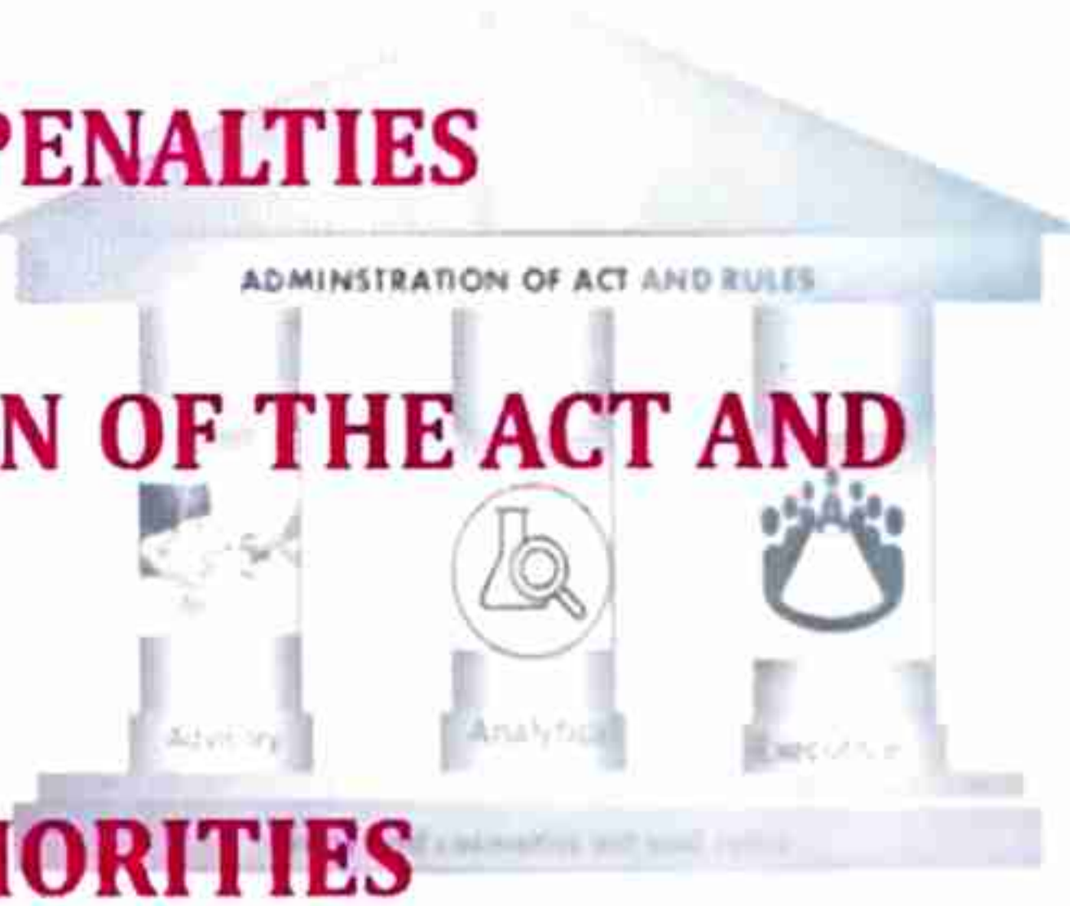
UNIT - II
CHAPTER - 2

DRUG AND COSMETIC ACT

Points to be covered in this topic

1. DETAILED STUDY OF THE SCHEDULES
2. SALE OF DRUGS
3. LABELLING AND PACKING OF DRUGS AND COSMETICS
4. LIST OF PERMITTED COLOURS
5. OFFENCES AND PENALTIES
6. ADMINISTRATION OF THE ACT AND RULES



7. LICENSING AUTHORITIES
8. CONTROLLING AUTHORITIES
9. DRUG INSPECTORS

❑ Detailed Study of the Schedules

SCHEDULE G

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

SCHEDULE H

- The drug label must display the texts **"Rx" on the left top corner of the label** and **"Schedule H drug. Warning : To be sold by retail on the prescription of a Registered Medical practitioner only".**
- It cannot be sold without a prescription and only the amount specified in the prescription should be sold.
- **Examples: Androgenic, estrogenic and progestational substances; Alprazolam, Hepatitis B vaccine, Ibuprofen, Vasopressin etc.**

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

SCHEDULE M (GMP-GOOD MANUFACTURING PRACTICES)

- It is defined as **"the part of quality assurance which is aimed to ensure that the product are consistently manufactured to the quality appropriate to their intended use".**
- It prescribes the **requirements of premises, plant and equipment needed for setting up manufacturing unit.** Also documents every stage of manufacture, packing, storage, transportation checking and testing of medicinal product, maintenance or keeping records.

Part-1: Requirements for Premises and Materials

1. Locations and Surroundings
2. Buildings and Premises
3. Water Supply
4. Disposable of Waste
5. Stores
6. Working Space
7. Sterile Products
8. Container's Cleaning
9. Machinery
10. Raw-Materials
11. Equipment
12. Batch Manufacturing Record
13. Health Clothing, Sanitation and Hygiene of Workers
14. Medical Services
15. Distribution Record
16. Record of Market Complaints
17. Quality Control

Part-2: Requirements for Plant and Equipments

1. **Area:**

(i) Basic installation: Requires minimum of 30 sq. mt. (for tablets manufacturing, upto 60 sq. mt.)

(ii) Ancillary area: 10 sq. mt. (for tablets mfg. upto 20 sq. mt.)

2. **Equipment:**

Colloidal mill, mixing and storage tanks, stainless steel containers, Planetary mixer, Triple roller mixer, disintegration test apparatus, air conditioners, polishing pan, leakage test apparatus etc.

Parts of Schedule M	
Part 1	**Good Manufacturing Practices** For Premises and Material.
Part 1A	Specific requirement **for** manufacture of **sterile products. Parenteral preparations** (Small Volume Injections and Large Volume Parenteral) **and Sterile Ophthalmic Preparations.**
Part 1B	**Specific requirements for manufacture of oral solid forms (Capsule and Tablets).**
Part 1C	**Specific requirements for manufacture of oral liquids (syrups, elixirs, emulsions and suspensions).**
Part 1D	Specific requirements for manufacture of **topical products i.e., External Preparations** (Cream, Ointments, Pastes, Emulsions, Lotions, Solutions, Dusting Powders and Identical Products).
Part 1E	**Specific requirements for manufacture of Metered Dose Inhaler.**

SCHEDULE N	
Describes the facilities and equipments for efficient **running of a Pharmacy**	
Entrance	Front of a pharmacy shall bear an **inscription "Pharmacy" in front.**
Premises	i. Separated from rooms, well built, dry and ventilated with sufficient dimensions for stock of medicaments. ii. Dispensing department shall be not less than 6 sq. m. for one pharmacist working there with additional 2 sq. m. for each additional pharmacist. iii. Height of the premises shall be at least 2.5 metres. iv. A pharmacy shall be provided with ample supply of good quality water.

Furniture and Apparatus	i. A pharmacy shall contain furniture and apparatus, drawers, containers, glasses of suitable sizes and designed to prevent dust entry. ii. Every container shall bear a labels, easily readable with names of medicaments as given in the Pharmacopoeias. iii. Shall be provided with a dispensing bench, washable top etc. iv. Separate cupboards with lock and key for Poisons, and shall be marked in red letters as "POISON" on a white background. v. All concentrated solutions shall be labelled as "To be diluted".
General provisions	Pharmacist shall always wear a clean white overalls, records and registers shall be maintained as per the law, medicaments must bear labels when supplied as per the law.

SCHEDULE P

- Describes the **life period of drugs in months** (unless otherwise specified) between date of manufacture and date of expiry which the labelled potency period of the drug shall not exceed under the conditions of storage specified.

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

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

Schedule P_1: Pack sizes of drugs			
Sr. No.	Drug	Dosage form	Pack size
1	Albendazole	Suspension	10 ml
2	Atenolol	Tablets	14
3	Piperazine	Granules	5 gm

SCHEDULE T

Various regulations and requirements for **manufacture of Ayurvedic, Siddha and Unani products**

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

General Requirements:

1. Location and Surroundings
2. Buildings
3. Water Supply
4. Disposable of Waste
5. Container's Cleaning
6. Stores
7. Working Space
8. Medical Services
9. Health Clothing, Sanitation and Hygiene of Workers
10. Machinery and Equipment
11. Batch Manufacturing Record
12. Distribution Record:
13. Record of Market Complaints
14. Quality Control

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

General Requirements	
1. Anjana/Pisti	8. Kajal
2. Churna/Nasya/Manjan/Lepa	9. Capsules

General Requirements	
3. Pills/Vati/Gutika Matirai and Tablets	10. Ointment/Marham Pasai
4. Kupi pakava/ Ksara/ Parpati/ Lavana/ Bhasma/Satva/Uppu/Param	11. Asava-Aristha
5. Pak/Avaleh/Khand/Modak/Lakayam	12. Sura
6. Panak, Syrup/Pravahi Kwath Manapaku	13. Ark Tinir
7. Aschyotan/Netra Malham Panir/Karn Bindu/Nasa-bindu	14. Tail/Ghrit Ney

SCHEDULE U

Particulars to be shown in **manufacturing record, records of raw materials** and **analytical drugs**. Following are included in **Schedule U**

1. **Manufacturing Records :**
   - i. Substances other than Parenteral Preparation
   - ii. Parenteral Preparations
2. **Records of Raw Materials :**

   Date of receipt, Name and address of the manufacture, Batch number, Pack size, Dates of manufacture and expiry, quantity and date of issue etc.
2. **Particulars to be recorded in the Analytical Records :**
   - i. Tablet, Capsules and for other drugs
   - ii. Parenteral Preparations
   - iii. Raw Materials
   - iv. Container and Packing Material

SCHEDULE U_1

Particulars to be shown in the manufacturing record for cosmetics

1. **Manufacturing Records:** Serial number, Product name, Reference of Master formula records, Date-time-duration conditions of the process for manufacture, Name of all the ingredients, etc.
2. **Records of Raw Materials:** Date of receipt, Invoice number, Quantities received, Pack size, Dates of manufacture and Expiry, Date of analysis and release/rejection by quality control etc.

SCHEDULE V

Standards for Patent or Proprietary medicines

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

Sr. No.	Drug	Unit	Adult (daily dose)
1	Vitamin A	I.U.	NLT 5,000 and NMT 10,000
2	Vitamin D	I.U.	NLT 400 and NMT 1,000
3	Vitamin B_1	Mg	NLT 4.5 and NMT 10
4	Vitamin B_6	Mg	NLT 1.5 and NMT 3

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

SCHEDULE F

Schedule F	Standards for running a blood bank.
Schedule F_1	Standards for bacterial vaccines, viral vaccines, antisera and diagnostic agents.
Schedule F_2	Standards for surgical dressing.
Schedule F_3	Standards for umbilical tapes (polyester and cotton tapes).
Schedule FF	Standards for ophthalmic preparations (solutions, suspensions and ointments). The label must bear: (i) The statement "use the solution within one month after opening the container" (ii) Name and concentration of the preservative used (iii) "Not for Injection" (iv) Storage instructions (v) Warning (a) If irritation persists or increases, discontinue the use and consult physician. (b) Do not touch the dropper tip or the other dispensing tip to any surface since this may contaminate the solution.

	• Requirements for the **premises, personnel, equipments and organizations and operation of a Blood Bank and/or for preparation of Blood components.**
Part XII-B	• It's a part **under** Schedule **F.** **I. Blood Banks/Blood Components** **II. Blood Donation Camps** **III. Processing of Blood Components from Whole Blood by a Blood Bank**

Drug and Magic Remedies (Objectionable Advertisement)

- **"Magic remedy"** as any **Talisman, Mantra, Kavachas** or any other object which is claimed to have **miraculous powers to cure, diagnose, prevent or mitigate a disease in humans or animal.** It also includes such devices that are claimed to have power to influence structure or function of an organ in humans or animals.
- The **law prohibits advertising of drugs and remedies** for –
  - **i. Inducing miscarriage or preventing conception in women.**
  - **ii. Improving or maintaining the capacity for sexual pleasure.**
  - **iii. Correction of menstrual disorders.**
  - **iv. Curing, diagnosing or preventing any disease or condition** mentioned in an included schedule.

❑ SALE OF DRUGS

❖ Wholesale, Retail and Restricted Sale Licenses

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

DRUG CONTROL ORGANIZATION ISSUES TWO TYPE OF LICENSE	
Retail Drug License (RDL) to run a chemist shop, and it is issued to only those persons who possess degree or diploma in pharmacy from a recognized university on the payment of the requisite fees.	Wholesale Drug License (WDL) which is issued to a person who is engaged in the business of wholesale of drugs and medicines.

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

➢ Conditions of Wholesale License:

1. **Area: Not be less than 10 sq. m.**
2. **Storage:** It is necessary to have a **refrigerator and air conditioner** on the premises because certain drugs such as **vaccines, insulin injections** etc. are needed to be **stored in the fridge.**
3. **Competent Staff:** The sale can be made either by a **registered pharmacist** or another **competent person** who must be a **graduate with one year** experience in drugs or in the presence of any **one who has passed S.S.L.C** having experience of **four years** in drugs, specially approved by drug control department.
4. **Supply** of drugs shall be made **against a cash memo**. Carbon copies of the same shall be preserved for **3 years from the date of last entry.**
5. Shall **maintain the records** of purchase, and produce all the registers and records during inspection. Records must be preserved for **2 years from the last entry.**

6. **Inspection book** shall be maintained in **Form 35.**
7. A **separate record shall be maintained** for the supply of **Schedule X drugs,** the copies of invoices of sale of such drugs to the retailer, shall be forwarded to the Licensing authority.
8. **No sale of any drug** should be made for the purpose of **resale to a person not holding the license to sell or distribute the drugs.**

➢ Conditions of Restricted License:

Restricted licences in **Forms 20A and 21A.**

1. Dealers or persons in respect of drugs whose sale **does not require the supervision of a qualified person**.
2. Licenses to itinerant vendors shall be issued only in exceptional cases for bonafide travelling agents of firms dealing in drugs.

3. The licensing authority may **issue a license in Form 21A** to a travelling agent of a firm but to no other class of itinerant vendors for the specific purpose of distribution to medical practitioners or dealers samples of biological and other special products specified in **Schedule C.**
4. The licensee must have **adequate premises equipped with facilities for the proper storage** of which the license applies, provided that, this condition does not apply to the vendors.
5. License should be **displayed in a prominent place** in a part of the premises **open to the public or must be kept on the person of vendor** who shall produce the **same on demand by authorized government officers.**
6. Drugs should be **purchased only from a duly licensed dealer or manufacturer.**
7. The licensee can deal only with such drugs, which can be **sold without the supervision of a qualified person.**
8. Drugs must be **sold in their original container.**

➢ Required Documents for obtaining Drug License:

1. **Application Form.**
2. **Cover letter with the name and designation of the applicant.**
3. **Copy of challan achieved by depositing fees for obtaining drug license.**
4. **Declaration in a prescribed manner.**
5. **Kite plan and site plan for the premises.**
6. **The basis of possession of premises.**
7. **In the case of rented property, ownership proof.**

8. **Document related to the constitution of business such as Incorporation certificate/ MOA (Memorandum of association)/AOA (Articles of association)/Partnership Deed.**
9. **Affidavit related to non-conviction of director/partner/proprietor.**
10. **Testimony of registered pharmacist or competent person and their appointment letter in case of an employed person.**

II. Offences and penalties relating to the Sale of drugs :

S.NO.	OFFENCE	PENALTY	
		First conviction	Second conviction
	Sale or distribution of		
1	(i) Any adulterated or spurious drugs or drug not of standard quality	Upto 5 years and extending upto lifetime and fine of not less than 10,000.	Upto 10 years or fine upto 20,000 or both.
	(ii) Any adulterated but not containing toxic or harmful substances injurious to health	1-3 years and fine of not less than 5,000	2-4 years / fine upto 10,000.
	(iii) Without a license	Less than a year and a lesser fine.	Not less than 2 years /fine upto 10,000.
	(iv) Spurious drugs but not manufactured under the name of any other drug	3-5 years/ fine of not less than 5,000.	Not less than 6-10 years / fine upto 10,000.
	(v) Any other	1 year	-
	(vi) Contravention of this act	Imprisonment from 1-2 years and fine.	Imprisonment for 2-4 years / fine upto 5,000 or both.
2	Not keeping records of sale in the specified manner.	Upto 3 years / fine upto1000 or both.	
3	Using the report of Government analyst for advertising any drug.	Fine upto 500	Upto 10 years / with fine or both.

❑ LABELLING AND PACKING OF DRUGS AND COSMETICS

❖ General Labelling Requirements

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

❑ LABELLING AND PACKING OF DRUGS AND COSMETICS

❖ General Labelling Requirements

1. **Drug name:** The proper name of the drug shall be printed or written in a more conspicuous manner than the trade name, if any.
2. **Net content:** Weight, volume, in metric system or units.
3. **Content of Active ingredients:**

Oral liquids	Contents per single dose, i.e. 5 ml or multiple .If dose is below 5 ml, then per ml.
Liquid parenteral	Contents per ml or in percentage or per dose.
Solid parenteral	Contents per mg or per gm or in terms of units.
Tablets, capsules and pills	Contents per tablet, capsule, pill.
For other preparations	Contents in terms of percentage by w/w or w/v or units per gm or ml.

4. **Name and address of manufacturer;** In case of the drug contained in an ampoule or a similar container
5. **Manufacturing license number:** Mfg. Lic. No. or M.L. No.
6. **Batch number:** Batch No. or Lot No.
7. **Date of manufacturing:** Mfg. Date.
8. **Date of expiry:** Exp. Date
9. **Free samples to medical profession:** "Physician's Sample - Not To Be Sold".
10. **Alcoholic preparations:** If alcoholic content exceeds 3% by volume, percentage of alcohol must be mentioned on the label.
11. **Information of handling, use, distribution, storage etc.**
12. **Maximum Retail Price:** M.R.P.
13. **Hair dyes containing coal tar colours:** on inner and outer label both, in English and local languages: "Caution: The product contains ingredients which may cause skin irritation in certain cases and so preliminary test according to the accompanying directions shall first be made. This product shall not be used for dyeing the eyelashes or eyebrows as such if used, may cause blindness".
14. **Toothpaste containing Fluoride:** Fluoride content in ppm (NMT 1000 ppm), Date of expiry.

❖ Special Labelling Requirements

CLASS OF DRUGS	PARTICULARS WHICH SHOULD APPEAR ON LABEL
Schedule C_1	• Date of manufacture and expiry • Import license number
Schedule F	The prescribed name
Schedule G	The words "Caution. It is dangerous to take this preparation except under medical supervision"
Schedule H	• Symbol R_X conspicuously on the left top corner of the label; "To be sold by retail on the prescription of a RMP only" • For Narcotic and Psychotropic drugs, symbol NR_X conspicuously on the left top corner of the label in red ink and "To be sold by retail on the prescription of a RMP only".
Schedule X	Symbol XR_X in red ink, conspicuously on the left top corner of the label; "To be sold by retail on the prescription of a RMP only".
Schedule D	• Date of manufacture • Date of expiry of potency
Schedule G	• Proper name • Import licence No. • Batch No.
Schedule W (Single ingredient)	Proper name (no trade name)
Preparations for External use	FOR EXTERNAL USE ONLY; eg: lotion, liniment, cream, ointment, liquid antiseptics
Pharmacopoeial preparations	It should have on label words other drugs printed as 'I.P.', 'B.P.', 'B.P.C', 'U.S.P', 'N.F.' etc.
Patents and Proprietary medicines	• Quantities of active ingredients • Name and address of the manufacture
Medicines for Animals	"NOT FOR HUMAN USE, FOR ANIMAL TREATMENT ONLY"; Symbol depicting the head of a domestic animals.

II. Specimen Labels

SCHEDULE H DRUG

R_x ERYTHROMYCIN ESTOLATE TABLETS IP 500 MG

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

SCHEDULE H DRUG

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

Mfg Lic. No. 2/20
Batch No. 2019
Mfg. Date
Exp. Date

M.R.P not to exceed ₹ .....
inclusive of all taxes

Manufactured by: XYZ Pharmaceuticals, India

EXTERNAL USE

15 gm

POVIDONE IODINE OINTMENT USP

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

FOR EXTERNAL USE ONLY

Mfg Lic. No. 2/20
Batch No. 2019
Mfg. Date
Exp. Date

M.R.P not to exceed ₹ .....
inclusive of all taxes

Manufactured by: XYZ Pharmaceuticals, India

SCHEDULE X DRUG

XRx PENTOBARBITONE SODIUM INJECTION USP

Each ml contains:

Pentobarbitone Sodium USP .....50 mg

For Intramuscular Injection only

Dosage: As directed by the Physician

SCHEDULE X DRUG

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

The Injection must be discarded if any precipitate is observed

Mfg Lic. No. 2/20
Batch No. 2019
Mfg. Date
Exp. Date

M.R.P not to exceed ₹ .....
inclusive of all taxes

Manufactured by: XYZ Pharmaceuticals, India

SCHEDULE G DRUG

PHENIRAMINE TABLETS IP

Each uncoated tablet contains:

Pheniramine maleate IP.....25 mg

Dosage: 1 tablet 2-3 times daily or as directed by the Physician.

Store protected from light

SCHEDULE X DRUG

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

Mfg Lic. No. 2/20
Batch No. 2019
Mfg. Date
Exp. Date

M.R.P not to exceed ₹ .....
inclusive of all taxes

Manufactured by: XYZ Pharmaceuticals, India

❑ LIST OF PERMITTED COLOURS

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

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

b) **Artificial Colours:** Caramel, Riboflavin.

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

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

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

❑ OFFENCES AND PENALTIES

Same as offences and penalties under sale of drugs.

❑ ADMINISTRATION OF THE ACT AND RULES

ADMINISTRATION

ADVISORY

1. Drugs Technical Advisory Board (DTAB)
2. Drugs Consultative Committee (DCC)

ANALYTICAL

1. Central Drugs laboratory
2. Drugs Control laboratories in states
3. Government analysis

EXECUTIVE

1. Licensing authorities
2. Controlling authorities
3. Drugs Inspectors
4. Collect collectors

I. The Drugs Technical Advisory Board (DTAB):

Ex-officio members (Total = 8)	Nominated members (Total = 5)	Elected members (Total = 5)
1. Director General of Health services – **Chairman**	1. **Two Person** nominated by the central govt. amongst person who are incharge of drug control in India	1. **A teacher** in pharmacy or pharmaceutical chemistry or pharmacognosy elected by executive committee of PCI
2. **Drug controller of India**	2. **1 person** from pharmaceutical industry nominated by central govt.	2. **A teacher** in medicine or therapeutics elected by executive committee of PCI
4. Director of Central Drug Laboratory, **Kolkata**	3. **2 govt.** analyst nominated by central govt.	2. **1 pharmacologist** elected by governing body of Indian council of medical research
4. Director of Central research institute, **Kasauli**		4. **1 person** elected by the council of central medical association
4. Director Indian Veterinary research institute, **Izatnagar**		5. **1 person** to be elected by the council of the Indian pharmaceutical association
6. Director of Central Drug Research Institute, **Lucknow**		
7. President - **Medical Council of India (MCI)**		
8. President - **Pharmacy Council of India (PCI)**		

II. The Central Drugs Laboratory (CDL):

- **Central Government** established a **CDL** under the control of a Director to be **appointed by the Central Government**
- This was **established in Calcutta** to carry out the following functions:
    1. **To analyse or test, samples of drugs as may be sent to it by the Custom Collectors or Courts.**

2. **CDL is not equipped for testing of all types of products**, some other Government labs and Institutes shall also perform the functions of CDL :

   i. **Central Research Institute,** Kasauli; carries out the assigned functions in respect of: Sera, vaccines, toxins, antigens, sterilized surgical sutures and ligatures, Bacteriophage.

   ii. **Pasteur Institute of India,** Coonoor and Enterovirus Research Centre, Mumbai in respect of Polio vaccine.

   iii. **Indian Veterinary Research Institute,** Izatnagar or Mukteshwar in respect of: antisera, toxoids, vaccines, diagnostic agents for veterinary use.

   iv. **Central Indian Pharmacopoeia Laboratory**, Ghaziabad in respect of Condoms.

   v. **Laboratory of the Serologist and Chemist examiner to the Government of India,** Calcutta in respect of VDRL antigen.

   vi. **Department of Biomedical engineering of the Indian Institute of Technology,** New Delhi in respect of Intra Uterine Devices.

   vii. **Homeopathic Pharmacopoeia Laboratory,** Ghaziabad in respect of Homeopathic medicines.

3. All **samples sent to the laboratories** are required to be **sent by registered post in a sealed packet enclosed together** with a memorandum in the prescribed form, addressed to the Director.

4. On receipt of the packet, it must be **opened by an authorized officer**, in this behalf by the Director.

5. After test, the results with complete protocols of the **tests applied, should be sent to the sender.**

6. Certificates issued by the Laboratory under the rules should be signed by the Director or any other Central Government authorized officer

III. The Drugs Consultative Committee (DCC) :

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

  1. **Two** representatives nominated by the **Central** Government.
  2. **One** representative nominated by each **State** Government.

IV. Government Drug Analysts :

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

❖ Qualifications of Government Analyst :

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

❖ Duties of Government Analysts :

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

On **completion of analysis**, he furnishes the reports of analytical and research work to the Inspector, along with test protocols applied.	Form 13
If **purchaser want to analyse** the drug or cosmetic, he has to make an application for analysis, with a prescribed fee.	Form 14A
The **reports of such drugs** will be furnished, by Government analyst.	Form 14B

❑ LICENSING AUTHORITIES

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

❖ Qualification of a Licensing Authority:

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

❑ CONTROLLING AUTHORITIES

- **Drug Inspectors appointed by the Central Government or the State Government act are under the control of a Controlling authority.**

❖ **Qualification of a Controlling Authority:**

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

I. Drug Control Department (DCD):

- **The department is vested with the licensing of manufacturing and sales premises of drugs and cosmetics in the state.**
- **It primarily strives to ensure the supply of quality drugs.**
- **It comprises 3 wings:**
  - **i. Enforcement wing**
  - **ii. Educational wing**
  - **iii. Drugs Testing Laboratory (DTL)**

II. The Central Drugs Standard Control Organisation (CDSCO):

- **Under Directorate General of Health Services, Ministry of Health and Family Welfare, Government of India is the National Regulatory Authority (NRA) of India.**
- **Its headquarter is located at New Delhi and also has six zonal offices, four sub zonal offices, thirteen Port offices and seven laboratories spread across the country.**

➢ **Responsibilities:**

1. **It envisages uniform implementation of the provisions of the Act and Rules made there under for ensuring the safety, rights and wellbeing of the patients by regulating the drugs and cosmetics.**
2. **CDSCO is constantly thriving upon to bring out transparency, accountability and uniformity in its services in order to ensure safety, efficacy and quality of the medical product manufactured, imported and distributed in the country.**
3. **CDSCO is responsible for approval of Drugs, Conduct of Clinical Trials, laying down the standards for Drugs, control over the quality of imported Drugs in the country and co-ordination of the activities of**

State Drug Control Organizations by providing expert advice with a view of bring about the uniformity in the enforcement of the Drugs and Cosmetics Act.

4. Further CDSCO along with state regulators, is jointly responsible for grant of licenses of certain specialized categories of critical Drugs such as blood and blood products, I. V. Fluids, Vaccine and Sera.

❑ DRUG INSPECTORS

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

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

❖ **Duties of Drug Inspector:**

1. **Inspect**
   - a) **Any premises wherein any drug or cosmetic is**
     - i. Manufactured and the means employed for standardizing and testing.
     - ii. Sold, or stocked or exhibited or offered for sale or distributed.
2. **Collection of samples**
   - i. Which is being manufactured or being sold or is stocked or exhibited or offered for sale, or is being distributed.

ii. From any person who is in the course of conveying, delivering or preparing to deliver such drug or cosmetic to a purchaser or a consignee

3. Search any person in connection with the offence under this Chapter at all reasonable times.
4. Enter and search any place or premises in which he has reason to believe that an offence is being committed or has been committed.
5. Stop and search any vehicle or other conveyance which is used for carrying any drug or cosmetic in respect of which offence has been or has being committed.
6. Give order (in writing) in possession of drug or cosmetic in respect of which offence has been committed or is being committed, not to dispose stock of such drug or cosmetic for a specified period not exceeding 20 days or unless the defect may be removed by the possessor of the drug or cosmetic, if necessary he may seize it.
7. Examine any record or any register of drug or cosmetic which is in contravention of the provisions of this Act.
8. Exercise the powers as may be necessary, for carrying out the purpose of this act.