DRUG AND COSMETIC ACT

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THE DRUG AND COSMETICS ACT WAS PASSED IN **10TH APRIL 1940.**

1940– DRUGS AND COSMETICS ACT

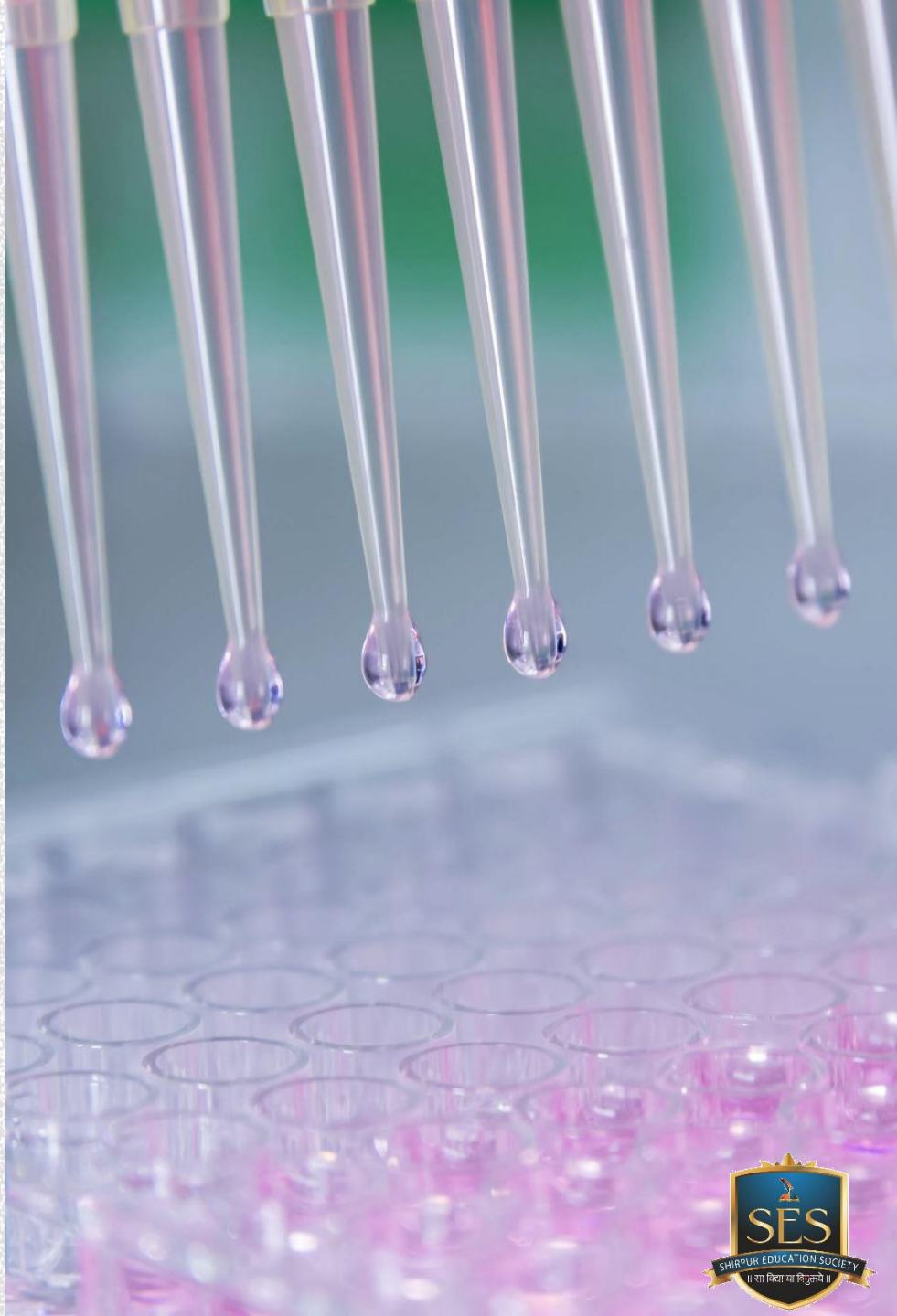
1945 – RULES UNDER THE ACT

OBJECTIVES

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

DEFINITIONS UNDER THE ACT:

- **Drugs :**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.



MISBRANDED DRUGS : (SECTION 17)

- if it is so **colored, coated, powdered** or **polished** that damage is concealed

OR

- if it is not **labelled** in the **prescribed manner**.

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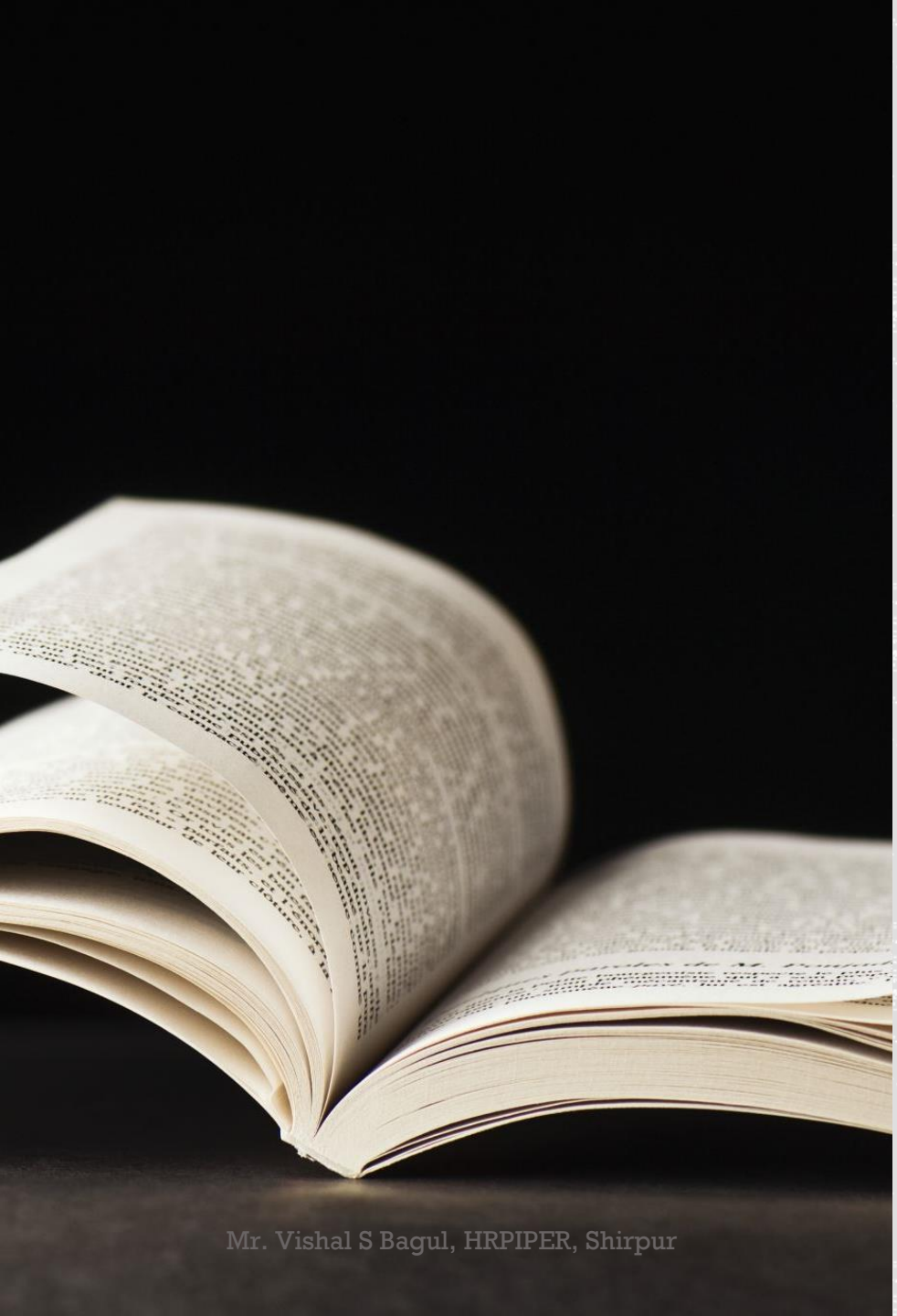
ADULTERATED DRUG : SECTION 17 (A)

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 whom 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):** it includes any process or part of a process for **making, altering, finishing, packing** and **labelling.**



SHEDULES TO THE ACT

- **FIRST SHEDULE: List of Ayurvedic, Sidha & Unani books.**
- **AYURVEDIC BOOK**
- Ex. Charak Samhita, Sushrut Samhita, Ark Prakasha
- **SIDHA BOOK**
- Ex. Sidha Vaidya Thiratu, Bhogar, Pulippani.
- **UNANI BOOK**
- Ex. Karabadin Quadri, Al Karabadin.

SECOND SHEDULE:

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 Govt. Analyst.
Schedule C	List of biological products whose import, sale, distribution and manufacture are governed by special provisions. Eg. Insulin, Vaccine for parenteral injections. etc
Schedule C1	List of other special products whose import, sale, distribution and manufacture are governed by special provisions. Eg. Fish liver oil, adrenaline, and vitamins.etc

Schedule D	**List of drugs exempted from the provisions of import of drugs. Eg. otats and ginger etc.**
Schedule E	**List of Poisonous substance under the Ayurvedic, Siddha and Unani Systems of Medicine. Eg. Nux-vomica etc**
Schedule F (i)	**Space, equipment and supplies required for a Blood Bank.**
Schedule F (ii)	**Min. requirement for grant of license to procure blood components.**
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's.**
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 U	**Particulars to be shown in manufacturing, raw materials and analytical records of Drug.**

Schedule U1	**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

No 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 DRUG AND COSMETICS:

Misbranded drugs and Cosmetics:

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

Adulterated drugs and Cosmetics

- if it contains any harmful or toxic substance which injurious to health.

- **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 whom it is not truly a Product.
- **Drugs of substandard quality:**
- no drug shall be imported unless it complies with the standard of **strength, quality, and purity** if any.
- Drugs whose manufacture, sale/distribution are prohibited in original country, except for the purpose of test, examination and analysis.
- Specially Cosmetics product which contains more than-2 ppm Arsenic, 20 ppm lead, 100 ppm heavy metals

DRUGS IMPORTED FOR EXAMINATION, TEST OR ANALYSIS

Conditions to be fulfilled

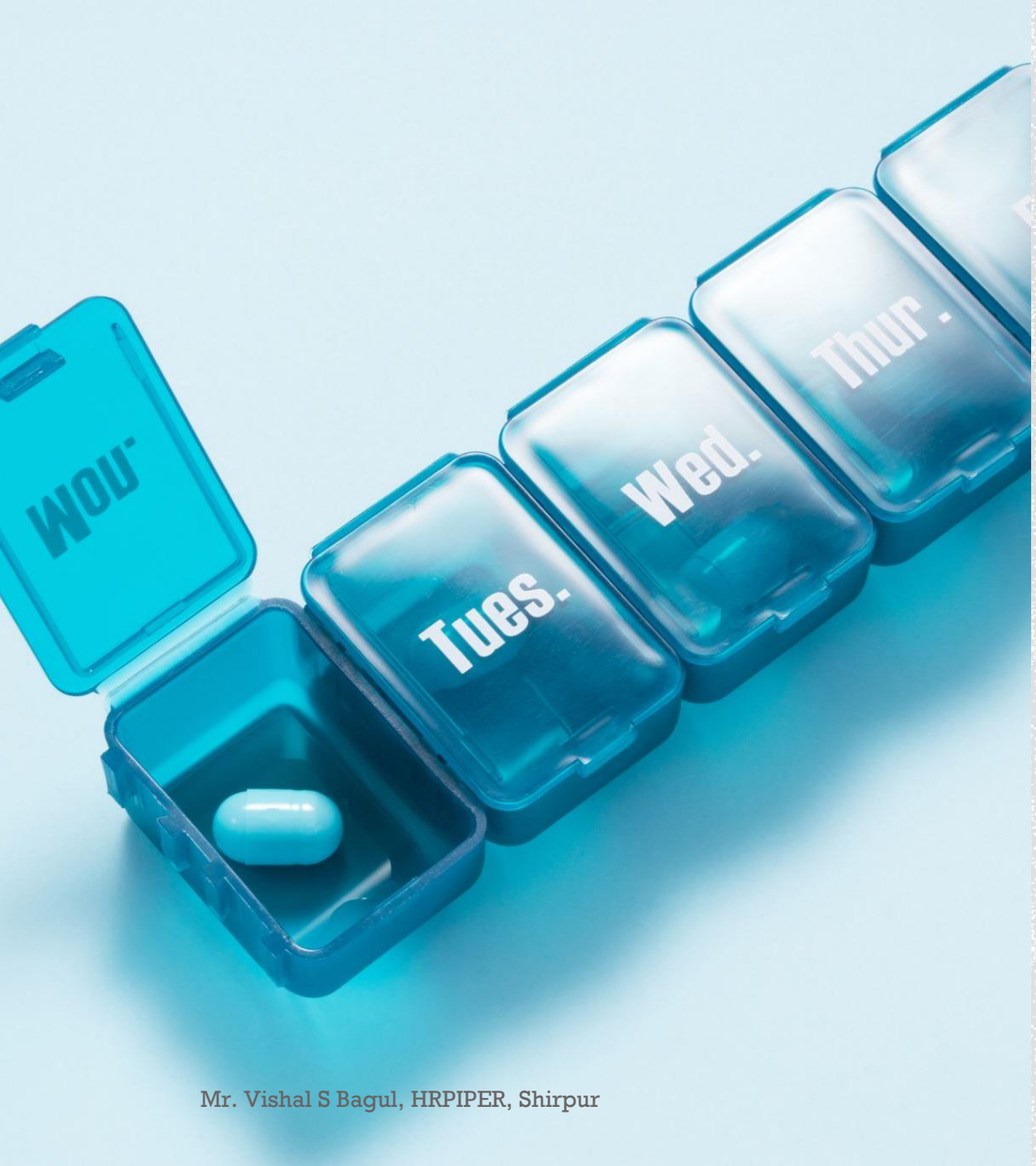
- License is necessary under form-11
- Must keep the **record** with respect to quantities, name of the manufacturer and date of import.
- Must **allow an inspector** to inspect the premises and check records.

IMPORT OF THE BIOLOGICAL DRUGS(C/C1)

- **Conditions to be fulfilled:**
- Licensee must have **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.

IMPORT OF THE SCHEDULE-X DRUGS (NARCOTIC & PSYCHOTROPIC DRUGS

- **Conditions to be fulfilled:**
- Licensee must have **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 and Psychotropic Substances Act.



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 no.-12-A,12-B
- Drugs must be bonafide personal use.

PLACES THROUGH WHICH DRUGS MAY BE IMPORTED IN INDIA

Ferozpur & Amritsar Railway station	In respect to drugs imported by **rail** across the Border with **Pakistan**
Bongaon Railway Stations	In respect to drugs imported by **rail** across the Border with **Bangladesh**
Raxaul	In respect to drugs imported by **road & rail** connecting **India & Nepal**
Chennai, Kolkata, Mumbai, Cochin & Kandla	In respect to drugs imported by **sea** into **India**
Chennai, Kolkata, Mumbai, Delhi, Ahmedabad & Hyderabad	In respect to drugs imported by **air** into **India**

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	a) **3 years** imprisonment OR **5000** Rs. fine on first conviction b) **5 years** imprisonment OR **10.000** Rs. Fine OR both for subsequent conviction

MANUFACTURE OF DRUG

- Manufacture in relation to any drug or cosmetic, includes any process or part of process for **making**, **finishing, packing, labeling**, or otherwise treating any drug or cosmetic with a view to its sale & distribution but does not include the compounding or dispensing of any drug.

- **Following licenses are provided for manufacture of drugs under D&C Act**

1. Drugs specified in Schedule C, & C1
2. Drugs specific in Schedule X but not in Schedule C & C1
3. Drugs for the purpose of examination, test or analysis
4. Repacking Licenses
5. Blood products

PROHIBITION FOR THE MANUFACTURE & 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;
- Any cosmetic which not of standard quality or is misbranded, adulterated or
- Spurious.
- Any patent medicine whose formulae is not disclosed on label or the container.

MANUFACTURE OF DRUGS SPECIFIED IN SCHEDULE C, C1 & X

- Application for the license of manufacturing drugs specified in Schedule **C, C1** excluding those specified in **Schedule X** should be made to the **Form 27.**
- 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 & **who is**
- A graduate in **pharmacy/pharmaceutical chemistry** at least **18 months** practical experience.
- A graduate in **science** of a recognized University at least **3 years** experience

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- A graduate in **medicine** of a recognized University at least **3 years** experience
- A graduate in **chemical engineering** at least **3 years experience**
- The factory conditions must comply with the conditions prescribed in **Schedule M.**
- Applicant should provide adequate space, plant & equipment for any or all manufacturing operations as prescribed in **Schedule M.**

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 drug is not recognized as safe for use, license in Form 29 is only granted after producing no objection certificate by Central Government.
- License remains valid for a period of one year time
- If the drugs are to be supplied, it should bear label stating name & address of manufacturer, & purpose for which it has been manufactured.

CONDITIONS FOR LICENSE

- Licensee to allow **inspector** to **inspect the premises** & satisfy himself that only examination, test or analysis is being conducted.
- Licensee to keep record of quantity of drugs manufactured and supplied to any person.
- Licensee to maintain inspection book to enable inspector to record his impression and defects noticed.

LOAN LICENSES

- 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.
- Application for license is made in Form **24-A** & the license is issued in Form **25-A**
- Factory conditions must specify conditions prescribed in **Schedule M**.
- License must be kept at licensed premises & produced on request of DI

REPACKING LICENSES

- Process of breaking up any drug from a bulk container into small packages and labeling with a view to their **sale** and **distribution.**
- 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 & produced on request of DI

OFFENCES & PENALTIES RELATED TO MANUFACTURE

OFFENCES	PENALTIES
Manufacture of any spurious drugs	**a) 1-3 years** imprisonment and **Rs.5000 fine.** **b) 2-6 years** imprisonment & **Rs.10.000 fine** on subsequent conviction
Manufacture of adulterated drugs	**a) 1 year** imprisonment & **Rs.2000 fine** **b) 2 years** imprisonment & **Rs.2000 fine** for subsequent conviction
Manufacture of drugs in contravention of the provisions	a) Imprisonment up to **3 months & Rs.500 fine** b) Imprisonment up to **6 months & Rs.1000 fine** on **subsequent conviction**

DETAIL STUDY OF SCHEDULE

SCHEDULE M (M_1 & M_2)

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

PART-I
FACTORY PREMISES
GENERAL REQUIREMENTS

- Location of factory & its surroundings should ensure freedom from **contamination** due to **dust, smoke** or **fumes** etc.
- **Factory building** should ensure production of drugs under **hygienic conditions**.
- **Operations** such as manufacturing, processing, packing labeling & testing should be carried out in such a way that **mix up & cross contamination** are prevented.
- There should be a **validated system** for the treatment of **water** so as to produce **purified water** confirming to **IP specification.**

- The disposal of **sewage** and **garbage** 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.**

Warehousing Area

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

Production Area

- Should be designed to allow the production preferably in uni-flow & with logical sequence of operations.
- The equipment's and materials must be placed orderly & 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 & similar service lines must be designed to avoid creation of recesses.

Quality control area

- Should be independent of production area & divided to separate sections for physio-chemical, biological, microbiological & radio isotope analysis.
- Laboratories shall be designed to avoid mix-ups and cross contamination. Separate instrument room with adequate area shall be provided for sensitive & sophiscated instruments employed for analysis.
- Suitable storage space shall be provided for test samples, reference standards, reagents & records.

Health, Clothing & Sanitation of workers

- All personnel coming to contact with products & raw materials should be free from contagious diseases & should undergo periodic health checkup. Just before entry to manufacturing area, room with facility for personnel cleanliness should be provided.
- All persons prior to & during the employment shall be trained in practices that ensure personnel hygiene.
- All persons should wear clean body coverings.
- Smoking, eating, drinking, chewing or keeping plants or food & personnel medicines shall not be permitted in production, laboratory storage & other areas.

Raw Materials:

All raw materials must be

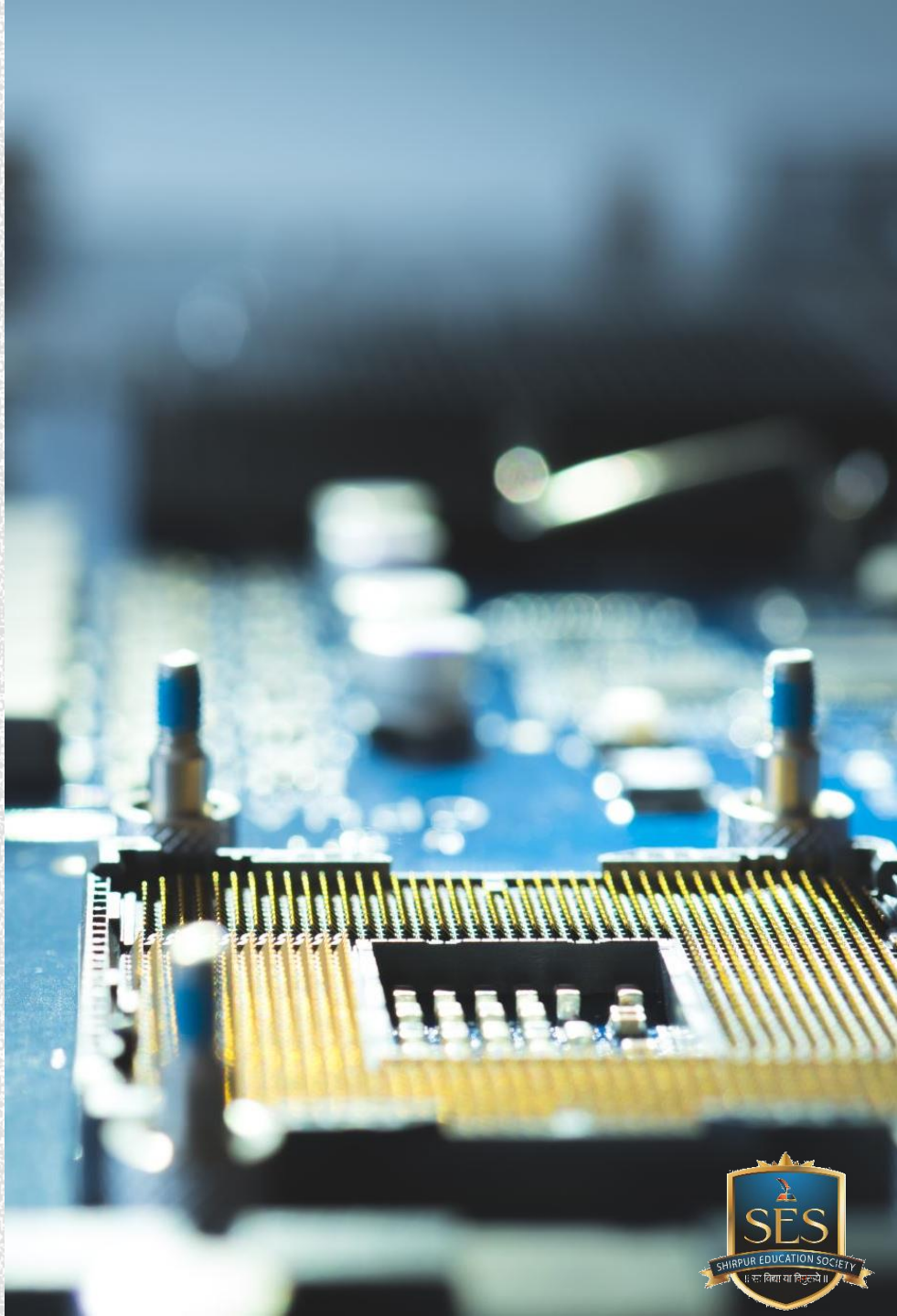
- Purchased from approved sources under valid purchase vouchers, possibly from producers directly.
- Identified & their containers examined for damage & assigned control number.
- There shall be separate areas for materials under test, approved & rejected.
- All incoming materials shall be quarantined immediately after receipt or processing.
- Only raw materials released by QC department.

Master Formula Records:

- Relating to all manufacturing procedures for each product. The master formula record shall give
- Labels & closures to be used.
- Identity, quality & quantity of each raw material to be used.
- Description of all equipment's & vessels & the size used in the process.
- Manufacturing & control instructions along with parameters for critical steps such as mixing, drying, blending, sieving, and sterilizing the product.

Product containers & closures

Has complied with Pharmacopoeial requirements. Suitable test methods, cleaning & sterilization procedures ‘d be used to assure that components, closures & other component part of drug packages are suitable & they are not reactive, additive, absorptive



PART II (PLANT & EQUIPMENT)

External Preparation.

- Ointment, Emulsion, Lotions, Pastes, Creams, Dusting powder and such identical products used for external applications whichever is applicable namely

1) Stainless Steel Containers

2) Mixer

3) A colloid mill or suitable emulsifier

4) A triple roller mill or an ointment mill

5) Liquid filling equipment's

6) Jar or tube filling equipment

Area

A min area of **30** square meters for basic installation and **10** Square meter for Supporting area is recommended.

Ares for Formulation meant for external use and internal use shall be **separately provided** to **avoid mix up**.

- **Oral Liquid Preparation**

The following equipment is recommended for the manufacturing of oral internal use preparation like Syrup, Emulsion and Suspension.

1) Mixing and Storage tank (SS)

2) Portable Stirrer

3) A Colloidal mill

4) Suitable Filtration equipment

5) Semi-automatic/automatic bottle filling machine

6) Cap sealing machine

7) Water distillation unit

8) Clarity testing inspection unit

Area

A minimum area of 30 Square meter for basic installation and 10 Square meter for Supportive area is recommended

- **Tablet**

The Tableting section shall be free from Dust and Floating Particles the tablet production department shall be divided in separate sections.

- **A) Mixing Granulations and drying section**
- **B) Compression Section**
- **C) Coating Section**
- **D) Packaging Section**

A) **Mixing Granulations and drying section**

Required basic equipment's : **Disintegrator, Powder mixer, Mass Mixer, Hot air Oven and Weighing balance.**

B) **Compression Section**

Required basic equipment's: Tablet Compression machine, Punch and dies storage cabinets, Tablet inspection Unit, Dissolution test Apparatus, hardness tester and Disintegration test apparatus.

- **C) Coating Section**

Required basic equipment's: Coating Pan, Polishing Pan, Weighing Balance, Exhaust System.

- **D) Packaging Section**

Required basic equipment's: Strips/blister packaging machine, leak test apparatus, Tablet counter.

Area

Mixing Granulations and drying, compression and coating section required minimum area of **60** square meter for basic installation and **20** square meter for supportive area is recommended.

And **Coating Section** required minimum area of **30** square meter for basic installation and **10** square meter for supportive area is recommended.

- **Powder**

Required basic equipment's: Disintegrator, Mixer, Filling equipment, Weighing Balance

Area

A Min Area 30 Sq. Meters is recommended to allow for the basic installation.

- **Capsule**

Required basic equipment's: Mixing equipment's, Capsule Filling Unit, Weighing balance, Disintegration test apparatus, Capsule polishing equipment's

Area

A Min Area 25 Sq. Meters is recommended to allow for the basic installation. and **10** Square meter for Supporting area is recommended.

- **Surgical Dressing**

Required basic equipment's: Rolling Machine, trimming Machine, Cutting Equipment, Folding and Pressing Machine, Hot air Dry Oven,

Area

A Min Area 30 Sq. Meters is recommended to allow for the basic installation.

- **Ophthalmic Preparation**

Required basic equipment's: Stainless Steel Tank, Colloid Mill or Ointment mill, Tube Cleaning Equipment, Tube Filling equipment, Laminar Air Flow Unit.

Area

A Min Area **35 Sq.** Meters is recommended to allow for the basic installation. and **10** Square meter for Supporting area is recommended.

- **Parenteral Preparation**

A) Parenteral Preparation in **glass** Container

B) Parenteral Preparation in **Plastic** Container

A) Parenteral Preparation in glass Container

Required basic equipment's: De-ionised water treatment Unit, Distillation Unit, Automatic Closures Washing Machine, Dryer, Solution Preparation and mixing Stainless Steel tank, Filtration, Automatic ampoule, Vial, Bottle Filling Equipment, Steam Sterilizer,Storage cabinet.

Area

A Min Area **150 Sq**. Meters is recommended to allow for the basic installation. and **100** square meter for supportive area is recommended.

Area for Formulation meant for External use and Internal Use shall be Separately Provided.

B) Parenteral Preparation in Plastic Container

Required basic equipment's: Distillation Unit, Solution Preparation tank, Sterile Form-Fill-Seal Machine, Dryer, Solution Preparation and mixing Stainless Steel tank, Filtration, Visual inspection Unit.

Area

A Min Area **250 Sq**. Meters is recommended to allow for the basic installation. and **100** square meter for supportive area is recommended.

Area for Formulation meant for External use and Internal Use shall be Separately Provided.

SCHEDULE N

LIST OF MINIMUM EQUIPMENT'S FOR THE EFFICIENT RUNNING OF PHARMACY

1. **Entrance**
2. **Premises**
3. **Furniture and apparatus**
4. **Books**
5. **General Provision .**

- **Entrance:** The Front of Pharmacy Shall bear an inscription pharmacy in front
- **Premises:** The area of the section to be used as dispensing department shall be not less than **6 square** meters. 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 oil painted** so as to maintain **smooth** and **washable** surface.
- 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.**

- **Furniture and apparatus**

Drugs, chemicals, and medicaments shall be kept in a appropriate room and their **containers.**

Every container shall bear a **label** of **Appropriate size**, **easily readable with names of medicaments.**

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.

- **Apparatus**

Balance, Bottles, prescription, Cork, extractor, Evaporating dishes, porcelain, Filter paper, Funnels, glass, Litmus paper, blue and red, Mortars and pestles, Spatulas, Spirit lamp, Thermometer, Tripod stand, Watch glasses, Water bath

- **Books**

  The Indian Pharmacopoeia (current Edition)

  National Formulary of Indian (Current Edition)

  The drugs and Cosmetics Act and their Rules , 1940, 1945

  The Pharmacy Act, 1948

- **General provisions**

A pharmacy shall be conducted under supervision of a Registered Pharmacist.

The Pharmacist shall always put on clean white overalls.(**one-piece garment**)

All records and registers shall be maintained in accordance with the laws.

SCHEDULE P

LIFE PERIOD OF DRUG

- 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**,
- **duration should be measured in months.**

Drugs	Drugs Life Period (Months)	Drugs Storage
Ampicillin trihydrate	30	In a cool place
Ampicillin Sodium	36	In a cool place
Adramycin	30	In a cool place
Ampicillin	36	In a cool place
Colistin Sulphate	60	Protected from light
Nystalin	36	At temp not exceeding 5°C
Penicillin Tablet	18	In a cool place

Schedule P_1

- The **Pack Size of Drugs** is specified in this schedule. It lists the medication names, as well as the dose type and pack size.

Drugs	Dosage Forms	Pack Size
Aspirin (Low Dose)	Tablets	14 tabs
Albendazole	Suspension	10ml
Atenolol	Tablet	14 tabs
Catalin	Ophthalmic Drops	15ml
Ciclopiroxolamine	Vaginal Cream	30gm
Haloperidol	Oral Solution	15ml
Isoniazide	Syrup	200ml

DETAIL STUDY OF SCHEDULE U

PARTICULARS TO BE SHOWN IN MANUFACTURING, RAW MATERIALS AND ANALYTICAL RECORDS 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 manufacture and the assigned date of expiry.
7. Name of all ingredients, specifications quantities required for the lot/Batch size and quantities actually used

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 necessry).
    - (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 n 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. The theoretical yield and actual productions yield and packing particulars indications the size and quantity of finished packing.

18. 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.

19. Signature with date of competent technical staff responsible for the manufacture.

20. 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.

21. Date of release of finished picking and quantity released for sale and distribution.

22. Quantity transferred to warehouse.

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 manufacture

7. Name of all ingredients, specifications and quantity required for the Lot/Batch size and quantity actually used.

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 test wherever applicable.

17. Records of checking of instruments and apparatus of sterilization (Indicators)

18. Records of cleaning and sterilization of containers and closure

19. Number and size of containers filled

20. The theoretical yield and actual yield and the percentage yield

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 packing.

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.

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

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.

CONTAINER, PACKING MATERIALS ETC.

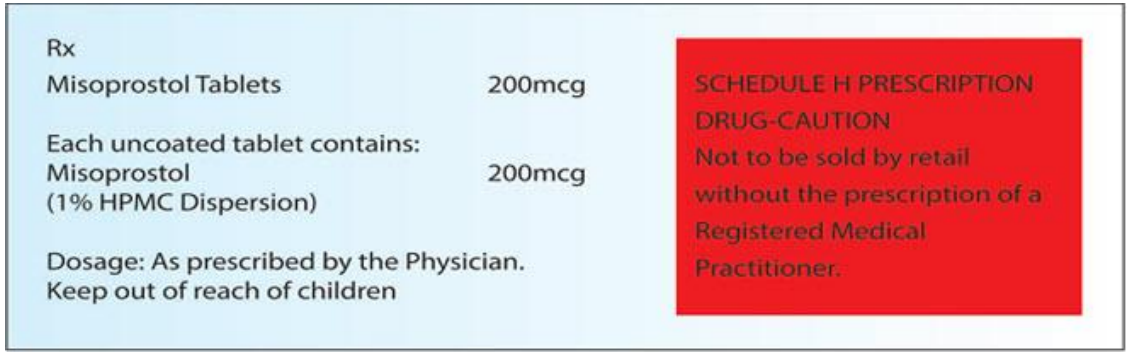
1. Serial number.
2. Name of the item.
3. Name of the manufacturer/supplier.
4. Quantity received.
5. Invoice/Challan number and date.
6. Results of tests applied
7. Remarks.
8. Signature of the examiner.

SCHEDULE G

- Medicines listed as schedule G carry a caution on the label. **“It is dangerous to take this preparation except under medical supervision”.**
- The caution is clearly printed and surround ed by a line no other words within.
- It is required to make proper bill of sale of Schedule G drugs.
- Records of purchase and sale of these medicines should be regulated for 2 years.
- Aminopterin, L -Asparaginase, Bleomycin, Insulin, Metformin, etc. are the **examples** of some drugs under schedule G.

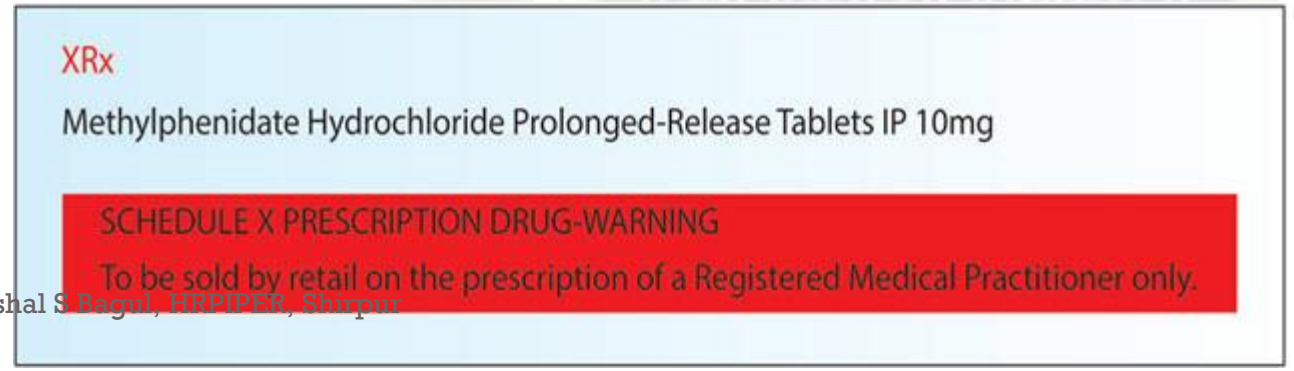
- This schedule contains the **prescription drugs**, i.e., drugs that should be sold by retail.
- The label should also bear **warning** that "To be sold by retail on the prescription of a registered medical practitioner only".
- Drugs under Schedule H if comes under **Narcotic Drugs and Psychotropic Substances Act, 1985** are labelled with the symbol "NRx" and Schedule H drug warning. Schedule H is a list of **536 drugs.**
- Some **examples** are Abxicimab, Acylovir, Diclofenac, Baclofen, Carbidopa, Terazosin, Verapamil hydrochloride, Tretinoin, Repaglinide, etc.

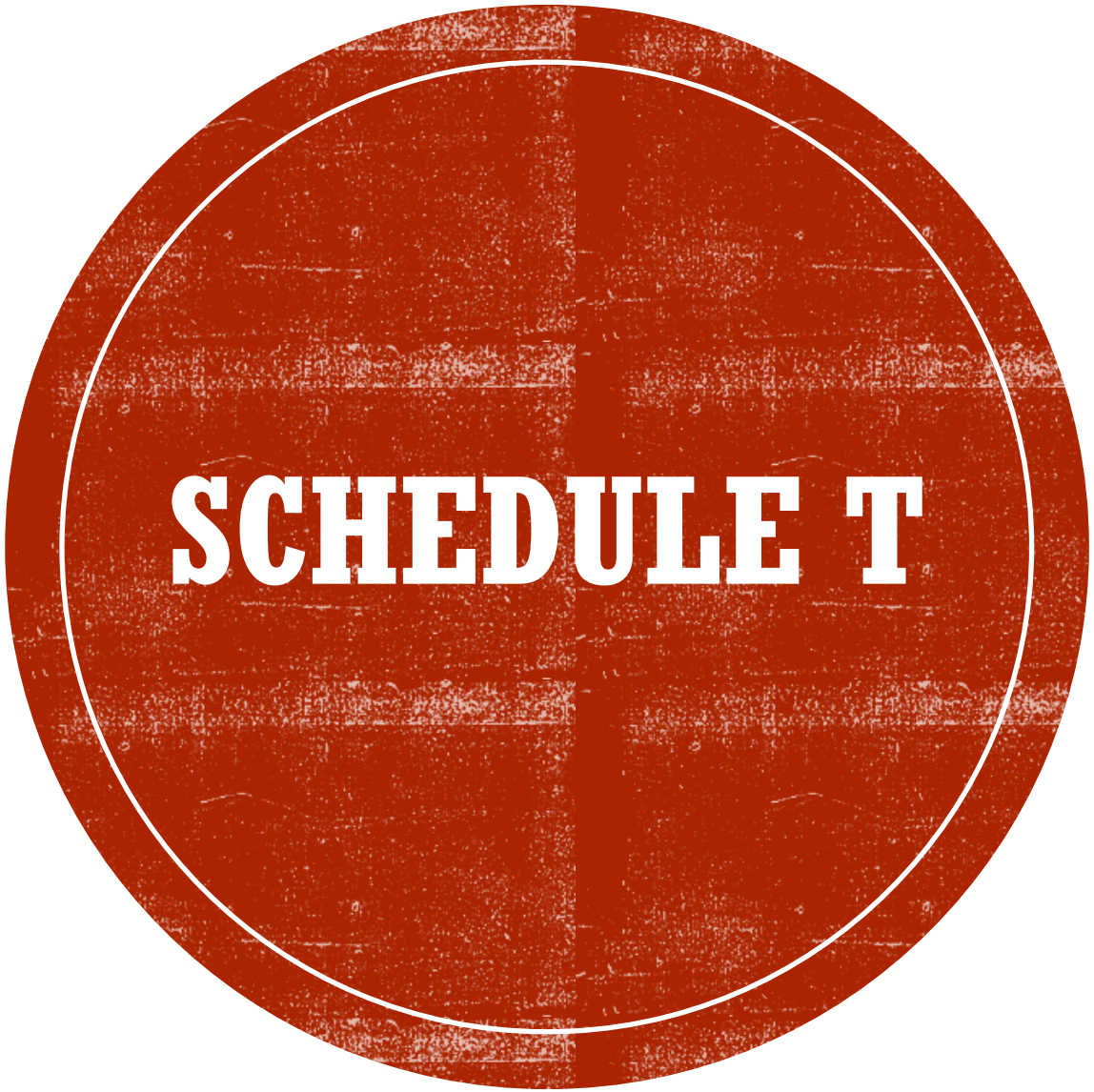
SCHEDULE H



SCHEDULE X

- This schedule deals with the **List of Narcotic Drugs and Psychotropic Substances**.
- Amobarbital, amphetamine, barbital, cyclobarbital, dexamphetamine, phenobarbital, secobarbital are the **examples** of drugs comes under schedule X.





Good Manufacturing Practices for Ayurvedic, Siddha, and Unani Medicines.

Mr. Vishal S Bagul, HRPIPER, Shirpur

1) **Factory Premises:** The manufacturing plant should have **adequate space** for:

i) Receiving and storing raw material,

ii) Manufacturing process areas,

iii) Quality control section,

iv) Finished goods store,

v) Office

vi) Rejected goods/drugs store.

2) **Location and Surroundings:** For the manufacturing of Ayurveda, Siddha , and Unani medicines, the factory building should be situated and constructed to **avoid contamination from open sewerage, drain, public lavatory for any factory forming loathsome odour or fumes or extreme soot, dust and smoke.**

3) Buildings: The factory buildings should facilitate drug production under **hygienic conditions.**

The buildings should have proper facility of light and ventilation.

The buildings used for manufacturing, processing, packaging and labelling should be in conformity with the provisions of the **Factory Act and Schedule M**

4) **Water Supply:** Pure and potable water should be used in manufacturing . Sufficient provisions of water should be available for washing the premises.

5) **Disposable of Waste:** The wastewater and the residues f rom the manufacturing section and laboratories should be disposed off properly as it may be harmful to the workers and public health.

6) **Container's Cleaning:** The factory areas where containers like glass bottles, vials and jars are used should have enough arrangements separated from the manufacturing operations for washing, cleaning and drying of such containers.

7) Stores: These areas should have appropriate ventilation and should be free from dampness. The stores should have ample of space for storing different types of material s, like raw material s, packaging material s, and finished products.

8) Raw Materials: For manufacturing the raw materials should be stored in the raw materials store. Every container for raw material storage should be appropriately labelled specifying the name of the raw material, its source of supply, and also the status like **UNDER TEST or APPROVED or REJECTED.**

9) Packaging Materials: Bottles, jars, capsules etc. should be suitably stored. All containers and closure s should be sufficiently cleaned and dried before packing the products.

Mr. Vishal S Bagul, HRPIPER, Shirpur

10) Batch Manufacturing Records: The licensee should maintain batch manufacturing record of each batch of Ayurvedic, Siddha and Unani drugs manufactured. These records give an account of the list of raw materials and their quantities obtained from the store, tests conducted during the different phases of manufacture such as taste, colour, physical features and chemical tests.

11) Distribution Records: Records of sale and distribution of each batch of Ayurveda, Siddha and Unani drugs should be maintained for the quick recall of the batch, whenever required.

12) Record of Market Complaints: A register to record all the reports of market complaints related to the products sold in the market should be maintained. The manufacturer should submit the record of such complaints to the licensing authority once in every six months.

13) Quality Control: Every licensee should provide a quality control section in his premises or by Government approved testing laboratory. The test s in this section should be conducted as per the Ayurveda, Siddha and Unani Pharmacopoeia standard

SCHEDULE V

- This schedule deals with **Standards for Patent or Proprietary Medicines**. Subject to the provisions of these **rules, patent or proprietary medicines should fulfil the following standards:**

i) Tablets: Medicines should fulfil the needs for tablets as given in the I.P. The nature of coating and the permitted colours should be added on the label. Nature of tablets (uncoated, sugar coated, or film coated) should be given on the label.

ii) Capsules: Medicines should fulfil the requirements for capsules as given in the I.P. 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 90-110% of the labelled contents.
- **Injections:** Medicines should fulfil the needs for injections as given in the I.P.
- **Ointments:** Medicines should fulfil the needs for ointments as given in the I.P.

SCHEDULE Y

- This schedule deals with the **Requirements and Guidelines for Permission to Import and/or Manufacture of New Drugs for Sale or to Undertake Clinical Trials**.

1) **Application for Permission:** Application for approval to import or manufacture new drugs for sale or to undertake clinical trials should be made in **Form 44** along with the following data:

i) Chemical and pharmaceutical information,

ii) Animal pharmacology data:

a) Certain pharmacological actions and therapeutic potential for humans should be defined as per the animal models and species used,

b) General pharmacological actions, and

c) Pharmacokinetic data of the test substance.

2) Clinical Trial:

- **i) Human Pharmacology (Phase I):** The aim of this phase is to estimate the safety with the initial administration of an investigational new drug to human(s). Drugs with potential toxicity (such as cytotoxic drugs) are mainly studied. Phase I trials should be conducted by investigators skilled in clinical pharmacology who carefully observe and monitor the subjects.

- **ii) Therapeutic Exploratory Trials (Phase II):** The main objective of phase II trials is to assess the efficiency of a drug for a specific indication/s in patients with the situations under study. Another objective is to determine the common short-term side-effects and risks related to the drug.

- **iii) Therapeutic Confirmatory Trials (Phase III):** The main objective of phase III trials is to demonstrate the therapeutic benefits, to confirm the results of Phase II that a drug is safe and effective for a parti cular indication and recipient population.

- **iv) Post Marketing Trials (Phase IV):** These studies are done after the approval of drug and related to the approved indication(s). These trials go beyond the previous demonstration of the drug,,s safety, efficacy, and dose.

SCHEDULE F - PART XII B

- **Requirements for the Functioning and Operation of a Blood Bank and/or for Preparation of Blood Components.**

- **General Requirements:**
- **Accommodation for a Blood Bank**
- **Personnel**
- **Maintenance**
- **Equipment and Instruments**
- **Criteria for Blood Donation**
- **Testing of Whole Blood**
- **Records**
- **Labels**

GENERAL REQUIREMENTS

i) Location and Surroundings: The blood bank should be at a place away from open sewage, drain, public lavatory, or unhygienic surroundings.

ii) **Buildings:** The building s used for operation of a blood bank and/or preparation of blood components should be build such that all the operations and manufacturing are done under hygienic conditions.

The building should be adequately lighted, ventilated , and screened.

The walls and floors of premises where collection of blood or preparation of blood components or blood products is done should be smooth, washable, and cleanable.

ACCOMMODATION FOR A BLOOD BANK

A blood bank should be of **100** Square metre area to carry out the operations, and an extra **50** Square metre area for preparation of blood components. It should have room for:

- i) Registration and medical examination with enough furniture and services for registration and selection of donors,
- ii) Blood collection (air-conditioned),
- iii) Blood component preparation (air-conditioned to maintain temperature between 20-25°C),
- iv) Laboratory for blood group serology (air-conditioned),

PERSONNEL

- **Each blood bank should have the following groups of full time competent technical staff:**

i) Blood bank technician(s) with:

- a) Degree in Medical Laboratory Technology (M.L.T) from a Central or State Government recognized university/institution and 6 months experience in the testing of blood and/or its components, or
- b) Diploma in Medical Laboratory Technology (M.L.T) from a Central or State Government recognized university/institution and a year's experience in the testing of blood and/or its components.

ii) Registered nurse(s), and

iii) Technical supervisor with:

- a) Degree in Medical Laboratory Technology (M.L.T) and 6 months‟ experience in the preparation of blood components, or
- b) Diploma in Medical Laboratory Technology (M.L.T) and a years experience in the preparation of blood components.

MAINTENANCE

The premises should be clean and properly manage d for accurate cleaning and operation maintenance. The following facilities should be included:

- i) Privacy and thorough examination of individuals should be done for determining whether they are suitable donors,
- ii) Collection of blood from donors with negligible risk of contamination of exposure to actions and equipment unconnected to blood collection,
- iii) Storage of blood or blood components pending completion of tests.

EQUIPMENT'S AND INSTRUMENTS

- **For Blood Collection Room:**

Donor beds, chairs and tables, stethoscope, Refrigerators, thermometer, Weighing devices for donor and blood containers.

- **For Haemoglobin Determination**

Copper sulphate solution**,** Sterile lancet and impregnated alcohol swabs**,** Capillary tube**,** Rubber bulbs for capillary tubing's**,** haemoglobinometer/Colorimetric method.

- **For Temperature and Pulse Determination**

Clinical thermometers, Watch (fitted with a second-hand) and a stop-watch

- **Emergency Equipment's**

Oxygen cylinder with mask, gauge and pressure regulator**,** 5 per cent Glucose or Normal Saline**,** Disposable sterile syringes and needles of various sizes**,** Disposable sterile I.V. infusion sets, Ampoules of adrenaline, noradrenaline, Aspirin

- **Laboratory Equipment**

Refrigerators, for storing diagnostic kits and regents, maintaining a temperature between 4 -6°C (±2°C) with digital dial thermometer, Compound microscope with low and high-power objectives, Centrifuge table model,Water bath between 37-56°C,Mechanical shakers, Pipettes, Glass slides, Test tubes of various sizes, Filter papers, ELISA reader with printer

CRITERIA FOR BLOOD DONATION

- No one should donate blood and no blood bank should draw blood from a person more than once in three months.
- The donor should be in good health, mentally alert, physically fit, and should not be drug –addicts.
- The donor should be in the age group of 18-65 years.
- The weight of the donor should not be less than 45kg.
- Temperature and pulse of the donor should be normal.

CRITERIA FOR BLOOD DONATION

- The systolic and diastolic blood pressure of the donor should be normal without medication.
- Hemoglobin should not be less than 12.5gm.
- The donor should not have any acute respiratory diseases.
- The donor should not have any disease that could be transmitted via blood transfusion

ADDITIONAL QUALIFICATIONS OF DONOR

Conditions	Deferment Period
Abortions	6 months
History of blood transfusion	6 months
Surgery	12 months
Typhoid	12 months after recovery
History of malaria and duly treated	2 months (endemic) and 3 years (non-endemic area)
Tattoo	6 months
Breast feeding	12 months after delivery
Immunisation (Cholera, Typhoid, Diphtheria, Tetanus, Plague, Gammaglobulin)	15 days
Rabies vaccination	1 year after vaccination
History of Hepatitis in family or close contact	12 months
Immunoglobulin	12 months

TESTING OF WHOLE BLOOD

- i) The licensee should confirm that the whole blood collected, treated, and supplied obeys the standards given in the I.P. and other tests published by the Government.
- ii) The licensee should get blood samples tested (prior to use) for freedom from **HIV 1 and HIV II antibodies.**
- iii) The blood units should also be tested to be free from **Hepatitis B surface antigen and Hepatitis C Virus antibody and malarial parasite**.
- The results of such tests should be mentioned on the container label.

RECORDS

The licensee should maintain records including the following particulars:

- **Blood Donor Record:** It shows serial number, date of bleeding, name, address, signature, age, weight, hemoglobin, blood group, blood pressure, and medical examination of the donor, bag number, and details of the patient.
- **Master Records for Blood and its Components:** It shows the bag serial number, date of collection, date of expiry.
- **Issue Register:** It shows serial number, date and time of issue bag serial number, ABO/RH Group, tot al quantity in ml, name and address of the recipient, group of recipient, unit/institution.
- Records of purchase, use and stock in hand of disposable needles, syringes, blood bags should be maintained.

LABELS

- The labels on bag s containing blood and/or blood components should bear the following particulars:

i) The product name in a prominent place and in bold letters on the bag.

ii) Name and address of the blood bank.

iii) License and serial number.

iv) The date on which blood was drawn and the date of expiry.

v) A colored label should be placed on the blood-containing bags.

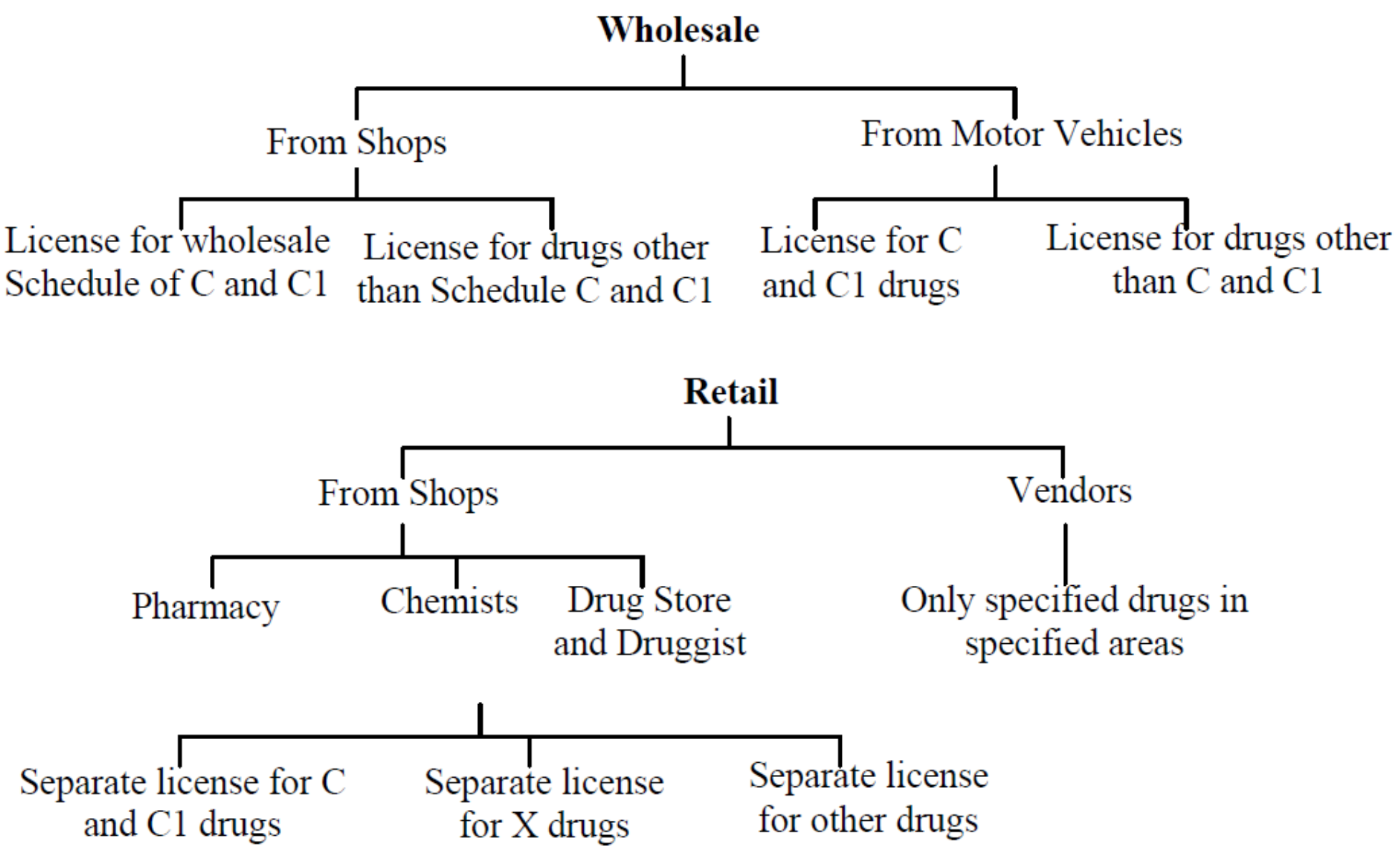
Blood Groups	Colour of the Label
O	Blue
A	Yellow
B	Pink
AB	White

DMR (OA)

- The Drugs and Magic Remedies (Objectionable Advertisements) Act, 1954 is passed for regulating the advertisements of some drugs, and the advertisements of remedies having qualities of magic.
- The objective of this Act is to maintain ethical standards when manufacturers advertise any drugs. Under the guidelines of this Act, advertisements offending the decency or morality can be banned. Also, those claiming magical powers for certain drugs.

SALE OF DRUG

- Drug and Cosmetics act and the Rules made there under restrict the **sale of drug only by License.** That is only **licensed person** are **eligible to sell the drug by wholesale** or **retail.**
- The license can be obtained from licensing are required for different types of sale drug like **Wholesale, Retail, and Vendor sale**.


Wholesale
From Shops
From Motor Vehicles
License for wholesale Schedule of C and C1
License for drugs other than Schedule C and C1
License for C and C1 drugs
License for drugs other than C and C1
Retail
From Shops
Vendors
Pharmacy
Chemists
Drug Store and Druggist
Only specified drugs in specified areas
Separate license for C and C1 drugs
Separate license for X drugs
Separate license for other drugs

Wholesale of biological (C/Cl)

- 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 **Reg. Pharmacist**.
- **Records** of purchase & sale.
- Records preserved for 3 years from date of sale.
- License should **display on premises.**

CLASSES OF DRUGS PROHIBITED TO BE SALE

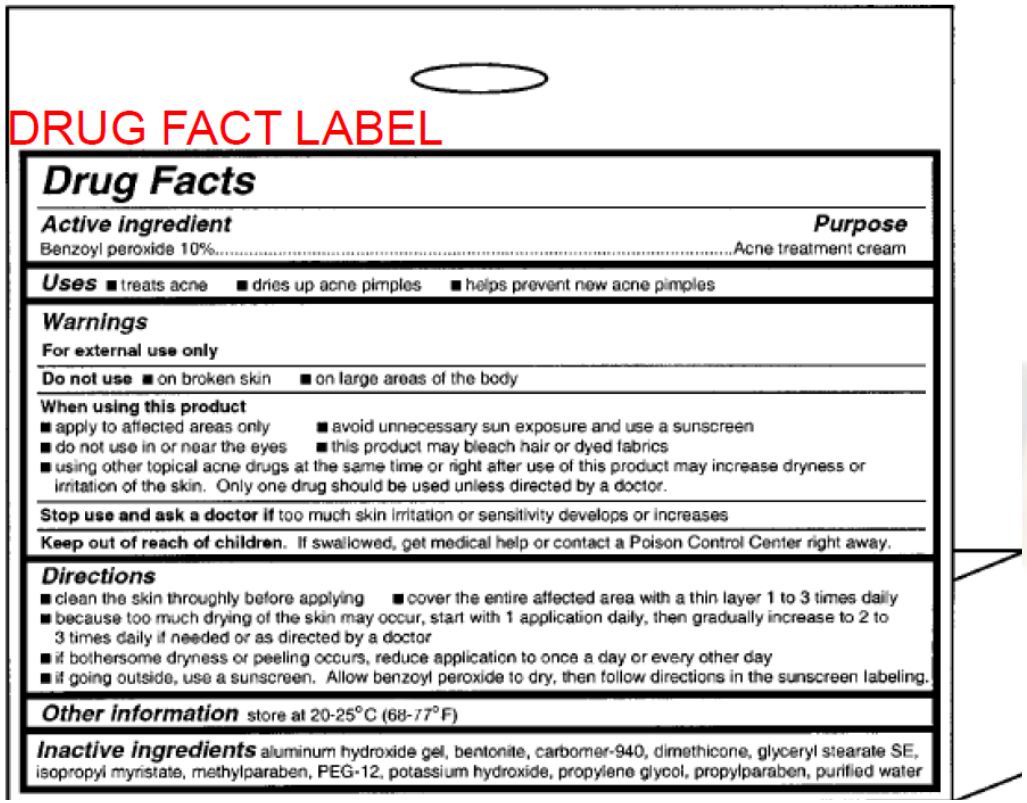
- Misbranded, spurious and adulterated drug
- Expired drugs.
- Drugs used for consumption by government schemes such as **Armed force** and **Government Supplies**
- Physician's samples.

OFFENSES 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 year imprisonment & Rs.2000 fine Or Both on first conviction
	10 years imprisonment & Rs.5000 fine or both for subsequent conviction

LABELING AND PACKING OF DRUG

- labeling" has been defined' to include the display of written material



DRUG FACT LABEL

Drug Facts

Active ingredient ***Purpose***

Benzoyl peroxide 10%.....Acne treatment cream

Uses ■ treats acne ■ dries up acne pimples ■ helps prevent new acne pimples

Warnings

For external use only

Do not use ■ on broken skin ■ on large areas of the body

When using this product

■ apply to affected areas only ■ avoid unnecessary sun exposure and use a sunscreen
■ do not use in or near the eyes ■ this product may bleach hair or dyed fabrics
■ using other topical acne drugs at the same time or right after use of this product may increase dryness or irritation of the skin. Only one drug should be used unless directed by a doctor.

Stop use and ask a doctor if too much skin irritation or sensitivity develops or increases

Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.

Directions

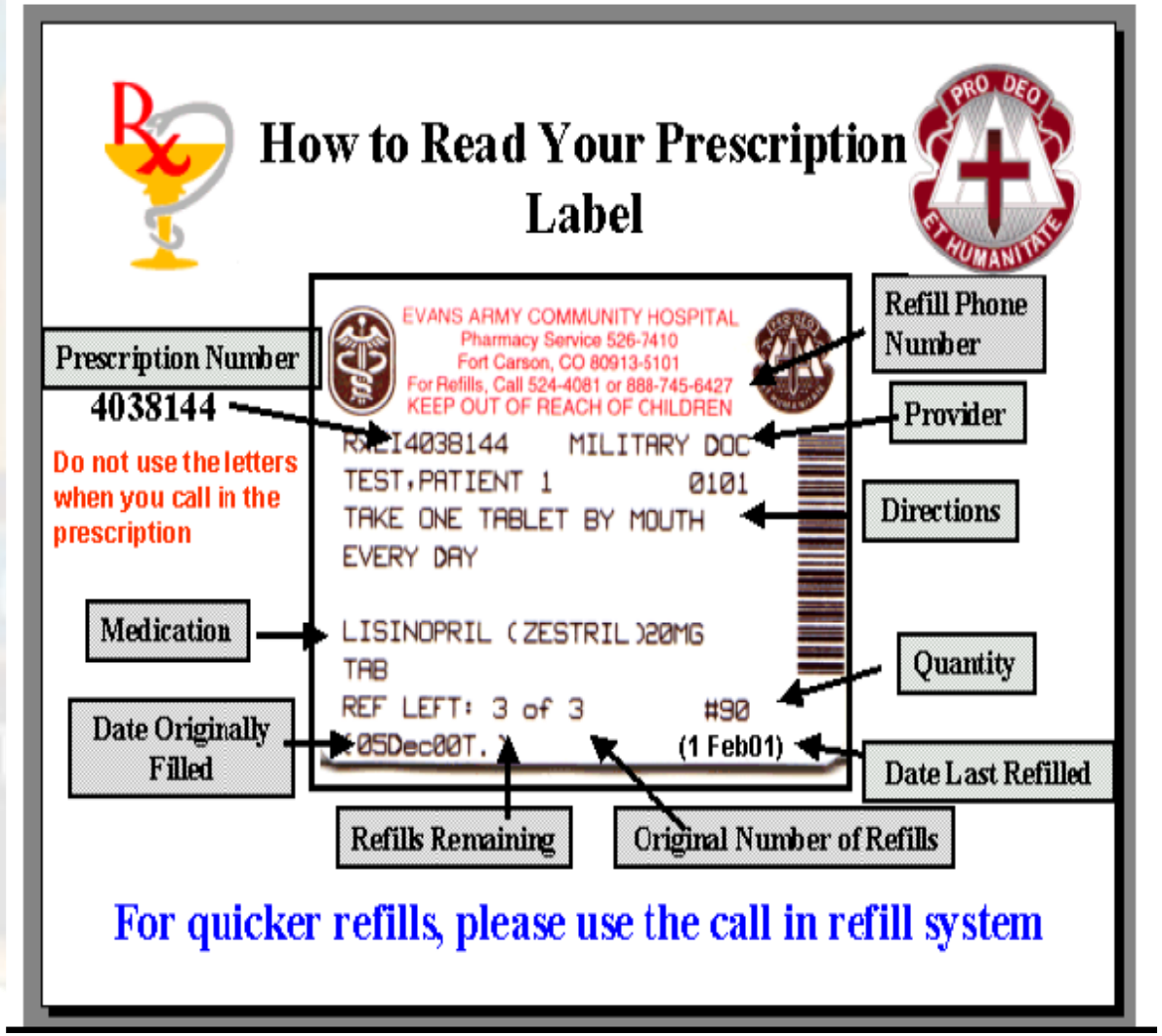
■ clean the skin throughly before applying ■ cover the entire affected area with a thin layer 1 to 3 times daily
■ because too much drying of the skin may occur, start with 1 application daily, then gradually increase to 2 to 3 times daily if needed or as directed by a doctor
■ if bothersome dryness or peeling occurs, reduce application to once a day or every other day
■ if going outside, use a sunscreen. Allow benzoyl peroxide to dry, then follow directions in the sunscreen labeling.

Other information store at 20-25°C (68-77°F)

Inactive ingredients aluminum hydroxide gel, bentonite, carbomer-940, dimethicone, glyceryl stearate SE, isopropyl myristate, methylparaben, PEG-12, potassium hydroxide, propylene glycol, propylparaben, purified water

PRESCRIPTION LABEL

- Patient name and address
- Prescriber's name
- Drug name
- Pharmacy name and date filled
- Special Precautions/ Instructions



Common Names of Colours	Colour Index Number	Chemical Names
Green		
Quinizarine Green SS	61565	1, 4-Bis (*p*-tolyamino) anthraquinone.
Alizarin Cyanine Green F	61570	Disodium salt of 1,4 -bis (*o*-sulfo-*p*-tulouino) anthraquinone
Fast Green FCF	42053	Disodium salt of 4 -{[4-(N-ethyl-p Sulfobenzylamino) -phenyl-]-(4-hydroxy2- sulfoniumphenyl)-methylene} [1 -(N-ethyl-N-p-sulfobenzyl]Δ 2, 5-cyclohexadienimine].
Green S	44090	
Yellow		
Tartrazine	19140	Trisodium salt of 3 -carboxy-5- hydroxy-lp-sulfophenyl-4-p- Sulfophenyl azopyrazole.
Sunset Yellow FCF	15985	Disodium salt of 1 -p-sulfophenyl azo -2- naphthol-6-sulfonic acid.
Quinoline Yellow WS	47005	Disodium salt of disulfonic acid of 2(2 - quinolyl)-1, 3 -indandione.
Red		
Amaranth	16185	Trisodium salt of 1(4 -sulfo-Inaphthylazo) 2 -naptho 1 -3, 6-disulfonic acid.
Erythrosine	45430	Disodium salt of 9 -o-carboxyphenyl 6 -hydroxy 2,4 -5,7-tetriodo-3-isoxanthone.

PRECAUTIONS FOR PRESCRIPTION

- Tell physician of previous problems/allergies
- Keep list of ALL meds. currently using
- Understand directions
- Discuss side effects / Interactions
- Store properly
- Don’t use expired medicines

ADMINISTRATION BODIES

ADMINISTRATION OF THE ACT AND RULES

A) Advisory:

- Drugs Technical Advisory Board (DTAB)
- Drugs Consultative Committee (DCC)

B) Analytical

- Central Drugs Laboratory (CDL)
- State Drug Control Laboratory (SDCL)

C) Executives

- Licensing authorities
- Controlling authorities
- Drug Inspectors

DRUGS TECHNICAL ADVISORY BOARD (DTAB)

Function: To advice the central and state government on technical matters

Constitution:

A. Ex-officio Member: (8 Members)

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

B. Nominated Member : (10 Member)

2 Person from in charge of the **drug control in the States**.

1 Person From **Pharmaceutical Industry**

2 Person **Government Analysts.**

1 Teacher in **Pharmacy, Pharmaceutical Chemistry or Pharmacognosy** on the Staff of a university or affiliated college elected by the executive committee of **PCI.**

1 Teacher in medicine or therapeutics on the staff of a university or affiliated college elected by the executive committee of **MCI.**

1 Pharmacologist, elected by the Governing Body of the **Indian Council of Medical Research.**

1 Person elected by the **Central Council of Indian Medical Association**.

1 Person elected by **Council of the Indian Pharmaceutical Association**.

DRUG CONSULTATIVE COMMITTEE (DCC)

Function:

- To advice the **central and state government and the DTAB** on any matter to secure uniformity throughout India in administration of the Act.
- The Drugs Consultative Committee shall Visit when required.

Constitution:

- **2 Representative** of Central Government nominated by central Government
- **1 Representative** of each State Government nominated by the concerned government.

CENTRAL DRUG LABORATORY (CDL)

Functions:

- **Analysis or test** of samples of drugs/cosmetics sent by the custom collectors or courts.
- Analytical **Q.C.** of the imported samples. Collection, storage and distribution of **internal standards.**
- Preparation of **reference standards** and their maintenance.
- **Any other duties** entrusted by Central Government.

STATE DRUG CONTROL LABORATORIES

- 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.
- Sample sent by the drug Inspector are analyzed in these laboratory.
- The laboratory has the following division:-
- **Pharmaceutical Chemistry Division**
- **Immunology Division**
- **Pharmacology Division**
- **Pharmacognosy Division**
- **Food Division**
- **Ayurvedic Division**

GOVERNMENT ANALYST

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

Qualification:

- Having a degree in **medicine, ayurvedic, sidha or unani system** and not less than **three year post graduate experience in the analysis of drugs in a laboratory under control of a government analyst.**

Duties

- to be analyzed or tested such samples or drugs and cosmetics as may be sent to him by **Inspectors.**
- time to time forward reports to the Government giving the result of analytical work and research with a view to their publication.

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

- having a degree in Medicine, ayurvedic, sidha or unani system and not less than **Three-year** experience in the analysis of drugs in a laboratory under control of
- A government analyst.
- A chemical examiner.

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.