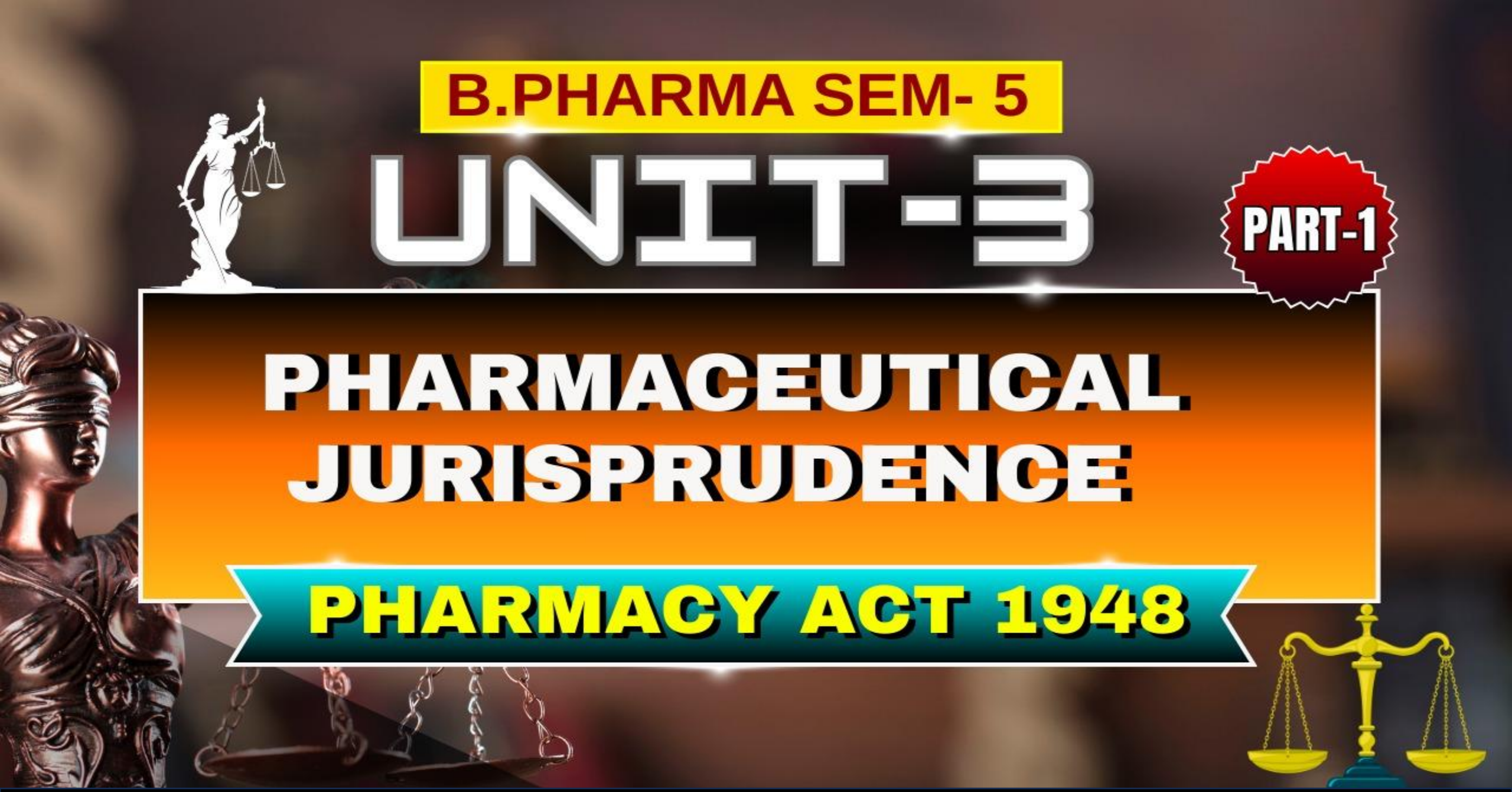

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B.PHARM SEMESTER – 5

JURISPRUDENCE

UNIT V I Part - 1

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TABLE OF CONTENT

Pharmacy Act –1948

- Objectives, Definitions,
- Pharmacy Council of India;
- Its constitution and functions,
- Education Regulations,
- State and Joint state pharmacycouncils;
- Constitution and functions,
- Registration of Pharmacists,
- Offences and Penalties

1. Objectives of the Pharmacy Act, 1948

- To regulate the profession and practice of pharmacy in India.
- To ensure that only qualified and registered persons dispense drugs.
- To establish Pharmacy Council of India (PCI) and State Pharmacy Councils for maintaining standards of pharmacy education and registration of pharmacists.
- To protect the public from unqualified persons handling medicines.

2. Definitions

- "agreement" means an agreement entered into under section 20 (inter-State agreement regarding constitution of State Councils)
- "approval" means approval by the State Council under section 12 (courses of study and examinations in pharmacy) or section 14 (foreign qualification) for the purpose of qualifying for registration under the Act
- "Central Council" means the Pharmacy Council of India constituted under Section 3.

- "Central Register" means the register of pharmacists maintained by the Central Council under Section 15-A
- "register" means a register of pharmacists prepared and maintained under the Act
- "Registered pharmacist" means a person whose name is for the time being entered in the register of the State in which he is for the time being residing or carrying on his profession or business of pharmacy
- "State Council" means a State Council of Pharmacy constituted under Section 19, and includes a Joint State Council of Pharmacy in accordance with an agreement under section 20 of the Act.

3. Pharmacy Council of India (PCI) – Constitution

Aspect	Key Points
Established	1949 under Pharmacy Act, 1948 by Central Government
Nature	Statutory body; corporate with perpetual succession and common seal
Elected Members	1. Six teachers (pharmaceutical chemistry/pharmacy/pharmacology) elected by universities2. One member elected by Medical Council of India3. One registered pharmacist elected by each State Council

Nominated Members	**1. Six persons with degree/diploma in pharmacy engaged in practice, nominated by Central Govt2. Representatives from UGC & AICTE3. One registered pharmacist nominated by each State/UT**
Ex-officio Members	1. Director General of Health Services2. Director of Central Drugs Laboratory3. Drugs Controller of India
President & Vice-President	Elected from Council members for max 5 years; can be re-elected

Powers/Functions	**Maintain Central Register of Pharmacists; prescribe standards of pharmacy education; approve courses & exams; advise on regulations; coordinate State Councils**
Special Provision	1976 Amendment: Union Territories could nominate one member instead of election (valid for 5 years)

4. Functions of the PCI

1. Prescribes minimum standards of pharmacy education in India.
2. Approves pharmacy institutions and their courses/examinations.
3. Maintains the Central Register of pharmacists.
4. Recognizes pharmacy qualifications (Indian and foreign) for registration.

5. Conducts inspections of pharmacy institutions to ensure compliance.

6. Advises Central and State Governments on pharmacy matters.

7. Withdraws recognition from non-compliant institutions or courses.

8. Promotes uniformity in pharmacy education and professional practice across India.

6. Education & Regulation

- PCI frames Education Regulations (approved by Central Government).
- These specify minimum qualification, training hours, equipment and facilities.
- Minimum 500 hours practical training over 3 months (250 hours dispensing).
- Amendments sent to States for comments and published in Gazette.
- Regulations effective in a State from the date notified by PCI.

❖ Application of Regulations to States

- Take effect in a State from notified date; remain in force until repealed or amended.
- PCI furnishes copies of minutes, annual reports, maintains accounts and audits annually.
- PCI also makes regulations for management of property, conducting meetings, and related matters.

❖ Approved Courses of Study and Examinations

- Institutions apply to PCI for approval of courses.
- Inspectors submit reports and recommendations to PCI.
- Approval essential for registration as a pharmacist.
- PCI coordinates with AICTE to avoid duplication and confusion.
- Approved institutions must provide data as required by PCI.

❖ Approval & Withdrawal of Courses

- PCI approves courses of study/examinations for pharmacists.
- Inspectors visit institutions to verify facilities and compliance with Education Regulations.
- PCI may withdraw approval if standards are not maintained, after notice and representation.

❖ Approval of Other Qualifications

- PCI can approve foreign qualifications for registration if standards match and reciprocal recognition exists.
- Can withdraw approval at any time if standards fall below required levels.

7. State Pharmacy Councils vs Joint State Councils

Category	State Pharmacy Council	Joint State Council
Elected Members	➢ 6 registered pharmacists elected from amongst themselves 1 member elected by the Medical Council of the State	➢ 3–5 registered pharmacists of each participating State elected from amongst themselves (may vary within 3–5) 1 member elected by the Medical Council of each State

➢ Nominated Members	➢ 5 members nominated by the State Government (at least 3 possessing degree/diploma in pharmacy or pharmaceutical chemistry or registered pharmacists)	➢ •2–4 members nominated by each participating State (more than half must possess degree/diploma in pharmacy or pharmaceutical chemistry or be registered pharmacists)
➢ **Ex-officio Members**	➢ Chief Administrative Medical Officer of the State Officer-in-charge of Drugs and Cosmetics Act, 1940 Government Analyst under Drugs and Cosmetics Act appointed by State Government	➢ Chief Administrative Medical Officer of each participating State Officer-in-charge of Drugs Control Organisation of each participating State Government Analyst of each participating State

7. Functions of State/Joint Pharmacy Councils

- **Maintain Register of Pharmacists – Prepare, maintain, and update the register of pharmacists within their jurisdiction.**
- **Registration & Renewal – Grant, renew, or transfer registration certificates to eligible pharmacists.**
- **Approval of Qualifications – Verify and approve the qualifications of applicants for registration.**
- **Remove or Suspend Names – Remove names from the register in case of misconduct, disqualification, or death of a pharmacist.**

- **Collect Fees – Levy and collect registration and renewal fees as prescribed.**
- **Issue Identity Certificates – Provide registration certificates and ID cards to registered pharmacists.**
- **Enforce Pharmacy Act Provisions – Ensure that only registered pharmacists dispense drugs under supervision.**
- **Inspect Premises – Authorize inspections of pharmacy premises and institutions to check compliance.**
- **Assist PCI & Government – Supply data and cooperate with the Pharmacy Council of India and State Government for policy and education matters.**
- **Conduct Elections – Organize and oversee elections for Council membership from among registered pharmacists.**

8. Regulation of Pharmacists (Registration)

9. Offences and Penalties

- ✓ **False representation as a registered pharmacist: Punishable with fine up to ₹500 for first offence and higher for subsequent offences.**
- ✓ **Dispensing by unregistered persons: Liable to penalty/fine.**
- ✓ **Failure to surrender certificate of registration after removal from register: Punishable.**
- ✓ **Institution running pharmacy course without PCI approval: PCI can withdraw approval and State Government may take action.**
- ✓ **Misuse of titles "Pharmacist" or "Registered Pharmacist": Legal action under the Act.**

Medicinal and Toilet Preparations (Excise Duties) Act, 1955

1. Objectives of the Act

- **Uniformity of Excise Duty: To provide for levy and collection of excise duties on medicinal and toilet preparations containing alcohol, opium or narcotics under a single central legislation, replacing multiple state laws.**
- **Control of Alcohol & Narcotics: To regulate manufacture, possession, sale and export of these preparations and prevent diversion for illegal use.**

- **Revenue Generation: To provide a reliable source of revenue to the government.**
- **Legal Framework: To lay down clear procedures for licensing, manufacturing and inspection of such preparations.**

2. Key Definitions (Section 2)

- **Medicinal Preparation: All drugs which include or contain alcohol, opium, Indian hemp or other narcotic drugs, whether used internally or externally for humans or animals.**
- **Toilet Preparation: Any preparation for use in perfumery, cosmetics or toilet purposes containing alcohol or narcotics.**

- **Bonded Manufactory: Licensed premises where alcohol is obtained without duty for manufacture and duty is paid only on removal of final product.**
- **Non-Bonded Manufactory: Licensed premises where alcohol used is duty-paid and excise duty is paid before or at the time of manufacture.**
- **Excise Commissioner: The authority appointed by the State Government to administer this Act.**

3. Licensing Provisions

- Compulsory License: No person can manufacture any medicinal or toilet preparation containing alcohol/narcotics without a license.
- Licensing Authority: State Excise Commissioner grants, renews, and cancels licenses.

- **Application Requirements: Detailed information about:**
  - **Type of preparation proposed to manufacture.**
  - **Source and quantity of alcohol/narcotics.**
  - **Storage facilities and security arrangements.**
- **Display of License: Must be displayed prominently at the premises.**
- **Renewal & Fees: Licenses must be renewed annually with prescribed fees.**
- **Separate Licenses: For bonded and non-bonded manufactories.**

4. Manufacture in Bond (Bonded Manufactory)

- Raw Alcohol Duty-Free: Manufacturers receive alcohol without paying excise duty initially.
- Excise Supervision: Entire process carried out under strict supervision of excise officers posted at the premises.
- Duty Payment on Removal: Excise duty paid only when finished products are removed from the factory.
- Advantages: Defers payment of duty, suited for large-scale manufacturers.
- Records: Stock and manufacturing registers must be maintained and periodically inspected.

5. Manufacture Outside Bond (Non-Bonded Manufactory)

- **Alcohol Duty Paid: Only duty-paid alcohol can be used for manufacturing.**
- **No Permanent Excise Officer: Less supervision compared to bonded manufacture.**
- **Duty at Procurement: Duty must be paid upfront or at the time of purchase.**
- **Suitable for Small Scale: Simplifies compliance but increases cost because duty is paid earlier.**

6. Export of Alcoholic Preparations

- **Export Permits: Required from excise authorities; no export without a valid permit.**
- **Duty Rebate/Refund: On export, duty already paid may be refunded subject to conditions.**
- **Customs Procedures: Exporter must comply with customs clearances and submit shipping bills.**
- **Inter-State Movement: Consignment must carry transport passes and permits.**

7. Manufacture of Alcoholic Preparations

- **Approved Formula: Manufacture only according to formula approved by the Excise Commissioner.**
- **Record Keeping: Daily accounts of alcohol received, used, wastage, and final output to be maintained.**
- **Inspections: Surprise inspections by excise officers to ensure compliance.**
- **Security Measures: Sealing of storage tanks, issue of permits for withdrawal of alcohol.**

8. Manufacture of Ayurvedic, Homeopathic, Patent & Proprietary Preparations

- **Ayurvedic / Unani / Siddha Preparations: Duty levied if the preparation contains self-generated or added alcohol above certain limits.**
- **Homeopathic Preparations: Dilutions with minimal alcohol are mostly exempt but stronger preparations attract duty.**
- **Patent & Proprietary Medicines: Allopathic or any system's patent/proprietary medicines containing alcohol/narcotics are treated like medicinal preparations and are dutiable.**
- **Separate Licensing: All categories must obtain licenses, maintain records and comply with inspections.**

9. Offences and Penalties (Sections 13–17)

- **Manufacture without License: Punishable with imprisonment up to 6 months and/or fine.**
- **Evasion of Duty: False records, tampering with excise seals, or diverting duty-free alcohol attract confiscation and penalties.**

- **Possession of Unaccounted Alcohol or Narcotics: Seizure of goods and prosecution under excise laws.**
- **Selling/Export without Permit: Prohibited and punishable with fine and imprisonment.**
- **Repeat Offences: Higher penalties and cancellation of license permanently.**
- **Failure to Maintain Records: Leads to suspension of license and monetary penalties.**

Narcotic Drugs and Psychotropic Substances Act (NDPS), 1985 and Rules

1. Objectives of the NDPS Act, 1985

- **Control and Regulation: To consolidate and amend laws relating to narcotic drugs and psychotropic substances.**
- **Prohibition: To prohibit production, manufacture, cultivation, possession, sale, purchase, transport, warehouse, import, export, and use of narcotic and psychotropic substances except for medical or scientific purposes.**
- **Prevent Abuse: To curb illicit traffic and abuse of drugs.**
- **Establish Authorities: To create mechanisms for control, enforcement, and international cooperation.**

2. Definitions (Important)

- Narcotic Drug: Opium, poppy straw, coca derivatives, cannabis and their preparations.
- Psychotropic Substance: Substances listed in the Schedule of the Act having hallucinogenic, stimulant or depressant properties (e.g. LSD, MDMA, amphetamines).
- Controlled Substance: Any substance declared by the Central Government to be controlled under this Act.
- Illicit Traffic: Cultivation, production, manufacture, possession, sale, purchase, transport or warehousing of narcotic/psychotropic substances in contravention of the Act.
- Small Quantity / Commercial Quantity: As notified by the Government for deciding penalties.

3. Authorities and Officers under NDPS Act

- Central Government: Overall policy and control.
- Narcotics Commissioner: Supervises opium poppy cultivation, opium processing factories, and licensing.
- Director General of Narcotics Control Bureau (NCB): Coordinates intelligence and enforcement at national level.
- State Governments: Designate officers for enforcement of the Act.
- Customs & Central Excise Officers: Authorized to detect and seize illicit drugs at ports and borders.

4. Narcotic & Psychotropic Substances Consultative Committee

- **Constitution: Comprises experts from law, medicine, pharmacy, enforcement, and social work.**
- **Functions:**
- **Advise the Central Government on administration and implementation of the Act.**
- **Suggest measures for preventing abuse.**
- **Coordinate between various ministries and enforcement agencies.**

5. National Fund for Controlling Drug Abuse (Section 7A)

- Constitution: Established by Central Government.
- Sources: Grants, donations, sale proceeds of confiscated properties.
- Utilization:
- Combating illicit trafficking.
- Controlling abuse of narcotic drugs and psychotropic substances.
- Educating public and rehabilitating addicts.

6. Prohibition, Control and Regulation

- **Absolute Prohibition:** No person shall cultivate, produce, manufacture, possess, sell, purchase, transport, store or consume narcotic drugs and psychotropic substances except as provided under the Act.
- **Medical and Scientific Use:** Allowed under license/authorization.
- **Central Government Powers:** To regulate cultivation, production, manufacture, sale, and consumption.
- **State Government Powers:** To regulate manufacture, possession, transport, inter-state movement within the State.

7. Opium Poppy Cultivation and Production of Poppy Straw

- **Licensed Cultivation: Only under license granted by the Central Government.**
- **Supervision: Narcotics Commissioner monitors area, yield, and storage.**
- **Poppy Straw: Stems and capsules (except seeds) of poppy after harvesting; production and processing regulated.**
- **Illegal Cultivation: Punishable with imprisonment and confiscation of crop.**

8. Manufacture, Sale and Export of Opium

- **Government Monopoly: The Central Government manages opium factories and export.**
- **Manufacture of Medicinal Opium/Derivatives: Only in government factories or under license.**
- **Export/Import: Subject to permits and international treaty obligations.**
- **Record Keeping: All transactions recorded and inspected.**

Registration of Pharmacists

1. Registered Pharmacist (Definition)

- A person whose name is entered in the State register where he resides or carries on the profession/business of pharmacy.

2. First Register

- Prepared by a Registration Tribunal appointed by State Government.
- Includes names of qualified persons (degree/diploma or ≥5 years' compounding/dispensing experience).
- Published officially; appeals within 60 days allowed.
- After constitution of State Council, register transferred to its custody.

3. Qualifications for Entry

- Degree/diploma in pharmacy/pharmaceutical chemistry or chemist & druggist diploma.
- ≥5 years' experience in compounding/dispensing under a medical practitioner.
- Passed an examination recognized by State Government for compounders/dispensers.

4. Subsequent Register

- **Maintained after Education Regulations take effect.**

Entry allowed for:

- **Those meeting prescribed qualifications or at least matriculate.**
- **Registered pharmacists from another State.**
- **Persons with recognized foreign qualifications.**

5. Special Provisions (1959 Amendment)

- Registration allowed for displaced persons, migrants, long-term compounders/dispensers (≥5 years), and pharmacists shifting between States due to reorganization.
- Citizens of India abroad practicing pharmacy may also be registered.

6. Scrutiny of Applications

- Applications with fee → Registrar verifies qualifications.
- If rejected → appeal to State Council within 3 months.
- Registrar issues certificate once name entered in register.

7. Renewal of Registration

- Annual renewal fee due before 1st April (retention after 31st December each year).
- Non-payment → removal; restoration possible on payment + conditions.
- Additional qualifications entered on payment of fee.

8. Removal of Names from Register

- By Executive Committee for error, misrepresentation, conviction, or infamous conduct.
- Employer's offences can also affect pharmacist's registration.
- Removal can be permanent or for a fixed period; must be confirmed by State Council.
- Appeal to State Government within 30 days.

9. Restoration of Names

- State Council may restore name on payment of prescribed fee.
- If appeal rejected by State Government, restoration only after confirmation.

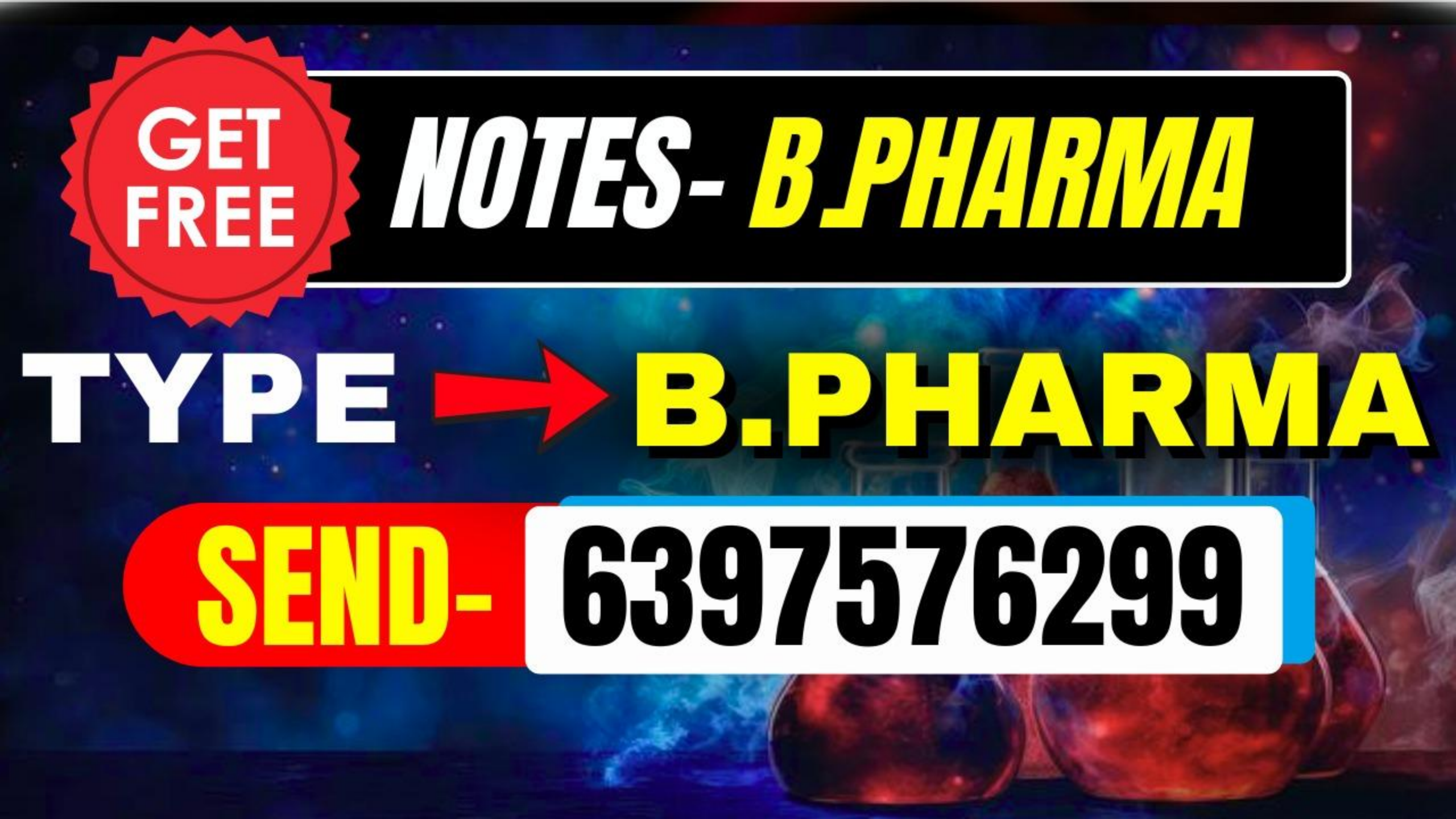
10. Duplicate Certificate

- Issued by Registrar if original certificate lost/destroyed on payment of fee.

9. Offences and Penalties

Offence	Punishment / Penalty
Possession of Small Quantity	Rigorous imprisonment up to 1 year or fine or both
Quantity More than Small but Less than Commercial	Rigorous imprisonment up to 10 years and fine up to ₹1 lakh
Commercial Quantity	Rigorous imprisonment 10–20 years and fine up to ₹2 lakh (can be increased)

Repeat Offenders	Higher punishment; in grave cases death penalty under Section 31A
Financing Illicit Traffic	Imprisonment up to 10–20 years
Forfeiture of Property	Property derived from or used in illicit traffic liable to seizure/confiscation
Bail Provisions	Stringent – Courts require reasonable grounds to believe accused not guilty before granting bail (Section 37)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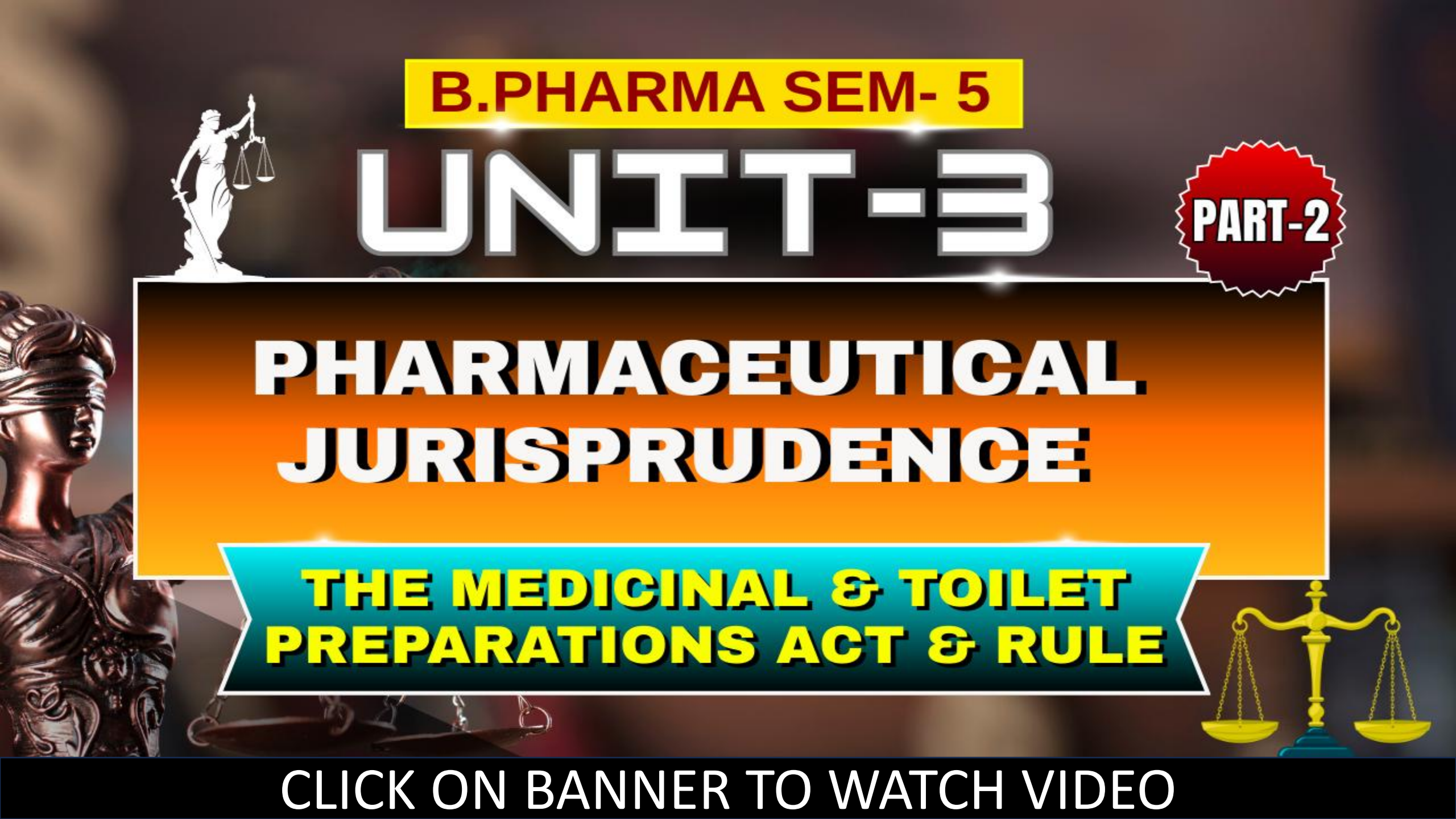
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B.PHARM SEMESTER – 5

JURISPRUDENCE

UNIT V

1. Impose **uniform excise duty** on medicinal and toilet preparations containing alcohol or narcotics.
2. Bring **central control** over manufacture instead of separate state controls.
3. **Prevent smuggling** and duty evasion through standardized rules.
4. **Streamline manufacture, storage, and transport** procedures.
5. Ensure **legitimate use** of alcohol/narcotics and prevent misuse.
6. Provide **licensing and regulation** framework for manufacturers.
7. Generate **uniform revenue** for the central government.
8. **Replace multiple state** laws with a single uniform legislation.

Definitions

- **Alcohol –** Ethyl alcohol (C_2H_5OH) of any strength and purity.
- **Dutiable Goods –** Medicinal and toilet preparations listed in the Schedule and subject to excise duty.
- **Excise Officer –** Any officer of the State Excise Department or a person empowered under this Act.
- **Manufacture –** Any process incidental or ancillary to completing dutiable goods.

- **Medicinal Preparation –** All drugs or remedies for human/animal use, for treatment, prevention, or mitigation of disease.
- **Narcotic Drug/Narcotic –** Coca leaf, coca derivative, opium, Indian hemp, or any other declared dependence-causing substance.
- **Toilet Preparation –** Any product used for cleansing, perfuming, beautifying, or altering appearance of the human body (skin, hair, teeth).
- **Absolute Alcohol –** Dehydrated alcohol meeting British Pharmacopoeia specifications.

- **Bonded Manufactory –** Licensed premises to make/store duty-unpaid medicinal or toilet preparations with alcohol/narcotics.
- **Non-Bonded Manufactory –** Licensed premises to make/store duty-paid medicinal or toilet preparations with alcohol/narcotics.
- **Denatured Alcohol/Spirit –** Alcohol rendered unfit for human use by adding approved substances.
- **Finished Store –** Area for storing completed preparations inside a manufactory.

- **Laboratory –** Area inside a manufactory where actual production of dutiable goods occurs.
- **Rectified Spirit –** Un-denatured alcohol ≥50° over proof (includes absolute alcohol).
- **Restricted Preparation –** Medicinal or toilet preparation declared restricted due to potential misuse.
- **Unrestricted Preparation –** Preparations not declared restricted by the government.
- **Spirit Store –** Area inside a manufactory where duty-free rectified spirit or narcotics are kept.

LICENSING

- No one can manufacture or use any duty-payable goods, preparations, narcotics, or drugs without a valid license.
- Licenses are issued by the Licensing Authority under the Drugs & Cosmetics Act/Rules or the Excise Commissioner (for bonded manufactories).
- Separate licenses are required if more than one type of business is carried out.
- Application for license or renewal must be submitted at least 6 months before the proposed start date.

Information Required in Application

1. **Name & Address of Applicant –** with manufacturing site details, partners, and directors.
2. **Capital –** Amount of capital proposed to be invested.
3. **Staff –** Appoint technical staff and ensure Excise staff facilities.
4. **Equipment Details –** List of plant, apparatus, vats, stills, and capacity of alcohol/opium to be used.
5. **Site & Building Plans –** Include elevations and layout for factory and quarters.

6. **Security Deposit –** Cash or Government Promissory Notes as security for due performance.
7. **License Requirement –** No one can produce or manufacture duty-payable goods, alcoholic preparations, narcotics, or drugs without a valid license under the Drugs & Cosmetics Act/Rules or Excise Commissioner.
8. **Separate Licenses –** Needed for each type of business or location. Apply at least 6 months before starting production.

The details of license fee are as follows:

Purpose of License	Under Bond (₹)	Outside Bond (₹)
1. Allopathic medicinal & toilet preparations containing alcohol		
(i) ≤125 L.P. litres/year	10	–
(ii) >125 L.P. litres <500 L.P. litres/year	25	–
(iii) ≥500 L.P. litres/year	200	200
(iv) <4000 L.P. litres/year	100	–
(v) >4000 L.P. litres/year	200	–

2. Non-alcoholic medicinal & toilet preparations (opium, Indian hemp, other narcotics)	**10**	**10**
3. Homeopathic preparations containing alcohol		
(i) ≤125 L.P. litres/year	10	–
(ii) >125 L.P. litres <500 L.P. litres/year	25	–
(iii) <4000 L.P. litres/year	100	25
(iv) ≥4000 L.P. litres/year	200	25

4. Medicinal preparations in Ayurvedic, Unani, or other indigenous systems using alcohol/distillation	25	25
5. Bonded warehouses	25	nil

Authority Enquiries Before Granting License:

1. Qualifications/experience of technical personnel.
2. Equipment of bonded/non-bonded laboratory.
3. Financial soundness of applicant.
4. Suitability of premises for manufacturing unit.

License Rules:

- License cannot be sold or transferred.
- Must be displayed conspicuously at licensed premises.
- If a licensee sells or transfers the business, the new person must obtain a fresh license.
- Partnership changes must be informed and fresh license obtained if required.

Renewal & Continuity:

- License must be renewed within prescribed time; application at least 15 days before expiry.
- License remains valid only if fees are paid and no breach occurs.
- License can be suspended/cancelled for breach of terms or conviction under Section 161 IPC or NDPS Act

Inspections & Record Keeping:

- Licensed premises can be visited by licensing officers/inspectors.
- Stock and accounts must be maintained and produced for inspection.
- Quarterly returns of sales/manufacture and duty payable must be submitted.
- A yearly fee is charged to cover establishment costs.
- Records of manufactured goods, stocks, and duty to be preserved for 1 year after verification.

MANUFACTURE

Supply of Rectified Spirit:

- For medicinal and toilet preparations, rectified spirit can be obtained from a distillery or spirit warehouse within or outside the State.
- Duty on loss of rectified spirit in transit may be waived fully/partly if loss is bona fide and not due to negligence or connivance (needs Excise Commissioner's approval).
- Concession not applicable to non-bonded manufactories without prior State Government sanction.

Mode of Manufacture:

- Manufacturing allowed both in bond (no duty paid) and outside bond (duty paid).
- In bond – alcohol without duty but under excise supervision.
- Outside bond – only alcohol on which duty has been paid can be used.

A. Manufacture in Bond

- Rectified spirit without duty can be issued only if the manufacturer enters a bond with security for duty payment and rule compliance.
- Only one entrance to the bonded manufactory and one door to each compartment; doors secured with excise ticket locks in the officer’s absence.

Bonded Laboratory Provisions:

1. **Spirit Store:** Must have a plain spirit store (unless attached to a distillery/warehouse).
2. **Manufacturing Rooms:** Large room for medicinal preparations and separate area for toilet preparations.
3. **Storage Rooms:** Separate rooms for finished medicinal and toilet preparations.
4. **Officer Accommodation:** Provide furnished space for the officer-in-charge.

5. **Security Bars:** Windows fitted with iron rods (≥3/4" thick, ≤4" apart) and strong wire netting/expanded metal.
6. **Room Identification:** Name and serial number painted clearly outside each room.
7. **Drainage & Utilities:** Sink pipes must discharge into general drainage; gas/electricity supply must be lockable at day's end.
8. **Fixtures & Storage:** Any permanent change needs prior approval; storage vessels must have excise locks, serial numbers, capacity markings, and depth tables

Manufacture Outside the Bond

- Manufacture and sale must be between sunrise and sunset on days/hours fixed by the Excise Commissioner.
- Non-bonded manufactory must have a Spirit Store, Laboratory, Finished Store — each with one door and one entrance.
- Windows and other provisions same as bonded manufactory.
- Spirit Store and Finished Store should be separate for rectified spirit bought at different rates.

- Alterations in plant/building need prior sanction of the Excise Commissioner.
- State Government may relax rules for small manufacturers (≤100 gallons/year) or for those making preparations only for dispensing to their patients.

Storage & Supply of Rectified Spirit

- Permanent vessels/receptacles with proper labels must be provided for alcohol and narcotic preparations.
- Rectified spirit obtained from distillery/warehouse via indent in triplicate; duty paid to Treasury.
- Spirit transported under excise supervision; entries and registers must be maintained.

Manufacturing, Storage & Sale

- Manufacture and storage allowed only in licensed premises.
- Each preparation registered and given a batch number.
- Finished goods moved from laboratory to finished store after checking and recording.
- Quantity of rectified spirit used must not exceed licensed limit.
- Excise officer may take samples without notice; samples sealed, labelled, and sent for chemical testing.
- Manufacturer liable to penalty (10× duty shortfall) if alcohol content below declared proof strength.

Employees Manufacturer must inform the Excise Commissioner of all employees needing access to non-bonded premises.

- Changes in employee details to be reported promptly.
- No one else may enter without special permission of the proper officer.

Inspection

- Excise Commissioner, proper officer, and authorised state officers can inspect non-bonded premises at reasonable times.
- Proper officer must inspect at least once every month.

Ayurvedic Preparations

- 'Asavas' and 'Aristas' contain self-generated alcohol.
- Preparations with ≤2% proof spirit = non-alcoholic and exempt from excise duty.
- Preparations >2% alcohol but not consumable as ordinary beverage also exempt from duty.
- Consumable as alcoholic beverage = duty Re 1 per L.P. litre.

- Registered Ayurvedic practitioners may manufacture and dispense such preparations free of duty to their patients with license.
- Ayurvedic preparations by distillation or added alcohol at any stage treated as alcoholic preparations = duty Rs 30 per L.P. litre.

Homeopathic Preparations

American/British homeopathic pharmacopeias recognized. All alcoholic homeopathic preparations attract prescribed duties as restricted preparations.

Patent and Proprietary Preparations

Allopathic medicinal preparations classified as:

1. Official preparations — made strictly to pharmacopoeial formulas (B.P., B.P.C., I.P., U.S.P., N.F., etc.).
2. Non-official proprietary preparations — conforming to allopathic system.

- Medicinal/toilet preparations capable of being consumed as ordinary alcoholic beverages = restricted preparations.
- Those not capable = unrestricted preparations.
- Aqua Anisi under non-pharmacopoeial preparations (treated as ordinary beverage).
- If misuse occurs, restricted status may be imposed by Central/State Government or Standing Committee.

Warehousing of Alcoholic Preparations

- Manufacturers/dealers may establish bonded warehouses for dutiable goods.
- A private warehouse license from the Excise Commissioner may be required with a bond and security.
- Warehouses must meet Act/Rules requirements and be secured by locks/fastenings.

Receipt and Dealing with Warehoused Goods

- All goods brought must be produced to the officer-in-charge, gauged, assessed, and verified. Details of goods, marks, numbers, and duty must be recorded. Goods awaiting clearance should be kept separate, and any breaking, repacking, or disposal requires officer sanction.
- No transfer to another warehouse/export without proper documents.
- If warehoused goods are lost or destroyed without unavoidable accident, the licensee is responsible for duty.

Clearance on Payment of Duty

- For removing goods on payment of duty, the licensee must apply in triplicate to the officer-in-charge at least 12 hours before removal.
- The officer assesses the duty, and on evidence of payment, the goods are allowed to be cleared.

Returns

- Within 7 days after the end of each month, the licensee must submit details of all warehouse transactions and other prescribed details to the State Government.

1. Export Under Bond

- Alcoholic preparations exported duty-free under bond directly from bonded manufacturer/warehouse.
- Goods must be packed in cases/packages, legibly marked in ink or oil colour with:
  - Progressive number commencing with 1 for each year.
  - Owner's name and special mark (if any).
  - Total quantity of dutiable goods with alcoholic content in L.P. gallons.

- After verifying particulars, the officer records on each package:
  - Name and address of consignee.
  - Description of goods.
  - Total quantity packed.
  - Alcoholic content (L.P. gallons).
  - Gross weight of the package.

2. Export by Post / Parcel

- After goods are identified for export by post/parcel, officer issues a certificate of export with sealed packages.
- Packages sent by post must be accompanied by the officer's certificate.
- Duplicate certificate retained in office; original accompanies goods.

3. Inter-State Transport of Alcoholic Goods

- Medicinal/toilet preparations containing alcohol/narcotics can only be moved inter-state after permission and under bond with security.
- Application in triplicate to Excise Commissioner/officer-in-charge before removal.
- Officer verifies goods, issues transport permit and verification certificate.
- Copy of permit sent to receiving officer of destination warehouse.

- Proof of arrival of goods must be returned to Excise Officer within 90 days of removal.
- The Excise Commissioner may permit transfer from one warehouse to another within the state subject to conditions.

4. Failure to Pay Duty

- If owner fails to pay duty demanded, goods may be detained and sold by public auction.
- Net proceeds adjusted against unpaid duty; surplus (if any) paid to owner.
- Owner may pay the duty and redeem goods within 10 days of detention to avoid auction.

5. Export of Duty Paid Goods

- A manufacturer/owner can export duty-paid goods by presenting them to the officer-in-charge for supervision and sealing.
- Packages sealed by officer with official seal and signed application.
- Officer notes alcohol content and particulars on body of package:

- Name and address of consignee.
- Description of goods.
- Total quantity packed.
- Alcoholic content (L.P. gallons).
- Gross weight.

- Export by rail/post/parcel allowed after officer's certification with certificate of export attached.

Offences and Penalties

Offence	Penalty
Non-compliance with license conditions, failure to pay duty	Imprisonment up to 6 months or fine up to ₹200 or both
Failure to supply information or supplying false info	Same as above
Committing/abetting offence	Same as above
Continuance of offence by owners	Imprisonment up to 6 months or fine up to ₹500 or both
Obstructing/seizing officer	Fine up to ₹100 for every offence

Refusal to produce license/records	**Imprisonment up to 3 months or fine up to ₹500 or both**
Improper keeping of stocks/accounts	Fine up to ₹100
Making false entries	Fine up to ₹2000 and goods liable to confiscation
Prescribed containers not bearing label	Fine up to ₹1000 and goods liable to confiscation
Removing goods without payment of duty	Fine up to ₹2000 and goods liable to confiscation

Private removal/concealment before duty paid	**Same as above**
Wilfully misrepresenting/false statement to officers	Imprisonment up to 2 years or fine up to ₹2000 or both
Breach of any rule without specific penalty	Fine up to ₹1000 and goods liable to confiscation

Prosecutions

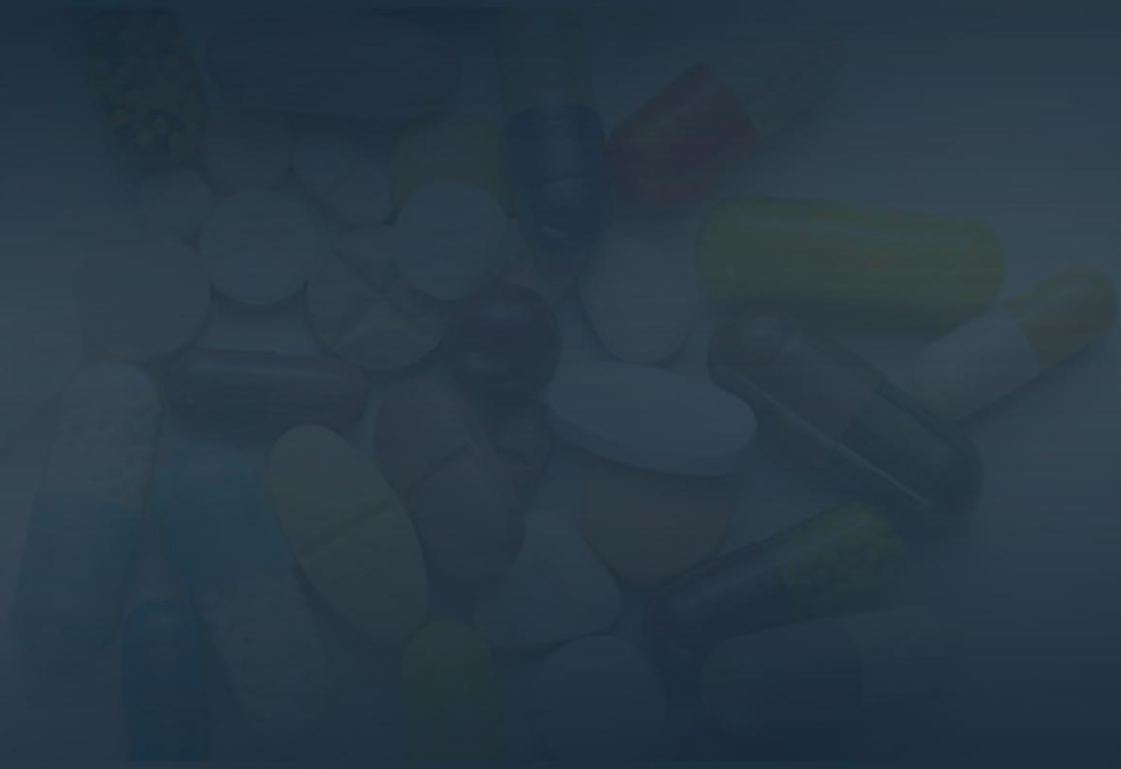
- No prosecution under the Act without authorization of an Excise Officer not below the rank of Sub-Inspector.

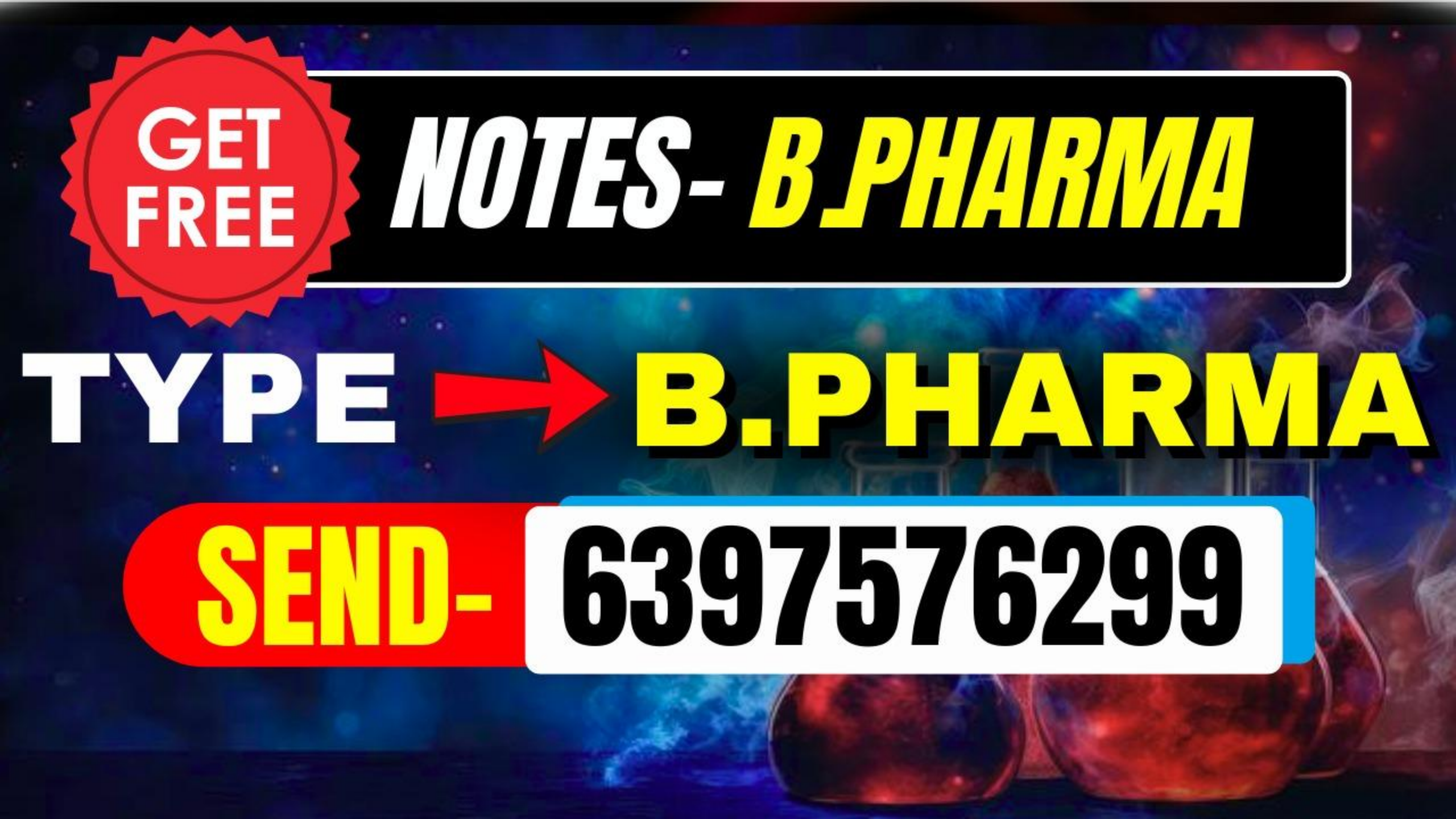
Appeals & Revision

- Appeal against Excise Officer's order → Excise Commissioner of the State.
- Appeal against Excise Commissioner's order → State Government.
- File appeal within 3 months of decision.
- Central Government may modify any order/decree on application.

Confiscations

- Any goods, articles, alcohol, drugs, receptacles, packages, coverings, animals, vehicles, or vessels confiscated under the Act/Rules are disposed of as per Government directions.
- Court may order forfeiture of goods connected with the offence.

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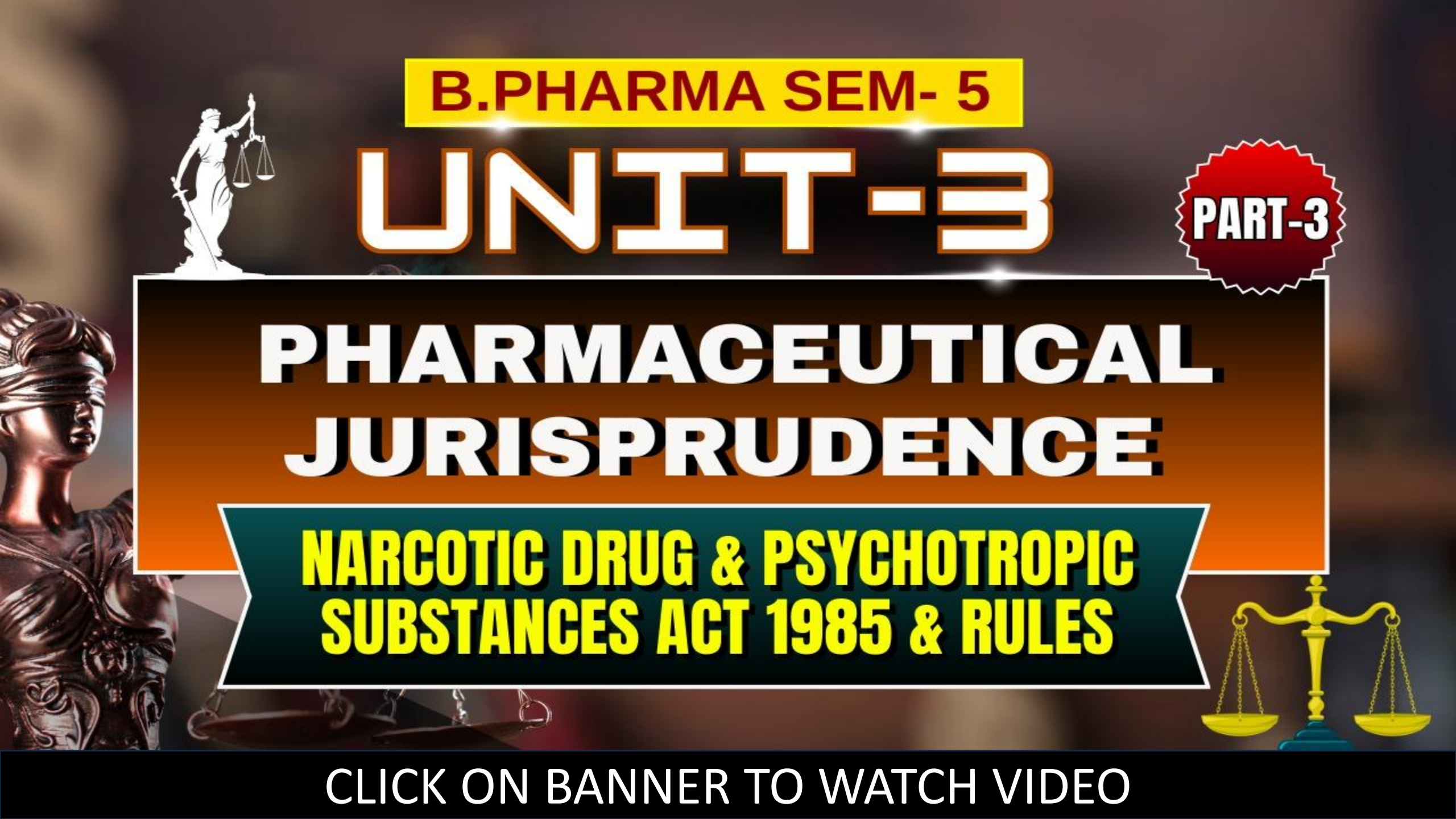
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TABLE OF CONTENT

Narcotic Drugs and Psychotropic substances Act-1985 and Rules

Narcotic Drugs and Psychotropic substances Act-1985 and Rules

The NDPS Act, 1985 prohibits production, manufacture, possession, sale, purchase, transport, use, and consumption of narcotic drugs and psychotropic substances except for medical/scientific purposes.

Objectives:

- Consolidate and amend laws related to narcotic drugs and psychotropic substances.
- Provide strict provisions for control, regulation, and licensing (Central & State governments).
- Regulate manufacture, distribution, import, export, sale, and transport.

Definitions:

- **Addict:** A person dependent on narcotic drugs or psychotropic substances.
- **Cannabis:** Includes charas (resin), ganja (flowering/fruiting tops), and cannabis mixtures but excludes seeds and leaves when not accompanied by tops.
- **Coca Plant:** Plant of the genus *Erythroxylon*.
- **Coca Derivatives:** Includes crude cocaine and any extract/refined preparation.
- **Coca Leaf:**

  (a) The leaf of the coca plant except a leaf from which all ecgonine, cocaine, and derivatives have been removed.
  (b) Any mixture with or without neutral material, but not containing more than 0.1% cocaine.
  (c) Includes all species of the genus *Erythroxylon*.

Manufacture (in relation to narcotic drugs or psychotropic substances):

(a) All processes other than production by which drugs or substances may be obtained.

(b) Refining of drugs or substances.

(c) Transformation of one drug or substance into another.

(d) Making of preparations (other than in a pharmacy on prescription).

Medicinal Cannabis (hemp):

Medicinal cannabis or hemp is any extract/tincture of cannabis which the Central Government may allow by official gazette notification for medical/scientific purposes.

Opium:

(a) Coagulated juice of the opium poppy.

(b) Mixtures with or without neutral material of opium poppy juice, but not including any preparation with more than 0.2% morphine content.

Preparations:

(a) Prepared opium: product obtained by dry series of operations designed to transform opium into extract.

(b) Medicinal opium.

(c) Morphine, codeine, thebaine, and their salts.

(d) All preparations containing not more than 0.2% morphine or cocaine.

Opium Poppy: *Papaver somniferum* or other notified *Papaver* species from which opium/alkaloids can be extracted.

Poppy Straw: All parts (except seeds) of opium poppy after harvesting (original, cut, crushed, or powdered; juice not extracted).

Poppy Straw Concentrate: Material from poppy straw after processing to concentrate alkaloids.

Preparation: Any narcotic drug/psychotropic substance mixed, processed, or in solution containing one or more such drugs.

Prescribed: As specified under rules of the Act.

Production: Separation of opium, poppy straw, coca leaves, or cannabis from plants.
Psychotropic Substance: Any natural/synthetic substance or preparation listed in the Schedule.

Small Quantity: Quantity less than the limit notified by the Central Government.
Import Inter-State: Bringing narcotic drugs/psychotropic substances into one State/UT from another.

- **To Import into India:** Bringing narcotic drugs/psychotropic substances into India (including transit at port/airport) without removal from the vessel/aircraft.
- **To Export from India:** Taking narcotic drugs/psychotropic substances out of India.

- **To Export Inter-State:** Taking narcotic drugs/psychotropic substances from one State/UT to another.

- **To Transport:** Taking narcotic drugs/psychotropic substances from one place to another within the same State/UT.

- **Illicit Traffic:**
  - Cultivation of coca/opium poppy/cannabis.
  - Production, manufacture, possession, sale, purchase, transport, warehousing, or use.
  - Import/export inter-State or from/to India.
  - Dealing in activities related to narcotic drugs/psychotropic substances illegally.
  - Allowing premises or handling for any such illegal activities.
  - **Essential Narcotic Drug:** Narcotic drug notified by Central Government for medical/scientific use.

Central Government Factories: Factories owned by Central Government or companies with ≥51% government shareholding producing narcotic drugs.

Authorities and Officers

Measures for Preventing and Combating Abuse of Narcotic Drugs and Illicit Traffic (NDPS Act)

Central Government under the NDPS Act may take measures related to:

1. **Coordination of Actions:** Coordinate activities of State Governments, authorities, and other agencies for enforcing the provisions of the Act.
2. **International Obligations:** Fulfill obligations under international conventions.
3. **Assistance to Foreign Bodies:** Support foreign governments and international organizations in preventing and suppressing illicit traffic in narcotic drugs and psychotropic substances.

3. **Identification and Rehabilitation:** Include training, education, aftercare, rehabilitation, and social reintegration of addicts.
4. **Other Measures:** Any other steps necessary for effective implementation of the Act and combating the abuse and illicit traffic of narcotic drugs and psychotropic substances.

Officers of Central Government – NDPS Act

Appointment:

- Central Government may appoint a **Narcotic Commissioner** and other officers.
- The Narcotic Commissioner supervises cultivation of opium poppy, production of opium, and other functions as directed by the Central Government.
- State Government may appoint officers as deemed fit for the Act.

The Narcotic Drugs and Psychotropic Substances Consultative Committee

- **Purpose:** Assists Central Government in effective administration of the Act.
- **Composition:** Chairman + up to 20 members appointed by the Central Government.
- **Role:** May form sub-committees for efficient discharge of functions.
- **Function:** Advises Central Government on matters related to the administration of the Act.

Prohibition, Control & Regulation

Section 8:

- Prohibits cultivation of coca plant, opium poppy, and cannabis plant.
- Prohibits manufacture, possession, sale, purchase, transport, import, and export of narcotic drugs and psychotropic substances.
- Only allowed for **medical and scientific purposes** under authorization.

Section 9:

- Empowers the **Central Government** to **permit, control, and regulate** certain operations related to narcotic drugs and psychotropic substances through rules.

(a) Prohibition of Certain Operation

1. Cultivate any coca plant or gather any portion of coca plant.
2. Cultivate the opium poppy or any cannabis plant.
3. Produce, manufacture, possess, sell, purchase, transport, warehouse, use, consume, import inter-State, export inter-State, import into India, export from India, or transship any narcotic drug or psychotropic substance except for medical and scientific purposes and as per rules/orders.

(b) Power of Central Government to Permit, Control & Regulate:

1. Permission & Regulation of Certain Operations by Central Government:

(i) Cultivation or gathering of any portion of coca plant (only on account of Central Government); production, sale, purchase, transport, import inter-State, export inter-State, use or consumption of coca leaves.

(ii) Cultivation of opium poppy (only on account of Central Government).

(iii) Production and manufacture of opium and production of poppy straw.

(iv) Sale of opium and opium derivatives from Central Government factories to State Government or manufacturing chemists.

(vi) Manufacture, possession, transport, import inter-State, export inter-State, sale, purchase, consumption or use of psychotropic substances.

(vii) Import into India, export from India, and trans-shipment of narcotic drugs and psychotropic substances.

Central Government Control on Operations

Licensing: Govt. fixes time limits for opium poppy cultivation and grants licenses.
Delivery: Licensed cultivators must deliver opium to Govt. officers.

Pricing: Central Govt. fixes the price to be paid to cultivators.

- **Licenses/Permits:** Rules prescribe forms, conditions, and fees for manufacture, possession, transport, import/export, sale, purchase, consumption, or use of narcotic drugs/psychotropic substances.
- **Cultivation & Manufacture:** Rules set conditions for cultivation and production of opium; authorities can grant, withhold, suspend, or cancel licenses.
- **Weighment & Classification:** Rules define weighing, examination, classification, and allowable deductions for opium at delivery.
- **Manufactured Drugs:** Rules prescribe licensing and fees for manufacture of manufactured drugs.
- **Adulterated Opium:** Any adulterated or contaminated opium delivered may be confiscated by Govt. officers.

Other Manufactured Drugs: Permit possession, transport, sale, inter-State import/export, use or consumption of manufactured drugs other than prepared opium, coca leaf, or any preparation containing a manufactured drug.

Prepared Opium: Allow manufacture/possession by registered addicts on medical advice for personal use.

State Government Control

Licensing: State Govt. fixes time limits for cannabis cultivation licenses.
Authorized Cultivators: Only licensed cultivators can grow cannabis.
Delivery: All cannabis produced must be delivered to State Govt. officers.

Delivery: All cannabis produced must be delivered to State Govt. officers.

Pricing: State Govt. fixes price for cannabis delivered.

Licenses/Permits: State Govt. prescribes forms and conditions for possession, transport, inter-State import/export, warehousing, sale, purchase, consumption, and use of poppy straw, opium, and cannabis (excluding charas).

National Fund for Control of Drug Abuse Creation:

Central Govt. sets up the Fund; money comes from Parliament allocation, sale of forfeited property, grants, and investment income.

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Governing Body: Chairman (≥Additional Secretary rank) + up to 6 members; regulates its own procedure.

Annual Report: Central Govt. publishes yearly report with activities and accounts in the Official Gazette.

Use of Fund: For combating illicit drug trafficking, controlling drug abuse, identifying/treating/rehabilitating addicts, and preventing drug abuse

Offences & Penalties Table

S. No.	Offence / Contravention	Punishment
1	Poppy Straw	Contravention punishable
2	Coca Plant/Leaves	Contravention punishable
3	Prepared Opium	Contravention punishable
4	Opium Poppy & Opium	Contravention punishable
5	Embezzlement of Opium by Cultivator	Punishable
6	Cannabis (Cultivation)	Rigorous imprisonment up to 10 years + fine
6 (b)	Cannabis (Other Contraventions)	Rigorous imprisonment 10–20 years + fine
7	Manufactured Drugs & Preparations	Contravention punishable

8	Psychotropic Substances	Contravention punishable
9	Illegal Import/Export/Transshipment	Punishable
10	External Dealings (in Contravention)	Rigorous imprisonment 10–20 years + fine ₹1–2 lakh
11	Allowing Premises for Offence	Rigorous imprisonment 10–20 years + fine ₹1–2 lakh
12	Contravention by Licensee/Servants	Punishable
13	Not Maintaining Accounts	Punishable
14	Failure to Produce License/Permit on Demand	Punishable

15	Illegal Possession (Small Quantity – Cocaine, Morphine, Diacetyl-Morphine, etc.)	Imprisonment up to 2 years or fine or both
15 (b)	Illegal Possession (Small Quantity – Other Substances)	Imprisonment up to 6 months or fine or both
16	Abetment and Criminal Conspiracy	Same punishment as main offence
17	Enhanced Punishment for Repeat Offences	On second and every subsequent conviction
18	Offence with No Specific Punishment Provided	Imprisonment up to 6 months or fine or both

Opium Poppy Cultivation and Production of Poppy Straw

- NDPS Act empowers Central Government to permit and regulate cultivation of opium poppy for medical/scientific purposes.
- Government of India notifies tracts where opium can be legally cultivated as per General Conditions for License.
- Opium and poppy straw are raw materials derived from *Papaver somniferum* (opium poppy plant).
- Concentrated poppy straw is obtained from extracting alkaloids from poppy straw.

Production and Supply of Opium

- Opium ("latex") is obtained by making incisions on green capsules of the opium poppy plant.
- Cultivation only in notified areas.
- Licenses granted to eligible cultivators for a fixed area.
- Cultivation supervised by government officials; records maintained and verified.
- Whole opium collected by district officers and delivered to opium factories.

Opium Cultivation & Manufacture

- **Cultivators:** Paid by govt., cannot dispose or adulterate produce; must cultivate full allotted area; cultivation restricted to UP & MP (as per 1934 rules).

- **Poppy Straw Concentrate (PSC):** Made by pulverizing and washing poppy straw in acidified water to increase solubility; contains 10–30× morphine concentration compared to poppy straw.

Manufacture & Sale of Opium

Delivery of Opium: All opium produced must be delivered to District Opium Officer or authorized officer as specified by Narcotics Commissioner.
Manufacture of Opium: Only by Central Govt. Opium Factories at Ghazipur & Neemuch; opium from lawful sources may be processed under authorised rules.
Export of Opium: Prohibited except when done on behalf of Central Government.

Sale to State Govts./Manufacturing Chemists:

- Opium sold only to State Govts. or licensed manufacturing chemists from Government Opium Factories.
- Sale allowed under permit/authorization granted by State Govt. within whose jurisdiction the chemist/manufacturer operates.

Manufacture of Manufactured Drugs

Drugs Included: Morphine, thebaine, dihydro-morphine, codeine, diacetylmorphine and salts.

Manufacture Restricted: Cocaine and derivatives manufacturing prohibited except under license; medicinal hemp manufacturing allowed under State/Chief Excise Authority license.

Synthetic Drugs: Manufacture prohibited except under authorization of Narcotics Commissioner.

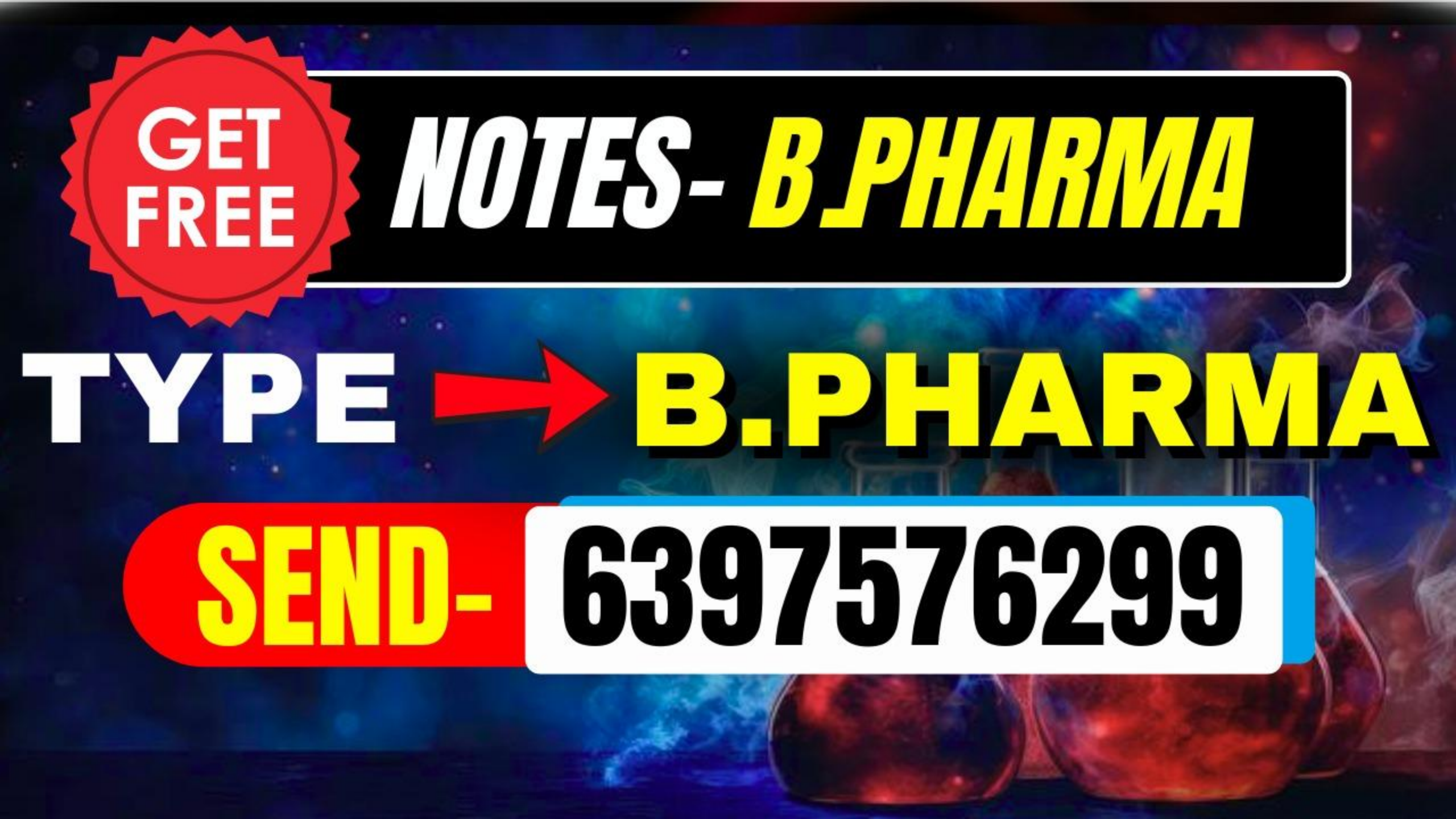
License Requirement: All manufacturing requires license issued by competent authority.

Manufacturing Requirements:

- Must hold a drug manufacturing license under Drugs & Cosmetics Act, 1940.
- Deposit ₹5000 as security; production must meet international narcotics standards.
- Give 15 days' prior notice before starting manufacture.
- Maintain security arrangements and obtain manufacturing permit.

Offences & Penalties:

- ✓ **Violation of Act/Rules:** Imprisonment 10–20 years + fine ₹1–2 lakh; in certain cases 15–30 years + fine ₹1.5–3 lakh.
- ✓ **Illegal Possession of Opium:** Imprisonment up to 10 years + fine.
- ✓ **Failure to Keep Accounts/Submit Returns:** Punishable under law.
- ✓ **Failure to Produce Records/License/Permit/Authorization on Demand:** Imprisonment up to 5 years or fine or both.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