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Legal definitions of schedule to the act & rule

Schedule K to Y

❑ Schedules to the Rules

Schedule	Subject / Provision	Example(s)
K	Drugs exempted from certain provisions related to manufacture	Surgical dressings like gauze, Bandages, Ayurvedic medicines from village cooperatives
M	GMP for **allopathic drugs** — factory premises, plant, and equipment	Tablet compression room with HEPA filter
M-I	GMP for **Homoeopathic preparations**	Preparation area for Arsenicum album

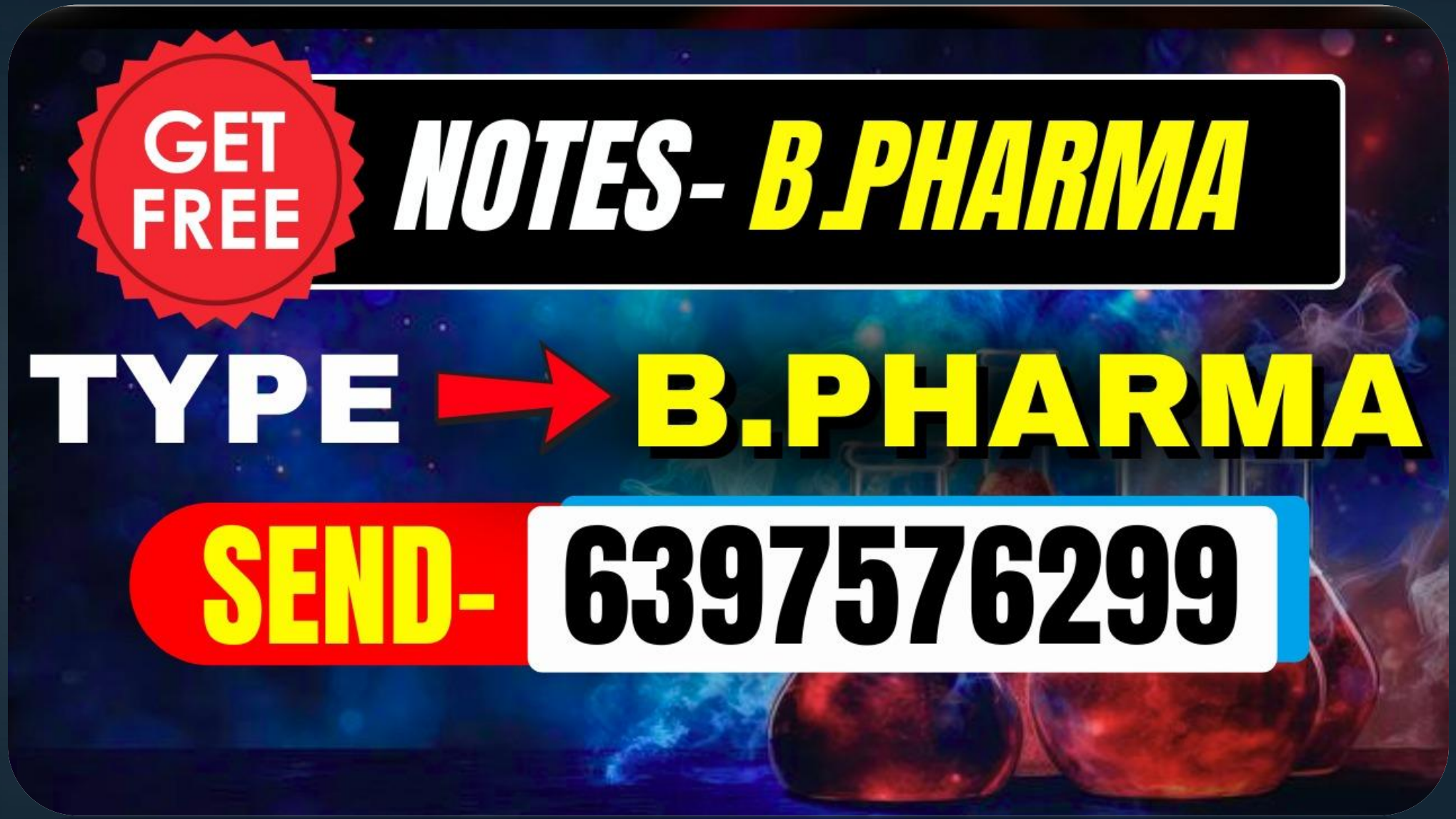
Schedule	Subject / Provision	Example(s)
M-II	GMP for **Cosmetics**	Lipstick manufacturing area with temp. control
M-III	Requirements for manufacture of **Medical Devices**	Surgical gloves production cleanroom
N	Minimum equipment list for running a pharmacy	Dispensing balance, Refrigerator for vaccines

Schedule	Subject / Provision	Example(s)
O	Standards for disinfectant fluids	Phenyl solution meeting ISI bactericidal standards
P	Life period (shelf life) of drugs	Amoxicillin capsules — 2 years shelf life
P-I	Pack sizes of drugs	Paracetamol 500 mg — Strip of 10 tablets

Schedule	Subject / Provision	Example(s)
Q	Permitted colours, dyes, pigments in cosmetics/soaps	Tartrazine in face cream
R	Standards for condoms & contraceptives	Rubber latex condom bursting strength
R-I	Standards for medical devices	BP monitor — accuracy ±3 mmHg

Schedule	Subject / Provision	Example(s)
S	Standards for cosmetics	Cold cream — free from harmful microbes
T	GMP for Ayurvedic, Siddha, Unani medicines	Chyawanprash manufacturing area
U	Particulars in manufacturing records	Batch manufacturing record for antibiotic syrup

Schedule	Subject / Provision	Example(s)
U-I	Additional particulars in manufacturing records	Raw material logbook with supplier details
V	Standards for patent/proprietary medicines	Branded cough syrup meeting D&C standards
X	Psychotropic substances	Diazepam, Alprazolam — special license needed
Y	Requirements & guidelines for clinical trials	Phase I trial for new anticancer drug



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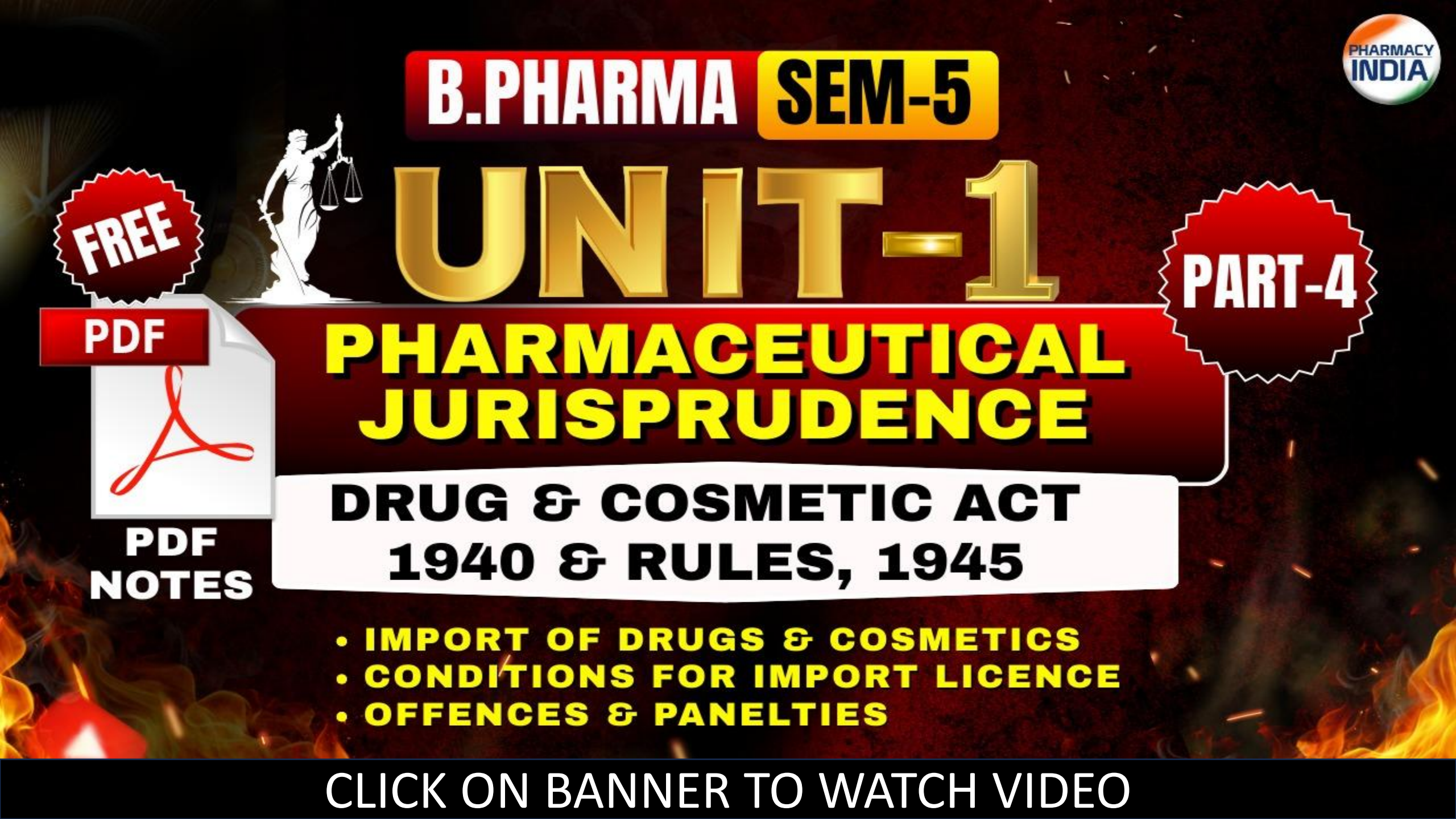
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SEM-5
FREE
UNIT-1
PART-4
PDF
PDF NOTES
PHARMACEUTICAL JURISPRUDENCE
DRUG & COSMETIC ACT 1940 & RULES, 1945
• IMPORT OF DRUGS & COSMETICS
• CONDITIONS FOR IMPORT LICENCE
• OFFENCES & PANELTIES
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Unit I Part - 4

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Import of drugs and cosmetics

The import of drugs and cosmetics is regulated by the provisions of Drug & Cosmetic Act.

Classes of drugs and cosmetics prohibited from import:

The following categories of drugs and cosmetics are prohibited from import:

1. Drugs or cosmetics which are not of standard qualities.
2. Drugs or cosmetics which are misbranded, spurious and adulterated.
3. Drugs or cosmetics for import of which licence is required.
4. Any patent or proprietary medicine without true formula or list of active ingredients and their quantities.

5. Any drug or formulation which claims to prevent or cure diseases mentioned schedule J.

6. Any drug or cosmetic for which manufacture, sale or distribution is prohibited in country of its origin.

7. Any drug which is not packed or not labeled in conformity with the Rules of the Act.

8. Any cosmetic containing an ingredient which may render it unsafe or harmful.

9. Any drug or cosmetic the import of which is prohibited by Act.

Exemptions:

Class of Drugs	Extent & Conditions of Exemption
1. Substances not intended for medicinal use	These can be imported freely in bulk, provided the importer certifies that they are for non-medicinal purposes.
2. Substances listed in Schedule C1 (for manufacturing but not for medicinal ause)	Exempted from all import regulations, except that the importer must hold a valid license to manufacture Schedule C and C1 drugs.
3. Substances used both as drugs and as common articles (e.g., powdered milk, Farex, oats, lactose, etc.)	Fully exempted from import regulations.
4. Spices and condiments (e.g., ginger, pepper, cumin, cinnamon) except those of official quality	Fully exempted from import regulations.

Import of drugs under license

1. License is required for the import of drugs.
2. License is obtained on application to the proper licensing authority
3. License is valid up to 31st December.
4. Licensee should inform to licensing authority if any changes.

Import under license or permit

The licensing authority grants a license for the import of following classes of drugs

A. Drugs specified in schedule C and C1 excluding those specified in schedule X

B. Drugs specified in schedule X

C. Small quantities of drugs imported for examination, test or analysis

D. Drugs for personal use prescribed by a Registered Medical Practitioner

E. Any new drug

A. Drugs specified in schedule C and C1 excluding those specified in schedule X

Conditions to be fulfilled

1. Licensee must have adequate facilities for storage.
2. Licensee must maintain a record of the sale, showing the particulars of the names of drugs and of the persons to whom they have been sold.
3. Licensee must allow an inspector to inspect premises and to check the records.
4. Licensee must furnish the sample to the authority.
5. Licensee must comply with undertaking given in the Form No:09.

B. Drugs specified in schedule X

Conditions to be fulfilled

1. A license is necessary.
2. Licensee must have adequate facilities for storage.
3. Applicant must be reputable in the occupation, trade or business.
4. The license granted ever before should not be suspended or cancelled.

C. Small quantities of drugs imported for examination, test or analysis

Conditions to be fulfilled

1. A license is necessary.
2. Imported under license in Form-11.

3. The licensee must use the imported drug only for the said purpose and use at the place specified in the license.
4. The licensee must keep the record to the quantities, name of the manufacturer and date of import.

D. Drugs for personal use prescribed by a Registered Medical Practitioner

Conditions to be fulfilled

1. The drug must be bonified personal use.
2. The quantity should be reasonable and covered by RMP prescription.
3. The drug must be declared to the Custom Collector if so directed.
4. More than 100 doses are imported with license. Applying in Form No. 12A and 12B.

E. Any new drug

Conditions to be fulfilled

1. License is required.
2. The licensee is required to provide the documents of standards of quality, purity and strength.

❑ Application and Duration of Import Licence & Registration Certificate

- Application for Import Licence:
  - Made to the licensing authority in Form 8 (for drugs excluding Schedule X).
  - Made in Form 8-A (for Schedule X drugs).
  - Licence is issued in Form 10 or Form 10-A.

- Application for Registration Certificate:
  - Submitted to the Licensing Authority in **Form 40**.
  - Certificate is issued in **Form 41**.

Who can apply?

- The **manufacturer** himself, or
- His **authorized agent in India** holding a valid licence.

Validity:

- Both Import Licence and Registration Certificate are valid for **3 years** from the date of issue.

Renewal condition:

- If the application for renewal is made **3 months before expiry**, the licence/certificate remains valid until official orders are passed.

❑ Permitted Places for Import of Drugs

The import of drug into India is permitted only from following places:

(i) By rail: Ferozepur Cantonment and Amritsar railway stations for drugs from Pakistan. Ranaghat, Bongaon and Mohiassan railway stations for drugs from Bangladesh

(ii) Raxual for drugs from Nepal

(iii) By sea: By road: Chennai, Kolkatta, Mumbai, Nhava Sheva, Kandla, and Cochin

(iv) By air: Mumbai, Chennai, Kokatta, Delhi, Ahmedabad and Hyderabad.

❑ Conditions of Import Licence

The importer has to fulfil the conditions that are stipulated in the Rules and also comply with following conditions.

Manufacturer's Undertaking

- The manufacturer must submit an undertaking in **Form 9**.

Record Maintenance

- Licensee must keep proper records of imported drugs.
- Records should include: stock details, distribution, recipient details, price charged, remaining stock, and quantity imported.
- Drugs imported only for test or analysis or new drugs cannot be used for general sale.

Storage Facilities

- Proper storage facilities must be maintained as per the provisions of the Act.

Inspection by Authorities

- Importer must allow inspectors (from State/Central Government) to examine premises, storage, records, and analytical details related to imported drugs.

❑ Other Features of Import

- **Homeopathic Medicines** → Need **written permission** from Licensing Authority.
- **Small Quantity of New Drug** → Can be imported by **Govt. hospital/medical institute** for treating **life-threatening diseases** (with conditions).
- **Drugs for Test/Analysis** →
  - Can be imported **only for testing purpose**.
  - Licence issued in **Form 11**.
  - Importer must **keep records** and **allow inspection**.

Offences & Penalties Related to Import of Drugs

Offence	First Conviction	Subsequent Conviction
Import of adulterated, spurious or misbranded drugs/cosmetics	Jail up to **3 years** + Fine up to **₹5000**	Jail up to **5 years** + Fine up to **₹10,000**
Import of drugs/cosmetics not allowed (forbidden items)	Jail up to **6 months** OR Fine up to **₹500** (or both)	Jail up to **12 months** OR Fine up to **₹1000** (or both)
Import in violation of any notification under Section 10-A	Jail up to **3 years** + Fine up to **₹5000**	Jail up to **5 years** + Fine up to **₹10,000**

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DRUG & COSMETIC ACT 1940 & RULES, 1945

MANUFACTURING OF DRUGS

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Manufacture of Drugs

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Manufacture of Drugs

- **Means:** making, altering, finishing, packing, labeling, breaking up or treating any drug for **sale & distribution.**
- **Excludes:** compounding/dispensing in retail pharmacy.
- Blend of **art & science.**
- Must follow **Good Manufacturing Practices (GMP).**

❑ Prohibition of Manufacture & Sale of Certain Drugs

1.Substandard, misbranded, adulterated, or spurious drugs/cosmetics
2.Patent/proprietary medicine without clear list of ingredients
3.Drugs claiming cure/prevention of **Schedule J diseases**
4.Formulations imported illegally (against Act/Rules)
5.Drugs/cosmetics containing harmful ingredients
6.Drugs manufactured against the provisions of Act/Rules

Exception: Small quantities for **test/examination/analysis** (with license).

❑ Manufacture of drugs

Licences are required for the manufacturing of following categories of drugs.

1. Manufacturing of drugs for examination, test or analysis
2. Manufacture of new drug
3. Manufacturing under Loan licences
4. Licence for Repacking
5. Licence to Manufacture of drugs other than Schedule C, C(1), and Schedule X
6. Licence to Manufacture of Biologicals and Special Products in Schedules C and C (1)
7. Manufacturing of drugs belonging to Schedule X

1. Manufacture of Drugs for Test / Analysis

1.A manufacturer needs **Form 29 license** if no separate license is available.
2.Prohibition rules do not apply when the drug is made only for test or analysis.
3.The license for this purpose is valid for **one year**.

Conditions

- Drugs must be in **properly labeled containers** (purpose mentioned).
- Drugs to be used **only for intended purpose** (test/analysis).
- If supplied to another manufacturer → label must show:
  - Name & address of manufacturer
  - Scientific name of drug
  - License no. & date of manufacture

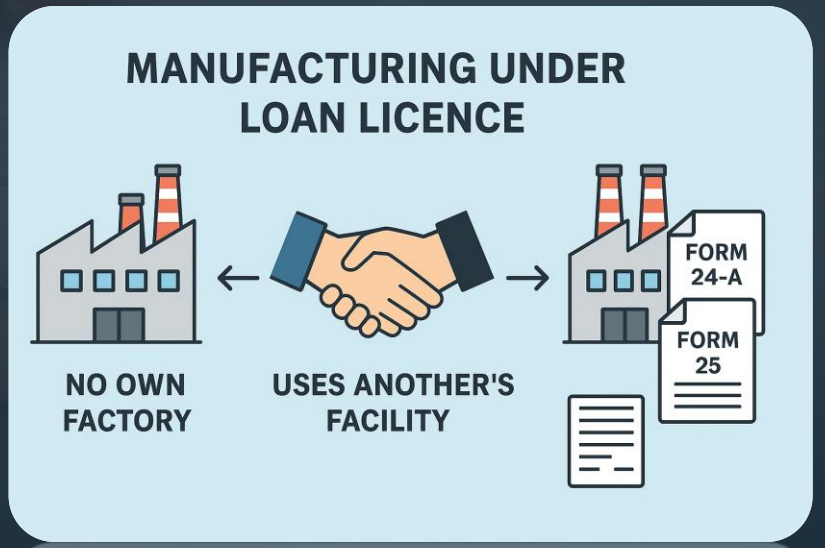
- Inspector allowed to check premises, records & take samples.
- Maintain an **Inspection Book** and show to Inspector.
- Licensee must follow any extra requirements **(with 1-month notice from authority).**

2. Manufacture of New Drug

- To make a new drug, evidence of **quality, purity, and safety** is required.
- **Clinical trial results** must be shown.
- Approval is taken under **Schedule Y.**

3. Manufacturing under Loan License

Meaning: A loan license is given when a person has **no factory of their own** but wants to use another's manufacturing facility.



License:

- Applied in **Form 24-A**.
- Issued in **Form 25**, valid for **1 year**.

Conditions:

1. Application form + fees must be submitted.
2. Drug Inspector checks the premises and approves facilities.
3. Separate applications needed for drugs under **Schedule C, C1, X**.

4. Records of production must be kept for **5 years** (2 years for expiry-limited drugs).
5. Proper space is required for raw materials and finished goods.
6. Work must be supervised by **qualified technical staff**.

4. Licence for Repacking

Meaning: Breaking bulk drugs into small packs for sale/distribution.

- Requires a **repacking licence** (Form 25-B).
- Issued for drugs other than Schedule C, C1, X

Procedure:

- Apply in **Form 24-B**.
- License issued in **Form 25-B** after inspection.

Conditions:

- Adequate space & equipment must be provided.
- Hygienic conditions should be maintained.
- Repacking must be supervised by competent staff.
- Facility should have proper testing arrangements.
- Licence should be displayed at the repacking site.
- Factory must follow **Schedule M** rules.
- Adequate staff and proper building required.
- Containers should be labeled with **"Rep. Lic. No."**
- Validity = **till 31stDecember each year** → renewable.

5. Licence to Manufacture Drugs (other than Schedule C, C1, X)

Application:

- Apply in **Form 24** with fees.
- Licence issued in **Form 25**.

Conditions

- Factory must follow **Schedule M**.
- Supervision by **Competent Technical Staff**.
- Separate **testing facility** required.
- Adequate **storage facility** required.
- Inspector must be allowed to inspect.
- Licence must be displayed at premises.
- Fees & endorsement required for additional products.

- **Records** of testing/manufacture (Schedule U):
  - Keep for **2 years** (expiry drugs).
  - Keep for **5 years** (other drugs).
- Provide **samples** to authority if asked.
- Furnish **stability data** if demanded.
- Provide additional requirements as directed.
- Maintain **Inspection Book**.
- Must comply with **GMP**.

7. Licence to Manufacture Biological & Special Products (Schedule C & C1)

Application:

- Apply in **Form 27** with prescribed fees.
- Licence is issued after inspection.

General Conditions

- Same as for other drugs (except Schedule C, C1, X).

Special Conditions for Biologicals

- Schedule C drugs → must be packed in **sterile, sealed glass** or suitable containers.
- Containers must follow **Schedule F/F1**.
- Drugs must meet **standards in Schedule F**.
- Serum must be tested for **freedom from abnormal toxicity**.
- **Multidose containers** → add preservative to prevent microbial growth.
- **Sterility testing** is compulsory.
- Some substances → test for absence of **aerobic & anaerobic bacteria**.
- Solutions for parenteral use >10 ml → test for **pyrogens**.
- Adequate **laboratory & trained staff** for culture and testing of organisms.

7. Manufacture of Drugs under Schedule X

Application:

- Apply in **Form 27B** with prescribed fees.
- Licence issued in **Form 28B**.

General Condition

- Same as for other drugs (Schedule C, C1, X).

Special Conditions

- Maintain **bound register** of all transactions (for 5 years).
  - Accounts of drugs used in manufacture (date, name, batch, qty).
  - Accounts of production (date, raw material, wastage, qty).
  - Accounts of sale (date, batch, qty sold, purchaser details).

- Submit **copies of invoices/sale records** to licensing authority.
- Manufacturing records must be preserved.
- Labels must have a **red "XRx" symbol.**
- Drugs in Schedule X → sold only on **prescription of a doctor**.
- Pack size limits:
  - 100 units (tabs/caps)
  - 300 ml oral liquid
  - 5 ml injection.

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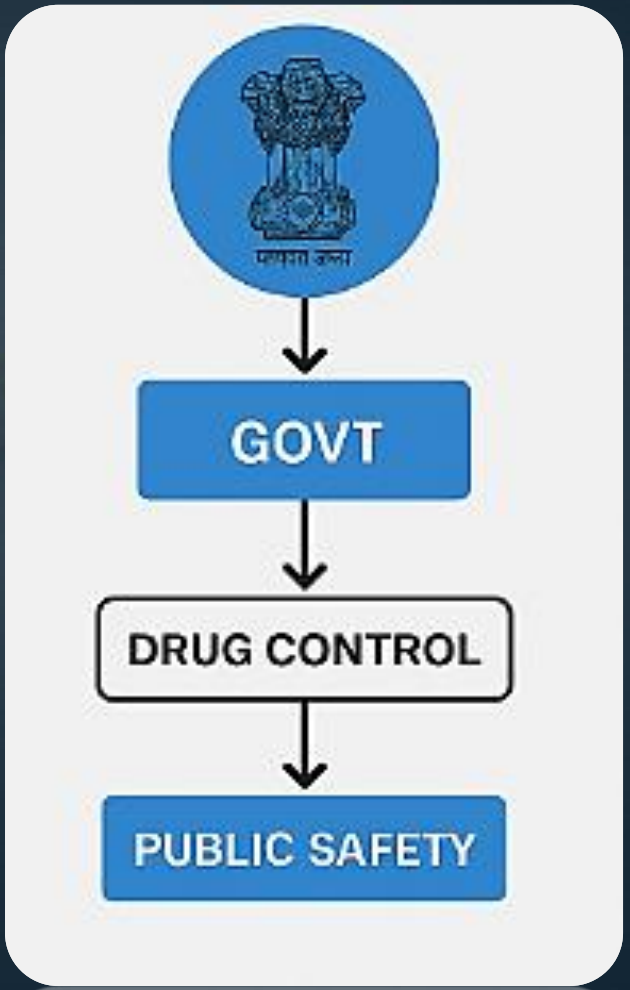
Introduction

- Drugs are essential commodities needed for treatment and healthcare.
- Regulation is necessary for their import, manufacture, sale, and distribution.
- Central & State Governments are responsible for ensuring drug quality and safety.

- The Government must build a strong regulatory network to:
- Prevent circulation of adulterated, misbranded, and spurious drugs.
- Ensure availability of genuine and effective medicines to the public.



OBJECTIVES OF DRUGS & COSMETICS ACT

S. No.	Objective	Description
1	**Prevent substandard drugs**	Ensure quality standards to protect public health and avoid harmful or inffective medications
2	**Control import, manufacture, sale & distribution**	Enforce licensing system to regulate all stages of the drug and cosmetic supply chain
3	**Qualified persons only**	Ensure that only trained and licensed individuals handle drugs and cosmetics
4	**Regulation of traditional systems**	Monitor and regulate manufacture & sale of Ayurvedic, Siddha, and Unani drugs
5	**Establish DTAB & DCC**	Form Drug Technical Advisory Board (DTAB) and Drug Consultative Committee (DCC) for expert guidance and policy framing

Important Definitions

❑ Drug

- All medicines used internally or externally for humans or animals, including those for diagnosis, treatment, prevention, or relief from disease.
- Substances (other than food) that affect body structure/function or help destroy insects/vermin causing diseases.
- Components used to make drugs, like empty gelatin capsules.
- Medical devices (internal or external) used in diagnosis or treatment, as notified by the government

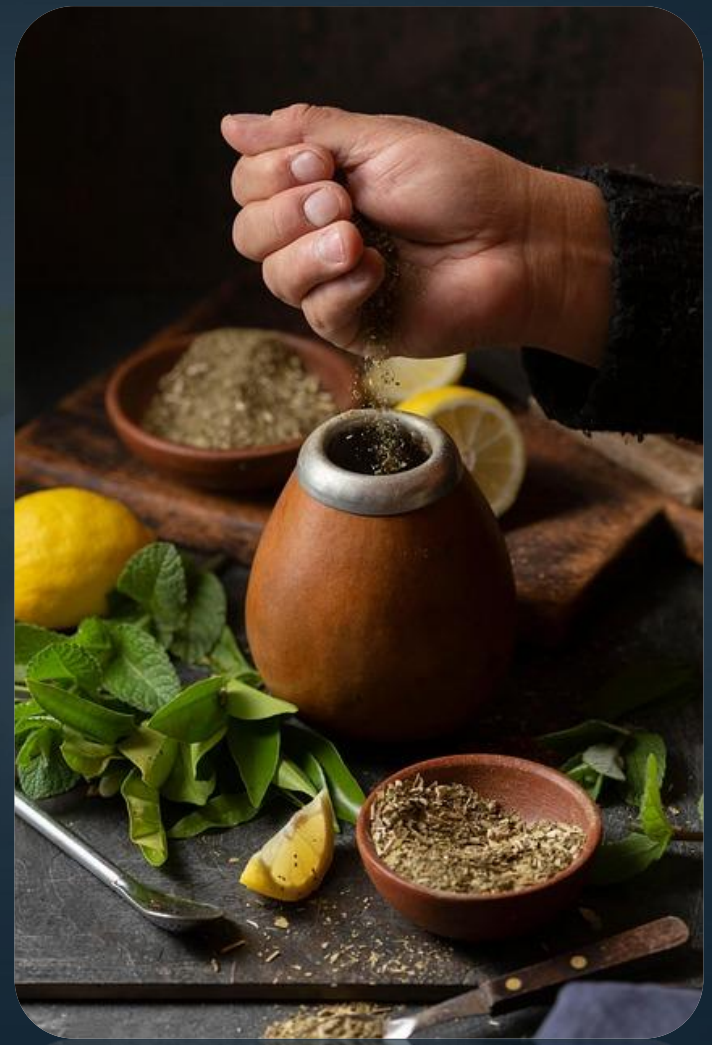
Cosmetic

- Any product used on the human body for:
  - Cleansing
  - Beautifying
  - Promoting attractiveness
  - Altering appearance
- It includes items that are:
  - Sprayed, rubbed, poured, sprinkled, or applied to the body
  - Used as a component or ingredient of a cosmetic

Ayurvedic, Siddha & Unani Drugs (ASU)

These drugs include:

- Medicines used for internal or external use
- Used in the diagnosis, treatment, prevention, or relief of diseases
- Made exclusively as per formulas given in authoritative books listed in the First Schedule of the Act



Gudakhu

- It is a tobacco product used for rubbing against human teeth.
- It contains tobacco powder, lime and molasses along with red mineral matter.
- It is a cosmetic within the provisions of the Act.

Patent or Proprietary Medicine

1. For Ayurvedic, Siddha or Unani Medicines:

- These are medicines made using only ingredients listed in approved books (First Schedule of the Act).
- They should not be given by injection (parenteral route).

Example: An Ayurvedic syrup made from Tulsi, Giloy, Amla as per Ayurvedic texts = **Proprietary medicine**

But if the same is made for injection = **Not allowed as proprietary medicine**

2.For Other Systems (like Allopathy):

- These are **readymade medicines** (tablets, syrups, creams etc.) that are:
  - Ready for use (internal or external)
  - **Not listed** in Indian Pharmacopoeia (IP) or any official pharmacopoeia

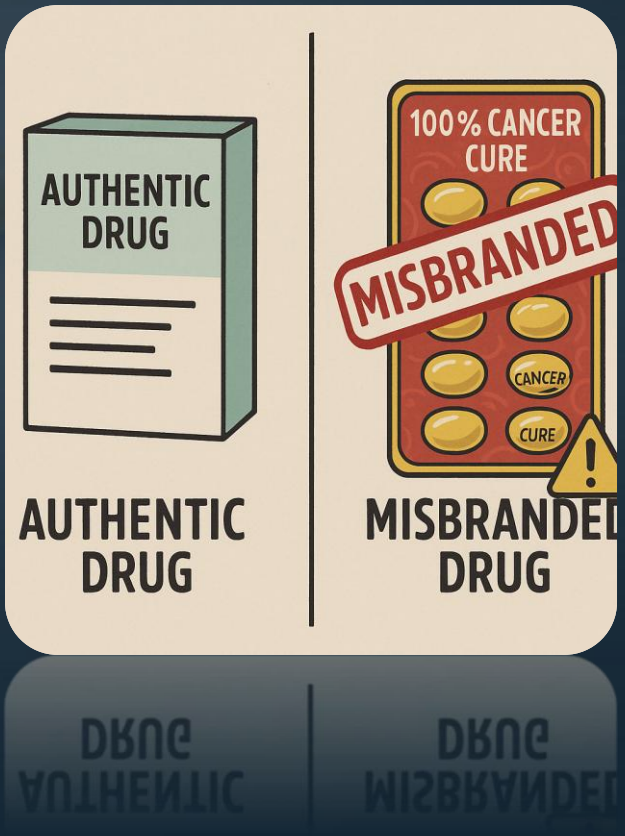
❑ **Example**:

✓ A new cold tablet containing a unique mix of paracetamol + herbal extract + caffeine, not listed in IP = **Proprietary medicine**

✓ PA regular aracetamol tablet listed in IP = **Not proprietary**, it's a standard drug.

Misbranded Drug

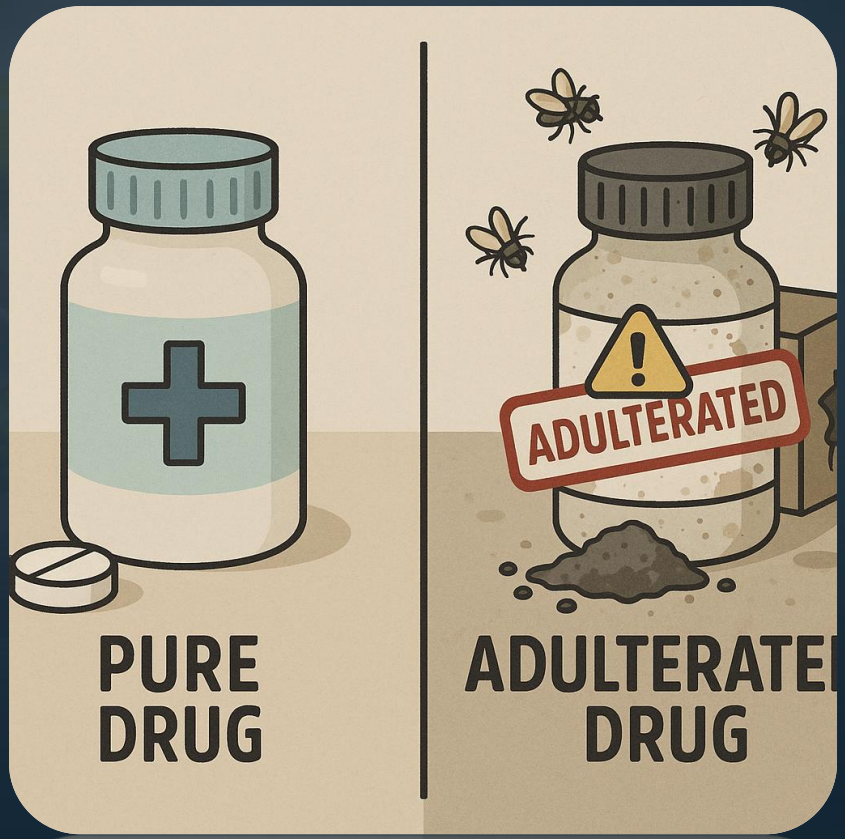
- A drug that violates labeling or appearance regulations under the Drugs and Cosmetics Act.
- A drug is considered misbranded if:
  - ✓ Improper Labeling: Not labeled as per legal requirements.
  - ✓ Concealed Damage or False Appearance: Coloured, coated, or polished to hide defects or to look more effective than it actually is.
  - ✓ False or Misleading Claims: Label, container, or accompanying material gives fake therapeutic claims or misleading info.



Adulterated Drug

A drug is considered **adulterated** under the Drugs and Cosmetics Act if:

- Filthy or Decomposed– Contains dirty, rotten, or decomposed materials.
- Unhygienic Conditions– Made or stored in unsanitary places that can cause contamination.



- Poisonous Container– Packaging contains harmful materials that can make the drug toxic
- Unapproved Colour– Coloured using a non-permitted dye or pigment.
- Toxic Additives– Contains harmful chemicals that may affect health.
- Diluted Drug– Mixed with other materials to reduce quality or potency.

Manufacture in relation to Drug/Cosmetic

- Refers to any process done to prepare a drug/cosmetic for sale or distribution.
- Includes:
  - Making or altering the product
  - Ornamenting, finishing, or labeling
  - Packing, breaking up, or treating it in any form
- Purpose: All these steps are done with commercial intent (sale/distribution).
- Excludes:

  Retail-level compounding or dispensing

  Packing done in ordinary retail business

Spurious Drug

A drug is considered spurious if:

- False Naming: Imported using the name of a different drug.
- Imitation or Lookalike: Looks like another drug to mislead or deceive users.
- Substitution: The drug content has been partially or completely replaced with another substance.
- Fake Manufacturer Claim: Claims to be from a manufacturer it actually doesn't belong to.

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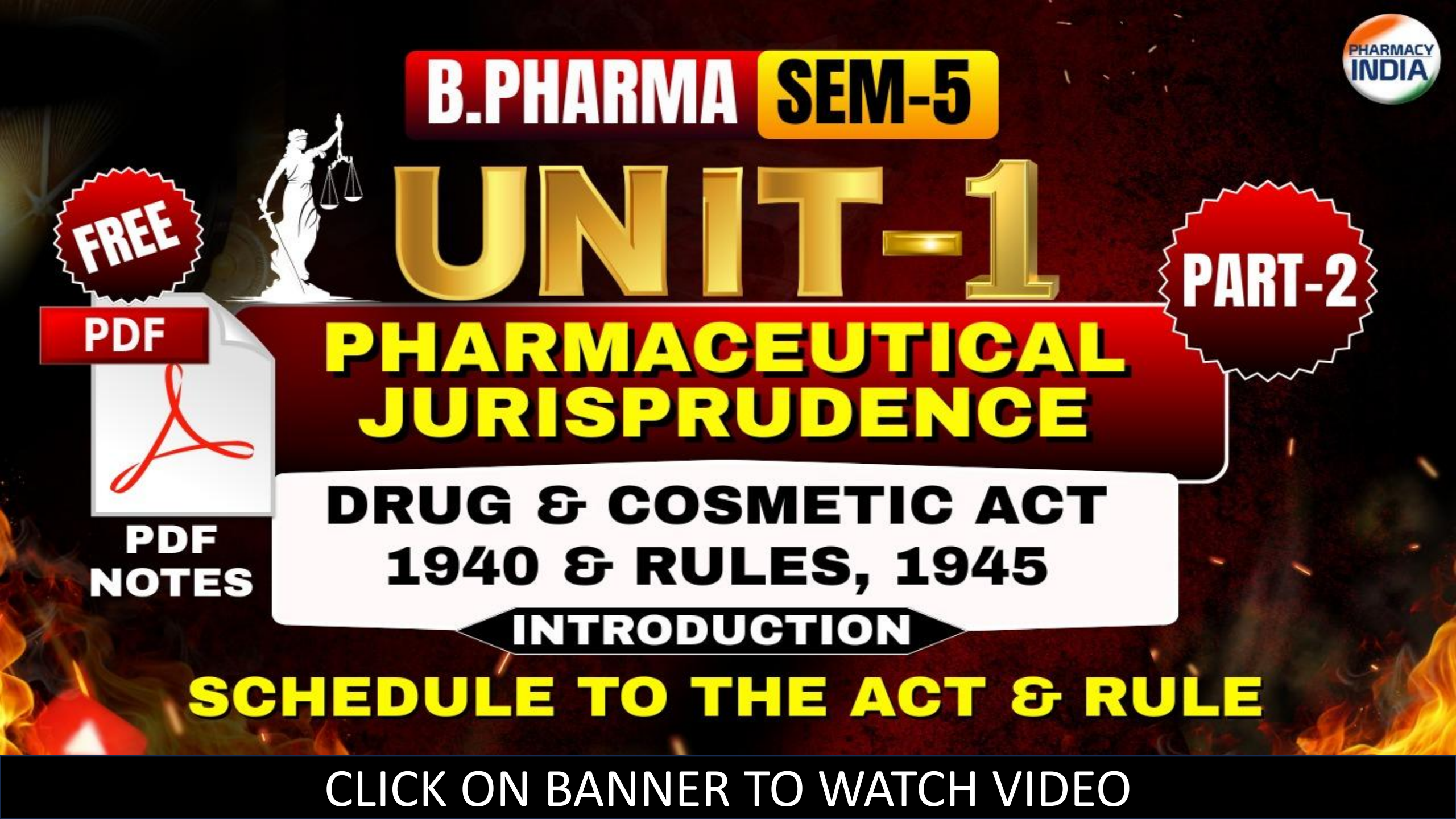

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LEGAL DEFINITIONS OF SCHEDULE TO THE ACT & RULE

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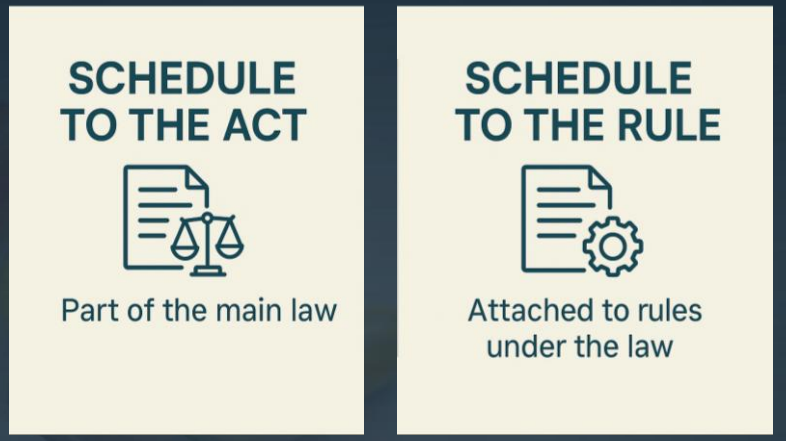
Introduction

- **Schedules** are lists or appendices attached to legal documents.
  They provide **detailed specifications, forms, categories, or conditions** without overloading the main text.

Term	Legal Definition	Example
Schedule to the Act	An appendix attached to the primary legislation (the Act) which contains specific lists or details forming part of the law.	Schedule X of Drugs & Cosmetics Act lists certain controlled drugs.
Schedule to the Rule	An appendix attached to subordinate legislation (Rules) framed under the Act.	Schedule M under Drugs & Cosmetics Rules for GMP.

Schedules to the Act and Rules

- **Schedules to the Act:** 2 Schedules
- **Schedules to the Rules:** 35 Schedules



These schedules provide lists, forms, standards, exemptions, and other legal details necessary for implementing the **Drugs and Cosmetics Act, 1940** and the **Drugs and Cosmetics Rules, 1945**.

Schedules to the Act

1. First Schedule

- Books of references for **Ayurvedic, Siddha & Unani** medicines.
- **57 Ayurveda, 30 Siddha, 13 Unani Tibb** reference books.
- Used for authentic formulation preparation.

2. Second Schedule

- Specifies **standards** for imported and manufactured drugs.
- Covers sale, stocking, storage, and quality compliance.

❑ Schedules to the Rules

Schedule	Content Focus	Detailed Description	Example
A	Forms & formats	Official application, renewal, and licensing forms for manufacturing, selling, or importing drugs.	Form 19 – manufacturing license
B	Fees for tests	Prescribes fees for testing and analysis of drugs, cosmetics, and raw materials in govt. labs.	Lab analysis fee for antibiotics
C	Biological & special products	Lists products needing special storage/transport due to sensitivity.	Vaccines, sera, toxins

Schedule C1, D, E1

Schedule	Content Focus	Detailed Description	Example
C1	Additional biologicals	Biological products not in Schedule C but needing similar control.	Insulin, penicillin
D	Exemptions from provisions	Drugs exempted from some legal requirements under certain conditions.	Imported life-saving drugs for personal use
E1	Poisonous substances	Highly toxic substances requiring “Poison” label and special handling.	Arsenic compounds, mercury salts

Schedule F, F1, G

Schedule	Content Focus	Detailed Description	Example
F	Standards for biological products	Standards for manufacturing, storage, and quality control.	Vaccine cold chain requirements
F1	Standards for ophthalmic preparations	Standards for sterility, packaging, and quality of eye products.	Eye drops
G	Prescription drugs (Rx)	Drugs to be sold only on prescription, labeled “Rx”.	Broad-spectrum antibiotics

Schedule H, J

Schedule	Content Focus	Detailed Description	Example
H	Prescription-only drugs	Stricter control, labeled: "Schedule H – To be sold by retail on prescription only."	Anti-TB drugs
J	Prohibited drugs	Drugs banned for manufacture/import/sale in India.	Certain banned fixed-dose combinations

"A Big Cat Caught Dogs Eating Fish For Good Healthy Jump“

A – Forms & formats
B – Fees
C – Biological products
C1 – Additional biologicals
D – Exemptions
E1 – Poisonous substances
F – Standards (biologicals)
F1 – Standards (ophthalmic)
G – Prescription drugs
H – Prescription-only drugs
J – Prohibited drugs

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For
ANY QUERIES

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Thank You!