

# Unit-3

## Pharmaceutical Jurisprudence

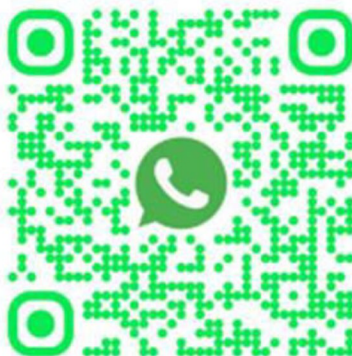
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### B.Pharma 5<sup>th</sup> Sem Notes

#### Unit: 3

- **Pharmacy Act -1948:** Objectives, Definitions, Pharmacy Council of India; its constitution and functions, Education Regulations, State and Joint state pharmacy councils; constitution and functions, Registration of Pharmacists, Offences and Penalties
- **Medicinal and Toilet Preparation Act -1955:** Objectives, Definitions, Licensing, Manufacture In bond and Outside bond, Export of alcoholic preparations, Manufacture of Ayurvedic, Homeopathic, Patent & Proprietary Preparations. Offences and Penalties.
- **Narcotic Drugs and Psychotropic substances Act-1985 and Rules:** Objectives, Definitions, Authorities and Officers, Constitution and Functions of narcotic & Psychotropic Consultative Committee, National Fund for Controlling the Drug Abuse, Prohibition, Control and Regulation, opium poppy cultivation and production of poppy straw, manufacture, sale and export of opium, Offences and Penalties

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## SECTION A: THE PHARMACY ACT – 1948

### PHARMACY ACT – 1948

#### Introduction & Background

The Pharmacy Act, 1948 was enacted by the Indian Parliament to regulate the profession of pharmacy in India. It came into force on 15th March, 1948. Before this Act, there was no uniform law governing pharmacy practice in India, and the profession was largely unregulated. The Act creates a statutory framework for pharmacy education, registration of pharmacists, and professional standards.

#### Objectives of Pharmacy Act – 1948

##### KEY OBJECTIVES

- To regulate the profession and practice of pharmacy in India
- To prescribe minimum standards of education required for pharmacists
- To establish the Pharmacy Council of India (PCI) at the central level
- To establish State Pharmacy Councils at the state level
- To maintain a central and state register of pharmacists
- To ensure that only qualified persons practice as pharmacists
- To prescribe duties and code of conduct for registered pharmacists
- To protect the public from unqualified practitioners of pharmacy
- To promote and develop pharmacy education in India

#### Important Definitions

Term	Definition
Pharmacist	A person who is registered under the provisions of this Act to practice pharmacy
Pharmacy	Any premises where pharmacy is practiced, including hospitals, nursing homes, dispensaries
Approved Institution	An institution that has been approved by the Pharmacy Council of India for pharmacy education
Register	The Register of Pharmacists maintained under this Act
Registered Pharmacist	A pharmacist whose name appears in the register maintained under this Act
Prescribed	Prescribed by rules made under this Act

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State Council	State Pharmacy Council constituted under Section 19 of this Act
Central Council	The Pharmacy Council of India constituted under Section 3 of this Act
Diploma / Degree in Pharmacy	Qualification awarded by a recognized institution after prescribed course
Approved Examination	Examination held by a recognized body approved by PCI for pharmacy qualification

## Pharmacy Council of India (PCI)

### ◆ A. Constitution of PCI

The Pharmacy Council of India (PCI) is a statutory body constituted under Section 3 of the Pharmacy Act, 1948. It is the apex body regulating pharmacy education and profession in India.

Membership Category	Details
Elected Members	6 members – elected by registered pharmacists from each zone (North, South, East, West, Central, North-East)
Ex-officio Members	DGHS (Director General of Health Services) – Ex-officio President; DCGI – Ex-officio member
Nominated by Central Govt.	3 members to represent Central Government interests
Nominated by State Councils	1 representative from each State Pharmacy Council
University Representatives	Members representing universities teaching pharmacy in India
Total Strength	Approximately 52 members (as per amendments)
Presiding Officer	President (ex-officio) – DGHS; Vice President – elected by members
Term of Office	5 years for elected/nominated members

### ◆ B. Functions of PCI

#### **FUNCTIONS OF PHARMACY COUNCIL OF INDIA**

- Prescribe standards for courses, examinations and other requirements for getting a pharmacy qualification
- Prescribe conditions to be satisfied by institutions for approval as approved institutions
- Inspect institutions applying for approval for pharmacy courses
- Approve examinations and training requirements for registration as pharmacist

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- Withdraw approval from an institution if it fails to maintain standards
- Maintain a Central Register of Pharmacists
- Recognize foreign pharmacy qualifications for reciprocal registration purposes
- Advise the Central and State Governments on matters relating to pharmacy education
- Prescribe standards for pharmacy practice and code of professional ethics
- Review and update pharmacy curriculum as per changing healthcare needs
- Coordinate with state councils on implementation of the Act

## Education Regulations

The Pharmacy Council of India has the authority to prescribe minimum standards of education for pharmacists. The key Education Regulations are:

Aspect	Regulation Details
D.Pharm Course	2-year diploma course; minimum eligibility – 10+2 with Physics, Chemistry, Biology/Mathematics
B.Pharm Course	4-year degree course; minimum eligibility – 10+2 with PCM/PCB (50% marks)
M.Pharm Course	2-year postgraduate degree; minimum – B.Pharm degree
Pharm.D Course	6-year (or 3-year post B.Pharm) Doctor of Pharmacy program
Internship	Compulsory 500 hours of practical training (internship/apprenticeship)
Approval of Institutions	PCI inspects and approves pharmacy colleges; unapproved institutions cannot award recognized qualifications
Curriculum	PCI prescribes the minimum curriculum, syllabus, and examination pattern
Faculty Standards	Minimum qualification and experience standards prescribed for teaching staff

## State Pharmacy Councils & Joint State Pharmacy Councils

### ◆ A. State Pharmacy Council – Constitution

Each state is required to constitute a State Pharmacy Council by notification in the Official Gazette.

Composition	Details
Elected Members	Pharmacists registered in the state elect their representatives

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Ex-officio Members	State Director of Health Services; Drug Controller of the State
Nominated by State Govt.	Members representing state government interests in pharmacy
Medical Practitioners	Representation from medical profession as specified
Presiding Officer	President – elected by council members; Vice President – elected by members
Term	5 years; eligible for re-election

### ◆ B. Functions of State Pharmacy Council

#### FUNCTIONS OF STATE PHARMACY COUNCIL

- Maintain the State Register of Pharmacists (primary responsibility)
- Register qualified pharmacists who meet PCI-prescribed qualifications
- Issue registration certificates to registered pharmacists
- Renew registrations and collect prescribed fees
- Remove names from register for misconduct or disqualification
- Regulate and control pharmacy practice in the state
- Inspect pharmacy premises and establishments
- Send copies of state register to PCI for Central Register maintenance
- Inquire into charges of professional misconduct by pharmacists
- Advise state government on pharmacy-related matters

### ◆ C. Joint State Pharmacy Council

When two or more states agree, they may constitute a Joint State Pharmacy Council by an agreement. The Joint Council performs the functions of a State Pharmacy Council for all the participating states. It maintains a joint register of pharmacists for all participating states. The constitution and procedure of the Joint Council are similar to the State Pharmacy Council. Delhi, for example, functions under a Joint State Pharmacy Council arrangement.

## Registration of Pharmacists

### ◆ A. Central Register

PCI maintains the Central Register of Pharmacists containing names of all pharmacists registered with State Councils. It serves as a reference for reciprocal recognition between states.

### ◆ B. State Register

Each State Pharmacy Council maintains a State Register of Pharmacists.

Aspect	Details
Eligibility	Must possess a recognized pharmacy qualification (D.Pharm/B.Pharm) from an approved institution
Application	Apply to State Pharmacy Council in prescribed form with prescribed fee
Documents Required	Educational certificates, character certificate, training/internship completion certificate
Renewal	Registration must be renewed as per state regulations (usually annually or biennially)
Reciprocal Registration	A pharmacist registered in one state can apply for registration in another state
Foreign Qualifications	PCI may recognize foreign qualifications for registration if reciprocity exists
Provisional Registration	May be granted to students during internship/apprenticeship period

### ◆ C. Removal from Register

A pharmacist's name may be removed from the register on grounds of: (1) Professional misconduct, (2) Conviction for an offence, (3) Obtaining registration by fraud or misrepresentation, (4) Unsound mind declared by a competent court, (5) Failure to renew registration.

### Offences & Penalties

Offence	Penalty
Compounding or dispensing of drugs without being a registered pharmacist in a hospital/dispensary	Imprisonment up to 6 months, or Fine up to Rs. 1000, or Both
Practice as a pharmacist without registration (second offence)	Imprisonment up to 1 year, or enhanced fine, or Both
Obstruction of inspection by authorized officer	Fine up to Rs. 500
Obtaining registration by misrepresentation or fraud	Removal from register; prosecution for fraud

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Allowing unregistered persons to practice pharmacy under one's name	Liable for penalties as if the person were the offender
Failure to renew registration and continuing to practice	Prosecution and removal from register

### **IMPORTANT NOTE – Pharmacy Act 1948**

- Section 42: No person other than a registered pharmacist shall compound, prepare, mix or dispense any medicine in any hospital or dispensary
- Section 43: Penalties for practicing without registration
- Section 44: Penalties for obstructing inspectors
- Cognizance of offences: No court shall take cognizance of an offence unless complaint is made by or on behalf of the State Pharmacy Council

## **MEDICINAL & TOILET PREPARATIONS ACT – 1955**

### **MEDICINAL AND TOILET PREPARATION (EXCISE DUTY) ACT – 1955**

#### **Introduction & Background**

The Medicinal and Toilet Preparations (Excise Duties) Act, 1955 regulates the levy and collection of excise duties on medicinal and toilet preparations containing alcohol, narcotic drugs, or psychotropic substances. It was enacted to control the misuse of ethyl alcohol used in pharmaceutical manufacturing and to ensure that alcohol-containing preparations are used only for legitimate purposes.

#### **Objectives**

##### **OBJECTIVES**

- To levy and collect excise duties on medicinal and toilet preparations containing alcohol, narcotic or psychotropic substances
- To control and regulate the use of alcohol in the manufacture of medicinal and toilet preparations

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- To prevent misuse and diversion of industrial/potable alcohol through pharmaceutical channels
- To distinguish between preparations manufactured under bond (duty-free) and outside bond (duty-paid)
- To regulate the manufacture, export, and import of such preparations
- To facilitate the manufacture of Ayurvedic, Homeopathic, and other traditional preparations
- To prevent evasion of excise duty on alcohol-containing products

## Important Definitions

Term	Definition
Medicinal Preparation	Preparations for internal or external use containing alcohol, narcotic drugs, or psychotropic substances including patent/proprietary medicines
Toilet Preparation	A preparation intended for use in the toilet of the human body or any part thereof (e.g., perfumes, hair oils, cosmetics containing alcohol)
Alcoholic Liquor	Any liquor containing alcohol (ethyl alcohol/ethanol) above prescribed limit
Rectified Spirit	Ethyl alcohol (at least 95% v/v ethanol)
Denatured Spirit	Ethyl alcohol rendered unfit for human consumption by addition of denaturants
Bond	A warehouse licensed under the Act for duty-free storage and manufacture
Dutiable Goods	Medicinal and toilet preparations on which excise duty is leviable
Approved Institution	Institution recognized by the authority for manufacture in bond
Excise Commissioner	Officer in charge of excise administration in a state
Manufacture	Any process incidental to the making of a medicinal or toilet preparation

## Licensing

Every manufacturer of medicinal or toilet preparations containing alcohol, narcotic drugs, or psychotropic substances must obtain a license from the appropriate authority.

Type of License	Details
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License for Manufacture in Bond	Granted for manufacturing preparations duty-free; alcohol is used without paying excise duty; strict supervision by excise officers
License for Manufacture Outside Bond	Granted for manufacturing preparations after paying full excise duty on alcohol used
Conditions for License	Adequate premises, equipment, qualified staff, proper record-keeping
License Fees	Prescribed by state government under the rules
Renewal	Annual renewal of license required
Cancellation/Suspension	Can be suspended/cancelled for violation of conditions or provisions of the Act
Authority	State Excise Department / Excise Commissioner

## Manufacture In Bond vs. Outside Bond

Aspect	Manufacture IN BOND	Manufacture OUTSIDE BOND
Meaning	Manufacturing under excise supervision without payment of duty	Manufacturing after payment of duty on alcohol
Duty Payment	No duty on alcohol (duty-free)	Full excise duty paid on alcohol before use
Supervision	Continuous supervision by Excise Officer	Periodic inspection; less strict supervision
Bond Warehouse	Must operate from a licensed bond warehouse	Can operate from own licensed premises
Records	Detailed records of receipt, use, and disposal of alcohol	Records of duty-paid alcohol purchases
Suitability	Large-scale manufacturers; hospitals; exporters	Small-scale manufacturers; retail preparations
Advantage	Lower cost due to duty-free alcohol	More operational freedom; less supervision
Common For	Allopathic medicines, injections, large volume preparations	Cough syrups, tonics, ayurvedic preparations

## Export of Alcoholic Preparations

Medicinal and toilet preparations containing alcohol can be exported from India under the following provisions:

### EXPORT PROVISIONS

- Export can be made from bond (duty-free export) or from outside bond (with drawback of duty paid)
- Exporter must obtain an export license or permission from the Excise Commissioner
- Export from bond: Preparations manufactured in bond can be exported without payment of duty; alcohol is not charged
- Duty drawback: If preparations are manufactured outside bond and then exported, the manufacturer can claim a refund (drawback) of the excise duty paid
- Export documentation: Prescribed forms, invoices, and shipping bills must be maintained
- Conditions: Preparations must meet the standards of the importing country
- The Central Government has powers to regulate/prohibit export in specific circumstances

## Manufacture of Special Preparations

### ◆ A. Ayurvedic Preparations

Ayurvedic preparations (like Asavas and Arishtas) are traditionally fermented preparations containing self-generated alcohol. The Act makes special provisions for these:

### AYURVEDIC PREPARATIONS

- Asavas and Arishtas are self-generated alcoholic preparations – alcohol is produced during the fermentation process
- They do not require addition of external alcohol; hence, the duty situation is different
- They must be manufactured as per Ayurvedic texts (Shastra) and approved formulations
- License under the Drug and Cosmetics Act is also required for manufacture
- Duty may be levied on such preparations if they contain alcohol above prescribed limits
- State governments may grant exemptions from excise duty for genuine Ayurvedic preparations

### ◆ B. Homeopathic Preparations

### HOMEOPATHIC PREPARATIONS

- Homeopathic preparations use alcohol as a vehicle/menstruum (carrier for the active medicine)
- They are manufactured under special provisions of the Act
- Mother tinctures and dilutions contain significant quantities of alcohol
- Exemptions or concessions in duty may be available for recognized homeopathic preparations
- Must be manufactured as per Homeopathic Pharmacopoeia

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- Licensing is required both under this Act and the Drugs & Cosmetics Act

### ◆ C. Patent & Proprietary Preparations

Patent medicines and proprietary preparations containing alcohol are regulated under this Act. These must be manufactured with a valid license, and excise duty applies based on the alcohol content and whether manufactured in bond or outside bond.

### Offences & Penalties

Offence	Penalty
Manufacture without a valid license	Imprisonment up to 3 years AND/OR Fine up to Rs. 5000
Removing goods without payment of duty (where due)	Duty demand PLUS penalty up to 3 times the duty evaded
Violating conditions of license or bond	Cancellation/Suspension of license; Fine up to Rs. 2000
Failure to maintain proper records as required	Fine up to Rs. 1000
Obstructing an Inspector/Excise Officer in discharge of duty	Fine up to Rs. 500
Making false statements or submitting false documents	Prosecution; Fine and/or Imprisonment
Second/Subsequent offences	Enhanced penalties; possible permanent revocation of license

## NARCOTIC DRUGS & PSYCHOTROPIC SUBSTANCES ACT – 1985

# NARCOTIC DRUGS & PSYCHOTROPIC SUBSTANCES (NDPS) ACT – 1985

## Introduction:

The Narcotic Drugs and Psychotropic Substances (NDPS) Act, 1985 is a comprehensive legislation enacted by the Indian Parliament to consolidate and amend the laws relating to narcotic drugs and psychotropic substances. It came into force on 14th November, 1985, replacing the earlier Opium Act 1857, Dangerous Drugs Act 1930, and Opium Act 1878. India enacted this law in compliance with its obligations under international conventions on narcotic drugs and psychotropic substances.

## Objectives of NDPS Act – 1985

### OBJECTIVES OF NDPS ACT

- To make stringent provisions for the control of narcotic drugs and psychotropic substances
- To prohibit, except for medical and scientific purposes, the use of narcotic drugs and psychotropic substances
- To prevent drug trafficking and drug abuse in India
- To provide for forfeiture of property derived from, or used in, illicit traffic in narcotic drugs
- To implement India's international obligations under UN Conventions on narcotic drugs (1961), psychotropic substances (1971) and drug trafficking (1988)
- To provide for National Fund for Controlling Drug Abuse
- To constitute a Narcotic and Psychotropic Consultative Committee
- To lay down penalties and establish special courts for speedy trial of offences
- To facilitate scientific research and medical use of narcotic substances under strict controls

## Important Definitions

Term	Definition
Narcotic Drug	Coca leaf, cannabis (hemp), opium, poppy straw, and includes all manufactured drugs as listed in the Schedule
Psychotropic Substance	Any substance, natural or synthetic, or any natural material or any salt or preparation of such substance, listed in Schedule II of the Act

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Illicit Traffic	Cultivation, production, manufacture, possession, sale, purchase, transport, warehousing, use, export, import, or financing of any narcotic drug contrary to the provisions of the Act
Addict	A person who has dependence on any narcotic drug or psychotropic substance
Cannabis (Hemp)	Includes charas (resin), ganja (flower/fruit), and any mixture thereof; does NOT include seeds, leaves, stalk without flower/fruit
Cocaine	Any extract of coca leaf that can be used directly or indirectly for the manufacture of cocaine alkaloid
Manufactured Drug	All coca derivatives, medicinal cannabis, opium derivatives (including morphine, heroin, codeine) and other narcotics
Opium	The coagulated juice of the opium poppy ( <i>Papaver somniferum</i> ) and mixture/preparation of such coagulated juice
Poppy Straw	All parts of the opium poppy (after harvesting) except the seeds
Preparation	A mixture, solution or solid material containing a narcotic drug or psychotropic substance
Small Quantity / Commercial Quantity	As notified by the Central Government in the Official Gazette for each drug

## Authorities and Officers

Authority/Officer	Role & Powers
Central Government	Empowered to prohibit/regulate cultivation, production, manufacture, possession, sale, purchase, transport, import/export, and use of narcotic drugs
State Government	Exercise similar powers within the state; can appoint officers for enforcement
Narcotics Commissioner	Central authority for overall administration; controls cultivation of opium poppy; manages Government Opium and Alkaloid Works (GOAW) at Ghazipur and Neemuch
Central Bureau of Narcotics (CBN)	Regulates and controls legitimate cultivation, production, and manufacture of opium; acts as a nodal agency for international cooperation
Narcotics Control Bureau (NCB)	Apex body under Ministry of Home Affairs; coordinates drug law enforcement; collects and disseminates intelligence; combats drug trafficking
Officers of NCB	Empowered to arrest, investigate, seize contraband; powers similar to police officers

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State Drug Control Officers	Enforce NDPS Act at state level; coordinate with NCB
Customs Officers	Control import/export of narcotic drugs; authority to search, seize, arrest
Empowered Officers	Officers of rank of Inspector or above; revenue/customs officers – empowered to carry out searches, seizures, arrests

## Narcotic Drugs & Psychotropic Substances Consultative Committee (NCCC)

### ◆ A. Constitution of NCCC

The Central Government constitutes the Narcotic and Psychotropic Consultative Committee under Section 8A of the Act.

#### CONSTITUTION OF NCCC

- Chairman: A person of eminence in the field of public health, social welfare, or drug abuse prevention
- Members: Experts in medicine, pharmacology, law enforcement, education, social welfare, and other relevant fields
- Ex-officio Members: Senior officers from Ministry of Home Affairs, Ministry of Health, Finance, Agriculture
- Representatives from State Governments
- Total Membership: As prescribed by Central Government from time to time
- Term: 3 years; eligible for re-appointment
- Meetings: At least once in six months; Secretary provided by Central Government

### ◆ B. Functions of NCCC

#### FUNCTIONS OF NCCC

- Advise the Central Government on measures for preventing drug abuse and addiction
- Advise on the requirements of narcotic drugs and psychotropic substances for medical and scientific purposes
- Recommend licensing policies for manufacture, cultivation, and distribution of narcotic substances
- Advise on India's stance in international forums on drug control
- Review and recommend amendments to the Schedules of the Act
- Advise on rehabilitation of drug addicts and de-addiction programs
- Coordinate between various government departments on drug control measures

## National Fund for Controlling Drug Abuse

### NATIONAL FUND FOR CONTROLLING DRUG ABUSE

- Constituted by the Central Government under Section 7A of the NDPS Act
- Purpose: To combat illicit drug traffic; rehabilitate addicts; educate public about drug abuse
- Sources of Fund: Government grants, donations, fines and forfeitures under the Act
- Utilization: Funding for NCB operations; awareness campaigns; de-addiction centers; research on drug abuse; training of enforcement personnel
- Administration: Managed by Central Government; accounts audited by Comptroller and Auditor General of India
- Grants: Given to state governments, NGOs, and research institutions for anti-drug activities

## Prohibition, Control & Regulation

### ◆ A. General Prohibition

No person shall cultivate any coca plant or gather any portion of a coca plant; cultivate the opium poppy or any cannabis plant; produce, manufacture, possess, sell, purchase, transport, warehouse, use, consume, import inter-State, export inter-State, import into India, export from India or tranship any narcotic drug or psychotropic substance EXCEPT for medical or scientific purposes and in the manner and to the extent provided by the Act and Rules.

### ◆ B. Central Government's Powers of Control

#### CENTRAL GOVERNMENT POWERS UNDER SECTION 9

- Grant licenses/permits/authorizations for cultivation, production, manufacture
- Prescribe conditions for such licenses and permits
- Prohibit production/manufacture of narcotic drugs except at specified establishments
- Allow import/export of narcotic drugs for medical and scientific use
- Establish or authorize government establishments for manufacture (e.g., GOAW Ghazipur, Neemuch)
- Prescribe the quantity of drug that shall constitute 'small quantity' and 'commercial quantity'
- Allow use of narcotic drugs in compounding of formulations under strict controls

## Opium Poppy Cultivation & Production of Poppy Straw

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Aspect	Details
Cultivation Authority	Only the Central Government (through Narcotics Commissioner) can permit cultivation of opium poppy ( <i>Papaver somniferum</i> )
Licensed Cultivators	Individual farmers must obtain a license from the Narcotics Commissioner; only licensed farmers can cultivate
States Permitted	Cultivation permitted in specified areas of Madhya Pradesh, Rajasthan, and Uttar Pradesh
Government Purchase	The entire opium yield must be sold to the Government (Central Government) at price fixed by it
Prohibited Activities	No private sale of raw opium; no possession of opium beyond licensed quantity; no diversion
Poppy Straw	All parts of opium poppy plant after harvesting (except seeds) – regulated similarly to opium
Poppy Seeds	Not a narcotic; can be used in food; trade is relatively unregulated
Opium Processing	Government Opium and Alkaloid Works (GOAW) at Ghazipur (UP) and Neemuch (MP) process opium into alkaloids for medical use

## Manufacture, Sale & Export of Opium

### ◆ A. Manufacture of Opium Derivatives

#### MANUFACTURE PROVISIONS

- Only Government-authorized factories can manufacture opium alkaloids (morphine, codeine, etc.)
- GOAW Ghazipur and GOAW Neemuch are the two major government establishments
- Private manufacturers may be licensed under special circumstances for manufacturing under strict supervision
- All manufactured narcotic substances must be sold to government-authorized distributors
- Detailed records of manufacture, stock, and disposal must be maintained
- Regular inspections by Narcotics Commissioner's officials

### ◆ B. Sale of Opium & Psychotropic Substances

Sale of narcotic drugs is strictly controlled. Morphine, codeine, and other opium derivatives can be sold only by licensed dealers to hospitals, pharmacies, and medical practitioners holding valid licenses. Retail sale to patients is possible only against a valid prescription from a licensed medical practitioner.

### ◆ C. Export of Opium

#### EXPORT PROVISIONS FOR OPIUM

- Export of narcotic drugs is regulated by the Central Government
- Only the Central Government or its authorized agencies can export opium and opium derivatives
- Export requires prior permission from the Narcotics Commissioner
- Export is permitted only to countries with which India has treaty arrangements or bilateral agreements
- Detailed documentation: export permit, shipping bill, customs clearance required
- Quantities exported must match international conventions' requirements
- Export of preparations containing narcotic drugs in small concentrations may be permitted under specific conditions

### Offences & Penalties

The NDPS Act provides for extremely stringent penalties, including minimum imprisonment terms, to deter drug trafficking.

Offence [Section]	Penalty
Cultivation of opium poppy without license [Sec 18]	Small qty: Rigorous Imprisonment (RI) up to 1 year or Fine or Both; Commercial qty: RI 10–20 years + Fine Rs. 1–2 lakh
Possession/Sale/Purchase of opium [Sec 18]	Small qty: RI up to 1 year; Commercial qty: RI 10–20 years + Fine (Min Rs. 1 lakh)
Manufacture of narcotic drugs without license [Sec 19]	Commercial qty: RI 10–20 years + Fine Rs. 1–2 lakh
Possession/Trafficking of cannabis [Sec 20]	Small qty: RI up to 1 year or Fine or Both; Commercial qty: RI 10–20 years + Fine (up to Rs. 2 lakh)
Trafficking in manufactured drugs (heroin, morphine, codeine) [Sec 21]	Small qty: RI up to 1 year; Commercial qty: RI 10–20 years + Fine Min Rs. 1 lakh (Max Rs. 2 lakh)
Trafficking in psychotropic substances [Sec 22]	Small qty: RI up to 1 year; Commercial qty: RI 10–20 years + Fine
Financing illicit drug traffic [Sec 27A]	RI 10–20 years + Fine Rs. 1–2 lakh

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Death due to consumption of adulterated narcotic substance [Sec 31A]	Death Penalty or Life Imprisonment (repeat offenders with commercial quantity)
Repeat offences (commercial quantity)	Minimum RI 15 years – up to Death penalty in extreme cases
Consumption of narcotic drug/psychotropic substance for personal use [Sec 27]	Small qty for personal use: Imprisonment up to 1 year or Fine up to Rs. 20,000 or Both

### IMPORTANT ASPECTS OF NDPS PENALTIES

- Burden of Proof: Reversed – accused must prove innocence once possession is established (Section 54)
- Bail: Difficult to obtain for commercial quantity offences; Section 37 imposes strict bail conditions
- Forfeiture: Property of drug traffickers can be seized and forfeited under Sections 68A–68T
- Special Courts: Designated Courts (Sessions Courts) try NDPS offences for speedy justice
- Death Penalty: Applicable only in case of repeat offences involving commercial quantities of most dangerous drugs
- Compounding: Not allowed for NDPS offences – all offences are non-compoundable
- Cognizance: Only courts of Sessions Judge or above can take cognizance of commercial quantity offences

## EXAM-ORIENTED MCQs – PHARMACEUTICAL JURISPRUDENCE UNIT 3

**Q1. The Pharmacy Act was enacted in the year:**

- a) 1940 b) 1945 c) 1948 d) 1950

✓ Answer: c) 1948

**Q2. Pharmacy Council of India is constituted under which Section of Pharmacy Act?**

- a) Section 2 b) Section 3 c) Section 10 d) Section 15

✓ Answer: b) Section 3

**Q3. Which body maintains the Central Register of Pharmacists?**

- a) State Pharmacy Council b) DGHS c) Pharmacy Council of India d) Ministry of Health

✓ Answer: c) Pharmacy Council of India

**Q4. Under Pharmacy Act 1948, a person can be removed from the register on grounds of:**

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a) Professional misconduct b) Obtaining registration by fraud c) Conviction for offence d) All of the above

✓ **Answer: d) All of the above**

**Q5. The MTP Act 1955 deals with:**

a) Narcotic drugs b) Excise duty on alcohol-containing preparations c) Pharmacy education d) Drug quality

✓ **Answer: b) Excise duty on alcohol-containing preparations**

**Q6. In 'Manufacture IN Bond', excise duty on alcohol is:d**

a) Paid in advance b) Not paid (duty-free) c) Paid at time of sale d) Refunded after manufacture

✓ **Answer: b) Not paid (duty-free)**

**Q7. The NDPS Act was enacted in:**

a) 1971 b) 1978 c) 1985 d) 1988

✓ **Answer: c) 1985**

**Q8. Which Act replaced the Dangerous Drugs Act of 1930?**

a) Pharmacy Act 1948 b) MTP Act 1955 c) NDPS Act 1985 d) Drugs & Cosmetics Act 1940

✓ **Answer: c) NDPS Act 1985**

**Q9. National Fund for Controlling Drug Abuse is constituted under which section of NDPS Act?**

a) Section 4 b) Section 7A c) Section 8A d) Section 9

✓ **Answer: b) Section 7A**

**Q10. Under NDPS Act, who can cultivate opium poppy?**

a) Any licensed farmer b) Any Indian citizen c) Only under license from Narcotics Commissioner d) State governments

✓ **Answer: c) Only under license from Narcotics Commissioner**

**Q11. Death penalty under NDPS Act applies to:**

a) First-time offenders b) Repeat offenders in commercial quantity of most dangerous drugs c) All NDPS offenders d) Only cannabis cases

✓ **Answer: b) Repeat offenders in commercial quantity of most dangerous drugs**

**Q12. The Government Opium and Alkaloid Works are located at:**

a) Mumbai and Chennai b) Delhi and Kolkata c) Ghazipur and Neemuch d) Lucknow and Bhopal

✓ **Answer: c) Ghazipur and Neemuch**

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