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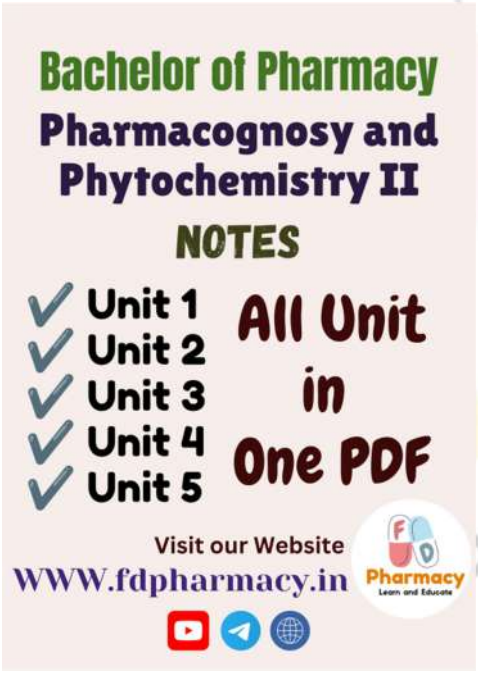
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PHARMACEUTICAL JURISPRUDENCE

UNIT 1

TOPIC :

- **Manufacture of drugs –** Prohibition of manufacture and sale of certain drugs, Conditions for grant of license and conditions of license for manufacture of drugs, Manufacture of drugs for test, examination and analysis, manufacture of new drug, loan license and repacking license.

Manufacture of Drugs

- The Drugs and Cosmetics Act, 1940 and Rules, 1945 regulate every step in the manufacture, sale, and distribution of drugs and cosmetics in India.
  The main purpose is to ensure that all drugs manufactured in India are safe, effective, pure, and of standard quality.
- The provisions related to the manufacture of drugs are mainly covered under Chapter IV (Sections 16 to 33) of the Act.

Objectives of Regulation of Drug Manufacture

- To maintain the quality, purity, and efficacy of all drugs.
- To prevent the manufacture and sale of substandard, adulterated, spurious, or misbranded drugs.
- To ensure that manufacturing premises meet Good Manufacturing Practices (GMP).
- To regulate and monitor the production, storage, and labeling of drugs.
- To safeguard public health by enforcing strict legal controls.

Prohibition of Manufacture and Sale of Certain Drugs

- According to Section 18 of the Drugs and Cosmetics Act, 1940, no person shall manufacture, sell, stock, or distribute certain classes of drugs unless specific conditions are fulfilled.
- This section is the most important legal provision regulating manufacture and sale.

Drugs Whose Manufacture and Sale Are Prohibited

The following classes of drugs cannot be manufactured or sold in India:

Class of Drug	Reason for Prohibition / Legal Basis
1. Misbranded Drugs	Drugs whose labeling, packaging, or information is false or misleading (Section 17).
2. Adulterated Drugs	Drugs contaminated with impurities or manufactured under unhygienic conditions (Section 17A).
3. Spurious Drugs	Imitation or substitution of another drug; false claims of origin (Section 17B).
4. Drugs not of Standard Quality	Drugs that fail to meet pharmacopoeial standards (Section 16).
5. Patent or Proprietary Medicines with False Claims	Drugs making false or misleading therapeutic claims.
6. Drugs Containing Prohibited Substances	Certain drugs or fixed dose combinations (FDCs) banned by the Central Government under Section 26A.
7. Drugs for Diseases Listed in Schedule J	No drug may claim to cure or prevent diseases such as cancer, diabetes, epilepsy, etc.
8. Cosmetics Containing Harmful Substances	Cosmetics that contain injurious or toxic ingredients prohibited under Schedule Q.

Conditions for Manufacture and Sale

A drug can be manufactured or sold only under the following legal conditions:

Condition	Explanation
Valid Manufacturing License	Must be obtained from the State Licensing Authority (Form 25/28).
Good Manufacturing Practices (GMP)	Premises must follow Schedule M requirements.
Qualified Technical Staff	At least one competent person with a pharmacy, pharmaceutical chemistry, or microbiology background must supervise production.
Proper Labeling and Packaging	Must comply with labeling provisions (Rule 96).
Standard Quality Assurance	Must conform to standards in the Indian Pharmacopoeia (IP) or other prescribed standards.
Inspection and Record Keeping	Inspectors may visit premises anytime to verify compliance.

Legal Provisions Related to Prohibition

Section 18 – Prohibition of Manufacture and Sale

This section prohibits:

- Manufacture for sale or distribution of misbranded, adulterated, spurious, or not of standard quality drugs.
- Sale or distribution of drugs not labeled as per rules.
- Manufacture or sale of drugs without a valid license.
- Manufacture of cosmetics containing unsafe ingredients.

Section 18A – Disclosure of Manufacturer

Every person selling a drug must disclose the name and address of the manufacturer when asked by an Inspector.

Section 18B – Maintenance of Records

Manufacturers and sellers must maintain records and registers as prescribed under the Rules for verification.

Central Government's Power to Prohibit Certain Drugs

Under Section 26A, the Central Government may, in the public interest, prohibit the manufacture, sale, or distribution of:

- Any drug or cosmetic that is unsafe or harmful to humans or animals,
- Any drug that lacks therapeutic value, or
- Any drug whose use involves risk greater than benefit.

Example:
Banned fixed-dose combinations (FDCs), Analgin, Phenylpropanolamine, Rofecoxib, etc.

Important Schedules Related to Manufacture

Schedule	Relevance
Schedule M	Specifies GMP requirements for manufacture of allopathic drugs.
Schedule M1	GMP for homeopathic drugs.
Schedule T	GMP for Ayurvedic, Siddha, and Unani (ASU) drugs.
Schedule U	Specifies records to be maintained during manufacturing.
Schedule V	Standards for patent and proprietary medicines.

Licensing Forms for Manufacture

Form No.	Purpose
Form 24	License to manufacture for sale or distribution of drugs (other than those in Schedules C, C1, X).
Form 25	License to manufacture for sale of Schedule C and C1 drugs (biologicals, sera, vaccines).
Form 28	License for manufacture of Schedule X (narcotic) drugs.
Form 29	License to manufacture small quantities for test, analysis, or examination.
Form 25-A / 28-A	Loan license (when production is done in another approved facility).

Offences and Penalties

Type of Offence	Punishment / Penalty
Manufacture or sale of spurious or adulterated drugs likely to cause death or injury	Imprisonment up to 10 years (may extend to life imprisonment) and fine ≥ ₹10 lakh or 3 times the value of drugs.
Manufacture or sale of substandard or misbranded drugs	Imprisonment up to 3 years and/or fine up to ₹5,000.
Manufacture or sale without valid license	Imprisonment up to 5 years and/or fine up to ₹10,000.
Manufacture of cosmetics containing harmful ingredients	Imprisonment up to 3 years and/or fine up to ₹5,000.
Repeat offences	Harsher punishments, including cancellation of license and imprisonment up to life.

Conditions for Grant of License for Manufacture of Drugs

- Before granting a manufacturing license, certain essential conditions must be satisfied as per Rule 71 and 76 of the Drugs and Cosmetics Rules, 1945.

(a) Application for License

- The manufacturer must apply in the prescribed Form 24, 24-B, 24-F, etc., depending on the category of drug.
- Application must be made to the Licensing Authority (generally the State Drugs Control Department).

(b) Premises and Equipment

- The manufacturing premises must comply with Good Manufacturing Practices (GMP) as per Schedule M.
- Adequate area, ventilation, lighting, and cleanliness should be maintained.
- Proper equipment and instruments must be available for manufacturing and quality control.

(c) Competent Technical Staff

- Manufacturing must be conducted under the supervision of competent technical staff.
- Qualifications of technical staff:
  - Pharmaceutical Chemist, or
  - Graduate in Pharmacy/Science with appropriate experience.

(d) Quality Control Laboratory

- A separate Quality Control Laboratory must exist.
- Qualified analytical chemists and microbiologists should be employed.
- Instruments for analysis and testing of raw materials and finished products must be available.

(e) Storage Facility

- Adequate arrangements for storage of raw materials, intermediates, and finished goods under suitable conditions must be ensured.

(f) Records and Documentation

- Detailed records of manufacture, testing, distribution, and sales must be maintained.
- Records should be preserved for at least 2 years after the expiry of the drug.

(g) Inspection

- Premises are inspected by Drug Inspectors before granting or renewing a license.

Conditions of License

➢ Once the license is granted, the manufacturer must comply with the following conditions:

General Conditions

- Drugs must be manufactured under hygienic conditions and as per GMP.
- Drugs must comply with standards prescribed in the official pharmacopoeias (IP, BP, USP).
- Every batch must undergo quality testing before release.
- The licensee must report any adverse reactions or product defects to the Licensing Authority.
- Labeling and packing must comply with the Act and Rules (Schedule P and Schedule F).
- The license should be displayed prominently on the premises.
- The license is non-transferable and must be renewed periodically.
- The Drug Inspector has the right to inspect premises and take samples at any time.

Manufacture of Drugs for Test, Examination and Analysis

Regulation:

- Governed by Rule 89 to Rule 90.
- A special license is required to manufacture drugs for test, examination, or analysis purposes.

Application:

- Application must be made in Form 29 to the Licensing Authority.
- The license is granted in Form 30.

Conditions:

1. Drugs manufactured must be used only for experimental or research purposes.
2. Drugs cannot be sold or used for commercial distribution.
3. Records of quantity manufactured and used must be maintained.
4. The license is usually valid for one year unless otherwise specified.

Manufacture of a New Drug

A new drug is defined under Rule 122E as:

- A drug which has not been used in India to a significant extent and requires clinical trials and approval from the Central Licensing Authority (CLA) before manufacture.

Approval Process:

1. The manufacturer must apply to the Central Drugs Standard Control Organization (CDSCO) with data on:
    - Pharmacology and toxicology
    - Clinical trial results
    - Safety and efficacy data
2. Permission is granted by the Drugs Controller General of India (DCGI) under Rule 122A.

Manufacturing License:

- Once approved, the license is granted in Form 25 (for allopathic drugs) or Form 28 (for others).
- Manufacturing must comply with GMP and approved specifications.

Loan License

- A Loan License (Rule 75A and 76A) is a license granted to an applicant who does not have his own manufacturing premises but intends to use the facilities of another licensed manufacturer.

Application:

- Application made in Form 24-A.
- License is issued in Form 25-A.

Conditions:

1. The manufacturer (loan licensee) must employ qualified technical staff.
2. The parent manufacturing unit must be licensed and have adequate facilities.
3. Records must clearly indicate which products are manufactured under the loan license.
4. The licensee must comply with all provisions of GMP and labeling rules.

Repacking License

- A Repacking License allows a person to purchase a drug in bulk and repack it into smaller packs for sale or distribution without altering its composition.

Application:

- Application made in Form 24-B.
- License issued in Form 25-B.

Conditions:

1. Repacking must be done under hygienic conditions.
2. Labels must bear correct information about the contents, batch number, expiry date, etc.
3. Adequate storage space and equipment for repacking must be available.
4. No alteration in the drug's composition or quality is allowed.
5. Proper records of repacking operations must be maintained.