B.PHARMA SEM- 5

UNIT-2

PART-1

PHARMACEUTICAL JURISPRUDENCE

DRUGS AND COSMETICS ACT, 1940 AND ITS RULES 1945.

STUDY OF SCHEDULES-

G, H, M, N, P,T,U,
V, X, Y, PART XII B,
SCH F & DMR (OA)

CLICK ON BANNER TO WATCH VIDEO

Pharmaceutical Jurisprudence

B.Pharm I Sem – 5

Unit – 02 | Part - 1

Drugs and Cosmetics Act, 1940 and its rules 1945

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

DOWNLOAD "PHARMACY INDIA" MOBILE APP

SCAN ME

Mobile Phone Par Click karein

Download Pharmacy India Mobile App from Play Store

DAILY UPDATES

जुड़िए PHARMACY INDIA

के साथ.....

WHATSAPP & TELEGRAM SE JUDNE KE LIYE ICONS PAR CLICK KARE

SCAN ME

WhatsApp

SCAN ME

❑ Introduction (Drugs and Cosmetics Act, 1940 & Rules, 1945)

- Passed to regulate **import, manufacture, distribution, and sale** of drugs and cosmetics.
- All operations related to drugs must be carried out by **qualified persons**.
- To ensure compliance, **Central and State Drug Control Authorities** were established.
- **Drugs and Cosmetics Rules** are divided into **18 parts**, each dealing with a specific subject.
- The Act contains **2 schedules,** while the Rules contain **25 schedules**.

Schedule G

Definition:

- Schedule G lists drugs that should be used **only under medical supervision**.

Label Requirement:

- Every drug in Schedule G must carry this caution on the label:
  "Caution: It is dangerous to take this preparation except under medical supervision."

Nature of Drugs:

- Mostly **potent drugs** with potential for **serious adverse effects or toxicity** if misused.

Examples:

- Hormones (e.g., Insulin, Corticosteroids), Cytotoxic drugs (Cyclophosphamide, Aminopterin), certain Antineoplastic & Immunosuppressive agents.

Prescription Rule:

- Though not as strictly controlled as Schedule H/X, they are **not to be sold freely** without doctor's advice.

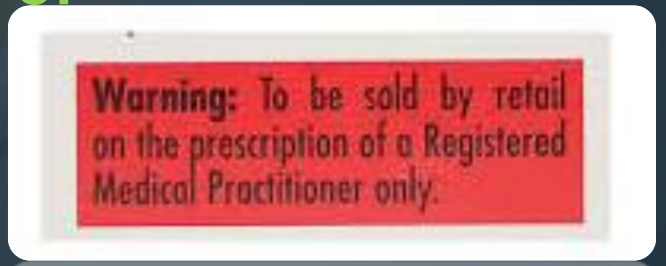
Pharmacist's Role:

- Pharmacist must **counsel the patient** about dosage, duration, and precautions while dispensing these medicines.

Schedule H

Definition:

- Schedule H contains the list of **prescription-only drugs** which must be sold **by retail only on the prescription of a Registered Medical Practitioner (RMP).**



Label Requirement:

- Each container must be labeled with the symbol **"Rx"** in red and the following warning:
  "Schedule H Drug – Warning: To be sold by retail on the prescription of a Registered Medical Practitioner only."

Nature of Drugs:

- Includes **antibiotics, antihypertensives, anticancer drugs, hormones, and CNS drugs** which require strict medical supervision.

Control of Sale:

- These drugs **cannot be advertised** to the public.
- Record of prescriptions must be maintained by the pharmacist.

Examples:

- Tetracyclines, Sulphonamides, Corticosteroids, Antidepressants, and Antipsychotics.

Schedule H1

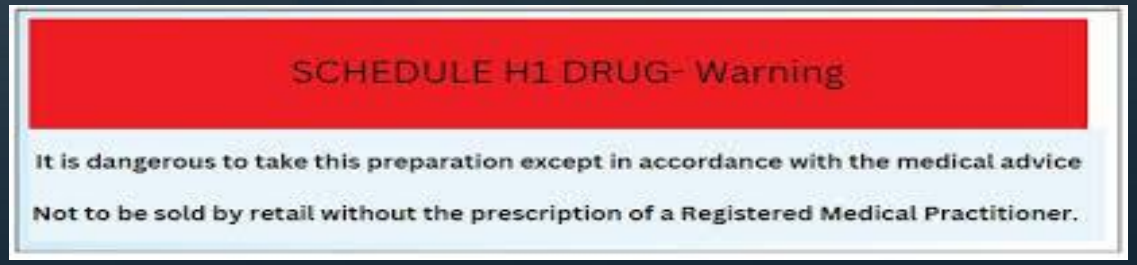
Definition: Introduced in 2013 to control **antibiotic misuse**.

Key Points:

- Contains strict regulations to prevent unauthorized sales.
- Must display **"Rx" sign**.
- Label warning (red box):

  "It is dangerous to take this preparation except in accordance with medical advice. Not to be sold without prescription of RMP."

Examples: Alprazolam, Diazepam, Levofloxacin, Zolpidem.



Schedule M

Definition:

- Schedule M prescribes the **Good Manufacturing Practices (GMP)** and **requirements of premises, plant, and equipment** for pharmaceutical products.

Purpose:

- To ensure **quality, safety, and efficacy** of drugs by maintaining proper standards in manufacturing and testing.

Main Requirements:

- **Factory Premises** – Adequate location, building design, ventilation, water supply, waste disposal.

- **Working Space** – Sufficient to prevent mix-ups and contamination.
- **Health & Hygiene** – Staff must follow proper clothing, cleanliness, and medical fitness.
- **Sanitation** – Clean environment with pest control and sterilization facilities.

Equipment:

- Should be designed to avoid contamination.
- Examples: mixers, dryers, tablet punching machines, autoclaves, ovens, storage tanks.

Quality Control (QC):

- Separate QC laboratories required.
- Records of tests on raw materials, intermediate, and finished products must be maintained.

Schedule N

Equipment:

- Should be designed to avoid contamination.
- Examples: mixers, dryers, tablet punching machines, autoclaves, ovens, storage tanks.

Quality Control (QC):

- Separate QC laboratories required.
- Records of tests on raw materials, intermediate, and finished products must be maintained.

Furniture & Facilities:

- Storage racks, dispensing counter, cupboards, and a **separate cupboard for poisons**.
- Refrigerator for storing temperature-sensitive medicines (e.g., insulin, vaccines).

Books & References:

- Every pharmacy must keep the latest editions of:
  - Indian Pharmacopoeia (IP)
  - Drugs & Cosmetics Act, 1940 and Rules, 1945
  - National Formulary of India (NFI)

Records & Registers:

- Prescription registers, poison registers, and purchase/sale invoices must be maintained for **inspection**.

General Provisions:

- Adequate arrangements for safe storage of medicines.
- Expired drugs should not be kept with saleable stock.
- All drugs must be purchased from **licensed dealers or manufacturers**.

Schedule P

Definition:

- P specifies the **life period (expiry date)** and **specific storage conditions** for different drugs and pharmaceutical products.

Purpose:

- To ensure **drug stability, potency, and safety** throughout its shelf life.
- Helps pharmacists and manufacturers maintain proper storage practices.

Contents:

- Lists drugs with:
  - **Maximum life period** (in months/years).
  - **Recommended storage conditions** (cool, dry, refrigeration, etc.).

Examples:

- Ampicillin → 36 months.
- Insulin injection → 24 months at **2–8 °C**.
- Vitamin preparations, sera, vaccines, and antibiotics are commonly included.

Storage Conditions:

- *Cool place* = 8–25 °C.
- *Cold place* = below 8 °C.
- *Dry place* = free from moisture/humidity.

•Legal Binding:

- Manufacturers must follow the shelf life & storage rules of Schedule P.
- Dispensing pharmacies must **not sell drugs beyond this period**.

Schedule T

Definition:

- Schedule T lays down the **Good Manufacturing Practices (GMP)** specific for **Ayurvedic, Siddha, and Unani drugs**.

Premises Requirements:

- Factory must be located in a clean environment with adequate space, proper ventilation, drainage, and storage facilities.

Plant & Equipment:

- Provision for washing raw materials, drying, grinding, mixing, and packaging.
- All equipment must be non-toxic, easy to clean, and maintained in hygienic condition.

Raw Materials & Stores:

- Raw materials should be of **authentic quality** and stored in clean, labeled containers.
- Separate storage for finished products, raw materials, rejected, recalled, and returned goods.

Quality Control:

- Each manufacturer must have a **Quality Control section** with necessary equipment and reference texts (Ayurvedic Formulary of India, API, Siddha Formulary, Unani Pharmacopoeia, etc.).

Health & Hygiene of Workers:

- Workers must wear protective clothing, maintain personal hygiene, and undergo medical check-ups regularly to avoid contamination of medicines.

Schedule U

Definition:

- Schedule U specifies the **details of records** to be maintained for **manufacture and quality testing** of drugs.

Manufacturing Records:

- Must include:
  - Name of product & batch number
  - Batch size
  - Date of manufacture & expiry
  - Details of raw materials used (name, quality, quantity)
  - Manufacturing process followed

Testing Records:

- Must record results of all tests performed on raw materials, intermediate, and finished products.
- Includes chemical, biological, and microbiological tests.

Retention of Records:

- Records must be preserved for **at least 5 years** from the date of manufacture.

Legal Importance:

- Ensures **traceability and accountability** in case of drug quality complaints, recalls, or adverse effects.

Schedule V

Definition:

- Schedule V lays down the **standards for patent or proprietary medicines** not included in the official pharmacopoeias (IP, BP, USP).

Scope:

- Applies to dosage forms such as **tablets, capsules, liquid orals, injections, ointments, and creams**.

Labeling Requirement:

- Labels must display the **active ingredients with their quantities**.

Standards:

- Medicines must conform to **quality, purity, and strength** standards equivalent to official pharmacopoeial requirements.

Purpose:

- To ensure **safety and efficacy** of branded/proprietary formulations that are not listed in IP.

Schedule X

Definition:

- Schedule X contains a list of **habit-forming, narcotic, and psychotropic drugs** with **high abuse potential**.

Examples:

- Amphetamines, Barbiturates (Amobarbital, Pentobarbital, Secobarbital), Methaqualone, Methamphetamine, Methylphenidate.

Sale & Storage Rules:

- Can be sold only on a **prescription of a Registered Medical Practitioner (RMP)**.
- Must be stored **separately under lock and key**.

Records:

- Every transaction must be recorded in a **separate register (Form 3C)**.
- Records to be preserved for at least **2 years**.

Purpose:

- To prevent **misuse, abuse, and illegal trafficking** of narcotic/psychotropic substances.

Schedule X

Definition:

- Schedule Y lays down the **requirements and guidelines for clinical trials** and approval of new drugs in India.

Application:

- Manufacturer/importer must apply to the **Licensing Authority (DCGI)** for permission to conduct trials and market new drugs.

Phases of Clinical Trials:

- **Phase I** – Human pharmacology & safety (healthy volunteers).
- **Phase II** – Therapeutic exploratory (small group of patients).
- **Phase III** – Therapeutic confirmatory (large patient group).
- **Phase IV** – Post-marketing surveillance.

Schedule Y

Good Clinical Practice (GCP):

- Clinical trials must follow **ethical guidelines, informed consent, and safety monitoring**.

Documents Required:

- Investigator's brochure, clinical trial protocol, informed consent forms, case report forms.

Purpose:

- To ensure that **new drugs are safe, effective, and scientifically tested** before being approved for public use.

Schedule F – Part XII B

Definition:

- Schedule F (Part XII B) prescribes the **minimum standards for operation of blood banks** and preparation, storage, and distribution of **blood and blood components**.

General Requirements:

- Blood bank must be located in a **clean, hygienic, and well-ventilated premises** with adequate space.
- Proper facilities for electricity, refrigeration, and water supply are mandatory.

Accommodation & Staff:

- Separate rooms for blood collection, donor examination, testing, and storage.
- Qualified medical officer, technicians, and trained staff must be employed.

Equipment:

- Mandatory equipment includes:
  - Blood collection monitors, sterilized containers, refrigerators.
  - Equipment for **hemoglobin determination**, pulse & BP measurement.
  - Emergency equipment for donor reaction management.

Maintenance & Records:

- Records must be maintained for **donor details, blood collected, storage, and utilization.**
- Labels should specify donor number, collection date, expiry date, and blood group.

Safety & Hygiene:

1. Staff must maintain **health, clothing, and sanitation** standards.
2. Proper disposal system for biomedical waste and used materials.

Purpose:

- To ensure **safe collection, storage, and supply of blood and its components** to prevent contamination, infection, or transmission of diseases.

DMR (OA) Act, 1954

Purpose:

- Enacted to **control and regulate advertisements** of certain drugs and remedies.
- Prevents misleading or false claims that may endanger public health.

Scope:

- Applies to advertisements of **drugs used for diagnosis, cure, mitigation, treatment or prevention of diseases**, and so-called **"magic remedies."**

Prohibition of Advertisements:

- Bans advertisements related to:
  - Drugs for abortion or miscarriage.
  - Drugs for improving sexual capacity.
  - Drugs claiming to cure diseases like diabetes, cancer, epilepsy, TB, etc.
  - Any advertisement that is **offensive to decency or morality**.

Magic Remedies:

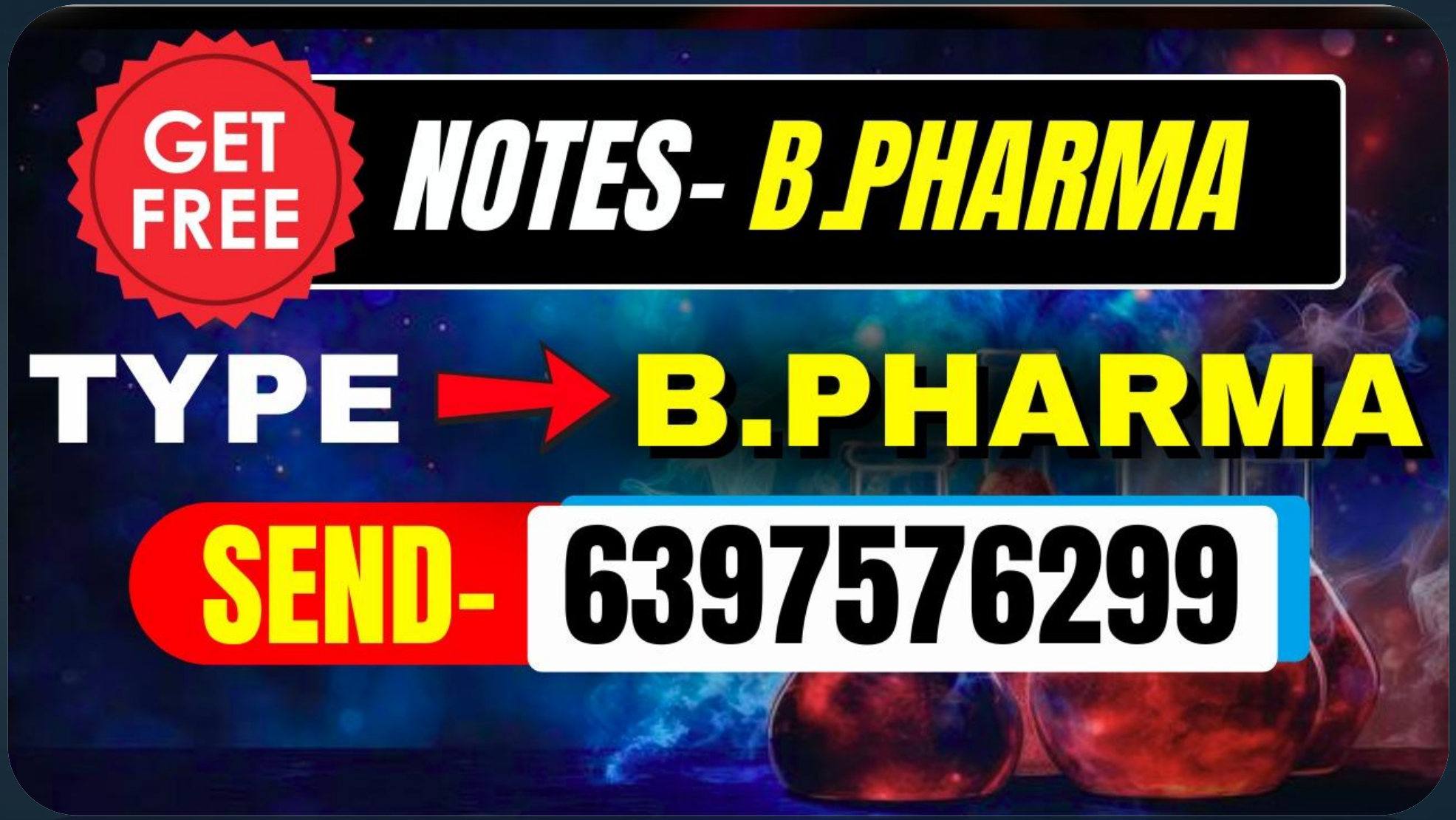
- Includes "mantras, tantras, kavachas" or any object claimed to have **supernatural powers** for curing disease.

Punishment:

- First offence → Imprisonment up to **6 months**, or fine, or both.
- Subsequent offence → Imprisonment up to **1 year**, or fine, or both.

Authority:

- The Act empowers the **Central Government** to add or remove diseases and conditions from the prohibited list.



Thank You !

B.PHARMA SEM- 5

UNIT-2

PART-2

PHARMACEUTICAL JURISPRUDENCE

DRUGS AND COSMETICS ACT, 1940 AND ITS RULES 1945.

WHOLESALE, RETAIL SALE
& RESTRICTED LICENSE
OFFENCE AND PENALTIES

B.Pharm I Sem II

Pharmaceutical Jurisprudence

Unit -2 Part -2

Table Of Content

Sales Of Drug

- Whole Sale
- Retail Sale
- Restricted License
- Offences & Penalties

@PharmacyIndiaPlus

Download Lecture Notes - www.pharmacyindia.in

DOWNLOAD "PHARMACY INDIA" MOBILE APP

SCAN ME

Mobile Phone Par Click karein

Download Pharmacy India Mobile App from Play Store

DAILY UPDATES

जुड़िए PHARMACY INDIA

के साथ.....

WHATSAPP & TELEGRAM SE JUDNE KE LIYE ICONS PAR CLICK KARE

SCAN ME

WhatsApp

SCAN ME

Sale of Drugs

Definition

- Sale = Transfer of drugs to a buyer for a price.
- Wholesale = Dealer/agent/stockist appointed by manufacturer to sell to retailer.
- Retail = Dealer selling directly to consumers.
- For sale of drugs → License is compulsory.

❖ Categories of Sale

1. Drugs other than Schedule C, C1, and X
2. Drugs in Schedule C & C1 (excluding X).
3. Drugs in Schedule X.

- **Conditions for Retail Sale License**

1. **Application & Forms:**
   - **Form 20 → Other than C, C1, X.**
   - **Form 21 → Schedule C & C1.**
   - **Form 20F → Schedule X.**

2. Premises & Pharmacist:
   - Adequate premises with proper storage.
   - Sale must be under the personal supervision of a qualified pharmacist.
   - License must be displayed prominently.

3. Records:
   - Non-Schedule X drugs → enter in register/credit memo book.
   - Schedule C drugs → enter in register/credit memo.
   - Schedule X drugs → enter in separate register, preserved for 2 years.
   - Prescriptions for Schedule H and X → signed and dated by RMP, preserved 2 years.

4. Purchase of Drugs:
   - Only from licensed manufacturer, dealer, or importer.

5. Inspection:
   - All registers & records must be produced on demand for inspection.

6. Special Rules for Schedule H & X:
   - Supplied only on prescription of RMP/hospital/nursing home.
   - Drugs to be stored separately → Schedule X under lock & key.
   - No substitutions allowed.
   - Not more than one dispensing per prescription.

6. Special Rules for Schedule H & X:
   - Supplied only on prescription of RMP/hospital/nursing home.
   - Drugs to be stored separately → Schedule X under lock & key.
   - No substitutions allowed.
   - Not more than one dispensing per prescription.

7. Prohibitions:
   - Expired drugs, physician's samples, and government supply drugs cannot be sold.
   - Additional Schedule C & C1 drugs require prior permission of Licensing Authority.

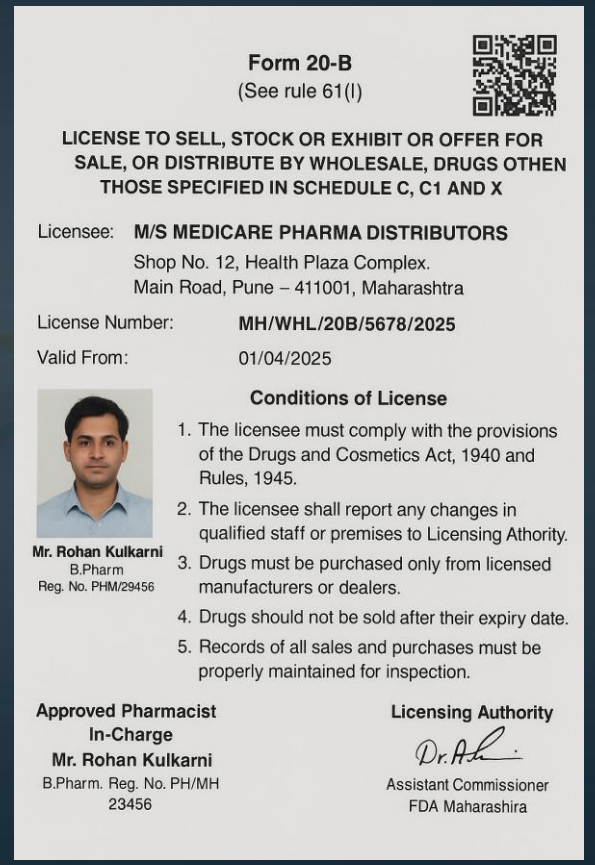
Application

- Application made in Form 19 → For drugs other than Schedule X.
- Application made in Form 19C → For drugs in Schedule X.
- After verification, license is issued:
  - Form 20B → For drugs other than Schedule C, C1, X.
  - Form 21B → For drugs in Schedule C and C1 (excluding X).
  - Form 20G → For drugs in Schedule X.

Conditions of Wholesale License

(Points simplified from your text)

1. Premises must not be less than 10 sq. meters.
2. In charge → Registered Pharmacist OR a person with 4 years' experience in dispensing drugs (minimum matriculation).
3. Premises should have adequate facilities for storage.
4. License must be displayed in a visible place.



Form 20-B
(See rule 61(I))

LICENSE TO SELL, STOCK OR EXHIBIT OR OFFER FOR SALE, OR DISTRIBUTE BY WHOLESALE, DRUGS OTHEN THOSE SPECIFIED IN SCHEDULE C, C1 AND X

Licensee: **M/S MEDICARE PHARMA DISTRIBUTORS**
Shop No. 12, Health Plaza Complex.
Main Road, Pune – 411001, Maharashtra

License Number: **MH/WHL/20B/5678/2025**

Valid From: 01/04/2025

Mr. Rohan Kulkarni
B.Pharm
Reg. No. PHM/29456

Conditions of License

1. The licensee must comply with the provisions of the Drugs and Cosmetics Act, 1940 and Rules, 1945.
2. The licensee shall report any changes in qualified staff or premises to Licensing Athority.
3. Drugs must be purchased only from licensed manufacturers or dealers.
4. Drugs should not be sold after their expiry date.
5. Records of all sales and purchases must be properly maintained for inspection.

Approved Pharmacist In-Charge
Mr. Rohan Kulkarni
B.Pharm. Reg. No. PH/MH 23456

Licensing Authority
Assistant Commissioner
FDA Maharashira

5. Drugs can only be purchased from a licensed manufacturer/dealer.
6. Supply of drugs → made against a cash/credit memo.
   - Records to be preserved for 3 years from last entry.
7. Purchase records must be serially numbered, signed, and maintained in proper order.
8. Registers & records must be produced for inspection when required.
9. All records must be preserved for at least 2 years from date of last entry.

10. Inspection book (Form 35) must be maintained.
11. Expired drugs must not be sold or stocked.
12. Physician's samples & government supply drugs must not be sold.
13. Schedule X drugs must be:
    - Stored in separate register and separate pages.
    - Supplied only on prescription.
14. Copies of invoices of Schedule C, C1, X drugs supplied to retailer must be forwarded to Licensing Authority.
15. Any change in firm/staff must be reported to Licensing Authority.

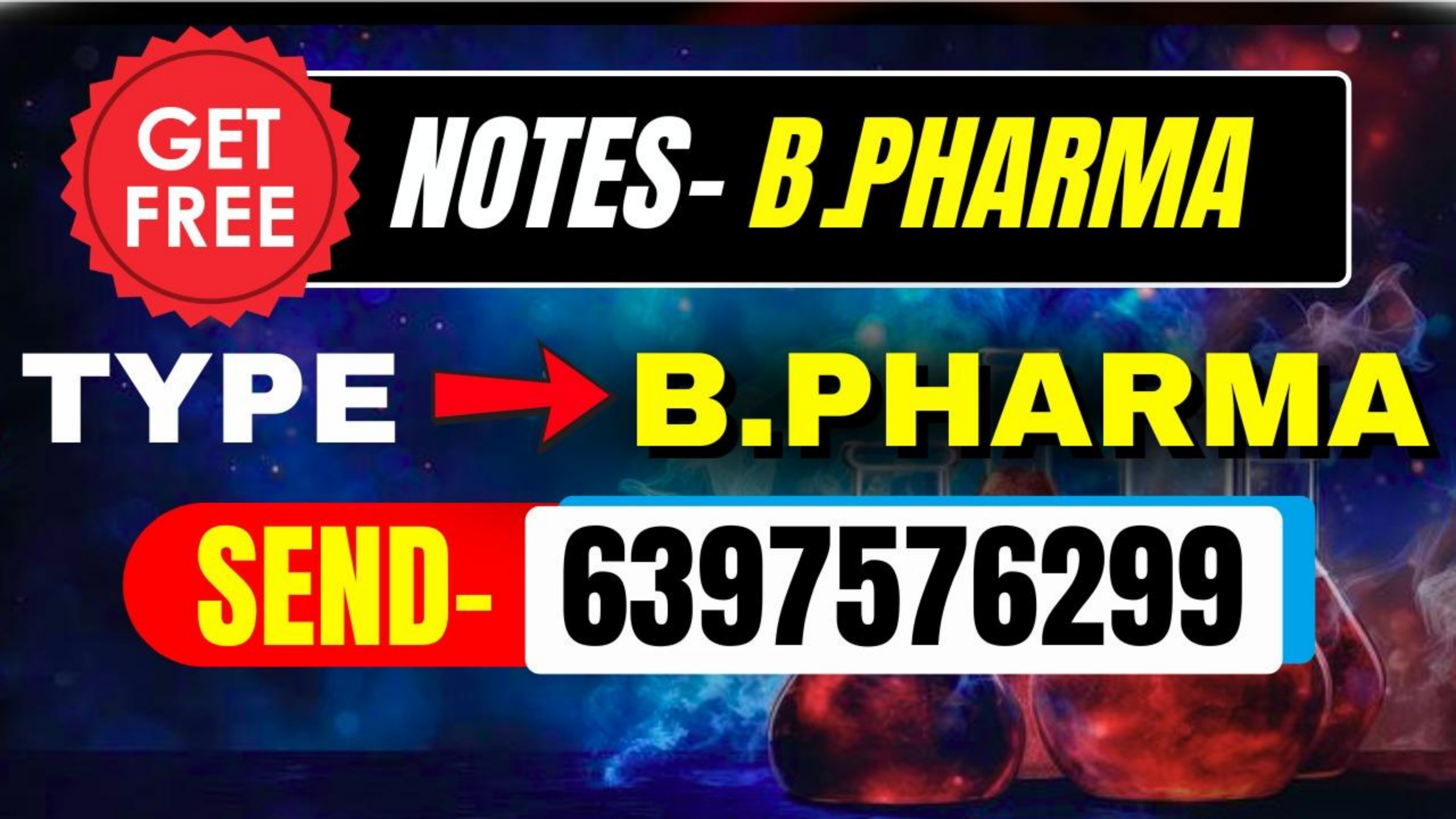
❖ Restricted License

1. Issued for retail sale of certain drugs where a qualified pharmacist is not available.
2. Dealers or vendors:
   - Itinerant vendors (e.g., in fairs, rural areas).
   - Bona fide travelling agents of licensed firms.

3. Restricted license may be issued to:
   - Vendors in remote/rural areas.
   - Vendors at fairs/exhibitions.
   - Medical practitioners or dealers supplying special drugs (e.g., Schedule C biological products).

❖ Offences & Penalties (Drugs & Cosmetics Act, 1940)

Offence	First Conviction	Subsequent Conviction
Manufacture, sale, distribution, or stocking of adulterated/spurious drug or drug not of standard quality	Imprisonment min 5 years (may extend to life) + fine ≥ ₹10,000	Imprisonment up to 10 years + fine up to ₹20,000, or both
Manufacture, sale, distribution, or stocking of drugs not containing toxic substances but still injurious to health	Imprisonment 1–3 years + fine ≥ ₹5,000	Imprisonment 2–4 years + fine ≥ ₹10,000
Manufacture, sale, distribution, or stocking of drug without license	Court may reduce → imprisonment <1 year + fine <₹1,000 (if reasons recorded)	Court may reduce → imprisonment <2 years + fine <₹2,000 (if reasons recorded)
Failure to keep records / furnish information	Imprisonment up to 1 year + fine up to ₹1,000	Same as first conviction
Giving false report by Government Analyst	Imprisonment up to 3 years + fine up to ₹5,000	Imprisonment up to 10 years, or with fine, or both


GET FREE
NOTES- B.PHARMA
TYPE
B.PHARMA
SEND-
6397576299

B.PHARMA SEM- 5

UNIT-2

PART-3

PHARMACEUTICAL JURISPRUDENCE

DRUGS AND COSMETICS ACT, 1940 AND ITS RULES 1945.

LABELLING & PACKAGING OF DRUGS

CLICK ON BANNER TO WATCH VIDEO

B.Pharm I Sem II

Pharmaceutical Jurisprudence

Unit -2 Part -3

TABLE OF CONTENT

DOWNLOAD "PHARMACY INDIA" MOBILE APP

SCAN ME

Mobile Phone Par Click karein

Download Pharmacy India Mobile App from Play Store

DAILY UPDATES

जुड़िए PHARMACY INDIA

के साथ.....

WHATSAPP & TELEGRAM SE JUDNE KE LIYE ICONS PAR CLICK KARE

SCAN ME

WhatsApp

SCAN ME

1. Labeling of Drugs & Cosmetics - General Requirements

Proper labeling is essential to ensure the safe and effective use of drugs. Rule 96 of the Drugs and Cosmetics Rules, 1945, specifies that the following particulars must be conspicuously printed in indelible ink on the label of the innermost container and on every other covering.

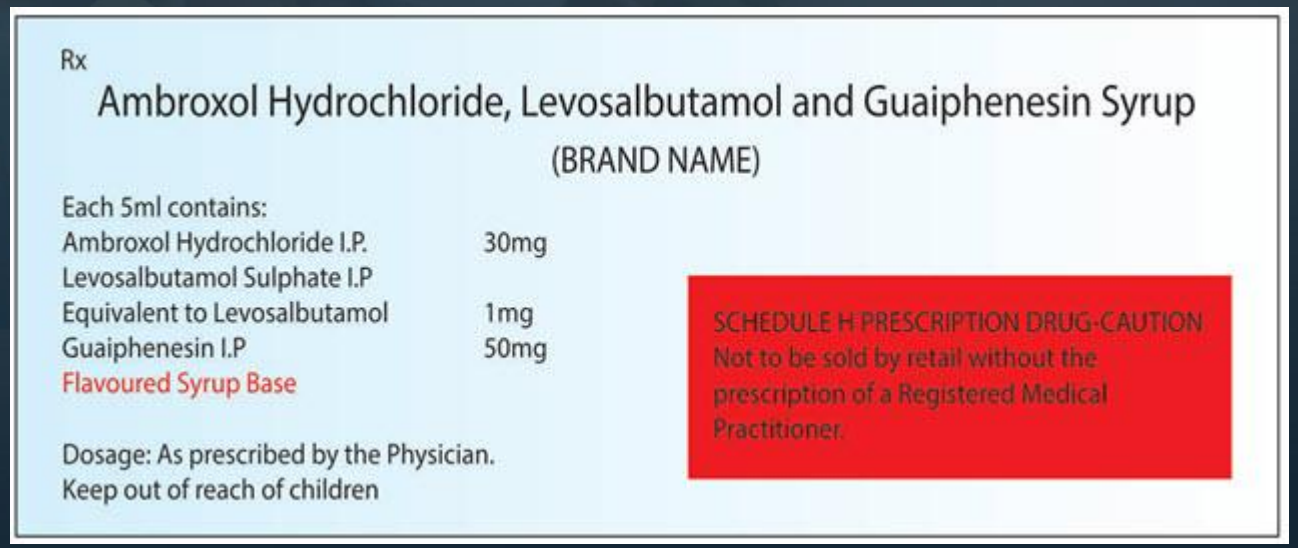
Key Information Required on a Drug Label:

Information Category	Details Required
Name of the Drug	The official or "proper name" of the drug must be more conspicuous than the trade name (brand name).
Net Content	The quantity of the drug must be stated in terms of weight (e.g., mg, g), measure (e.g., ml), or the number of units.
Content of Active Ingredients	The quantity of each active ingredient per unit dose. For oral liquids, this should be per 5 ml or 1 ml.
Manufacturer Details	The name and full address of the licensed manufacturer.

Manufacturing License No.	**The license number under which the drug is manufactured, preceded by "Mfg. Lic. No." or "M.L."**
Batch Number	A distinctive batch number, preceded by "Batch No." or "B. No.," which allows tracing of the manufacturing history.
Manufacturing & Expiry Dates	The date of manufacture and the date of expiry must be clearly stated.
Storage Conditions	Any special instructions regarding storage and handling to ensure the drug's stability and potency.
Special Warnings	Specific warnings or cautionary text are required for certain categories of drugs (e.g., Schedule G, H, H1, and X drugs). Preparations for external use must be labeled "FOR EXTERNAL USE ONLY".

2. Specimen Labels

Specimen labels provide a standardized template for manufacturers to ensure all regulatory information is presented correctly.



Rx

Ambroxol Hydrochloride, Levosalbutamol and Guaiphenesin Syrup

(BRAND NAME)

Each 5ml contains:

Ambroxol Hydrochloride I.P.	30mg
Levosalbutamol Sulphate I.P Equivalent to Levosalbutamol	1mg
Guaiphenesin I.P	50mg
Flavoured Syrup Base	

Dosage: As prescribed by the Physician.

Keep out of reach of children

SCHEDULE H PRESCRIPTION DRUG-CAUTION
Not to be sold by retail without the prescription of a Registered Medical Practitioner.

Specimen Label for a Schedule H Drug

Field	Example Content
Symbol	Rx (on the top left corner of the label)
Drug Name	AMOXICILLIN CAPSULES IP 500 MG
Warning	SCHEDULE H DRUG - CAUTION: To be sold by retail only on the prescription of a Registered Medical Practitioner.
Composition	Each hard gelatin capsule contains: Amoxicillin Trihydrate IP equivalent to Amoxicillin 500 mg
Dosage	As directed by the Physician.
Storage	Store in a cool, dry place, protected from light.
Mfg. Lic. No.	123/AP/2020
Batch No.	AC54321
Mfg. Date	09/2025
Exp. Date	08/2027
Manufactured by	ABC Pharma Ltd., Hyderabad, India.

Specimen Label for a Schedule X Drug

Field	Example Content
Symbol	Rx (in red ink on the top left corner)
Drug Name	PHENOBARBITONE TABLETS IP 50mg
Warning	SCHEDULE X DRUG - WARNING: To be sold by retail only on the prescription of a Registered Medical Practitioner. The prescription must be presented in duplicate.
Composition	Each uncoated tablet contains: Phenobarbitone IP 50 mg
Storage	Store in a secure place, protected from light and moisture.

Specimen Label for a Schedule X Drug

Mfg. Lic. No.	456/MH/2021
Batch No.	PT98765
Mfg. Date	10/2025
Exp. Date	09/2028
Manufactured by	XYZ Pharmaceuticals, Mumbai, India.

3. Packaging of Drugs

The packaging of a drug is as crucial as its manufacturing. The primary purpose is to ensure the safety, stability, and integrity of the pharmaceutical product until it is consumed. Proper packaging:

- Protects the drug from environmental factors like light, moisture, oxygen, and temperature extremes.
- Prevents microbial contamination.
- Ensures the product remains stable and retains its therapeutic efficacy throughout its shelf life.

4. List of Permitted Colors

The use of coloring agents in drugs and cosmetics is strictly regulated under Schedule Q of the Drugs and Cosmetics Rules, 1945, to ensure safety and prevent the masking of poor product quality.

The label of a medicine must specify the common name and quantity of the permitted color used.

Categories of Permitted Colors

Color Category	Description & Examples
Natural Colors	Derived from plant or mineral sources. Examples: Annatto, Carotene, Chlorophyll, Caramel, Red Oxide of Iron.
Artificial Colors	Synthetic organic colors, also known as Coal Tar Colors. Their use requires adherence to stringent purity standards.

Table of Permitted Coal Tar Colors

Common Name	Colour Index No.
Tartrazine	19140
Sunset Yellow FCF	15985
Amaranth	16185
Erythrosine	45430
Indigo Carmine	73015
Brilliant Blue FCF	42090

5. Offences and Penalties

The Drugs and Cosmetics Act, 1940, prescribes severe penalties for offences related to the manufacturing and sale of substandard, misbranded, adulterated, or spurious drugs.

Key Offences Related to Labeling and Quality

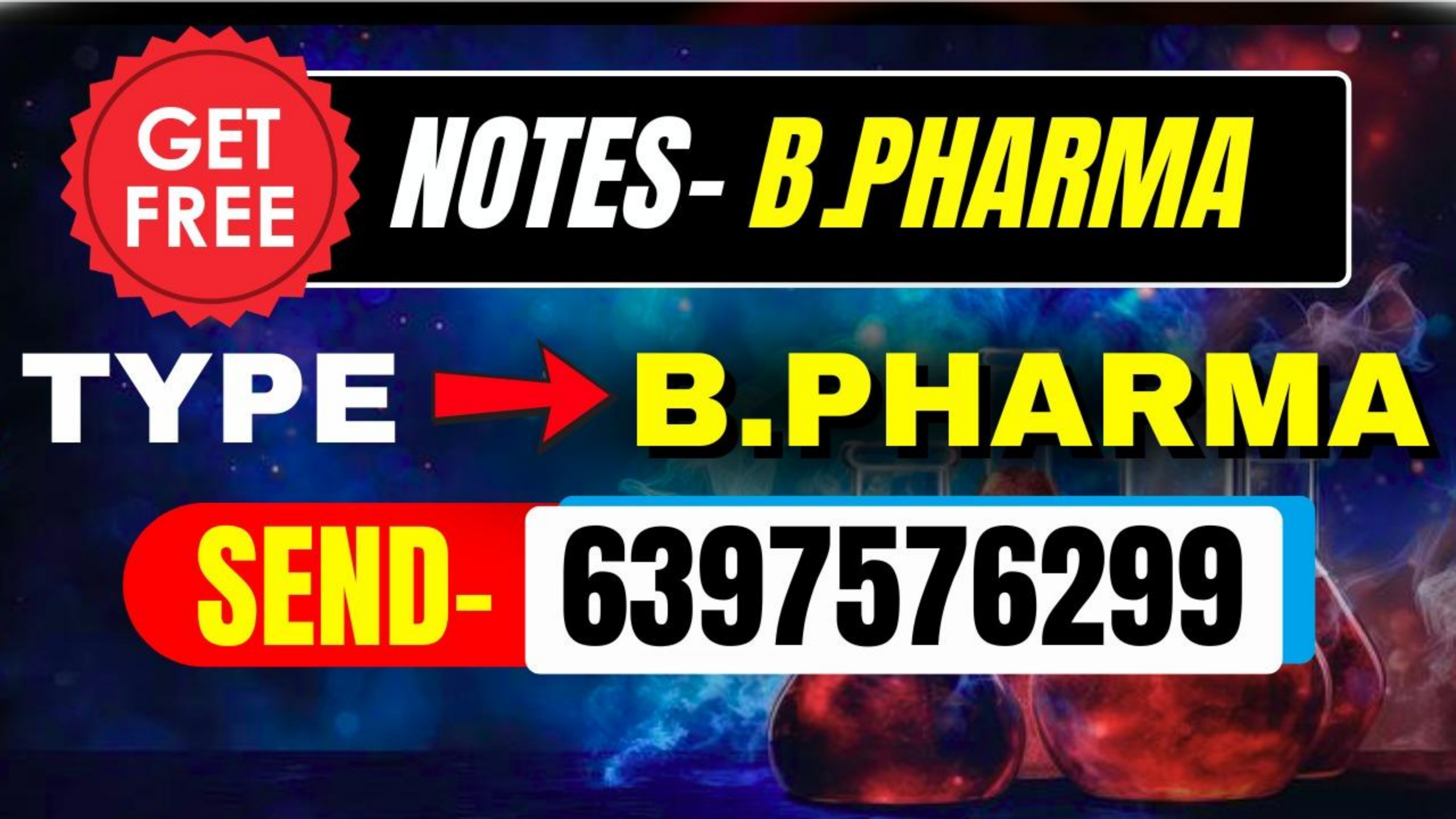
Offence	Definition
Misbranded Drug	A drug that is not labeled in the prescribed manner; makes false or misleading claims on its label; is colored or coated to conceal damage or appear of greater therapeutic value; or whose label does not bear all the required information.
Adulterated Drug	A drug that consists of any filthy, putrid, or decomposed substance; has been prepared or stored under unsanitary conditions; contains any harmful or toxic substance; or contains a color that is not permitted.
Spurious Drug	A drug manufactured under a name that belongs to another drug; an imitation or substitute for another drug; or falsely claims to be the product of a specific manufacturer.

Penalties for Non-Compliance

Offence	Penalty for First Conviction	Penalty for Subsequent Conviction
Manufacture/Sale of Adulterated or Spurious Drugs likely to cause death or grievous bodily harm.	Imprisonment of not less than 10 years, which may extend to life, AND a fine of not less than ₹10 Lakhs.	Not Applicable
Manufacture/Sale of Adulterated Drugs.	Imprisonment of 1 to 3 years AND a fine of not less than ₹1 Lakh.	Imprisonment of 2 to 6 years AND a fine of not less than ₹2 Lakhs.
Manufacture/Sale of Spurious Drugs.	Imprisonment of 3 to 5 years AND a fine of not less than ₹1 Lakh.	Imprisonment of 6 to 10 years AND a fine of not less than ₹2 Lakhs.

Penalties for Non-Compliance

Manufacture/Sale of a Misbranded Drug.	Imprisonment of 1 to 3 years AND a fine.	Imprisonment of 2 to 4 years AND a fine.
Contravention of any other provision of the Act or Rules (e.g., minor labeling error).	Imprisonment up to 1 year OR a fine up to ₹20,000, or both.	Imprisonment up to 2 years OR a fine up to ₹20,000, or both.


GET FREE
NOTES- B.PHARMA
TYPE
B.PHARMA
SEND-
6397576299

B.PHARMA SEM- 5

UNIT-2

PART-4

PHARMACEUTICAL JURISPRUDENCE

DRUGS AND COSMETICS ACT, 1940 AND ITS RULES 1945.

ADMINSTRATION OF THE ACT & RULE

CLICK ON BANNER TO WATCH VIDEO

Jurisprudence

B.Pharm Sem 5

Unit – 2 I Part – 4

DOWNLOAD "PHARMACY INDIA" MOBILE APP

SCAN ME

Mobile Phone Par Click karein

Download Pharmacy India Mobile App from Play Store

DAILY UPDATES

जुड़िए PHARMACY INDIA

के साथ.....

WHATSAPP & TELEGRAM SE JUDNE KE LIYE ICONS PAR CLICK KARE

SCAN ME

WhatsApp

SCAN ME

ADMINISTRATION OF THE ACT AND RULES

- The Drugs and Cosmetics Act, 1940 and Rules, 1945 are administered in India through a three-tier structure – Advisory, Analytical, and Executive bodies.

Administration of the Act and Rules

A) Advisory Bodies

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

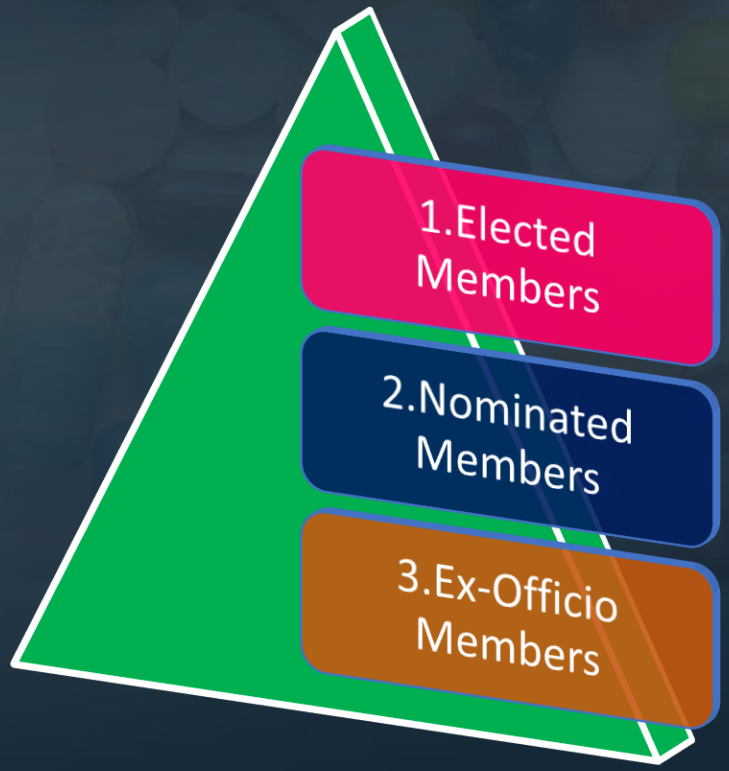
B) Analytical Bodies

- Central Drugs Laboratory (CDL)
- Drug Control Laboratories in States
- Government Analysts

C) Executive Bodies

- Drug Inspectors
- Controlling Authorities
- Licensing Authorities

Drugs Technical Advisory Board



Ex-Officio Members

- Director General of Health Services (Chairman)
- Drugs Controller, India
- Director of the Central Drugs Laboratory, Calcutta
- Director of the Central Research Institute, Kasauli
- Director of Indian Veterinary Research Institute, Izatnagar
- President of Medical Council of India
- President of Pharmacy Council of India
- Director of Central Drug Research Institute, Lucknow

✓ Nominated Members

1.State Drug Control Officials:

- Two persons nominated by the Central Government from among persons in charge of drug control in the States.

2.Pharmaceutical Industry:

- One person nominated by the Central Government from the industry.

3.Government Analysts:

- Two persons holding the appointment of Government Analyst under the Act, nominated by the Central Government.

✓ Elected Members

1. Pharmacy Council of India:
   - o One person elected by the Executive Committee from among teachers in pharmacy, pharmaceutical chemistry, or pharmacognosy in Indian universities or affiliated colleges.

2. Medical Council of India:
   - o One person elected by the Executive Committee from among teachers in medicine or therapeutics in Indian universities or affiliated colleges.

3. Indian Council of Medical Research (ICMR):
   - o One pharmacologist elected by the Governing Body.

4. Indian Medical Association:
   - o One person elected by the Central Council.

5. Indian Pharmaceutical Association:
   - o One person elected by the Council.

❑ Functions

- To advise the Central Government and the State Governments on technical matters arising out of the administration of the Drugs and Cosmetics Act.
- To carry out the other functions assigned to it under the Act.
- Tenure: The nominated and elected members hold office for three years but are eligible for re-nomination and re-election.

❖ Drugs Consultative Committee (DCC)

- The DCC is an advisory body set up by the Central Government under the Drugs and Cosmetics Act.
- Its main purpose is to coordinate between Central and State Governments and ensure uniform application of the Act throughout India.

Constitution

- Central Representation: Two members nominated by the Central Government.
- State Representation: One member nominated by each State Government.

❑ Functions

1. Advises the Central Government, State Governments, and the Drugs Technical Advisory Board on any matter necessary to achieve nationwide uniformity in implementing the Act.
2. Meets as needed — no fixed schedule; convened whenever issues arise.
3. Has the authority to frame and regulate its own procedures for meetings and decision-making.

❖Central Drug Laboratory (CDL)

- The Central Drug Laboratory (CDL) is India's apex drug testing laboratory.
- It is located in Kolkata (Calcutta) and is headed by a Director appointed by the Central Government.

❑ Main Functions

1. Testing and Analysis: Conducts analysis of drug and cosmetic samples sent by customs or courts.

2. Quality Control of Imports: Performs analytical quality checks (Q.C.) on imported samples.

3. Standards Management: Collects, stores, and distributes internal standards and prepares and maintains reference standards.

4. Microbial Cultures: Maintains official microbial cultures used for testing.
5. Government-Entrusted Duties: Carries out any additional duties assigned by the Central Government.
6. Appellate Role: Acts as an appellate authority in disputes regarding analysis results.

❑ Government Analyst & Testing Procedures

Procedure Followed by Analysts

1. When the analyst receives a sample, they must note the condition of the seal and match it with the specimen seal impression sent separately.

2. After completing the analysis, the analyst must prepare a detailed report in triplicate and submit it to the concerned authority.

❑ Qualifications for Analysts

A) Testing of Non-Biological Products

- **Graduates in Medicine/Science/Pharmacy/Pharmaceutical Chemistry:**
  - Need 5 years' post-graduate testing experience or 2 years' training in testing (including Schedule C in CDL).
- **Postgraduates in the above fields:**
  - Need 3 years' experience or 2 years' training in testing (including Schedule C in CDL).
- **Associateship Diploma holders of the Institution of Chemists:**
  - Need 3 years' experience or 2 years' training in testing of drugs (including Schedule C in CDL).

B) Testing of Biological Products (Human Use – Schedule C)

- Graduates trained in physiology/bacteriology/serology/pathology/pharmacology/microbiology:
  - o Must have 5 years' experience in testing and 6 months' training in an approved lab.

- **Postgraduates or Diploma holders of the Institution of Chemists:**
  - o Recognized for analysis of drugs & pharmaceuticals.

- **Special Training:**
  - o Need 3 years' experience plus 6 months' training in an approved laboratory and 2 years' training in testing drugs, including Schedule C in CDL.

C) Testing of Biological Products (Veterinary Use)

- **Graduates in Veterinary Science/General Science/Medicine/Pharmacy:**
  - o Require 5 years' experience in testing.
- **Postgraduates in Veterinary Science/General Science/Medicine/Pharmacy/Pharmaceutical Chemistry:**
  - o Require 3 years' experience in testing.

❑. Duties of Government Analysts

1. Analyze and test drugs and cosmetics sent by inspectors or other authorized persons and issue reports.

2. Conduct research work and forward reports to the government for possible publication.

❑ Appointment Rules

- • State Government appoints analysts to test drug and cosmetic samples.
- • Central Government may also appoint analysts.
- • Analysts must remain independent — no direct or indirect involvement in the import, manufacture, or sale of drugs and cosmetics.

❑ Special Testing Arrangements

• Biological and Microbiological Tests: Done at the Central Research Institute, Kasauli (not by CDL).

• Veterinary Biological Tests: Conducted at Indian Veterinary Research Institute, Izatnagar.

• Condom Testing: Performed at the Central Indian Pharmacopoeial Laboratory, Ghaziabad.

❑ Procedure for Sending Samples to CDL

1. All drug/cosmetic samples are sent to CDL by registered post along with a memorandum and sealed properly.
2. A separate copy of the memorandum and specimen seal impression are sent separately by registered post.
3. On receiving the packet, the Director/Officer records the condition of the seal.
4. After analysis, the Director issues an official report of the findings.

❑ Executives

1. Licensing Authorities (Reframed)

Import Licences

- The Central Government designates specific officers as Licensing Authorities to grant licences for drug imports.

Manufacture and Sale Licences

- State Governments appoint Licensing Authorities for granting licences to manufacture and sell drugs and cosmetics within their territories.

Possible Designations of Licensing Authorities

- Drug Controller
- Director
- Drug Control Administration
- Officer-in-Charge, Drug Control
- Commissioner (FDCA)

2. Controlling Authorities

Role

- All Drug Inspectors function under the supervision of a Controlling Authority, which ensures compliance with the Drugs and Cosmetics Act.

Qualification

- Educational Background: A graduate in Medicine, Pharmacy, Pharmaceutical Chemistry (Clinical Pharmacology) or Microbiology.
- Professional Experience: Minimum five years' experience in the manufacture, testing, or enforcement related to drugs.

❖ Drug Inspectors

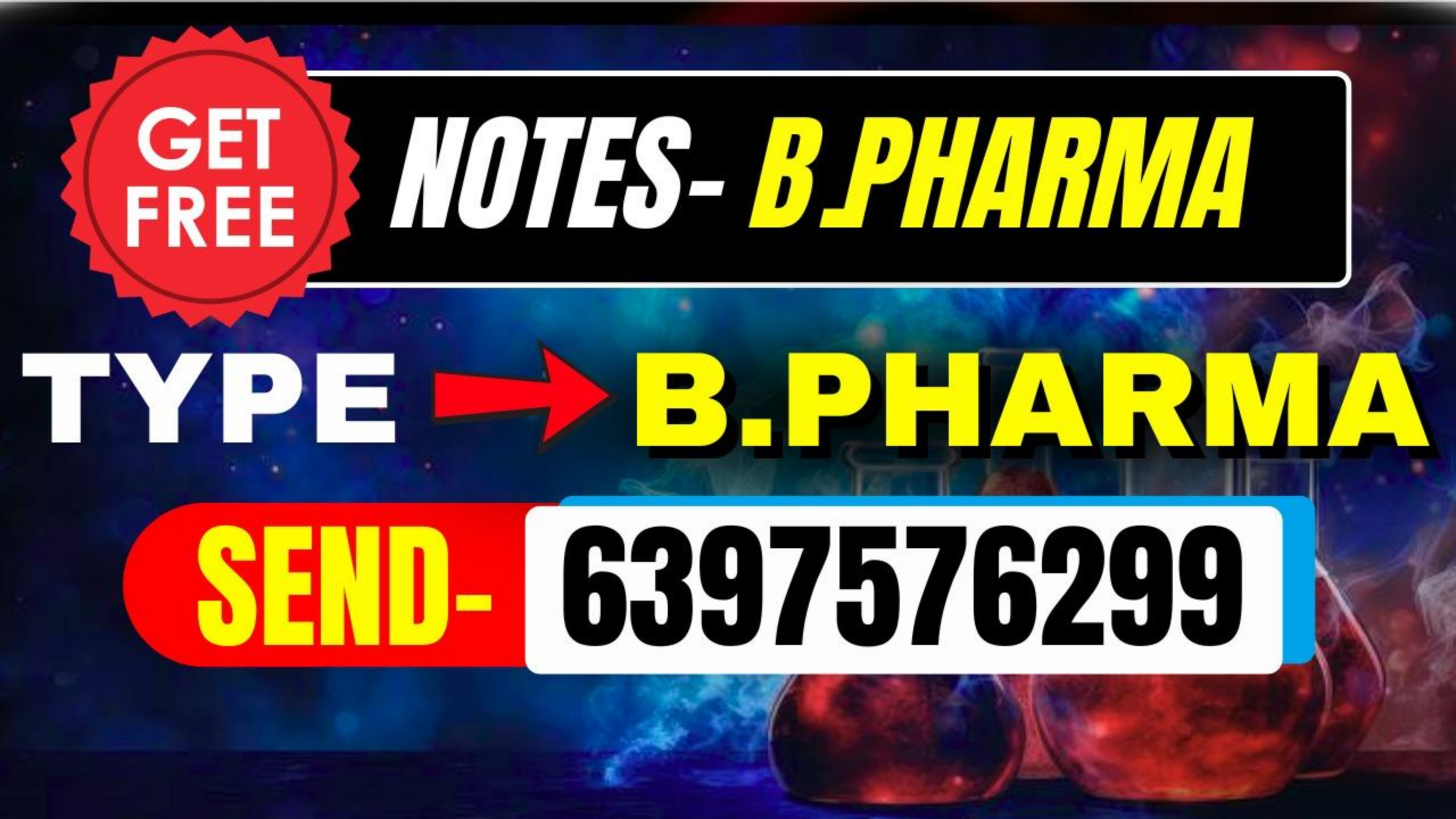
A Drug Inspector is a government-appointed officer (by the State Government or the Central Government) under the Drugs and Cosmetics Act, 1940 who is responsible for inspecting and ensuring that drugs and cosmetics manufactured, stored, distributed, and sold in India comply with legal standards of quality, safety, and licensing.

Appointment

- State Governments recruit Drug Inspectors to monitor facilities licensed for the manufacture and sale of drugs and cosmetics.
- The Central Government also has the authority to appoint Drug Inspectors wherever needed.

Conditions of Service

- Must remain free from any financial involvement in import, manufacture, or sale of drugs/cosmetics.
- Recognized as public servants under the Indian Penal Code.
- Bound by strict confidentiality—they cannot disclose any information obtained during inspections.


GET FREE
NOTES- B.PHARMA
TYPE
B.PHARMA
SEND-
6397576299

Thank You!