Considerations

- The production of sterile preparations should be carried out in clean areas, entry to which should be through airlocks for personnel and/or for equipment and materials. Clean areas should be maintained to an appropriate standard of cleanliness and supplied with air that has passed through filters of the required efficiency.
- The various operations of component preparation (such as those involving containers and closures), product preparation, filling and sterilization should be carried out in separate areas within the clean area. These areas are classified into four grades (*see* Section 4).

Manufacturing operations are divided here into two categories:

- First, those where the product is terminally sterilized; and
- Second, those which are conducted aseptically at some or all stages.

Quality Control

- The sterility test applied to the finished product should only be regarded as the last in a series of control measures by which sterility is assured. The test should be validated for the product(s) concerned.
- Samples taken for sterility testing should be representative of the whole of the batch but should, in particular, include samples taken from parts of the batch considered to be most at risk of contamination. For example:
- Products that have been filled aseptically, samples should include containers filled at the beginning and end of the batch and after any significant interruption of work; for products

that have been heat sterilized in their final containers, consideration should be given to taking samples from that part of the load that is potentially the coolest.

- The sterility of the finished product is assured by validation of the sterilization cycle in the case of terminally sterilized products, and by "media simulation" or "media fill" runs for aseptically processed products. Batch-processing records and, in the case of aseptic processing, environmental quality records, should be examined in conjunction with the results of the sterility tests.
- The sterility test procedure should be validated for a given product. Pharmacopoeial methods should be used for the validation and performance of the sterility test. In those cases where parametric release has been authorized in place of sterility testing special attention should be paid to the validation and the monitoring of the entire manufacturing process.
- For injectable products the water for injection and the intermediate, if appropriate, and finished products should be monitored for endotoxins, using an established pharmacopoeial method that has been validated for each type of product. For large volume infusion solutions, such monitoring of water or intermediates should always be done, in addition to any tests required by an approved monograph for the finished product. When a sample fails a test, the cause of the failure should be investigated and necessary action should be taken. Alternative methods to those in the pharmacopoeias may be used if they are validated, justified and authorized.

Sanitation

- The sanitation of clean areas is particularly important. They should be cleaned frequently and thoroughly in accordance with an approved written programme. Where disinfectants are used, more than one type should be employed. Monitoring should be regularly undertaken to detect contamination or the presence of an organism against which the cleaning procedure is ineffective. Interactions between different cleaning materials should be validated. Appropriate cleaning validation should be carried out to ensure disinfectant residuals can be detected and are removed by the cleaning process.

- Disinfectants and detergents should be monitored for microbial contamination; dilutions should be kept in previously cleaned containers and should only be stored for defined periods unless sterilized. Disinfectants and detergents used in Grade A and B areas should be sterile before use.
- A disinfectant programme should also include a sporicidal agent since many common disinfectants are ineffective against spores. The effectiveness of cleaning and disinfectant procedures should be demonstrated.
- Fumigation of clean areas may be useful for reducing microbial contamination in inaccessible places.

Manufacture of Sterile Preparations

Clean areas for the manufacture of sterile products are classified according to the required characteristics of the environment. Each manufacturing operation requires an appropriate level of environmental cleanliness in the operational state to minimize the risks of particulate or microbial contamination of the product or materials being handled.

For the manufacture of sterile pharmaceutical preparations, four grades of clean areas are distinguished as follows:

Grade A: The local zone for high-risk operations, e.g. filling and making aseptic connections. Normally such conditions are achieved by using a unidirectional airflow workstation. Unidirectional airflow systems should provide a homogeneous air speed of 0.36–0.54 m/s (guidance value) at a defined test position 15–30 cm below the terminal filter or air distributor system. The velocity at working level should not be less than 0.36 m/s. The uniformity and effectiveness of the unidirectional airflow should be demonstrated by undertaking airflow visualization tests.

Grade B: In aseptic preparation and filling, this is the background environment for the Grade A zone.

Grades C and D: Clean areas for carrying out less critical stages in the manufacture of sterile products or carrying out activities during which the product is not directly exposed (i.e. aseptic connection with aseptic connectors and operations in a closed system).

A unidirectional airflow and lower velocities may be used in closed isolators and glove boxes.

- In order to reach the B, C and D air grades the number of air changes should be appropriate for the size of the room and the equipment and personnel present in it.
- High efficiency particulate air (HEPA) filters should be subjected to an installed filter leakage test in accordance with ISO 14644–3 (3) at a recommended interval of every 6 months, but not exceeding 12 months. The purpose of performing regular leak tests is to ensure the filter media, filter frame and filter seal are free from leaks. The aerosol selected for HEPA leak testing should not support microbial growth and should be composed of a sufficient number or mass of particles.

Table 1.4: Maximum permitted airborne particle concentrate

Grade	*Maximum permitted number of particles per m^3 greater than or equal to the tabulated size*			
	At rest		*In operation*	
	0.5 µm	*5.0 µm*	*0.5 µm*	*5.0 µm*
A	3520	20	3520	20
B	3520	29	352000	2900
C	352000	2900	3520000	29000
D	3520000	29000	Not defined	Not defined

- The "at rest" state is the condition where the installation is complete with equipment installed and operating in a manner agreed upon by the customer and supplier, but with no personnel present.
- The "in operation" state is the condition where the installation is functioning in the defined operating mode and the specified number of personnel is present. The areas and their associated environmental control systems should be designed to achieve both the "at rest" and "in operation" states.

Terminally Sterilized Products

- Components and most products should be prepared in at least a Grade D environment to ensure low microbial

bioburden and particulate counts prior to filtration and sterilization. Where the product is at unusual risk of microbial contamination (e.g. because it actively supports microbial growth, must be held for a long period before sterilization, or is necessarily processed mainly in open vessels), the preparation should generally be done in a Grade C environment.

- The filling of products for terminal sterilization should generally be done in at least a Grade C environment.
- Where the product is at unusual risk of contamination from the environment (e.g. because the filling operation is slow, the containers are wide-necked or are necessarily exposed for more than a few seconds before sealing), the filling should be done in a Grade A zone with at least a Grade C background.
- The preparation and filling of ointments, creams, suspensions and emulsions should generally be done in a Grade C environment before terminal sterilization.

Aseptic Preparation

- Components after washing should be handled in at least a Grade D environment. The handling of sterile starting materials and components, unless subjected to sterilization or filtration through a microorganism-retaining filter later in the process, should be undertaken in a Grade A environment with a Grade B background.
- The preparation of solutions which are to be sterile-filtered during the process should be undertaken in a Grade C environment (unless a closed system is used, in which case a Class D environment may be justifiable). If not sterile-filtered (therefore an aseptic manipulation) the preparation of materials and products should be undertaken in a Grade A environment with a Grade B background.
- The handling and filling of aseptically prepared products, as well as the handling of exposed sterile equipment, should be undertaken in a Grade A environment with a Grade B background.
- The transfer of partially closed containers, as used in freeze-drying, before stoppering is completed, should be undertaken either in a Grade A environment with a Grade B background or in sealed transfer trays in a Grade B environment.

Processing

- Precautions to minimize contamination should be taken during all processing stages, including the stages before sterilization.
- In general preparation containing live microorganism should not be made nor should container be filled in areas used for the processing of other pharmaceutical products.
- Validation of aseptic processing should include a process simulation test using a nutrient medium (media fill). Selection of the nutrient medium should be made based on dosage form of the product and selectivity, clarity, concentration and suitability for sterilization of the nutrient medium.

PART IB

Specific requirements for manufacture of oral solid dosage forms (tablets and capsules).

- In this article we will discuss about manufacturing process. Read: Documentations, requirements and other formalities to start solid dosage form manufacturing company.
- Solid dosage form is well accepted and most popular dosage form in pharmaceutical industry. Accuracy in dose and easy to take like advantage give it popularity among professionals and patients. Today we are going to discuss about manufacturing of solid dosage form, i.e. tablet and capsule.

Technical Staff

- Manufacturing chemist
- Analytical chemist
- Quality assurance manager
- Production supervisors

Non-technical Staff

- Machine operators
- Helpers

Section Required

- Mixing, granulation and drying section
- Tablet punching section

- Coating (film coating and sugar coating) section
- Capsule filling section (in case of capsule)
- Packaging section

Machinery used

Weighing machines and testing equipment (e.g. electronic balance, hardness tester, friability and disintegrated test apparatus, tablet inspection units, dissolution test apparatus etc.), disintegrator and shifter, mixer (mass/rapid/planetary mixer), granulator, drier (trey/fluid bed drier), rotatory (tablet compression machine)—single or multi-punch, punches and dies (as per tablet size/s), packaging machines (blister/strip/alu-alu, etc.) and testing equipment, coating and polishing pan (in case of coated tablets), capsule filling machine.

Tablet Manufacturing

Tablet manufacturing process involves following steps:

- Dispensing of ingredients
- Sizing
- Blending
- Formulation
- Milling and granulation
- Drying
- Final blending:
  - Tablet compression
  - Coating
  - Packaging

Three processes are used to manufacture tablet dosage form:

- Direct compression
- Wet granulating
- Dry granulating

Direct Compression Method

This method is used for tablet compression only if powder/s is easily compressible and does not require any additional requirement for compression. All powders are mixed and directly compressed into tablet punching machine for making

a tablet. Powdered should be blended together and should remain in mixed form.

Wet Granulating Method

Widely used method for making tablets if powders used are not easily compressible or floppy in nature or do not mix well then wet granulating process is used. Wet granulating method follows following steps:

- Mixing of active ingredients and excipients
- Preparation of binding material
- Addition or mixing of mixed powders and binding solution
- Sieved or milled to convert into granules
- Drying and sieve again
- Mix disintegrant, glidant and lubricant into it.

Dry Granulating Method

- If the material used is sensitive to heat or volatile in nature then we have to compress tablet without use of heat and solvents. There are two basic procedures used in dry granulating method. One is to form a pack or compact by compression and then sieved or milled to convert into granules.
- In dry granulation, one method is to recompress powder into slugs and milled to form granules and second method is to form compacts through pressure. Compaction of powder is accomplished by rolling powder under pressure.

Method used for manufacturing tablet is depended at raw material nature used for making tablets. Wet granulating method is widely accepted and used to compress raw material into tablet form.

Procedure for Tablet Manufacturing

Dispensing: Each ingredient including active ingredient/s should be accurately dispenses as per dose. It is one of the critical steps and any type of formulation. Weighing and measuring should be done under technical supervision.

Sizing: If all ingredients are of equal size, it becomes easier to mix all of them. Sizing is an important part in tablet manufacturing. Reduce all ingredients to equal size for better flow property and easy mixing.

Blending: Blend all powders to make a uniform and homogeneous mixer.

Formulation: Mix this mixture with binding agent.

Pre-milling: Now above formulation passed through mills or sieves to form granules.

Drying: Granules need to be dried for a particular time period in trey dry or fluid bed drier.

Milling: Again pass through this mixture into mills and sieve it.

Final blending: Blend above granules finally with disintegrants, lubricates and glidants.

Rotary machine: Next step is to compress these granules into tablet form. Rotary machine contains punch and die. Size and shape of punch and die may vary according to your need. Compression is crucial for tablet manufacturing. It should not be low or high. If it will be low, tablet will not have hardness. If compression is high then tablet dissolution time will be affected. Granules or powder is flowed toward dye; fill the space obtained by vacuum in die. After filling of die, punch compression is obtained to convert powder or granules into tablet.

Coating pan: If tablets need to be coated then a coating material is prepared and sprayed at tablets in coating pan till desired coating film is obtained.

Tablets defect that should be consider during manufacturing:

- Weight variation
- Friability variation
- Capping and molting
- Sticking and picking
- Laminating
- Double press
- Chipping

Test during and after manufacturing:

- Weight variation
- Hardness

- Dissolution time
- Friability testing
- Assay

Principles of capsule filling machines:

- Positioned all incoming capsules into upright position
- Separate cap and body of capsule shell
- Attained pre-determined volume
- Fill powder/granules/pallets in capsule shell body
- Remove excess material
- Rejoined cap and body of capsule shell
- Polishing of capsule shell
- Eject capsule from machine
- Packaging

Preparation for filling hard gelatin capsules: At large scale and small scale generally filling of capsule could be divided into following steps:

- Developing and preparing the formulation and selecting the capsule size
- Filling the capsule shells
- Capsule sealing (optional)
- Cleaning and polishing the filled capsules.

PART IC

Specific requirements for manufacture of oral liquids (syrups, elixirs, emulsions, and suspensions).

Oral liquids are homogeneous liquid preparations, usually contains a solution, an emulsion or a suspension of one or more active ingredients in a suitable liquid base. They are prepared for oral administration either as such or after dilution. They may contain other substances such as suitable dispersing, solubilizing, wetting, emulsifying, stabilizing, suspending, thickening agents and antimicrobial substances for preservation.

Building and Equipment

- The premises and equipment shall be designed, constructed and maintained to suit the manufacturing of oral liquids.

The layout and design of the manufacturing area shall strive to minimize the risk of cross-contamination and mix ups.

- Manufacturing area shall have entry through double door air-lock facility. It shall be made fly proof by use of flycatcher and/or 'air curtain'.
- The production area shall be cleaned and sanitized at the end of every production process. Tanks, containers, pipework and pumps shall be designed and installed so that they can be easily cleaned and sanitized. Equipment design shall be such as to prevent accumulation of residual microbial growth or cross-contamination.
- Stainless steel or any other appropriate material shall be used for parts of equipment coming in direct contact with the products. The use of glass apparatus shall be minimum.
- Arrangements for cleaning of containers, closures, and droppers shall be made with the help of suitable machines/devices equipped with high pressure air, water, and steam jets.
- The furniture used shall be smooth, washable and made of stainless steel or any other appropriate material which is scratch proof, washable and smooth.

Purified Water

The chemical and microbiological quality of purified water used shall be specified and monitored routinely. The microbiological evaluation shall include testing for the absence of pathogens and shall not exceed 100 CFU/ml (as per Appendix 12.5 of IP 1996).

Manufacturing

- Manufacturing personnel shall wear wherever required non-fiber shedding clothing to prevent contamination of the product.
- Materials likely to shed fiber-like gunny bags, or wooden pallets shall not be carried into the area, where products or cleaned-containers are exposed.
- Care shall be taken to maintain the homogeneity of the emulsion by use of appropriate emulsifier and suspensions by use of appropriate stirrer during filling. Mixing and filling

processes shall be specified and monitored. Special care shall be taken at the beginning of the filling process, after a stoppage due to any interruption and at the end of the process to ensure that the product is uniformly homogenous during the filling process.

- The primary packaging area shall have an air supply which is filtered through 5 µm filters. The temperature of the area shall not exceed 30°C.
- When the bulk product is not immediately packed, the maximum period of storage and storage conditions shall be specified in the master formula. The maximum period of storage time of a product in the bulk stage shall be validated.

PART ID

Specific requirements for manufacture of topical products, i.e. external preparations (creams, ointments, pastes, emulsions, lotions, solutions, dusting powders and identical products).

Note: The general requirements as given in Part I of this Schedule relating to requirements of good manufacturing practices for premises and materials for pharmaceutical products shall be complied with, mutatis mutandis, for the manufacture of topical products, i.e. external preparations (creams, ointments, pastes, emulsions, lotions, solutions, dusting powders and identical products used for external applications). In addition to these requirements, the following specific requirements shall also be followed, namely:

1. The entrance to the area where topical products are manufactured shall be through a suitable airlock. Outside the airlock, insectocutors shall be installed.
2. The air to this manufacturing area shall be filtered through at least 20 µm air filters and shall be air-conditioned.
3. The area shall be fitted with an exhaust system of suitable capacity to effectively remove vapors, fumes, smoke or floating dust particles.
4. The equipment used shall be designed and maintained to prevent the product from being accidentally contaminated with any foreign matter or lubricant.

5. Suitable cleaning equipment and material shall be used in the process of cleaning or drying the process equipment or accessories used.
6. Water used in compounding shall be purified water IP.
7. Powders, whenever used, shall be suitably sieved before use.
8. Heating vehicles and a base-like petroleum jelly shall be done in a separate mixing area in suitable stainless steel vessels, using steam, gas, electricity, solar energy, etc.
9. A separate packing section may be provided for primary packaging of the products.

PART IE

Specific requirements for manufacture of metered-dose inhalers (MDI)

Note: The general requirements as given in Part I of this Schedule relating to requirements of good manufacturing practices for premises and materials for pharmaceutical products shall be complied with, mutatis mutandis, for the manufacture of metered-dose inhalers (MDI). In addition to these requirements, the following specific requirements shall also be followed.

General

Manufacture of metered-dose inhalers shall be done under conditions which shall ensure minimum microbial and particulate contamination. Assurance of the quality of components and the bulk product is very important. Where medicaments are in suspended state, uniformity of suspension shall be established.

Building and Civil Works

- The building shall be located on a solid foundation to reduce risk of cracking walls and floor due to the movement of equipment and machinery.
- All building surfaces shall be impervious, smooth and non-shedding. Flooring shall be continuous and provided with a cover between the floor and the wall as well as between the wall and the ceiling. Ceiling shall be solid, continuous and preceded a cone with the walls. Light fittings and air-grills

shall be flush with the ceiling. All service lines requiring maintenance shall be erected in such a manner that these are accessible from outside the production area.

- The manufacturing area shall be segregated into change rooms for personnel, container preparation area, bulk preparation and filling area, quarantine area and spray testing and packing areas.
- Secondary change rooms shall be provided for operators to change from factory clothing to special departmental clothing before entering the manufacturing and filling area.
- Separate area shall be provided for de-cartooning of components before they are air washed.
- The propellants used for manufacture shall be delivered to the manufacturing area distribution system by filtering them through 2 μm filters. The bulk containers of propellants shall be stored, suitably identified, away from the manufacturing facilities.

Environmental Conditions

- Where products or clean components are exposed, the area shall be supplied with filtered air of Grade C.
- The requirements of temperature and humidity in the manufacturing area shall be decided depending on the type of product and propellants handled in the facility. Other support areas shall have comfort levels of temperature and humidity.
- There shall be a difference in room pressure between the manufacturing area and the support areas and the differential pressure shall be not less than 15 pascals (0.06 inches or 1.5 mm water gauge).
- There shall be a written schedule for the monitoring of environmental conditions. Temperature and humidity shall be monitored daily.

Garments

- Personnel in the manufacturing and filling section shall wear suitable single piece-garment made out of non-shedding, tight weave material. Personnel in support areas shall wear clean factory uniforms.

- Gloves made of suitable material having no interaction with the propellants shall be used by the operators in the manufacturing and filling areas. Preferably, disposable gloves shall be used.
- Suitable department-specific personnel protective equipment like footwear and safety glasses shall be used wherever hazard exists.

Sanitation

- There shall be written procedures for the sanitation of the MDI manufacturing facility. Special care should be taken to handle residues and rinses of propellants.
- Use of water for cleaning shall be restricted and controlled. Routinely used disinfectants are suitable for sanitizing the different areas. Records of sanitation shall be maintained.

Equipment

- Manufacturing equipment shall be of closed system. The vessels and supply lines shall be of stainless steel.
- Suitable check weights spray testing machines and labeling machines shall be provided in the department.
- All the equipment shall be suitably calibrated and their performance validated on receipt and thereafter periodically.

Manufacture

- There shall be an approved master formula records for the manufacture of metered-dose inhalers. All propellants, liquids and gases shall be filtered through 2 µm filters to remove particles.
- The primary packing material shall be appropriately cleaned by compressed air suitably filtered through 0.2 µm filter. The humidity of the compressed air shall be controlled as applicable.
- The valves shall be carefully handled and after de-cartoning, these shall be kept in clean, closed containers in the filling room.
- For suspensions, the bulk shall be kept stirred continuously.
- In-process controls shall include periodical checking of weight of bulk formulation filled in the containers. In a

two-shot-filling process (liquid filling followed by gaseous filling), it shall be ensured that 100% check on weight is carried out.

- Filled containers shall be quarantined for a suitable period established by the manufacturer to detect leaking containers prior to testing, labelling and packing.

Documentation

In addition to the routine good manufacturing practices documentation, manufacturing records shall show the following additional information:

1. Temperature and humidity in the manufacturing area.
2. Periodic filled weights of the formulation.
3. Records of rejections during online check weighing.
4. Records of rejection during spray testing.

PART IF

Specific requirements of premises, plant and materials for manufacture of active pharmaceutical ingredients (bulk drugs).

Note: The general requirements as given in Part I of this Schedule relating to requirements of good manufacturing practices for premises and materials for pharmaceutical products shall be complied with, mutatis mutandis, for the manufacture of active pharmaceutical ingredients (bulk drugs). In addition to these requirements, the following specific requirements shall also be followed.

Buildings and Civil Works

Apart from the building requirements contained in Part I, the active pharmaceutical ingredient facilities for manufacture of hazardous reactions, β-lactam antibiotics, steroids and steroidal hormones/cytotoxic substances shall be provided in confined areas to prevent contamination of the other drugs manufactured.

The final stage of preparation of a drug, like isolation/filtration/drying/milling/sieving and packing operations shall be provided with air filtration systems including pre-filters and finally with a 5 µm filter. Air handling systems with

adequate number of air changes per hour or any other suitable system to control the airborne contamination shall be provided. Humidity/temperature shall also be controlled for all the operations wherever required.

Air filtration systems including pre-filters and particulate matter retention air filters shall be used, where appropriate, for air supplies to production areas. If air is re-circulated to production areas, measures shall be taken to control recirculation of floating dust particles from production. In areas where air contamination occurs during production, there shall be adequate exhaust system to control contaminants.

Ancillary area shall be provided for boiler house. Utility areas like heat exchangers, chilling workshop, store and supply of gases shall also be provided.

For specified preparation like manufacture of sterile products and for certain antibiotics, sex hormones, cytotoxic and oncology products, separate enclosed areas shall be designed. The requirements for the sterile active pharmaceutical ingredient shall be in line with the facilities required for formulations to be filled aseptically.

Sterile Products

Sterile active pharmaceutical ingredient filled aseptically shall be treated as formulation from the stage wherever the process demands like crystallization, lyophilisation, filtration, etc. All conditions applicable to formulations that are required to be filled aseptically shall apply mutatis mutandis for the manufacture of sterile active pharmaceutical ingredients involving stages like filtration, crystallization and lyophilisation.

Utilities/Services

Equipment like chilling plant, boiler, heat exchangers, vacuum and gas storage vessels shall be serviced, cleaned, sanitized and maintained at appropriate intervals to prevent malfunctions or contamination that may interfere with safety, identity, strength, quality or purity of the drug product.

Equipment Design, Size and Location

Equipment used in the manufacture, processing, packing or holding of an active pharmaceutical ingredient shall be of

appropriate design, adequate size and suitably located to facilitate operations for its intended use and for its cleaning and maintenance.

If equipment is used for different intermediates and active pharmaceutical ingredients, proper cleaning before switching from one product to another becomes particularly important. If cleaning of a specific type of equipment is difficult, the equipment may need to be dedicated to a particular intermediate or active pharmaceutical ingredient.

The choice of cleaning methods, detergents and levels of cleaning shall be defined and justified. Selection of cleaning agents (e.g. solvents) should depend on:

a. The suitability of the cleaning agent to remove residues of raw materials, intermediates, precursors, degradation products and isomers, as appropriate.
b. Whether the cleaning agent leaves a residue itself;
c. Compatibility with equipment construction materials like centrifuge/filtration, dryer/fluid bed dryer, rotocone proton dryer, vacuum dryer, frit mill, multi-mill/jet mills/ sewetters cut sizing;
d. Test for absence of intermediate or active pharmaceutical ingredient in the final rinse.

Written procedures shall be established and followed for cleaning and maintenance of equipment, including utensils used in the manufacture, processing, packing or holding of active pharmaceutical ingredients. These procedures shall include but should not be limited to the following:

a. Assignment of responsibility for cleaning and maintaining equipment.
b. Maintenance and cleaning program schedules, including where appropriate, sanitizing schedules.
c. A complete description of the methods and materials used to clean and maintain equipment, including instructions for dis-assembling and reassembling each article of equipment to ensure proper cleaning and maintenance
d. Removal or obliteration of previous batch identification.
e. Protection of clean equipment from contamination prior to use.

f. Inspection of equipment for cleanliness immediately before use.
g. Establishing the maximum time that may elapse between completion of processing and equipment cleaning as well as between cleaning and equipment reuse.

Equipment shall be cleaned between successive batches to prevent contamination and carry-over of degraded material or contaminants unless otherwise established by validation.

As processing approaches the final purified active pharmaceutical ingredient, it is important to ensure that incidental carry over between batches does not have adverse impact on the established impurity profile. However, this does not generally hold good for any biological, active pharmaceutical ingredient where many of the processing steps are accomplished aseptically and where it is necessary to clean and sterilize equipment between batches.

In-process Controls

In-process controls for chemical reactions may include the following:

a. Reaction time or reaction completion;
b. Reaction mass appearance, clarity, completeness or pH solutions;
c. Reaction temperature;
d. Concentration of a reactant;
e. Assay or purity of the product;
f. Process completion check by TLC/any other means.

In-process controls for physical operations may include the following:

a. Appearance and color
b. Uniformity of the blend
c. Temperature of a process
d. Concentration of a solution
e. Processing rate or time
f. Particle size analysis
g. Bulk/tap density
h. pH determination
i. Moisture content.

Product Containers and Closures

- All containers and closures shall comply with the Pharmacopoeial or any other requirement, suitable sampling methods, sample sizes, specifications, test methods, cleaning procedures and sterilization procedures, when indicated, shall be used to assure that containers, closures and other component parts of drug packages are suitable and are not reactive, additive, adsorptive or leachable to an extent that significantly affects the quality or purity of the drug.
- The drug product container shall be re-tested or re-examined as appropriate and approved or rejected and shall be identified and controlled under a quarantine system designed to prevent their use in manufacturing or processing operations for which these are unsuitable.
- Container closure system shall provide adequate protection against foreseeable external factors in storage/transportation and use that may cause deterioration or contamination of the active pharmaceutical ingredient.
- Bulk containers and closures shall be cleaned and, where indicated by the nature of the active pharmaceutical ingredient, sterilized to ensure that they are suitable for their intended use.
- The container shall be conspicuously marked with the name of the product and the following additional information concerning:
  a. quality and standards, if specified;
  b. Manufacturing license number/drug master file number (whichever applicable), batch number;
  c. Date of manufacture and date of expiry;
  d. Method for container disposal (label shall give the methodology, if required);
  e. Storage conditions, if specified and name and address of the manufacturer, if available.

Areas for different operation of active pharmaceutical ingredients (bulk drugs) section shall have appropriate areas which may be suitably partitioned for different operations.

DETAIL STUDY OF SCHEDULE H AND H1

- These are drugs which cannot be purchased **over-the-counter** without the prescription of a qualified doctor.
- Another provision needs to be followed is that, only the required amount of medications mentioned in the prescription can be dispensed.
- It is a class of prescription drugs which cannot be purchased over-the-counter the present list included 536 drugs.

SCHEDULE H (*See* Rules 65 and 97) PRESCRIPTION DRUGS

1. Abacavir
2. Abciximab
3. Acamprosate calcium
4. Acebutol hydrochloride
5. Aclarubicin
6. Albendazole
7. Alclometasone dipropionate
8. Actilyse
9. Acyclovir
10. Adenosine
11. Adrenocorticotrophic hormone (ACTH)
12. Alendronate sodium
13. Allopurinol
14. Alphachymotrypsin
15. Alprazolam
16. Alprostadil
17. Amantadine hydrochloride
18. Amifostine
19. Amikacin sulphate
20. Amiloride hydrochloride
21. Amineptine
22. Aminoglutethimide
23. Aminosalicylic acid
24. Amiodarone hydrochloride
25. Amitriptyline
26. Amlodipine besylate
27. Amoscanate
28. Amoxopine
29. Amrinone lactate
30. Analgin
31. Androgenic anabolic, oestrogenic and progestational substances
32. Antibiotics
33. Apraclonidine
34. Aprotinin
35. Organic compound of arsenic
36. Arteether
37. Artemether
38. Artesunate
39. Articaine hydrochloride
40. Atenolol 2
41. Atracurium besylate injection
42. Atorvastatin
43. Auranofin
44. Azathioprine
45. Aztreonam
46. Bacampicillin
47. Baclofen
48. Balsalazide
49. Bambuterol
50. Barbituric acid
51. Basiliximab
52. Benazepril hydrochloride
53. Benidipine hydrochloride

54. Benserazide hydrochloride
55. Betahistine dihydrochloride
56. Bethanidine sulphate
57. Bezafibrate
58. Bicalutamide
59. Biclotymol
60. Bifonazole
61. Bimatoprost
62. Biperiden hydrochloride
63. Biphenyl acetic acid
64. Bitoscanate
65. Bleomycin
66. Primonidine tartrate
67. Bromhexine hydrochloride
68. Bromocriptine mesylate
69. Budesonide
70. Bulaquine
71. Bupivacaine hydrochloride
72. Bupropion
73. Buspirone
74. Butenafine hydrochloride
75. Butorphanol tartrate
76. Cabergoline
77. Calcium dobesilate
78. Candesartan
79. Capecitabine
80. Captopril
81. Carbidopa
82. Carbocisteine
83. Carboplatin
84. Carboquone
85. Carisoprodol
86. L-carnitine
87. Carteolol hydrochloride
88. Carvedilol
89. Cefadroxyl
90. Cefatoxime sodium
91. Cefazolin sodium
92. Cefdinir
93. Cefepime hydrochloride
94. Cefetamet pivoxil
95. Cefpirome
96. Cefpodoxime poxetil
97. Ceftazidime pentahydrate
98. Ceftizoxime sodium
99. Cefuroxime
100. Celecoxib
101. Centchroman
102. Centbutindole
103. Centpropazine
104. Cetirizine hydrochloride
105. Chlordiazepoxide
106. Chlormezanone
107. Omitted vide GSR 790 (E) dated 29.10.2009
108. Chlorpromazine
109. Chlorzoxazone
110. Ciclopirox olamine
111. Cimetidine
112. Cinnarizine
113. Ciprofloxacin hydrochloride monohydrate/lactate
114. Cisplatin
115. Citalopram hydrobromide
116. Clarithromycin
117. Clavulanic acid
118. Clidinium bromide
119. Clindamycin
120. Clobazam
121. Clobetasol propionate
122. Clobetasone 17-butyrate
123. Clofazimine
124. Clofibrate
125. Clonazepam
126. Clonidine hydrochloride
127. Clopamide
128. Clopidogrel bisulphate
129. Clostebol acetate
130. Clotrimazole

131. Clozapine
132. Codeine
133. Colchicine
134. Corticosteroids
135. Cotrimoxazole
136. Cyclandelate
137. Cyclosporins
138. Daclizumab
139. Danazole
140. Dapsone
141. Desloratadine
142. Desogestrol
143. Dexrazoxane
144. Dextranomer
145. Omitted vide GSR 790 (E) dated on 29.10.2009
146. Dextropropoxyphene
147. Diazepam
148. Diazoxide
149. Diclofenac sodium/potassium/ acid 3
150. Dicyclomin hydrochloride
151. Didanosine
152. Digoxin
153. Dilazep hydrochloride
154. Diltiazem
155. Dinoprostone
156. Diphenoxylate, its salts
157. Dipivefrin hydrochloride
158. Di-sodium pamidronate
159. Disopyramide
160. Docetaxel
161. Domperidone
162. Donepezil hydrochloride
163. Dopamine hydrochloride
164. Dothiepin hydrochloride
165. Doxapram hydrochloride
166. Doxazosin mesylate
167. Doxepin hydrochloride
168. Doxorubicin hydrochloride
169. Drotrecogin-alpha
170. Ebastine
171. Econozole
172. Efavirenz
173. Enalapril meleate
174. Enfenamic acid
175. Epinephrine
176. Epirubicine
177. Eptifibatide
178. Ergot, alkaloids of whether hydrogenated or not, their homologoues, salts
179. Esomeprazole
180. Estradiol succinate
181. Estramustine phosphate
182. Etanercept
183. Ethacridine lactate
184. Ethambutol hydrochloride
185. Ethamsylate
186. Ethinyloestradiol
187. Ethionamide
188. Etidronate disodium
189. Etodolac
190. Etomidate
191. Etoposide
192. Exemestane
193. Famciclovir
194. Famotidine
195. Fenbendazole
196. Fenofibrate
197. Fexofenadine
198. Finasteride
199. Flavoxate hydrochloride
200. 5-fluorouracil
201. Fludarabine
202. Flufenamic acids
203. Flunarizine hdrochloride
204. Fluoxetine hydrochloride
205. Flupenthixol

206. Fluphenazine enanthate and decanoate
207. Flurazepam
208. Flurbiprofen
209. Flutamide
210. Fluticasone propionate
211. Fluvoxamine maleate
212. Formestane
213. Fosfestril sodium
214. Fosinopril sodium
215. Fossphenytoin sodium
216. Fotemustine
217. Gabapentin
218. Galanthamine hydrobromide
219. Gallamine, its salts, its quaternary compound
220. Gancyclovir
221. Ganirelix
222. Gatifloxacin
223. Gemcitabine
224. Gemfibrozil
225. Gemtuzumab
226. Genodeoxycholic acid
227. Gliclazide
228. Glimepiride
229. Glucagon
230. Glycopyrrolate
231. Glydiazinamide
232. Goserelin acetate
233. Granisetron
234. Guanethidine
235. Gugulipid
236. Halogenated hydroxyquinolines
237. Haloperidol
238. Heparin
239. Hepatitis B vaccine
240. Hyaluronidase
241. Hydrocorisone 17-butyrate
242. Hydrotalcite
243. Hydroxizine
244. Ibuprofen
245. Idebenone
246. Indapamide
247. Imipramine
248. Indinavir sulphate
249. Indomethacin
250. Insulin human
251. Interferon
252. Intravenous fat emulsion
253. Iobitridol
254. Iohexol
255. Iopamidol 4
256. Iomeprol
257. Iopromide
258. Irbesartan
259. Irinotecan hydrochloride
260. Iron preparation for parenteral use
261. Isepamicine
262. Isocarboxazid
263. Isoflurane
264. Isonicotinic acid hydrazine and other hydragine derivatives of isonicotinic acid
265. Isosorbide dinitrate/ mononitrate
266. Isotretinoin
267. Isoxsuprine
268. Itopride
269. Ketamine hydrochloride
270. Ketoconazole
271. Ketoprofen
272. Ketorolac tromethamine
273. Labetalol hydrochloride
274. Lacidipine
275. Lamivudine
276. Lamotrigine
277. Latanoprost
278. Lefunomide

279. Lercanidipine hydrochloride
280. Letrozole
281. Leuprolide acetate
282. Levamisole
283. Levarterenol
284. Levobunolol
285. Levocetirizine
286. Levodopa
287. Levofloxacin
288. Levovist
289. Lidoflazine
290. Linezolid
291. Lithium carbonate
292. Lofepramine decanoate
293. Loperamide
294. Lorazepam
295. Losartan potassium
296. Loteprednol
297. Lovastatin
298. Loxapine
299. Mebendazole
300. Mebeverine hydrochloride
301. Medroxyprogesterone acetate
302. Mefenamic acid
303. Mefloquine hydrochloride
304. Megestrol acetate
305. Meglumine iocarmate
306. Melagenina
307. Melitracen hydrochloride
308. Meloxicam
309. Mephenesin, its esters
310. Mephentermine
311. Meropenem
312. Mesterolone
313. Metaxalone
314. Methicillin sodium
315. Methocarbamol
316. Methotrexate
317. Metoclopramide
318. Metoprolol tartrate
319. Metrizamide
320. Metronidazole
321. Mexiletine hydrochloride
322. Mianserin hydrochloride
323. Miconazole
324. Midazolam
325. Mifepristone
326. Milrinone lactate
327. Miltefosine
328. Minocycline
329. Minoxidil
330. Mirtazapine
331. Misoprostol
332. Mitoxantrone hydrochloride
333. Mizolastine
334. Moclobemide
335. Mometasone furoate
336. Montelukast sodium
337. Morphazinamide hydrochloride
338. Mosapride
339. Moxifloxacin
340. Mycophenolate mofetil
341. Nadifloxacin
342. Nadolol
343. Nafarelin acetate
344. Nalidixic acid
345. Naproxen
346. Narcotic drugs listed in Narcotic Drugs and Psychotropic Substances Act, 1985
347. Natamycin
348. Nateglinide
349. N-butyl-2-cyanoacrylate
350. Nebivolol
351. Nebumetone
352. Nelfinavir mesylate
353. Netilmicin sulphate
354. Nevirapine
355. Nicergoline
356. Nicorandil

357. Nifedipine
358. Nimesulide
359. Nimustine hydrochloride
360. Nitrazepam 5
361. Nitroglycerin
362. Norethisterone enanthate
363. Norfloxacin
364. Octylonium bromide
365. Ofloxacin
366. Olanzapine
367. Omeprazole
368. Ornidazole
369. Orphenadrine
370. Orthoclone sterile
371. Oxazepam
372. Oxazolidine
373. Oxcarbazepine
374. Oxethazaine hydrochloride
375. Oxiconazole
376. Oxolinic acid
377. Oxprenolol hydrochloride
378. Oxybutynin chloride
379. Oxyfedrine
380. Oxymetazoline
381. Oxyphenbutazone
382. Oxytocin
383. Ozothine
384. Paclitaxel
385. Pancuronium bromide
386. Pantoprazole
387. Para-aminobenzene sulphonamide, its salts and derivatives
388. Parp-aminosalicylic acid, its salts, and derivatives
389. Parecoxib
390. Paroxetine hydrochloride
391. D-penicillamine
392. Pentazocine
393. Pentoxifylline
394. Pepleomycin
395. Phenelzine sulphate
396. Phenobarbital
397. Phenothiazine, its salts and derivatives
398. Phenylbutazone
399. Pimozide
400. Pindolol
401. Pioglitazone hydrochloride
402. Piracetam
403. Piroxicam
404. Pituitary gland, active principles of, not otherwise specified in this schedule and their salts
405. Polidocanol
406. Polyestradiol phosphate
407. Poractant alpha
408. Praziquantel
409. Prednimustine
410. Prednisolone stearoylglycolate
411. Prenoxdiazine hydrochloride
412. Promazine hydrochloride
413. Promegestone
414. Propafenon hydrochloride
415. Propanolol hydrochloride
416. Propofol
417. Protriptyline hydrochloride
418. Pyrazinamide
419. Pyrvinium
420. Quetiapine fumerate
421. Quinapril
422. Quinidine sulphate
423. Rabeprazole
424. Racecadotril
425. Raloxifene hydrochloride
426. Ramipril hydrochloride
427. Ranitidine
428. Rauwolfia, alkaloids of, their salts, derivatives of the alkaloids or Rauwolfia

429. Reboxetine
430. Repaglinide
431. Reproterol hydrochloride
432. Rilmenidine
433. Riluzone
434. Risperidone
435. Ritonavir
436. Ritodrine hydrochloride
437. Rituximab
438. Rivastigmine
439. Rocuronium bromide
440. Ropinirole
441. Rosoxacin
442. Rosiglitazone meleate
443. Salbutamol sulphate
444. Salicyl-azo-sulphapyridine
445. Salmon calcitonin
446. Saquinavir
447. Satranidazole
448. Secnidazole
449. Septopal beads and chains
450. Serratiopeptidase
451. Sertraline hydrochloride
452. Sibutramine hydrochloride
453. Sildenafil citrate
454. Simvastatin
455. Sirolimus
456. Sisomicin sulphate
457. S-neominophagen
458. Sodium picosulphate
459. Sodium cromoglycate
460. Sodium hyaluronate
461. Sodium valproate
462. Sodium and maglumine iothalamates
463. Somatostatin 6
464. Somatotropin
465. Sotalol
466. Sparfloxacin
467. Spectinomycin hydrochloride
468. Spironolactone
469. Stavudine
470. Sucralfate
471. Sulphadoxine
472. Sulphamethoxine
473. Sulphamethoxypyridazine
474. Sulphaphenazole
475. Sulpiride
476. Sulprostone hydrochloride
477. Sumatriptan
478. Tacrine hydrochloride
479. Tamsulosin hydrochloride
480. Trapidil
481. Tegaserod maleate
482. Teicoplanin
483. Telmisartan
484. Temozolamide
485. Terazosin
486. Terbutaline sulphate
487. Terfenadine
488. Terizidone
489. Terlipressin
490. Testosterone undecanoate
491. Teratolol hydrochloride
492. Thalidomide
493. Thiacetazone
494. Thiocolchicoside
495. Thiopropazate, its salts
496. Thymogene
497. Thymosin-alpha 1
498. Tiaprofenic acid
499. Tibolone
500. Timolol maleate
501. Tinidazole
502. Tizanidine
503. Tobramycin
504. Tolfenamic acid
505. Topiramate
506. Topotecan hydrochloride
507. Tramadol hydrochloride

508. Tranexamic acid
509. Tranylcypromine, its salts
510. Trazodone
511. Tretinoin
512. Trifluperazine
513. Trifluperidol hydrochloride
514. Triflusal
515. Trimetazidine dihydrochloride
516. Trimipramine
517. Tripotassium dicitrato bismuthate
518. Tromantadine hydrochloride
519. Urokinase
520. Valsartan
521. Vasopressin
522. Vecuronium bromide
523. Venlafaxine hydrochloride
524. Verapamil hydrochloride
525. Verteporfin
526. Vincristine sulphate
527. Vinblastine sulphate
528. Vindesine sulphate
529. Vinorelbine tartrate
530. Xipamide
531. Zidovudine hydrochloride
532. Ziprasidone hydrochloride
533. Zoledronic acid
534. Zolpidem
535. Zopiclone
536. Zuclopenthixol

Schedule H1

- The schedule H1 drugs were mainly allocated to restrict the selling of antibiotics through over-the-counter (OTC) sales, after it was noted that any number of these drugs could be bought from pharmacies across India without any limitations.
- Irrational prescribing of antibiotics and other drugs by doctors and chemists lacking a registered pharmacist has contributed to the increasing antibiotics resistance and tolerance of psychotropic. In response to these serious issues, antibiotic forums, scientific meetings and symposiums were conducted by medical fraternity and various educational institutions.
- As a result, the Government of India issued a gazette notification, GSR 588 (E) dated on 30. 08. 2013 regarding Schedule H1 drugs which show the importance of this Schedule.
- The Schedule H1 drug includes 3rd and 4th generation antibiotics, antituberculosis drugs and certain habit-forming drugs like psychotropic drugs.
- To dispense these drugs two main criteria have to be followed strictly.

- The drug supplied under the Schedule H1 specification should be recorded in a **separate register at the time of supply, mentioning the name and address of the prescriber, name of the patient, and the name of the drug along with the quantity supplied.** This register has to be maintained confidentially up to three years and should be open for inspection.
- The Schedule H1 drugs should be labeled with the **symbol Rx in red**, clearly displayed on the left top corner of the drug label. The label should also bear the following words in a box with a red border.
- The Schedule H1 drug list, however, shows no limitation of using the drugs as topical or for external use such as in ophthalmic, ear or nose preparations.
- It is a known fact that a gazette notification alone will not help. Apart from this several measures have to be executed by the respective authorities at all levels.
- Alprazolam, balofloxacin, buprenorphine, capreomycin, cefdinir, cefditoren, cefepime, cefetamet, cefexime, cefoperazone, ceftizoxime, ceftriaxone, chlordiazepoxide, clofazimine, codeine, diphenoxylate, nitrazepam, pentazocine, prulifloxacin, pyrazinamide, ribabutin, rifampicin, tramadol, zolpidem.

DETAIL STUDY OF SCHEDULE T

GOOD MANUFACTURING PRACTICES FOR AYURVEDIC, SIDDHA AND UNANI MEDICINES

- Raw materials used in the manufacture of drugs are authentic, of prescribed quality and are free from contamination.
- The manufacturing process is as has been prescribed to maintain the standards.
- Adequate quality control measures are adopted.
- The manufactured drug which is released for sale is of acceptable quality.
- To achieve the objectives above each licensee shall evolve methodology and procedures for following the prescribed

process of manufacture of drugs which should be documented as a manual and kept for reference and inspection.

DETAIL STUDY OF SCHEDULE G

- The Drugs and Cosmetics Rules, 1945 contains provisions for classification of drugs under given schedules and there are guidelines for the storage, sale, display and prescription of each schedule.
- The Rule 67 details the conditions of licenses. The Rule 97 contains the labeling regulations.
- List of substances included in Schedule G is as below:
- Aminopterin
- L-Asparaginase
- Bleomycin
- Busulphan; its salts
- Carbutamide
- Chlorambucil; its salts
- Chlorothiazide and other derivatives of 1, 2, 4-benzothiadiazine
- Chlorpropamide; its salts
- Chlorthalidone and other derivatives of chlorobenzene compound.
- Cisplatin
- Cyclophosphamide; its salts
- Cytarabine
- Daunorubicin
- Di-isopropyl fluorophosphate
- Disodium stilboestrol diphosphate
- Doxorubicin hydrochloride
- Ethacrynic acid; its salts
- Ethosuximide
- Glibenclamide
- Hydantoin; its salts; its derivatives, their salts
- Hydroxyurea
- Insulin: all types
- Lomustine hydrochloride
- Mercaptopurine; its salts
- Metformin; its salts

- Methsuximide
- Mustine; its salts
- Paramethadione
- Phenacemide
- Phenformin; its salts
- 5-Phenylhydantoin; its alkyl and aryl derivatives; its salts
- Primadone
- Procarbazine hydrochloride
- Quinethazone
- Sarcolysine
- Sodium-2-mercaptoethanesulfonate, tamoxifen citrate
- Testolactone
- Thiotepa
- Tolbutamide
- Tretamine; its salts
- Troxidone

Antihistaminic Substances and Salts of their Derivatives

- Antazoline
- Bromodiphenhydramine
- Buclizine
- Chlorcyclizine
- Chlorpheniramine
- Clemizole
- Cyproheptadine
- Diphenhydramine
- Diphenylpyraline

DETAIL STUDY OF SCHEDULE N

List of minimum equipment for the efficient running of a pharmacy.

Entrance

The front of a pharmacy shall bear an inscription "Pharmacy" in front.

Premises

- The premises of a pharmacy shall be separated from rooms for private use. The premises shall be well built, dry, well lit and ventilated and of sufficient dimensions to allow the goods in stock especially medicaments and poisons to be kept in a clearly visible and appropriate manner.
- The area of the section to be used as dispensing department shall be not less than 6 square meters for one pharmacist working therein with additional 2 square meters for each additional pharmacist. The height of the premises shall be at least 2.5 meters.
- The floor of the pharmacy shall be smooth and washable. The walls shall be plastered or tiled or oil painted so as to maintain smooth, durable and washable surface devoid of holes, cracks and crevices.
- A pharmacy shall be provided with ample supply of good quality water.
- The dispensing department shall be separated by a barrier to prevent the admission of the public.

Furniture and Apparatus

- The furniture and apparatus of a pharmacy shall be adapted to the uses for which they are intended and correspond to the size and requirements of the establishment.
- Drugs, chemicals, and medicaments shall be kept in a room appropriate to their properties and in such special containers as will prevent any deterioration of the contents or of contents of containers kept near them. Drawers, glasses and other containers used for keeping medicaments shall be of suitable size and capable of being closed tightly to prevent the entry of dust.
- Every container shall bear a label of appropriate size, easily readable with names of medicaments as given in the pharmacopoeias.
- A pharmacy shall be provided with a dispensing bench, the top of which shall be covered with washable and impervious material like stainless steel, laminated or plastic, etc.
- A pharmacy shall be provided with a cupboard with lock and key for the storage of poisons and shall be

clearly marked with the work 'poison' in red letters on a white background.

- Containers of all concentrated solution shall bear special label or marked with the works "To be diluted".

A pharmacy shall be provided with the following minimum apparatus and books necessary for making of official preparations and prescriptions.

Apparatus

- Balance, dispensing, sensitivity 30 mg.
- Balance, counter, capacity 3 kg, sensitivity 1 gm.
- Beakers, lipped, assorted sizes
- Bottles, prescription, ungraduated assorted sizes
- Corks assorted sizes and tapers.
- Cork, extractor
- Evaporating dishes, porcelain.
- Filter paper
- Funnels, glass
- Litmus paper, blue and red
- Measure glasses cylindrical 10 ml, 25 ml, 100 ml and 500 ml
- Mortars and pestles, glass
- Mortars and pestles, Wedgwood.
- Ointment pots with bakelite or suitable caps.
- Ointment slab, porcelain
- Pipettes, graduated, 2 ml, 5 ml and 10 ml
- Ring, stand (retort) iron, complete with rings.
- Rubber stamps and pad
- Scissors
- Spatulas, rubber or vulcanite
- Spatulas, stainless steel.
- Spirit lamp
- Glass stirring rods
- Thermometer, 0°C to 200°C
- Tripod stand
- Watch glasses
- Water bath
- Water distillation still in case eye drops and eye lotions are prepared.

- Weights, metric, 1 mg to 100 gm
- Wire gauze
- Pill finisher, boxwood
- Pill machine
- Pill boxes
- Suppository mould

Books

- The Indian Pharmacopoeia (Current Edition)
- National Formulary of India (Current Edition)
- The Drugs and Cosmetics Act, 1940
- The Drugs and Cosmetics Rules, 1945
- The Pharmacy Act, 1948
- The Dangerous Drugs Act, 1930

General Provisions

- A pharmacy shall be conducted under the continuous personal supervision of a registered pharmacist whose name shall be displayed conspicuously in the premises.
- The pharmacist shall always put on clean white overalls.
- The premises and fittings of the pharmacy shall be properly kept and everything shall be in good order and clean.
- All records and registers shall be maintained in accordance with the laws in force.
- Any container taken from the poison cupboard shall be replaced therein immediately after use and the cupboard locked. The keys of the poison cupboard shall be kept in the personal custody of the responsible person.
- Medicaments when supplied shall have labels conforming to the provisions of laws in force.

DETAIL STUDY OF SCHEDULE P

The life period of drugs and the storage conditions of drugs are covered in this Schedule. Between the date of production and the date of expiry, the duration should be measured in months.

Table 1.5: Life period of drug

Drugs	*Drugs life period (months)*	*Drugs storage*
Ampicillin trihydrate	30	In a cool place
Ampicillin sodium	36	In a cool place
Adriamycin	30	In a cool place
Ampicillin	36	In a cool place
Colistin sulphate	60	Protected from light
Nystatin	36	At temp not exceeding 5ºC
Penicillin tablet	18	In a cool place

Schedule P1

The pack size of drugs is specified in this schedule. It lists the medication names, as well as the dose type and pack size. Other than the pack sizes mentioned in this schedule, no other pack sizes should be noted.

Table 1.6: Pack sizes of drug

Drugs	*Dosage forms*	*Pack size*
Aspirin (low dose)	Tablets	14 tabs
Albendazole	Suspension	10 ml
Atenolol	Tablet	14 tabs
Catalin	Ophthalmic drops	15 ml
Ciclopirox olamine	Vaginal cream	30 gm
Haloperidol	Oral solution	15 ml
Isoniazid	Syrup	200 ml

DETAIL STUDY OF SCHEDULE U

The particulars to be shown in the manufacturing record, record of raw material and analytical record of drug.

Substances other than Parenteral in Preparations in General

1. Serial number.
2. Name of the product.

3. Reference of master formula records.
4. Lot/batch size.
5. Lot/batch number.
6. Date of commencement of manufacture and date of completion of manufacture and the assigned date of expiry.
7. Name of all ingredients, specifications and quantities required for the lot/batch size and quantities actually used. All weighing and measurements shall be carried out by a responsible person and initiated by him and shall be counter-checked and signed by the competent technical staff under whose personal supervision the ingredients are used for manufacture.
8. Control numbers of raw materials used in the formulations.
9. Date, time and duration of mixing.
10. Details of environmental controls like room temperature, relative humidity.
11. Date of granulation, wherever applicable.
12. Theoretical weight and actual weight of granules/powder blend.
13. Records of in-processes controls (periodically whenever necessary).
    a. Uniformity of mixing.
    b. Moisture content of granules/powder in case of tablet/capsules.
    c. pH of solution in case of liquid.
    d. Weight variation.
    e. Disintegration time.
    f. Hardness.
    g. Friability test
    h. Leak test in case of strip packing.
    i. Filled volume of liquids.
    j. Quantity of tablets/capsules in the final container.
    k. Content of ointment in the filled containers.
14. Date of compression in case of tablets/date of filling in case of capsules.
15. Date of sealing/coating/polishing in case of capsules/tablets wherever applicable.

16. Reference to analytical report number stating the result of test and analysis.
17. Separate records of the disposal of the rejected batches and of batches withdrawn from the market.
18. The theoretical yield and actual productions yield and packing particulars indications the size and quantity of finished packing.
19. Specimen of label/strip, carton with batch coding information like batch number, date of manufacturing, date of expiry, retail price as applicable, stamped thereon and inserts used in the finished packing.
20. Signature with date of competent technical staff responsible for the manufacture.
21. Counter-signature of the head of the testing units or other approved person in-charge of testing for having verified the batch records and for having released the batch for sale and distribution, the quantity released and date of release.
22. Date of release of finished packing and quantity released for sale and distribution.
23. Quantity transferred to warehouse.
24. For 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.

Parenteral Preparations

1. Serial number
2. Name of the product
3. Reference of the master formula record
4. Batch/lot size.
5. Batch no. and/or lot no.
6. Date of commencement of manufacture and date of completion.
7. Name of all ingredients, specifications and quantity required for the lot/batch size and quantity actually used. All weighing and measurements shall be carried out by a

responsible person and initialed by him and shall be counter-signed by the technical staff under whose personal supervision the stocks are issued and by another competent technical staff under whose supervision the ingredients are used for manufacture.

8. Control numbers of raw materials used in the formulation.
9. Date, time and duration of mixing.
10. Details of environmental controls like temperature, humidity, microbial count in the sterile working areas.
11. pH of the solution, wherever applicable.
12. Date and method of filtration.
13. Sterility test, reference on bulk batch wherever applicable.
14. Record of check on volume filled.
15. Date of filling.
16. Records of tests employed: (a) to ensure that sealed ampoules are leak-proof. (b) To check the presence of foreign particles. (c) Pyrogen test, wherever applicable. (d) Toxicity tests wherever applicable.
17. Records of checking of instruments and apparatus of sterilization (indicators).
18. Records of cleaning and sterilization of containers and closure, if necessary, sterilized including particulars of time, temperature and pressure employed. Such records should be marked to relate to the sterilized.
19. Number and size of containers filled and quantity rejected.
20. The theoretical yield and actual yield and the percentage yield thereof.
21. Reference of analytical report numbers stating whether of standard quality or otherwise.
22. Specimen of labels, cartons, etc. with batch coding information like batch number, date of manufacture, date of expiry, as applicable, stamped thereon, and inserts used in the finished packings.
23. Signature with date of the component technical staff responsible for manufacture.
24. Particulars regarding the precautions taken during the manufacture to ensure that aseptic conditions are maintained.

25. Counter-signature of head of the testing unit or person in-charge of testing for having verified the documents and for having released the product for sale and distribution, the quantity released and date of release.
26. Records for having transferred to warehouse giving packings and quantities.
27. Separate records of the disposal of the rejected batches and of all batches withdrawn from the market.
28. Records of reprocessing if any and particulars of reprocessing.

Records of Raw Materials

Records in respect of each raw material shall be maintained indicating the date of receipt, invoice number, name and address of manufacturer/supplier, batch number, quantity received, pack size, date of manufacture, date of expiry, if any, date of analysis and release/rejection by quality control, analytical report number, with special remarks, if any quantity issued, date of issue and the particulars of the name and batch numbers of products for the manufacture of which issued and the proper disposal of the stocks.

Tablets and capsules

1. Analytical report number.
2. Name of the sample.
3. Date of receipt of sample.
4. Batch/lot 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.
6. Signature of the analyst.
7. Opinion and signature of the approved analyst.

Parenteral preparations

1. Analytical report number.
2. Name of the sample.
3. Batch number.
4. Date of receipt of samples.
5. Number of containers filled.
6. Number of containers received.
7. Protocols of tests applied.
   a. Clarity.
   b. pH wherever applicable.
   c. Identification.
   d. Volume in container.
   e. Sterility:
      i. Bulk sample wherever applicable
      ii. Container sample.
   f. Pyrogen test, wherever applicable.
   g. Toxicity test, wherever applicable.
   h. Any other tests.
   i. Results of assay.
8. Signature of the analyst.
9. Opinion and signature if the approved analyst.

Pyrogen test

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.
5. Strength and volume of the drugs injected.
6. Date of injection.
7. Results and remarks.
8. Signature of analyst.
9. Opinion and signature of the approved analyst.

For other drugs

1. Analytical report number.
2. Name of the sample.
3. Batch/lot number.
4. Date of receipt of sample.
5. Protocol of tests applied.
   a. Description.
   b. Identification.
   c. Any other tests.
   d. Results of assay.
6. Signature of the analyst.
7. Opinion and signature of the approved analyst.

Raw materials

1. Serial number.
2. Name of the materials.
3. Name of the manufacturer/supplier.
4. Quantity received.
5. Invoice/challan number and date.
6. Protocols of tests applied.

Container, packing materials, 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.
7. Remarks.
8. Signature of the examiner.

DETAIL STUDY OF SCHEDULE V

Patent or proprietary medicines containing vitamins intended for prophylactic, therapeutic or pediatric use shall bear on label the words "For Prophylactic Use", "For Therapeutic Use" or "For Pediatric Use" as the case may be. In the cases of pediatric preparations the age of the infant or the child for whose use it is intended, shall be given in addition to the particulars required to be given under these rules.

Tablets

Medicines should fulfill the needs for tablets as given in the IP. The nature of coating and the permitted colors should be added on the label. Nature of tablets (uncoated, sugar coated, or film coated) should be given on the label.

Capsules

Medicines should fulfill the requirements for capsules as given in the IP. The capsules should be free from distortion, discoloration, and other physical defects such as leakage of powder from joints, pinholes or cracks.

Liquid Oral Dosage Forms

On shaking, emulsions and suspensions should disperse. Homogeneous solutions should have no sediments. Net content of the product in the container should not be less than the volume mentioned on the label. The ethanol content of pharmaceutical products should be between 90 and 110% of the labelled contents.

Injections

Medicines should fulfill the needs for injections as given in the IP.

Ointments

Medicines should fulfill the needs for ointments as given in the IP.

- The content of active ingredients, other than vitamins, enzymes, and antibiotics, should be between 90 and 110% of the labelled content. In dry formulations of antibiotics, the limit should be 90–130% of the labelled contents. In liquid antibiotics, the limit should be 90–140% of the labelled contents.
- All patent or proprietary medicines having aspirin should undergo free salicylic acid test, the limit of which should be 0.75%.
- Patent or proprietary medicines to be tested under the provisions of rule 121 A for pyrogen should be tested by injecting into rabbits in doses not below to that for the humans depending on the body weight of a 60 kg human.
- In injectable patent or proprietary medicines, the test for freedom from toxicity should be conducted as given in the IP.

DETAIL STUDY OF SCHEDULE X

Schedule X is a class of prescription drugs in **India** appearing as an appendix to the **Drugs and Cosmetics Rules** introduced in 1945. These are drugs which cannot be purchased over-the-counter without the prescription of a qualified doctor. Also, the retailer has to preserve the **prescription** for a period of two years.

Table 1.7: The list of Schedule X drugs

Amobarbital	*Methylphenobarbital*
Amphetamine	Cyclobarbital
Methylphenidate	Pentobarbital
Barbital	Dexamphetamine
Ketamine	Phenmetrazine
Phencyclidine	Glutethimide
Methamphetamine	Meprobamate

DETAIL STUDY OF SCHEDULE Y

Requirements and guidelines for permission to import and/or manufacture of new drugs for sale or to undertake clinical trials.

Table 1.8: List of licenses for permission

Rule	*Permission for*
122 A	To **import new drug**
122 B	To **manufacture new drug**
122 D	To import or manufacturing **fixed dose combination**
122 DA	To conduct **clinical trials for new drug/investigation of new drug**
122 DAA	Definition of **clinical trails**
122 E	Definition of **new drug**

Requirements and Guidelines on Clinical Trials for Import and Manufacture of New Drug

1. Application for permission
2. Clinical trial
3. Studies in special population
4. Post-marketing surveillance
5. Special studies: BA/BE studies

Application for Permission

It shall made in **Form 44** accompanied with following data in accordance with appendices, namely:

- Chemical and pharmaceutical information
- Animal pharmacology data
- Animal toxicology data
- Human clinical pharmacology data
- Regulatory status in other countries
- Prescribing information
- Form 12 to import study drug for examination, test or analysis.

Clinical Trial

Approval for Clinical Trials

CT on a new drug shall be initiated only after permission by licensing authority and approval from EC.

Responsibilities of Sponsor

- Implementing and maintaining QA
- Submit status report to the licensing authority periodically
- SAE should be reported to the licensing authority within 14 calendar days.

Responsibilities of Investigator

- Ensure adequate medical care is provided to the subject.
- SAE and unexpected AE should be reported to the sponsor within 24 hours and to the EC within 7 working days.

Informed Consent

- Freely given informed written consent
- Provide information about the study verbally
- Non-technical and understandable language.

Responsibilities of Ethics Committee

- Approval trial protocol to safeguard RSW of all trial subjects and to protect RSW of all vulnerable subjects
- Conduct ongoing review of the trials.

Human Pharmacology (Phase I)

Safety and tolerability—objective.

Therapeutic Exploratory Trials (Phase II)

- To evaluate the effectiveness of a drug for particular indication
- To determine the short-term side effects and risk associated with the drug
- To determine the dose and regimen for phase III trials.

Therapeutic Confirmatory Trials (Phase III)

- Demonstration of therapeutic benefit
- Drug is safe and effective for use and provides an adequate basis for marketing approval.

Post-marketing Trials (IV)

- Performed after drug approval and related to the approved indication.
- Includes drug–drug interaction, dose-response or safety studies, mortality/morbidity studies.

Studies in Special Population

- Geriatrics
- Pediatrics
- Pregnant or nursing women.

Post-marketing Surveillance

- Closely monitored new drugs clinical safety
- PSUR—to report all relevant new information
- PSUR shall be submitted every 6 months for the first 2 years.

Special Studies: BA/BE Studies

- Conducted according to the guidelines for BA and BE studies.
- Evaluation of the effect of food on absorption of following oral administration.

SALE OF DRUG

- Drugs and Cosmetics Act and the Rules made thereunder restrict the sale of drug only by license. That is only licensed person are eligible to sell the drug by wholesale or retail and to compound or dispense the drug.
- The license can be obtained from licensing is required for different types of sale drug like wholesale, retail, motor vehicle or vendor sale.

- If drugs are sold or stocked for sale at more than one place, separate licenses are to be obtained in respect of each such place.

Retail Sale

For retail sale, two types of licenses are issued:

i. General licenses

ii. Restricted licenses

Restricted License

Granted to those dealers who do not engage the services of a qualified person and only deal with such classes of drugs whose sales can be affected without qualified person and vendors who do not have fixed premises.

Wholesale of Biological (C/C1)

- Adequate premises, with **greater than 10 meter area**, with proper storage facility**.**
- Drugs sold **only to retailer having license.**
- Premises should be in-charge of competent person who is **registered pharmacist**.
- **Records** of purchase and sale.
- Records preserved for 3 years from date of sale.
- License should **display on premises.**

Wholesale from other than Specified in C/C1 and X

- All the conditions as discussed in for biological.
- Compounding is made by or under the direct and personal **supervision of a qualified person.**

Classes of Drugs Prohibited to be Sale

- Misbranded, spurious, adulterated and drugs not of standard quality
- Patent/proprietary drugs with undisclosed formula
- Expired drugs.

- Drugs used for consumption by government schemes such as, Armed Forces.
- Physician's samples.

Supply of Schedule C Drug

- Serial number of the entry
- Date of supply and date of expiry
- Name and address of the purchaser
- Name and quantity of drug supplied
- Name of the manufacturer
- Batch number of the drug supplied
- Signature of the qualified person

Supply of Schedule H Drug

- Schedule H drug should be sold against the prescription of registered medical practitioner.
- They should not be dispensed more than once, unless mentioned in the prescription.
- Date of supply and opening and closing stocks of drug on that day and relevant bill numbers.
- Name of drug, its manufacturer and batch number.
- Name and address of purchaser.
- Date of prescription, name and address of the registered medical practitioner.
- Signature of the qualified person.

Supply of Schedule X Drug

- Schedule X drug shall be kept in a separate cupboard under lock and key.
- Schedule X drug is supplied only against the prescription of registered medical practitioner in duplicate, one copy of which is retained by the licensee and preserved for two years.
- Date of purchase/transaction.
- Quantity received, name, address, and license number of the supplier.
- Batch no. or lot no.

Offences and Penalties

Table 1.9: Offences and penalties in the sale of drug

Offences	*Penalties*
Anyone sell, stocks, exhibits for sale or distribute any misbranded or adulterated or spurious drug without proper license	Less than **one year** but may extend up to **10 years imprisonment. First conviction 2 to 10 years** with fine on **subsequent convictions**
Anyone who sells, exhibits for sale or distributes any drug in contravention of the Act and Rules	**5 years** imprisonment and **₹ 2000 fine** or both on **first conviction** **10 years** imprisonment and **₹ 5000** fine or both for **subsequent conviction**

LABELING AND PACKING OF DRUGS

Drugs

- Articles intended for use in diagnosis, cure, mitigation, treatment, or prevention of disease
- Articles (other than food) intended to affect the structure or function of the body; and
- Articles intended for use as components in any of the above.

Types of Drugs

Over-the-counter (OTC) or Nonprescription Drugs

Examples: Aspirin, acetaminophen, cough medicine.

Prescription Drugs

Examples: Blood pressure medicines, blood thinners, antibiotics, eye drops.

For all medicines, you must read and follow the directions!

Labeling

- Labeling has been defined to include the display of written material.
- On the immediate container of a drug presenting vital prescription information.

- Any printed matter on a drug's containers or wrappers, and
- Any promotional or other material "accompanying such article."
- Classified as labeling are brochures, mailing pieces, detailing pieces.
- Literature reprints, reference publications containing manufacturer supplied data, and similar literature disseminated to physicians.

Prescription Label

- Patient name and address
- Prescriber's name
- Drug name

Drug Facts

Active ingredients (in each tablet) ***Purpose***
Chlorpheniramine maleate 2 mg ..... Antihistamine

Uses Temporarily relieves these symptoms due to hay fever or other upper respiratory allergies:
■ Sneezing ■ Runny nose ■ Itchy, watery eyes ■ Itchy throat

Warnings
Ask a doctor before use if you have
■ Glaucoma ■ A breathing problem such as emphysema or chronic bronchitis
■ Trouble urinating due to an enlarged prostate gland

Ask a doctor or pharmacist before use if you are taking tranquilizers or sedatives

When using this product
■ You may get drowsy ■ Avoid alcoholic drinks
■ Alcohol, sedatives, and tranquilizers may increase drowsiness
■ Be careful when driving a motor vehicle or operating machinery
■ Excitability may occur, especially in children

If pregnant or breastfeeding, ask a health professional before use.
Keee out of reach of children. In case of overdose, get medical help or contact a Poison Control Center right away.

Directions

Adults and children 12 years and over	Take 2 tablets every 4 to 6 hours; not more than 12 tablets in 24 hours
Children 6 years to under 12 years	Take 1 tablet every 4 to 6 hours; not more than 6 tablets in 24 hours
Children under 6 years	Ask a doctor

Other information: Store at 20–25°C (68–77°F) ■ Protect from excessive moisture

Inactive ingredients: D&C yellow no. 10, lactose, magnesium stearate, microcrystalline cellulose, pregelatinized starch

Fig. 1.1: Labeling manner of drug
Reference: US Food and Drug Administration (www.fda.gov)

- Pharmacy name and date filled
- Special precautions/instructions

Precautions for Prescription Medicines

- Tell physician of previous problems/allergies
- Keep list of all medicines currently using
- Understand directions
- Discuss side effects/interactions
- Store properly
- Never take drugs in the dark
- Flush old drugs
- Keep in labeled containers
- Do not use expired medicines

Medication Label a System of Information

- Primary container labels (state regulated, FDA requirements)
- Auxiliary labels (warning labels) (industry-generated, not standardized)
- Consumer medication information (CMI) (industry-generated)
- Medication guides—prescription only for providers (28 developed by FDA)
- Patient package information (PPI)—for provider (written by manufacturer approved by FDA).

Regulation Requirements

- Cosmetic ingredient declaration regulations apply only to retail products intended for home use.
- Products used exclusively by beauticians in beauty salons and labeled **"For professional use only"**.
- Cosmetic samples are not required to include the ingredient declaration. Must state the distributor, list the content's quantity, and include all necessary warning statements.
- Regulations require ingredients to be listed on product labels in descending order by quantity.
- Based on the amount used, an ingredient such as water is usually found at the beginning of the product's ingredient listing.

- Color additives and fragrances, used in small amounts, are normally seen at the end of the ingredient listing.
- FDA regulates only the labeling that appears on cosmetic products themselves. Unfair and deceptive advertising that appears in magazines, in newspapers, or on television falls under the authority of the Federal Trade Commission.

Label Content

- Source, ingredients
- Uses: Symptoms the medicine is approved to treat
- Warnings: Directions: Recommended daily dosage and frequency. Follow this strictly. Other information: Additional information such as proper storage.
- Storage conditions
- Contraindications
- Drug interaction
- Adverse effects
- Details of manufacturer, distributor

ADMINISTRATION OF THE ACT AND RULES

A1. Drugs Technical Advisory Board (DTAB)

The central government appoints the Drugs Technical Advisory Board.

Function: To advice the central and state governments on technical matters.

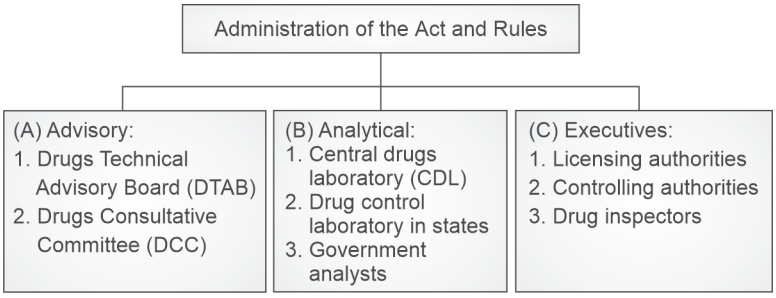

Fig. 1.2: Administration of the Act and Rules

Constitution

A. Ex-officio Member

1. The Director General of Health services.
2. The Member of Drug Controller of India.
3. The Director of the central Drug Laboratory, Calcutta.
4. The Director of Central Research Institute, Kausali
5. The Director of the Indian Veterinary Research Institute
6. The Director of Central Drug Research Institute, Lucknow
7. The President of PCI
8. The President of MCI.

B. Nominated Member

1. 2 person from in-charge of the drug control in the states.
2. 1 person from pharmaceutical industry
3. 2 government analysts.
4. 1 teacher in pharmacy, pharmaceutical chemistry or pharmacognosy on the staff of a university or affiliated college elected by the executive committee of **PCI.**
5. 1 teacher in medicine or therapeutics on the staff of a university or affiliated college elected by the executive committee of **MCI.**
6. 1 pharmacologist, elected by the Governing Body of the Indian Council of Medical Research.
7. 1 person elected by the Central Council of Indian Medical Association.
8. 1 person elected by Council of the Indian Pharmaceutical Association.

A2. Drug Consultative Committee (DCC)

This is an advisory committee constituted by central government.

Functions

- To advice the central and state governments and the DTAB on any matter to secure uniformity throughout India in administration of the Act.

- The Drugs Consultative Committee shall meet when required.
- Has power to regulate its own procedure.

Constitution

- 2 representative of central government nominated by central government, and
- 1 representative of each state government nominated by the concerned government.

There is separate **'The Ayurvedic, Siddha and Unani Drug Consultative Committee'** constituted under Section 33 D of the Act.

B1. Central Drug Laboratory (CDL)

Established in **Calcutta**, under the control of a director appointed by the central government.

Functions

- **Analysis or test** of samples of drugs/cosmetics sent by the custom collectors or courts.
- Analytical **QC** of the imported samples. Collection, storage and distribution of **internal standards.**
- Preparation of **reference standards** and their maintenance.
- Maintenance of **microbial cultures.**
- **Any other duties** entrusted by central government.
- Acting as an **appellate authority** in matter of disputes.

B2. Drug Control Laboratories in State

- Every state has a laboratory for analysis and testing of the drug and cosmetics manufactured or sold or to be sold within the respective areas.
- Drug samples sent by the drug inspector are analyzed in these laboratories.

The laboratory has the following divisions:

- Pharmaceutical chemistry division
- Immunology division

- Pharmacology division
- Pharmacognosy division
- Food division
- Ayurvedic division

B3. Government Analyst

In relation to Ayurvedic, Siddha and Unani drugs, a person appointed by central government or state government under Section 33 F.

These officers are appointed by the central or state government and perform the duties.

Qualification of Government Analyst

Persons having qualification for appointment as government as govermental analysis for allopathic drugs.

Having a degree in medicine, Ayurvedic, Siddha or Unani system and not less than three-year postgraduate experience in the analysis of drugs in a laboratory under control of a government analyst.

Duties

- The government analyst shall cause to be analyzed or tested such samples or drugs and cosmetics as may be sent to him by inspectors.
- A government analyst shall from time to time forward reports to the government giving the result of analytical work and research with a view to their publication.

C1. Licensing Authority

- Each state government appoints licensing authorities to issue licenses for manufacturing, distribution, and sale of drug or cosmetics for specified area.
- The licensing authorities have the power to issue or refuse licenses.
- The decision of licensing authority may be appealed before the state or central government as the case may be.

Qualification

- Graduate in Pharmacy or Pharmaceutical Chemistry or in Medicine with specialization in clinical pharmacology or microbiology from a university established in India by law.
- Experience in the manufacture or testing of drugs a minimum period of five years, provided that the requirements as to the academic qualification shall not apply to those inspectors.

Duties

- To inspect all establishments licensed for the sale of drugs within the area assigned to him.
- To satisfy himself that the conditions of the licenses are being observed.
- To procure and send for test or analysis, if necessary, imported packages.
- To investigate any complaint.
- To make such enquiries and inspections as may be necessary to detect the sale of drugs in contravention to the Act.
- To maintain a record of all inspections made and action taken by him in the performance of his duties.

C2. Controlling Authority

- All inspector appointed by the central government shall be under the control of an officer appointed in this behalf by the central government.
- All inspector appointed by the state government shall be under the control of an officer appointed in this behalf by the state government.

Qualification

- Graduate in Pharmacy or Pharmaceutical Chemistry or in Medicine with specialization in clinical pharmacology or microbiology from a university established in India by law.
- Experience in the manufacture or testing of drugs or enforcement of the provisions of the Act for a minimum period of five years.

C3. Drug Inspector

- A person to be appointed as a drug inspector should have no financial interest in the import, manufacture or sale of the drug and cosmetics.
- Drug inspector is a Public Servant under Section 21 of Indian Penal Code.

Qualification

- Persons having qualification for appointment as government as governmental analysis for allopathic drugs.
- Having a degree in Ayurvedic, Siddha or Unani system and not less than three-year postgraduate experience in the analysis of drugs in a laboratory under control of:
  - A government analyst.
  - A chemical examiner.
  - Head of an institution specially approved for this purpose.

Power

Inspect:

i. Any premises where in any drug or cosmetic is being manufactured.

ii. Any premises where in any drug or cosmetic is being sold, or stocked or exhibited or offered for sale, or distributed.

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.

SELF-ASSESSMENT EXERCISE

MCQs

1. The Drugs and Cosmetics Act was passed in _____.

a. 10th April 1945
b. 10th April 1940
c. 10th April 1943
d. 10th April 1941

2. Drugs and Cosmetics Rules under the Act in _____.

a. 1940 b. 1945
c. 1943 d. 1942

3. The Act was passed with the main objective to _____.

a. Register pharmacist
b. Raise the status of profession of pharmacy
c. Regulate the import, manufacture, distribution and sale of drugs and cosmetics
d. None of the above

4. The Act consists of _____ no. of chapters.

a. 2 b. 5
c. 4 d. 3

5. The Rules of the Act are divided into _____ parts.

a. 10 b. 13
c. 20 d. 23

6. How many schedules in D and C Act?

a. 1 b. 2
c. 3 d. 4

7. How many schedules to the rules?

a. 10 b. 15
c. 20 d. 27

8. Standards for medical device is prescribed under Schedule _____.

a. F1 b. R1
c. M1 d. S1

9. If a drug contains a colour other than prescribed it is termed as _____.

a. Spurious drug b. Bulk drug
c. Misbranded drug d. Adulterated drug

10. If a drug is not labeled in a prescribed manner it is termed as _____.

a. Spurious drug b. Bulk drug
c. Misbranded drug d. Adulterated drug

11. If a drug is imported under a name which belongs to another drug it is termed as _____.

a. Spurious drug b. Bulk drug
c. Misbranded drug d. Adulterated drug

12. Premises which have a qualified person and engage in compounding of drugs is:

a. Drug store
b. Pharmacy
c. Chemist and druggist
d. None of these

13. Premises licensed for sale of drugs which have a qualified person but where drugs are not compounded against premises are called _____.

a. Drug store b. Pharmacy
c. Chemist and druggist d. None of these

14. Substance which has a physiological effect when ingested or otherwise introduced into the body is called as _____.

a. Drugs b. Medicine
c. Compounds d. Material

15. Misbranded drugs come under Section _____.

a. 17 b. 17 *(a)*
c. 17 *(b)* d. 3

16. Adulterated drugs come under Section _____.

a. 17 b. 17 *(a)*
c. 17 *(b)* d. 3

17. If it consists, in whole or in part, of any filthy, putrid or decomposed substance is called as _____.

a. Spurious drug
b. Bulk drug
c. Misbranded drug
d. Adulterated drug

18. Spurious drugs come under Section _____.

a. 17 b. 17 *(a)*
c. 17 *(b)* d. 3

19. Inspector in relation to Ayurvedic, Siddha or Unani drug, an inspector appointed by central or state government under Section _____.

a. 33 *(c)* b. 33 *(d)*
c. 33 *(f)* d. 33 *(g)*

20. Inspectors come under Section _____.

a. 3 *(c)* b. 3 *(d)*
c. 3 *(e)* d. 3 *(g)*

21. Manufacture means:

a. Any process or part of a process for making, altering
b. Namenting, finishing, packing, labelling, breaking up
c. Otherwise treating or adopting any drug or cosmetic
d. All of the above

22. Patent or proprietary medicine comes under Section _____.

a. 1
b. 2
c. 3
d. 4

23. Schedule first from the D and C Act, 1940 and its Rules, 1945

a. List of drug books
b. List of Ayurvedic, Siddha and Unani books
c. List of homeopathy book
d. List of medicine

24. Standards to be complied with imported drug and by drugs manufactured for sale, sold, stocked or exhibited for sale or distributed under Schedule:

a. First schedule b. Second schedule
c. Third schedule d. None of these

25. List of poisonous substance under the Ayurvedic, Siddha and Unani systems of medicine present in Schedule _____.

a. C b. D
c. E d. F

26. Drugs exempted from certain provisions relating to the manufacture of drugs come under Schedule _____.

a. H b. I
c. J d. K

27. List of permitted dyes and coal tar colours in cosmetics come under Schedule _____.

a. O b. P
c. Q d. R

28. List of drugs which are habit forming, psychotropic and other drugs likely to be misused for addictive purposes come under Schedule _____.

a. W b. X
c. V d. U

29. Requirement and guidelines for clinical trials come under Schedule _____.

a. W b. X
c. V d. Y

30. Import means what?

a. To bring into India b. To bring out of India
c. Both a and b d. None of these

31. Import license is granted for the import of drugs specified in Schedule _____.

a. C b. C1
c. X d. C, C1 and X

32. For the import of drugs specified in Schedule C and C1, the license shall be granted in:

a. Form 11
b. Form 10
c. Form 10 *(a)*
d. Form 10 *(b)*

33. If it is not labeled in the prescribed manner of formulation is called as _____.

a. Adulterated drugs and cosmetics
b. Spurious drugs or cosmetics
c. Misbranded drugs and cosmetics
d. None of these

34. If it contains any harmful or toxic substance which may render it injurious to health is known as:

a. Adulterated drugs and cosmetics
b. Spurious drugs or cosmetics
c. Misbranded drugs and cosmetics
d. None of these

35. What is mean by adulterated drugs and cosmetics?

a. If any substance has been mixed therewith so as to reduce its quality or strength.
b. It contains any harmful for purposes of coloring only, a colour other than one which is prescribed.
c. Both a and b
d. None of these

36. Spurious drugs mean what?

a. Any substance has been mixed therewith
b. Drugs imported under a name which belongs to another drug
c. Both a and b
d. None of these

37. Which conditions to be fulfilled with import of the biological drugs?

a. Licensee must have adequate facility for the storage
b. Licensee must maintain a record of the sale
c. Licensee must furnish the sample to the authority
d. All of the above

38. Import of Schedule X drugs include:

a. Narcotic drugs and psychotropic substances
b. Biological drugs
c. Adulterated drugs
d. None of these

39. For the import of small quantities of drugs a license is granted in _____.

a. Form 11 b. Form 10
c. Form 10 *(a)* d. Form 10 *(b)*

40. The importer shall use the substances imported for the purpose of examination, test or analysis in the space specified in _____.

a. Token b. License
c. Agreement d. None of these

41. _____ can enter with or without notice at the premises where substances are kept for import.

a. Drug controller b. Government analyst
c. Inspector d. Manufacturer

42. The _____ shall keep and report the records of import to licensing authority.

a. Manufacturer b. Distributor
c. Exporter d. Importer

43. Drugs may be imported for personal use, if the quality of single dose so imported shall not exceed _____ doses.

a. 25 b. 50
c. 75 d. 100

44. Drugs may be imported for personal use, if _____ directs and declares that drug is for personal use.

a. Licensing authority b. Customs authority
c. Excise office d. Importer

45. Drugs may be imported for personal use, if that drug shall from the part of _____ bonafied baggage.

a. Passenger b. Inspector
c. Importer d. Manufacturer

46. Drugs may be imported for personal use, if more than 100 doses imported with license apply on Form ____.

a. 11 b. 10
c. 12 d. 13

47. Licensee must not sell drugs from which sample is withdrawn and he is advised not to sale, and _____ the batch from the market.

a. Stop b. Run
c. Publish d. Recall

48. Import of drugs without license include:

a. Substances used for medicinal purpose
b. Substances not used for medicinal purpose
c. Both a and b
d. None of these

49. After detaining the imported drugs or cosmetics, officer report it to _____.

a. Customs collector b. Drug Controller of India
c. Importer d. Exporter

50. Identify the classes of drugs which are not prohibited for import in India:

a. Misbranded drugs b. Standard drugs
c. Adulterated drugs d. Spurious drugs

51. Identify the classes of drugs which are prohibited for import in India:

a. Expired drugs
b. Patent and proprietary medicine of which formula is not disclosed
c. Drugs for disease mentioned in Schedule J
d. All of the above

52. Identify the classes of drugs which are not prohibited for import in India:

a. Drug which has not claimed therapeutic value
b. Drugs claimed therapeutic value

c. Drugs causing risk or injurious to human body or animal
d. Drugs not intended for import

53. Import license is valid for three years from date of its issue unless it is _____.

a. Suspended
b. Cancelled
c. Terminated
d. All of the above

54. No license is required for import of _____.

a. Drugs
b. Cosmetics
c. Medicines
d. Crude drugs

55. Identify the classes of cosmetics which are prohibited if contains:

a. More than 2 ppm of arsenic
b. 20 ppm of lead
c. 100 ppm of heavy metals
d. All of the above

56. If the importer gives an undertaking in writing not to dispose of the cosmetic, he shall _____ the consignment.

a. Destroy
b. Export
c. Import
d. Return

57. Manufacturer must observe at all times the undertaking given by him or on his behalf on _____.

a. Form 7
b. Form 8
c. Form 9
d. Form 10

58. Which state in respect to drugs imported by air into India?

a. Chennai, Kolkata
b. Mumbai, Delhi
c. Ahmedabad, Hyderabad
d. All of the above

59. Import of spurious OR adulterated drug OR drug which involves risk to human beings or animals OR drug not having therapeutic values punishable with _____.

a. 3 years imprisonment and ₹ 5000 fine on first conviction
b. 5 years imprisonment OR ₹1000 fine OR both for subsequent conviction
c. Both a and b
d. None of these

60. Contravention (an action which offends against a law of the provision in import of drugs punishable with _____.

a. 6 months imprisonment OR ₹ 500 fine OR both for first conviction
b. 1 year imprisonment OR ₹ 1000 fine for subsequent offence
c. Both a and b
d. None of these

61. Drugs imported into India by sea which placed are involved?

a. Chennai
b. Calcutta
c. Mumbai
d. All of the above

62. The drugs are prohibited to manufacture for sale under Section _____.

a. 15
b. 17
c. 18
d. 20

63. Which of the following drugs are prohibited to manufacture for sale under Section 18 of the Act?

a. Any drug or cosmetic which is not of a standard quality
b. Any patent or proprietary medicine, whose formula with the quantities, is not disclosed.
c. Any ingredient which may render it unsafe or harmful for use
d. All of the above

64. If drugs are manufactured in more than one set of premises, it required _____.

a. A separate application
b. separate license shall be issued
c. Both a and b
d. None of these

65. Licenses for manufacture or sale or distribution of drugs are granted or renewed by _____.

a. State License Approving Authority
b. Central License Approving Authority
c. Government Authority
d. License Authority

66. Central License Approving Authority (CLAA) appointed by the _____.

a. Central government
b. State government
c. Government Authority
d. License Authority

67. CLAA can delegate his power of signing licenses to any other person under his control with approval of the _____.

a. Central government b. State government
c. Government Authority d. License Authority

68. Allopathic drugs having own premises come under Schedule _____.

a. P b. M
c. X d. N

69. Application for the license of manufacturing drugs specified in Schedule C, C1 excluding those specified in Schedule X should be made to the CLAA in_____.

a. Form 25 b. Form 27
c. Form 23 d. Form 28

70. The manufacture of drugs specified in Schedule C, C1 and X in _____.

a. Form 25 b. Form 27 *(a)*
c. Form 27 *(b)* d. Form 28

71. Application for including any additional drug in the license should be accompanied by a fee of _____ for each drug subject to a maximum of ₹ 500.

a. ₹ 25 b. ₹ 50
c. ₹ 75 d. ₹ 100

72. License in Form 28 and 28B remains valid for a period of _____ on and from the date on which it is issued.

a. 3 years b. 5 years
c. 7 years d. 9 years

73. License shall deem to have expired if the application for its renewal is not made within _____ of its expiry.

a. 3 months b. 6 months
c. 9 months d. 12 months

74. Application for grand/renewal of such license shall be made for up to 10 items in each category in _____.

a. Form 24 *(a)* b. Form 24 *(b)*
c. Form 24 *(c)* d. Form 24 *(d)*

75. How many fees required for application for grand/ renewal of such license shall be made for up to 10 items in each category in Form 24 *(a)*?

a. 60 b. 600
c. 6000 d. 60000

76. How many inspection fees required for license issued in form 25 *(a)*?

a. 1000 b. 2000
c. 2500 d. 1500

77. _____ is necessary for the manufacture of any drug in small quantity for the purpose of examination, test or analysis.

a. License b. Permission
c. Grant d. Forms

78. If a person proposing to manufacture does not hold license it includes:

a. To manufacture drugs other than those specified in Schedule C, C1 and X
b. To manufacture drugs specified in Schedule C, C1 in respect to such drugs
c. He should obtain license in Form 29
d. All of the above

79. If drug is not recognized as safe for use, license in _____ is only granted after producing no objection certificate.

a. Form 29 b. Form 23
c. Form 28 d. Form 25

80. If drug is not recognized as safe for use, license in Form 29 is only granted after producing no objection certificate from LA appointed by _____.

a. Central government b. State government
c. Government Authority d. License Authority

81. License remains valid for a period of _____ year time in manufacture of any drug in small quantity for the purpose of examination, test or analysis.

a. 5 b. 3
c. 2 d. 1

82. A person (applicant) who does not have his own arrangements (factory) for manufacture but who wish to avail the manufacturing facilities owned by another licensee is called as _____.

a. Factory license b. Manufacturing license
c. Loan license d. None of these

83. Licensee is required to test each batch of raw materials and finished products and the records must be maintained for a period of _____ from the date of manufacture.

a. 3 years b. 4 years
c. 5 years d. 6 years

84. Application for loan license is made in Form _____ and the loan license is issued in Form _____.

a. 24 *(a)* b. 25 *(a)*
c. Both a and b d. None of these

85. Process of breaking up any drug from a bulk container into small packages and labelling with a view to their sale and distribution is called as _____.

a. Factory license b. Repacking license
c. Loan license d. None of these

86. Repacking license must be kept at licensed premises and produced on request of _____.

a. Director
b. Controller
c. Drug inspector
d. Commissioner

87. Before a license in Form _____ is granted or renewed.

a. 21 *(b)*
b. 28 *(c)*
c. 25 *(c)*
d. 20 *(a)*

88. Manufacture of any spurious drugs punishable with:

a. 1–3 years imprisonment and ₹ 5000 fine.
b. 2–6 years imprisonment and ₹ 10000 fine on subsequent conviction
c. Both a and b
d. None of these

89. Manufacture of adulterated drugs punishable with:

a. 1 year imprisonment and ₹ 2000 fine
b. 2 years imprisonment and ₹ 2000 fine for subsequent conviction
c. Both a and b
d. None of these

90. Manufacture of drugs in contravention of the provisions punishable with:

a. Imprisonment up to 3 months and ₹ 500 fine
b. Imprisonment up to 6 months and ₹ 1000 fine on subsequent conviction
c. Both a and b
d. None of the above

91. Provisions applicable for the manufacture of new drugs whether classifiable under _____.

a. Schedule C and C1
b. Schedule X and X1
c. Schedule M and M1
d. Schedule P and P1

92. The drugs are hormonal preparations consist in which of schedule?

a. Schedule I
b. Schedule G
c. Schedule H
d. Schedule M

93. What caution should be mentioned in drug label?

a. It is dangerous to take this preparation except under medical supervision
b. To be sold by retail on the prescription of a registered medical practitioner
c. Both a and b
d. None of these

94. _____ is the drug also comes under the purview of Narcotic Drugs and Psychotropic Substances Act, 1985.

a. Schedule I
b. Schedule G
c. Schedule H
d. Schedule M

95. Which warning should be mentioned in drug label?

a. It is dangerous to take this preparation except under medical supervision
b. To be sold by retail on the prescription of a registered medical practitioner only
c. Both a and b
d. None of these

96. Schedule P is for:

a. Life period of drugs
b. Drugs marketed under generic name only
c. Minimum equipment needed for retail pharmacy
d. Disease that a drug should not claim to cure

97. Schedule T is for:

a. Life period of drugs
b. Factory premises and hygienic conditions for Ayurvedic and Unani drugs
c. Minimum equipment needed for retail pharmacy
d. Disease that a drug should not claim to cure

98. Schedule W is for:

a. Life period of drugs
b. Drugs marketed under generic name only
c. Minimum equipment needed for retail pharmacy
d. Disease that a drug should not claim to cure

99. Schedule N is for:

a. Life period of drugs
b. Drugs marketed under generic name only
c. Minimum equipment needed for retail pharmacy
d. Disease that a drug should not claim to cure

100. Schedule J is for:

a. Life period of drugs
b. Drugs marketed under generic name only
c. Minimum equipment needed for retail pharmacy
d. Disease that a drug should not claim to cure

101. License to sell drugs specified in Schedule C and C1 is given in Form _____.

a. 19 b. 18
c. 21 d. 24

102. Requirements of factory premises cover under Schedule _____.

a. M b. V
c. N d. O

103. Standard for disinfectant fluids under Schedule _____.

a. M b. V
c. N d. O

104. Standard for cosmetic under Schedule _____.

a. S b. V
c. N d. O

105. Requirements of factory premises for manufacture of medical devices are for Schedule _____.

a. M b. M1
c. M2 d. M3

106. Which part of schedule includes with plant and equipment for the manufacture of drugs?

a. Part I
b. Part II
c. Part III
d. Part IV

107. The license has maintained:

a. Master formula record
b. Labels and closures
c. Identity, quality and quantity
d. None of these

108. Licensee has maintained batch manufacturing records, records of raw materials and analytical drugs:

a. Schedule S
b. Schedule V
c. Schedule U
d. Schedule O

109. The Schedule _____ drugs were mainly allocated to restrict the selling of antibiotics through over-the-counter (OTC) sales.

a. B
b. D
c. H
d. H1

110. The Schedule H1 drug includes:

a. 3rd and 4th generation antibiotics
b. Anti-tuberculosis drugs
c. Psychotropic drugs
d. All of the above

111. The Schedule P1 is:

a. Life period of drugs
b. The labeled potency period of the drug
c. Pack sizes of drugs
d. None of these

112. _____ contains various regulations and requirements for manufacture of Ayurvedic, Siddha and Unani products.

a. Schedule P
b. Schedule Q
c. Schedule R
d. Schedule T

113. _____ describes the standards for patent or proprietary medicines.

a. Schedule U
b. Schedule V
c. Schedule R
d. Schedule T

114. Patent or proprietary medicines containing vitamins for _____ use.

a. Prophylactic
b. Therapeutic
c. Paediatric use
d. All of the above

115. In which type of schedule, the drugs which cannot be purchased over the counter without the prescription of a qualified doctor?

a. Schedule U
b. Schedule V
c. Schedule X
d. Schedule T

116. Which of the following is schedule X drug?

a. Phenometrazine
b. Glutethimide
c. Meprobamate
d. All of the above

117. _____ Schedule describes requirements and guidelines on clinical trials for import and manufacture of new drugs.

a. U
b. Y
c. X
d. T

118. In Schedule Y (Rule 122A) for:

a. To manufacture new drugs
b. To import new drugs
c. Definition of clinical trials
d. None of these

119. Form _____ is for to import study drug for examination, test or analysis.

a. 10
b. 11
c. 12
d. 13

120. In which type of clinical trial phase to evaluate the effectiveness of a drug for particular indication?

a. Phase I
b. Phase II
c. Phase III
d. Phase IV

121. Schedule F is containing:

a. Regulations and standards for running a blood bank
b. Regulations and standards for bacterial vaccines, viral vaccines, antisera and diagnostic agents
c. Regulations and standards for surgical dressing
d. Regulations and standards for umbilical tapes

122. Schedule F1 is containing:

a. Regulations and standards for running a blood bank
b. Regulations and standards for bacterial vaccines, viral vaccines, antisera and diagnostic agents
c. Regulations and standards for surgical dressing
d. Regulations and standards for umbilical tapes

123. Schedule FF is containing:

a. Regulations and standards for running a blood bank
b. Regulations and standards for bacterial vaccines, viral vaccines, antisera and diagnostic agents
c. Regulations and standards for ophthalmic preparations
d. Regulations and standards for umbilical tapes

124. Schedule F2 is containing:

a. Regulations and standards for running a blood bank
b. Regulations and standards for bacterial vaccines, viral vaccines, antisera and diagnostic agents
c. Regulations and standards for surgical dressing
d. Regulations and standards for umbilical tapes

125. Schedule F3 is containing:

a. Regulations and standards for running a blood bank.
b. Regulations and standards for bacterial vaccines, viral vaccines, antisera and diagnostic agents
c. Regulations and standards for surgical dressing
d. Regulations and standards for umbilical tapes

126. From stockist to shopkeeper is called as _____.

a. Retail sale
b. Wholesale
c. Restricted sale
d. None of these

127. Which retail sale, type of licenses is issued for retail sale?

a. General licenses
b. Restricted licenses
c. Both a and b
d. None of these

128. What is the full form of RDL?

a. Retail drug list
b. Retail drug license
c. Retail dose license
d. Regulation drug license

129. Which type of conditions for whole sale license?

a. Area shall not be less than 10 sq.m.
b. Sale can be made either by a registered pharmacist
c. License shall be displayed in a prominent place
d. All of the above

130. Inspection book shall be maintained in Form _____.

a. 34
b. 35
c. 36
d. 37

131. Restricted licences in Forms _____ and _____.

a. 10 (*a*) and 11 (*a*)
b. 11 (*a*) and 12 (*a*)
c. 20 (*a*) and 21 (*a*)
d. 21 (*a*) and 22 (*a*)

132. Supply of Schedule C drug includes:

a. Serial number of the entry and date of supply
b. Name and address of the purchaser
c. Name and quantity of drug supplied and name of the manufacturer
d. All of the above

133. Supply of Schedule H drug includes:

a. Drug should be sold against the prescription of registered medical practitioner
b. Name of drug, its manufacturer and batch number
c. Signature of the qualified person.
d. All of the above

134. Supply of Schedule X drug includes:

a. Drug shall be kept in a separate cupboard under lock and key
b. Date of purchase/transaction
c. Both a and b
d. Name and address of purchaser

135. Anyone sell, stocks, exhibits for sale or distribute any misbranded or adulterated or spurious drug without proper license shall be punished with:

a. Imprisonment not less than one year but may extend up to 10 years
b. Imprisonment not less than one year but may extend up to 10 years on first conviction and 2 to 10 years with fine on subsequent convictions.
c. Imprisonment not less than one year but may extend up to 20 years
d. None of these

136. Anyone who sells, exhibits for sale or distributos any drug in contravention of the Act and Rules shall be punished with:

a. Imprisonment up to 5 years. Or fine both on first conviction and up to 10 years with fine on subsequent convictions
b. Imprisonment not less than one year but may extend up to 10 years on first conviction and 2 to 10 years with fine on subsequent convictions
c. Imprisonment not less than one year but may extend up to 20 years
d. None of these

137. Failure to not keeping records of sale in the specified manner punishable with:

a. Fine up to ₹ 500
b. Imprisonment up to 3 years or fine up to ₹ 1000 or both
c. Imprisonment for 3–5 years and fine of not less than ₹ 5,000
d. None of these

138. Label should be:

a. Printed or written in indelible ink
b. Appear in a conspicuous manner on the label of the innermost container of any drug
c. Both a and b
d. None of the above

139. Articles intended for use in diagnosis, cure, mitigation, treatment, or prevention of disease is called as _____.

a. Medicine
b. Compound
c. Drug
d. Substances

140. Full form of OTC is called as _____.

a. Over-the-counter
b. Open the counter
c. Over the class
d. Open the class

141. Over-the-counter drug is also called as _____.

a. Prescription drugs
b. Labelled drugs
c. Packed drugs
d. Nonprescription drugs

142. "Labelling" has been defined as:

a. Include the display of written material
b. On the immediate container of a drug presenting vital prescription information,
c. Any printed matter on a drug's containers or wrappers
d. All of the above

143. Labeling classifies as:

a. Brochures
b. Mailing pieces
c. Detailing pieces
d. All of the above

144. Prescription label consist of:

a. Patient name and address
b. Prescribers name
c. Drug name
d. All of the above

145. Precautions for prescription medicine includes:

a. Tell physician of previous problems/allergies
b. Keep list of all meds currently using
c. Both a and b
d. None of these

146. What precautions are give to medicine?

a. Flush old drugs
b. Keep in labeled containers
c. Do not use expired medicines
d. All of the above

147. Primary container labels regulated by:

a. State b. Central
c. Nation d. None of these

148. Auxiliary labels are also called as _____.

a. Primary container labels
b. Warning labels
c. Manufacture label
d. None of these

149. Full form of CMI:

a. Consumer market information
b. Consumer medication information
c. Customer market information
d. Customer medication information

150. Medication guides—prescription and patient package information for:

a. Consumer b. Patient
c. Provider d. None of these

151. Products used exclusively by beauticians in beauty salons and labeled:

a. For internal use only
b. For external use only
c. For professional use only
d. For topical use only

152. The labeling that appears on cosmetic products themselves. Unfair and deceptive advertising that appears in magazines, in newspapers, or on television falls under the authority of the:

a. Federal trade commission
b. FDA
c. State government
d. Central government

153. Recommended daily dosage and frequency is known as _____.

a. Contraindications
b. Drug interaction
c. Directions
d. Adverse effects

154. _____ is/are the section telling you what to avoid and who should not use this.

a. Drug interaction
b. Warnings
c. Directions
d. Adverse effects

155. Label content:

a. Source, ingredients
b. Drug interaction
c. Directions
d. All of the above

156. Advisory committee consists of:

a. Drugs Technical Advisory Board
b. Drugs Consultative Committee
c. Both a and b
d. None of these

157. Analytical committee consists of:

a. Central drugs laboratory
b. Drug control laboratory in states
c. Government analysts
d. All of the above

158. Executives committee consists of:

a. Licensing authorities
b. Controlling authorities
c. Drug inspectors
d. All of the above

159. The _____ appoints the Drugs Technical Advisory Board.

a. State government
b. Central government
c. Both a and b
d. None of these

160. What is the function of DTAB?

a. To advice the central government on technical matters
b. To advice the state government on technical matters
c. Both a and b
d. None of these

161. How many members in nominated committee in DTAB?

a. 5 b. 8
c. 9 d. 10

162. How many members in ex-officio committee in DTAB?

a. 5 b. 8
c. 9 d. 10

163. The Central Drug Laboratory is located in _____.

a. Mumbai b. Calcutta
c. Kausali d. Lucknow

164. Central Research Institute located in _____.

a. Mumbai b. Kausali
c. Lucknow d. Both b and c

165. Indian Veterinary Research Institute located in _____.

a. Mumbai b. Calcutta
c. Izatnagar d. Lucknow

166. The pharmacologist, elected by the Governing Body of the:

a. Indian Medical Association
b. Indian Pharmaceutical Association
c. Indian Council of Medical Research
d. None of these

167. The Central Drug Laboratory is separate 'The Ayurvedic, Siddha and Unani Drug Consultative Committee' constituted under Section _____ of the Act.

a. 33 (*a*) b. 33 (*b*)
c. 33 (*c*) d. 33 (*d*)

168. Central Drug Laboratory established in Calcutta, under the control of a Director appointed by the _____.

a. State government
b. Central government
c. Both a and b
d. None of these

169. What is the function of CDL?

a. Analysis or test of samples of drugs/cosmetics
b. Analytical QC of the imported samples
c. Preparation of reference standards and their maintenance
d. All of the above

170. Every state has a laboratory for analysis and testing of the drug and cosmetics manufactured or sold or to be sold within the respective areas is known as _____.

a. Drug control laboratories
b. Indian Veterinary Research Institute
c. Central Research Institute
d. None of these

171. Drug control laboratories in state consist of following:

a. Pharmaceutical chemistry division
b. Immunology and pharmacology division
c. Pharmacognosy and food division
d. All of the above

172. Government analyst in relation to Ayurvedic, Siddha and Unani drugs, a person appointed by central government or state government under Section _____.

a. 33 (*d*)
b. 33 (*f*)
c. 33 (*e*)
d. 33 (*c*)

173. What are the duties of government analyst?

a. Analysed or tested such samples or drugs and cosmetics as may be sent to him by inspectors
b. Time to time forward reports to the government giving the result of analytical work
c. Both a and b
d. None of these

174. Licencing authority appointed by the central and state governments _____ for the import, manufacture, sale, distribution, etc. of any drug or cosmetic.

a. For the grant
b. For the renewal of a licence
c. Both a and b
d. None of these

175. Each state government appoints _____ to issue licenses for manufacturing, distribution, and sale of drug or cosmetics for specified area.

a. Government analyst
b. Drug control laboratories
c. Licensing authorities
d. None of these

176. The licensing authorities have the power to:

a. Issue or refuse licenses
b. May be appealed before the state or central governments
c. Both a and b
d. None of these

177. What is the qualification of licensing authorities?

a. He must be a graduate in pharmacy or pharmaceutical chemistry
b. Graduate in medicine with specialization in clinical pharmacology microbiology
c. Experience in the manufacture or testing of drugs a minimum period of five years
d. All of the above

178. What are the duties of licensing authorities?

a. To inspect all establishments licensed for the sale of drugs
b. To investigate any complaint.
c. To maintain a record of all inspections
d. All of the above

179. 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:

a. Government analyst
b. Drug control laboratories
c. Licensing authorities
d. Controlling authority

180. What is the qualification of controlling authority?

a. Experience in the manufacture or testing of drugs
b. Enforcement of the provisions of the Act for a minimum period of five years
c. Both a and b
d. None of these

181. A person to be appointed as a _____ should have no financial interest in the import, manufacture or sale of the drug and cosmetics.

a. Licensing authorities
b. Controlling authority
c. Drug inspector
d. Government analyst

182. Drug inspector is a Public Servant under Section _____ of Indian Penal Code.

a. 20
b. 21
c. 19
d. 18

183. What is the qualification of drug inspector?

a. Persons having a degree in Ayurvedic, Siddha and Unani system
b. Person not less than three years postgraduate experience in the analysis of drugs
c. Both a and b
d. None of these

184. What are the duties of drug inspector?

a. To inspect
b. Take samples of any drug or cosmetic
c. For entering and searching any place, person or vehicle, etc.
d. All of the above

ANSWERS

1. b	**2. b**	**3. c**
4. b	**5. d**	**6. b**
7. d	**8. b**	**9. d**
10. c	**11. a**	**12. b**
13. c	**14. a**	**15. a**
16. b	**17. d**	**18. c**
19. d	**20. c**	**21. d**
22. c	**23. b**	**24. b**
25. c	**26. d**	**27. c**
28. b	**29. d**	**30. a**
31. d	**32. b**	**33. c**
34. a	**35. c**	**36. b**
37. d	**38. a**	**39. a**
40. b	**41. c**	**42. d**
43. d	**44. b**	**45. a**
46. c	**47. d**	**48. b**
49. b	**50. b**	**51. d**
52. b	**53. d**	**54. b**

55. d	**56. d**	**57. c**
58. d	**59. c**	**60. c**
61. d	**62. c**	**63. d**
64. c	**65. b**	**66. a**
67. a	**68. c**	**69. b**
70. c	**71. b**	**72. b**
73. b	**74. a**	**75. c**
76. d	**77. a**	**78. d**
79. a	**80. a**	**81. d**
82. c	**83. c**	**84. c**
85. b	**86. c**	**87. b**
88. c	**89. c**	**90. c**
91. a	**92. b**	**93. a**
94. c	**95. b**	**96. a**
97. b	**98. b**	**99. c**
100. d	**101. d**	**102. a**
103. d	**104. a**	**105. d**
106. b	**107. a**	**108. c**
109. d	**110. d**	**111. c**
112. d	**113. b**	**114. d**
115. c	**116. d**	**117. b**
118. b	**119. b**	**120. b**
121. a	**122. b**	**123. c**
124. c	**125. d**	**126. b**
127. c	**128. b**	**129. d**
130. b	**131. c**	**132. d**
133. d	**134. c**	**135. b**
136. a	**137. b**	**138. c**
139. c	**140. a**	**141. d**
142. d	**143. d**	**144. d**
145. c	**146. d**	**147. a**

148. b **149. b** **150. c**
151. c **152. a** **153. c**
154. b **155. d** **156. c**
157. d **158. d** **159. b**
160. c **161. d** **162. b**
163. b **164. d** **165. c**
166. c **167. d** **168. b**
169. d **170. a** **171. d**
172. c **173. c** **174. c**
175. c **176. c** **177. d**
178. d **179. d** **180. c**
181. c **182. b** **183. c**
184. d

SHORT QUESTIONS

1. What are the objectives of Drugs and Cosmetics Act, 1940?
2. What do you understand by CDL under Drugs and Cosmetics Act?
3. What are the classes of drugs prohibited from being sold?
4. Write a note on Drugs Consultative Committee (DCC).
5. What are the qualifications and duties required to be a government analyst?
6. Write a note on Licensing Authority.
7. Write in short on loan license and repacking license.
8. Write penalties and offences related import.
9. Write penalties and offences related sale of drug.
10. Write penalties and offences related manufacturing of drug.
11. Write prohibition for the manufacturing and sale of certain drug.

LONG QUESTIONS

1. Write in detail about imports of drugs.
2. Which are the Acts and Rules that regulate manufacturing export and clinical research of Drugs and Cosmetics in India?
3. How many schedules do the D and C Act have, elaborate it in details?
4. Which is prohibited as per D and C Act, 1940?
5. What is the minimum qualification to be appointed as drug inspector as per Drugs and Cosmetics Act, 1940?
6. Write detail study of Schedule M and M1.
7. Write detail study of Schedule H and X.
8. Write detail study of Schedule P and V.
9. Write detail administration bodies with their constitution and function.