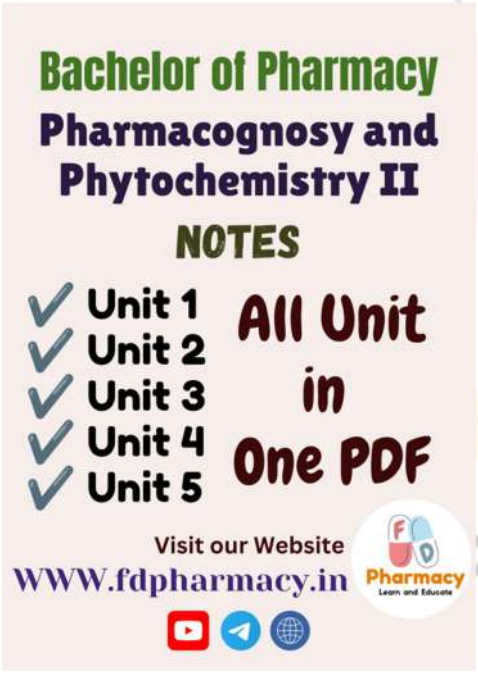
WELCOME

TO


Bachelor of Pharmacy
Pharmaceutical Jurisprudence
NOTES
Unit 1
Unit 2
Unit 3
Unit 4
Unit 5
All Unit in One PDF
Visit our Website
WWW.fdpharmacy.in
Pharmacy
Learn and Educate


Bachelor of Pharmacy
Industrial Pharmacy I
NOTES
Unit 1
Unit 2
Unit 3
Unit 4
Unit 5
All Unit in One PDF
Visit our Website
WWW.fdpharmacy.in
Pharmacy
Learn and Educate


Bachelor of Pharmacy
Medicinal Chemistry II
NOTES
Unit 1
Unit 2
Unit 3
Unit 4
Unit 5
All Unit in One PDF
Visit our Website
WWW.fdpharmacy.in
Pharmacy
Learn and Educate


Bachelor of Pharmacy
Pharmacognosy and Phytochemistry II
NOTES
Unit 1
Unit 2
Unit 3
Unit 4
Unit 5
All Unit in One PDF
Visit our Website
WWW.fdpharmacy.in
Pharmacy
Learn and Educate


Bachelor of Pharmacy
Pharmacology II
NOTES
Unit 1
Unit 2
Unit 3
Unit 4
Unit 5
All Unit in One PDF
Visit our Website
WWW.fdpharmacy.in
Pharmacy
Learn and Educate

PHARMACEUTICAL JURISPRUDENCE

UNIT 2

TOPIC :

- **Labeling & Packing of drugs –** General labeling requirements and specimen labels for drugs and cosmetics, List of permitted colors. Offences and penalties.

LABELING & PACKING OF DRUGS AND COSMETICS

- Labeling means the information printed or written on the container, wrapper, or any tag attached to a drug or cosmetic.
- Packing refers to the material and method used to enclose and protect the drug or cosmetic during storage, transport, and use.
- Proper labeling and packing ensure:
  - Safe and rational use of drugs.
  - Identification of the product and its composition.
  - Protection from contamination, deterioration, and misuse.
  - Legal compliance with the Drugs and Cosmetics Rules, 1945.

Legal Basis

- The rules regarding labeling and packing are given under Part IX of the Drugs and Cosmetics Rules, 1945:
  - Rules 96 to 105 – *Labeling and packing of drugs and cosmetics.*
  - Schedule F, F(1), P, and M – provide additional labeling and packaging standards for specific categories.

Objectives of Labeling and Packing

1. To provide complete and accurate information about the product.
2. To ensure correct identification of active ingredients.
3. To prevent misbranding or adulteration.
4. To protect the consumer from false claims or misuse.
5. To facilitate recall, traceability, and inspection.
6. To ensure storage stability and safety.

General labeling requirements (rule 96)

Every container of a drug (whether for sale or distribution) must bear a label containing the following information:

S. No.	Particulars	Details Required on Label
1.	Name of the Drug	- Proper or brand name of the product in clear, legible letters. - For combination drugs, all active ingredients should be mentioned.
2.	Manufacturer's Details	- Name and complete address of the manufacturer. - For imported drugs: name and address of importer and country of origin.
3.	Batch Number	- Must begin with "Batch No." or "B.No." - Helps in product recall and traceability.
4.	Manufacturing License Number	- Preceded by the words "Mfg. Lic. No."
5.	Date of Manufacture and Expiry	- Written as "Mfg. Date" and "Exp. Date". - Expiry month and year should be clearly mentioned.
6.	Net Contents / Quantity	- Weight, volume, or number of units (e.g., 100 mL, 10 tablets).
7.	Active Ingredients	- Generic names and strengths per dosage unit.
8.	Storage Instructions	- Example: "Store in a cool, dry place", "Protect from light", etc.
9.	Schedule Indication	- Drugs from certain schedules must bear statutory warnings (see below).
10.	Warnings and Precautions	- For prescription drugs: "To be sold by retail on the prescription of a Registered Medical Practitioner only."
11.	Dosage Form and Route of Administration	- Example: "Oral Tablets", "For External Use Only".
12.	Standard Reference	- Mention pharmacopoeial standard such as IP, BP, or USP.

Additional labeling for schedule drugs

Schedule	Labeling Requirement / Warning
Schedule G	"Caution: It is dangerous to take this preparation except under medical supervision." (in red on white background)
Schedule H	"Schedule H drug – Warning: To be sold by retail on the prescription of a Registered Medical Practitioner only."
Schedule H1	"Schedule H1 drug – Warning: It is dangerous to take this preparation except under medical supervision. Not to be sold without prescription of a Registered Medical Practitioner." (red box with red border)
Schedule X	"Schedule X drug – Warning: To be sold by retail on the prescription of a Registered Medical Practitioner only." (red label)
Schedule C and C(1)	Must bear storage instructions and date of expiry.
External Preparations	Must bear the words "For External Use Only".
Poisonous substances	Must bear the word "POISON" in red capital letters on a white background.

Labeling of different dosage forms

Dosage Form	Labeling Requirements
Tablets/Capsules	Name, strength, batch no., mfg. & exp. date, warning (if applicable).
Liquids for Oral Use	Name, strength per mL, direction for use, preservatives, storage.
Injections	Sterility statement, route (e.g., IM, IV), storage ("Do not freeze"), date of manufacture & expiry.
External Preparations	"For external use only", warnings if irritant/toxic, directions for use.
Ointments & Creams	Net weight, active ingredients %, precautions, manufacturer details.
Veterinary Drugs	"Not for human use – For animal treatment only."
Ayurvedic Drugs	Must carry "Ayurvedic Proprietary Medicine" or "Classical Medicine" as applicable.

Packing requirements (rules 105–105a)

Aspect	Requirement
Quality of container	Must not react or interact with the drug; should be non-toxic, clean, and dry.
Sealing	Every container should be properly sealed to prevent leakage or contamination.
Material used	Glass, plastic, metal, or laminated materials must be compatible with the formulation.
Sterile preparations	Packed aseptically in sterile containers.
Repackaging	Can be done only under a valid Repacking License.
Schedule P drugs	Must follow special packaging requirements for maintaining shelf-life (e.g., airtight, light-resistant).
Child-resistant packaging	Recommended for poisonous or Schedule X drugs.

Specimen labels

(A) For Schedule H Drug (Example: Amoxicillin Tablets)

Label:

Amoxicillin Tablets IP 500 mg
Each film-coated tablet contains:
Amoxicillin trihydrate IP equivalent to Amoxicillin 500 mg
Batch No.: A123
Mfg. Date: 05/2025
Exp. Date: 04/2028
Mfg. Lic. No.: 45/Pharma/2020
Manufactured by: XYZ Pharmaceuticals Pvt. Ltd., Mumbai
Schedule H Drug – Warning:
To be sold by retail on the prescription of a Registered Medical Practitioner only.
Storage: Store below 25°C. Protect from light and moisture.

(B) For External Preparation (Example: Antiseptic Cream)

Label:

ABC Antiseptic Cream
For External Use Only
Batch No.: C145
Mfg. Date: 03/2025
Exp. Date: 02/2028
Net Weight: 25 g
Mfg. Lic. No.: 12/Cos/2020
Manufactured by: Sunshine Cosmetics, Chennai
Caution: Avoid contact with eyes. Discontinue if irritation occurs.

(C) For Schedule X Drug (Example: Diazepam Tablets)

Label:

Diazepam Tablets IP 5 mg
Each tablet contains: Diazepam IP 5 mg
Batch No.: D220
Mfg. Date: 06/2025
Exp. Date: 05/2028
Mfg. Lic. No.: 98X/2020
Manufactured by: Medline Pharmaceuticals Ltd., Pune
Schedule X Drug – Warning:
To be sold by retail on the prescription of a Registered Medical Practitioner only.
Storage: Store below 30°C in a locked cabinet.

List of permitted colors (rule 127 & schedule q)

Permitted Colors for Drugs and Cosmetics

- Only colors specified in Schedule Q of the Drugs and Cosmetics Rules, 1945 are allowed.
  These are certified and non-toxic coloring agents suitable for pharmaceutical and cosmetic use.

Examples of Permitted Colors:

S. No.	Color Name	Color Index (CI) No. / Common Name
1.	Brilliant Blue FCF	CI 42090
2.	Tartrazine	CI 19140
3.	Sunset Yellow FCF	CI 15985
4.	Carmoisine	CI 14720
5.	Erythrosine	CI 45430
6.	Indigo Carmine	CI 73015
7.	Ponceau 4R	CI 16255
8.	Fast Green FCF	CI 42053
9.	Quinoline Yellow	CI 47005
10.	Titanium Dioxide	CI 77891 (used as white pigment)

Note: Only colors listed in Schedule Q are permitted.
Use of any unlisted or coal-tar color is strictly prohibited.

Offences and Penalties (Related to Labeling & Packing)

Nature of Offence	Relevant Section/Rule	Penalty
Sale of misbranded drugs (false or misleading label, omission of required info)	Section 17 & 27(b)	Imprisonment up to 1 year or fine up to ₹20,000, or both.
Sale of adulterated drugs (contaminated, decomposed, or packed in unclean containers)	Section 17A & 27(a)	Imprisonment from 10 years to life and fine not less than ₹10 lakh or 3× value of drugs.
Sale of spurious drugs (imitating another brand, fake labels)	Section 17B & 27(b)/(c)	Imprisonment up to 10 years to life, fine ₹10 lakh or more.
Failure to comply with labeling rules	Rule 96–105	License may be suspended or cancelled by the authority.
False or misleading advertisement	Section 29	Fine up to ₹1,000 (first offence), ₹2,000 or imprisonment for subsequent offences.
Repacking without license	Section 18(c)	Imprisonment up to 1 year or fine up to ₹10,000, or both.