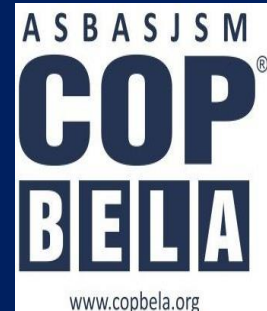




Amar Shaheed Baba Ajit Singh Jujhar Singh Memorial
COLLEGE OF PHARMACY
(An Autonomous College)
BELA (Ropar) Punjab



Name of Unit	Drugs and cosmetics act
Subject /Course name	Pharmaceutical Jurisprudence
Subject/Course ID	BP 505T
Class: B.Pharm. Semester	5
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Learning Outcome of Module 03

LO	Learning Outcome (LO)	Course Outcome Code
LO1	Discuss the Pharmacy council of India, State and joint state pharmacy councils, offences and penalties.	BP505.4
LO2	Discuss the objective, definition of medicinal and toilet preparation act	BP505.4
LO3	Explain the manufacturing of ayurvedic, homeopathic preparations.	BP505.5
LO4	Brief review about Narcotic drugs , various authorities.	BP505.5
LO5	Mention the regulation, control on opium poppy cultivation.	BP505.5

Content Table

Topic
<ul style="list-style-type: none"> • Definitions, objective , Administration of the pharmacy act and rules • State and joint state pharmacy council functions • Definitions, objective , Administration of alcoholic preparations according to medicinal and toilet preparation act • Definitions, objective of various authorities and officers of Narcotics department

Pharmacy Act 1948

Contents

- Definitions
- History & Amending of act
- Pharmacy Council of India and its functions
- State Pharmacy Council
- Constitution of Joint State Pharmacy Council
- Functions of Joint State Pharmacy Council
- Registration of Pharmacists
- Preparation of First and subsequent register
- Deletion of names from register
- Offences and penalties

Intended Learning Outcomes : At the end of this lecture, student will be able to

- Define the various terminologies of Pharmacy Act
- Explain the constitution and functions of Pharmacy Council of India
- Explain the constitution and functions of State Pharmacy Council
- Explain the constitution and functions of Joint State Pharmacy Council
- Describe the procedure for registration of Pharmacists
- Explain the Preparation and maintenance of first register
- Explain the Preparation and maintenance of subsequent register
- Discuss the offences and penalties pertaining to the act

HISTORY OF PHARMACY ACT

- In India there was no restriction to practise the profession of Pharmacy
- One could practise this profession as any other profession
- Persons, having no knowledge and having no education in pharmacy or pharmaceutical chemistry or pharmacology, were engaged in this profession
- Hundreds of cases were found by Government wherein the compounding, mixing, or dispensing of medicines was being done by persons who were not adequately educated in this line
- These causing great harm to the health of people
- It was found necessary to enact a law for the regulation of the profession and practice of

pharmacy

List of amending acts & adaptation orders

- The Adaptation of Laws Order, 1950
- The Adaptation of Laws (No.3) Order, 1956
- The Pharmacy (Amendment) Act, 1959
- The Pharmacy (Amendment) Act, 1976
- The Pharmacy (Amendment) Act, 1982
- The Delegated Legislation Provisions (Amendment) Act, 1985

OBJECTIVES

- To restore the Pharmacy profession in its due place in the health services
- Raising the status of the profession of Pharmacy in India
- To regulate the practice of Pharmacy in India
- To provide uniform education and training throughout India
- To maintain control over persons entering the profession of pharmacy
- To Protect the Public Health

– Medical Use of Drugs

– Drug Abuse

DEFINITIONS

- “Pharmacy Act” :

An Act to regulate the profession of pharmacy.

- “Medical practitioner “--

- A person,

(i) Holding a qualification granted by an authority notified under section 3 of the Indian Medical Degrees Act, 1916 or specified in the Schedules to the Indian Medical Council Act 1956; OR

(ii) Registered or eligible for registration in a Medical register of a State, meant for the registration of persons practicing the Modern scientific system of medicine; OR

(iii) Registered in a medical register of a State, who, although not falling within above first and second clause, but is declared by a general or special order made by the State Government; OR

(iv) Registered or eligible for registration in the register of Dentists for a State under the Dentists Act, 1948; OR

(v) Who is engaged in the practise of Veterinary medicine and who possesses qualifications approved by the State Government?

“REGISTERED PHARMACIST”

A person whose name is for the time being entered in the register of the State in which he or she is for the time being residing or carrying on his profession or business of pharmacy.

PHARMACY COUNCIL OF INDIA (PCI)

- The central council (P.C.I) is constituted by the Central government
- First central council was constituted in 1949
- It is reconstituted every five years

CONSTITUTION OF PCI

- It consists of three different types of members:
 - A. Elected member
 - B. Nominated member
 - C. Ex-officio member

A. Elected members 08:

- 1) Six members, elected by the University Grant commission (U.G.C) There is at least one teacher of each of the pharmaceutical chemistry, pharmacy, and pharmacognosy and pharmacology
- 2) One member , elected by Medical Council of India
- 3) One member , elected by State Council ,who shall be a registered Pharmacist

B. Nominated members 08:

- 1) Six members, nominated by the Central Government; of whom at least 4 shall be persons possessing a degree or diploma in, and practicing pharmacy or pharmaceutical chemistry
- 2) A Representative of the U.G.C. and a representative of the All India Council for Technical Education(A.I.C.T.E.)
- 3) One member nominated by each State Government, who shall be a registered pharmacist

C. Ex-officio members:

- 1) The Director General of Health Services
- 2) The Director of the Central Drugs Laboratory
- 3) The Drugs Controller of India

➤ Executive Committee consisting of:

- President
- Vice-president
- Five members elected by central council from its members
- President and Vice-President of Central Council shall be elected by the members of the Council from themselves.
- The council shall appoint,
 - A registrar, act as secretary
 - Other officer and personnel

FUNCTIONS OF PCI

A) Education Regulations (E.R.) -

Minimum standard of education laid down by P.C.I. are known as the “Education Regulation”.

- They include,
 - i. Minimum qualification for registration as a Pharmacist
 - ii. Minimum qualification for admission to Diploma in Pharmacy
 - iii. Duration of training and course of study to be covered
 - iv. Condition to be fulfilled by the academic Institution and by the Examining Authority
 - v. Nature and period of practical training
 - vi. The subjects of examination and minimum standard of passing
 - vii. Condition to be fulfilled by the institution to be recognized for giving practical training
 - viii. Practical training contract form for pharmacists

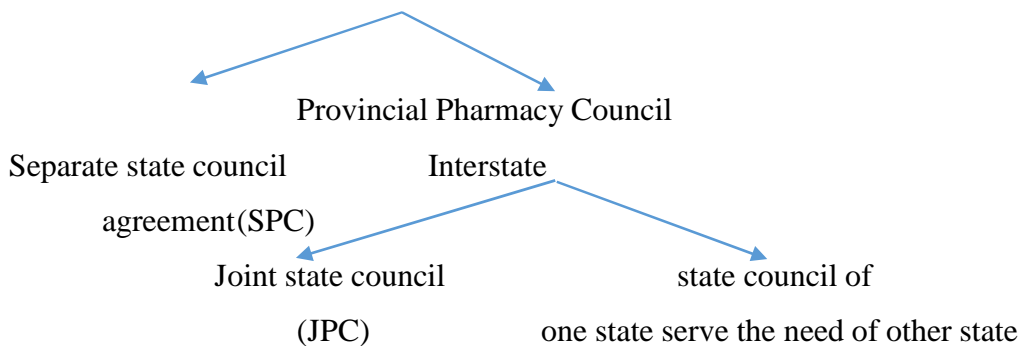
B) To regulate the Education Regulation in the states.

C) Approval of the Institutions providing course and examination for the pharmacists.

- Procedure:
 - i) Institution has to apply to P.C.I./A.I.C.T.E.
 - ii) P.C.I./A.I.C.T.E. deputed its inspector to visit the institution.

iii) Inspector then reports to council on which if council is satisfied, it approves the course of examination.

PROVINCIAL PHARMACY COUNCIL



CONSTITUTION OF STATE PHARMACY COUNCIL

➤ It consists of three different types of members:

- A. Elected member
- B. Nominated member
- C. Ex-officio member

A. Elected member:

- 1) Six members, elected from amongst themselves by registered pharmacists of the State;
- 2) One member elected from amongst themselves by the members of each Medical Council of the state.

B. Nominated member

Five members, of whom at least three shall be possessing a degree or diploma in pharmacy or pharmaceutical chemistry or be Registered Pharmacists, nominated by the State Government

C. Ex-officio member

- 1) Chief administrative medical officer of the State
- 2) Government analyst nominated by State government under the D & C act 1940
- 3) Officer in charge of drugs control organisation of the State

Joint State Pharmacy Council

➤ Two or more State Governments can agree that the State Council of one State is to serve the needs of the participating States

➤ **Composition of Joint State Councils:**

It consists of three different types of members:

- A. Elected member
- B. Nominated member
- C. Ex-officio member

A. Elected member:

- 1) 3-5 members elected amongst themselves by the Registered Pharmacists of each of the participating States
- 2) One member elected from amongst themselves by the members of each Medical Council of each Stat

B. Nominated member:

2-4 members nominated by each participating state, of whom more than half possess degree or diploma in pharmacy or be Registered Pharmacist

C. Ex-officio member:

- 1) The Chief administrative medical officer of each participating state
- 2) The Government Analyst of each participating state.
- 3) The officer in-charge of drugs control organisation of each participating state

➤ **Executive Committee consisting of:**

- President
- Vice-president
- The such other number of the member

REGISTRATION OF PHARMACISTS

➤ The Pharmacy Act, 1948, provides for the registration of pharmacists.

➤ There are two types of register,

- 1) First register
- 2) Subsequent register

➤ **The Preparation and maintenance of Register:**

The Register shall include the following particulars:

- a) The full name and residential address of the registered person;
- b) The date of his first admission to the register;
- c) His qualifications for registration;
- d) His professional address, and if he is employed by any person, the name of such person;
- e) Such further particulars as may be prescribed.

PREPARATION OF FIRST REGISTER

- For the preparation of the first register, the State Government has to constitute a Registration Tribunal.
- The Tribunal consisting of :
 - Three persons,
 - A Registrar, act as Secretary.
- Tribunal fixes the date on or before which all applications for registration with prescribed fees are accepted.
- All applications are examined.
- If tribunal is satisfied, it directs the entry of the name of the applicant on the register.

Qualifications for entry on first register

- Applicant should be at least 18 years old.
- Applicant should reside or carries on the business or profession of pharmacy in the concerned State.
- Applicant should hold,
 - a) A degree or diploma in pharmacy OR pharmaceutical chemistry OR
 - b) Chemist and Druggist diploma OR
- c) Qualification granted by authority outside India which is adequate for registration. OR
- d) Degree of an Indian universities with not less than 3 years' experience in dispensing in hospital. OR
- e) Passed an examination for dispensers recognized by state government. OR
- f) Not less than 5 years' experience of compounding prior to the date notified by Tribunal.

SUBSEQUENT REGISTERS

➤ Procedure for subsequent registration:

From the registered pharmacists of the first register constitution of State council take place Application are invited within fix date, addressed to the registrar

If registrar found that applicant has requisite qualification, he may direct his/her name to be entered in register. If application has been rejected by registrar, he/she may appeal to state council within 3 months of the rejection. The decision of the state council shall be final.

REQUIREMENTS FOR SUBSEQUENT REGISTRATION

- Applicants should be at least 18 years of the age.
- Applicants should carry on the profession of the pharmacy in the concerned state.

QUALIFICATIONS FOR SUBSEQUENT REGISTRATION

➤ There are 3 different types of qualifications prescribed:

- 1) After the preparation of first register and before E.R. take effect.
- 2) After E.R. take effect.
- 3) Special provisions.

1) After the preparation of First register and before E.R. take effect

- a) Satisfies the conditions prescribed by the Central Council
- b) A registered pharmacist in another State
- c) Possesses a qualification for registration granted outside the states and are at least matriculates.

2) After the Education regulations take effect:

- Those who have passed an approved examination
- Those who possesses a qualification granted by authority outside India and recognize by the P.C.I
- Those who are Registered Pharmacist in another State

3) Special provisions:

- Provision made under The Pharmacy Act 1959, apply to persons;
 - Affected by the partition in 1947
 - Due to reorganization of the state in 1956
 - Migrated to India
- Provision made under The Pharmacy Act 1976;
 - Those who possess degree or diploma in Pharmacy or Pharmaceutical chemistry. OR
 - Chemist & druggist diploma of Indian University OR
 - Passed an examination recognized for dispenser by State government. OR
 - Person approved as “Qualified persons” before 31st December 1969 under D & C Act.
 - Any displaced persons from Bangladesh, Burma, Uganda, Sri Lanka, were carrying profession of pharmacy for period of 5 years prior to date of application.

RENEWAL FEES

- Retention of a name on the register, subject to the payment of prescribed fee annually before the 1st day of April.
- If a renewal fee is not paid by the due date, the Registrar shall remove the name of the defaulter from the register.
- Provided that a name so removed may be restored to the register on such conditions as may be

prescribed.

- On payment of the renewal fee, the Registrar shall issue a receipt therefore and such receipt shall be proof of renewal of registration.
- Entry of additional qualifications obtained by registered pharmacist shall be entered in the register on payment of prescribed fees.

REMOVAL OF NAME FROM REGISTER

- The name of Pharmacist may be removed from register,
 - i) If his name has been entered into the register by error
 - ii) If he has been convicted of any offence in any professional respect which renders him unfit to be kept in the register OR
 - iii) If the employed person is registered pharmacist, his name may be removed from register If,
 - Convicted of offence or held guilty of infamous conduct
 - Offence was investigated by registered pharmacist himself
 - If the repetition of similar offence or conduct during the period of 12 month
 - Pharmacist may go to the appeal to the State Government within 30 days.
 - A person whose name has been removed from the register is required to surrender his certificate or registration to the Registrar.

OFFENCES	PENALTIES
1. Falsely claiming to be a registered pharmacist.	1. (a) Fine up to Rs. 500.00 on first conviction. (b) Fine up to Rs. 1000.00 and/or 6 months imprisonment of any subsequent conviction.
2. Dispensed by unregistered persons. Exception: Medical practitioners.	2. 6 months imprisonment OR Fine up to Rs. 1000.00 OR Both.
3. Failure to surrender certificate of registration.	3. Fine up to Rs. 50.00
4. Obstructing State pharmacy council Inspectors.	4. 6 months imprisonment OR Fine up to Rs. 1000.00 OR Both.

➤ Issue of duplicate certificates of registration:

Where it is shown to the satisfaction of the Registrar that a certificate of registration has been lost or destroyed, the Registrar may, on payment of the prescribed fee, issue a duplicate certificate in the prescribed form.

Medicinal and Toilet Preparations (Excise Duties) Act

The Medicinal and Toilet Preparations (Excise Duties) Act

- Objectives, legal definitions, licensing, bonded and non-bonded laboratory, warehousing
- Manufacture of ayurvedic, homeopathic, patent and proprietary preparations
- Offences and penalties

Intended Learning Outcomes

- **At the end of this lecture, student will be able to**
 - Write the introduction and reasons for implementation of The medicinal and Toilet Preparation Act, 1955
 - Describe the objective of Excise Duties Act, 1955
 - Define the related terms included in the Excise Duties Act, 1955

Objectives

- To provide for the collection of levy and duties of excise on medicinal and toilet preparations containing alcohol, narcotic drugs or narcotics
- To provide for uniformity in the rules and rates of Excise duties leviable on such preparations throughout the country

Definitions

- **Alcohol** means ethyl alcohol of any strength and purity having the chemical composition C_2H_5OH
- **Absolute alcohol** means ethyl alcohol containing less than 1% by weight of water
- **Dutiable Goods** means the medicinal and toilet preparations specified in the Schedule as being subject to the duties of excise levied under the Act
- **Medicinal Preparation** includes all drugs which are a remedy or prescription prepared for internal or external use of human being or animals and all substances intended to be used for or in the treatment, mitigation or prevention of disease in human beings or animals
- **Toilet Preparation** means any preparation which is intended to cleanse, improve or alter the complexion, hair, skin, or teeth, and includes deodorants and perfumes
- **Bonded Manufactory** means the premises approved and licensed for the manufacture and storage of medicinal and toilet preparations containing alcohol, opium, Indian hemp or any

other narcotic drug or narcotics on which duty has not been paid

- **Non- bonded Manufactory** means the premises approved and licensed for the manufacture and storage of medicinal and toilet preparations containing alcohol, opium, Indian hemp or any other narcotic drug or narcotics on which duty has been paid
- **Denatured Alcohol** or denatured spirit means alcohol of any strength which has been rendered unfit for human consumption by the addition of substances approved by the Central Government or by the State Government with approval of the Central Government
- **Rectified Spirit** means plain denatured alcohol of a strength not less than 50.0° over proof and includes absolute alcohol. It is highly concentrated ethanol which has been purified by means of repeated distillation, a process that is called rectification.
- **Restricted Preparation** means every medicinal and toilet preparation specified in the Schedule and includes every preparation declared by the Central Government as restricted preparation
- **Unrestricted Preparation** means any medicinal or toilet preparation containing alcohol but other than restricted preparation or a spurious preparation

What is an Excise?

- Is an **inland tax** on the sale, or production for sale, of specific goods or a tax on a good produced for sale, or sold, within a country or licenses for specific activities?
- It is different from Customs duties (border taxes)
- An excise tax is distinguished from a sales tax or VAT in three ways:
- (i) an excise typically applies to a narrower range of products;
- (ii) an excise is typically **heavier**, accounting for a higher fraction of the retail price of the targeted products; and
- (iii) an excise is typically a per unit tax, costing a **specific amount for a volume or unit of the item purchased**, whereas a sales tax or VAT is proportional to the price of the good
- *An excise is considered an indirect tax, meaning that the producer or seller who pays the tax to the government is expected to try to recover or shift the tax by raising the price paid by the buyer*

Central Board of Excise and Customs

- Central Board of Excise and Customs (CBEC) is a part of the Department of Revenue under the Ministry of Finance, Government of India

- It deals with the tasks of formulation of policy concerning levy and collection of Customs & Central Excise duties and Service Tax, prevention of smuggling and administration of matters relating to Customs, Central Excise, Service Tax and Narcotics to the extent under CBEC's purview
- The Board is the administrative authority for its subordinate organizations, including Custom Houses, Central Excise and Service Tax Commissionerates and the Central Revenues Control Laboratory.

Licensing

- Manufacturing of alcoholic and narcotic preparations can only be undertaken under the authority of a licence granted for this purpose
- A license will be granted only if the applicant holds the requisite license for the manufacture of drugs under the Drugs and Cosmetics act.
- The act also specifies procedures to be followed for the manufacture of Homeopathic and Ayurvedic preparations, removal of goods from bonded labs, interstate movement of preparations etc.
- Application for the licence or for its renewal is to be made to Licensing authority who is the **EXCISE COMMISSIONER**
- A separate application is to be made if more than one kind of licence is desired
- The application for the licence should be submitted in the prescribed form accompanied with the prescribed fee
- The particulars required to fill in the application for obtaining the licence are:
 - Name and address of the applicant and place and site on which the manufacturing unit is situated
 - The amount of the capital proposed to be invested in the venture
 - Approximate date from which the applicant desires to commence the manufactory
 - The number and full description of vats, still and other permanent **apparatus** and the **machinery** which the applicant wishes to get together with the maximum quantity of alcohol
 - The site and the elevation plans of the manufactory/**building** and also similar plans for the quarters of the Excise Officer together with relevant records
 - The amount on cash or Government Promissory Notes which the applicant is prepared to furnish for the due performance of the conditions on which the licence may be granted

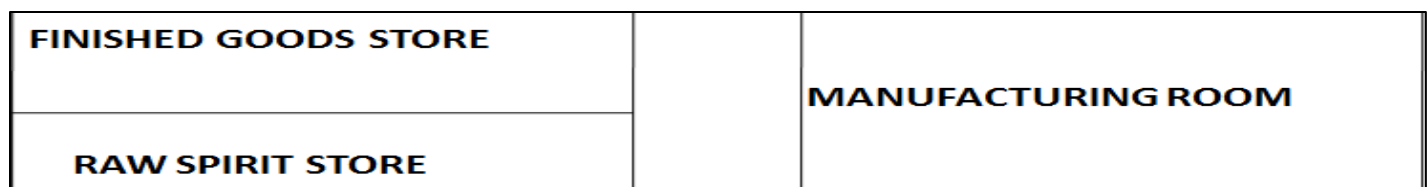
- The *kind and number of each licence under the Drugs and Cosmetics Act held by the applicant*
- A list of all preparations which the applicant proposes to manufacture and /or those manufactured during the preceding year showing the percentage or proportion of alcohol in preparations or opium, indian hemp or other narcotic drug.

Manufacture outside Bond

- Preparations are deemed to be manufactured in bond when they are manufactured in a premise, licensed or approved for this purpose and on which the **excise duty has been paid at the time of spirit purchase**
- A license is required for undertaking the manufacture of medicinal and toilet preparations without a bond
- The application for the licence should be submitted in the prescribed form accompanied with the prescribed fee at least 2 months before the date of commencement of the manufacture
- The conditions are similar to that of manufacture in bond

Conditions of License

- The form of application and other conditions for license is the same as that of manufacture in bond
 - Non- bonded laboratory should be separate from the rest of the business premises and should be used
 - **exclusively for the manufacture of spirituous medicinal and toilet preparations**
- Design and construction of a non-bonded laboratory**
1. A Spirit Store
 2. A room for the manufacture of medicinal preparations
 3. One or more rooms for the storage of finished medicinal preparations
 4. A non- bonded lab should consist of the compartments as per the following diagram



- **The manufacture and sale in a non- bonded lab should be conducted between sunrise and sunset only and on days as fixed by the excise commissioner for the purpose.**
- There should be only one entrance to the lab and only one door for each of its compartments
- Every window in the bonded premises should be provided with maleable iron rods, not less than 1.9 cm in thickness and set not more than 10 cm apart
- The rods should be embodied in brick work to a depth of atleast 5 cm and covered on the inside with strong netting or expanded metal of a mesh not more than 2.5 cm in diameter in length
- Each room in the lab should bear a board indicating its serial number and purpose
- The pipes from sinks inside the laboratory should be connected to the general drainage of the premises
- The gas and electric connections in the lab should be arranged in such a way that their supply can be cut off at the end of a day's work
- Permanent vessels should be provided for the storage of alcohol and other narcotic substances received under bond
- All vessels should bear a distinctive serial number and a statement of their full capacity

Manufacture in a non-bonded laboratory

- The essential steps are :
 1. Obtaining raw spirit from distillery after duty payment
 2. Manufacture
 3. Storage of finished preparations
 4. Returns

1. Obtaining raw spirit from distillery

- Raw spirit is obtained from a distillery approved by the Excise commissioner
- An indent is sent in the prescribed form, countersigned by the officer in charge of the lab (in Duplicate)
- One copy to the distiller or warehouse keeper and the other to the excise officer in charge of the distillery or warehouse
- Before sending a copy to the officer in charge of the distillery, the manufacturer should pay the excise duty on the alcohol to be purchased
- The treasury challan of the payment should be enclosed with the indent
- The treasury officer shall also send an advice to the Excise officer in charge of the distillery

- After verification of the payment details, the excise officer shall issue the spirit along with a permit covering the issue
- The spirit will then be transferred to the spirit store and entered in the register

2. Manufacture of alcoholic preparations

- The manufacture of preparations from duty paid spirit should be carried out only at the licensed premises
- Each preparation, soon after its manufacture, should be registered and given a distinctive batch number

3. Storage of finished preparations

- All finished preparations should be transferred from the lab to the finished goods store and so arranged that they can be easily checked from the stock register
- Preparations stored in bulk should be measured in the storage vessel nearest to 28.350 ml
- The quantities taken out from time to time should be entered in the stock maintained for the purpose

4. Sampling

- The excise officer of the concerned jurisdiction, without any previous notice to the manufacturer, shall take samples of not less than 10% and more than 15% of the total batches manufactured during the month
- All such samples should be taken personally by the officer in the presence of the manufacturer
- Every sample shall be taken in duplicate and the labels of the bottles should be signed by the officer taking the samples
- The cork of every bottle should be fixed with the seal of the officer
- The manufacturer can also add his seal to the sample bottles
- If the alcoholic content differs by more than 3⁰ proof on either side from the strength declared by the manufacturer, he shall pay a penalty at the rate of 10 times the duty payable

5. Returns

- The manufacturer should maintain up to date and proper accounts of all transactions and deliver them to the concerned officers on the 5th of each month
- Any change in staff should be intimated to the excise commissioner

6. Inspection

- The non-bonded lab shall be open to inspection by officers of the excise department

- It shall be inspected at least once every month

Fees

- The fees to be paid for obtaining a license are:

SL. NO.	PURPOSE FOR WHICH LICENCE IS REQUESTED	LICENCE FEE PAYABLE PER ANNUM
1	2	3
1.	Manufacture under bond for payment of duty--	
	(a) Allopathic medicinal preparations and toiler preparations containing alcohol-	
	(i) where, in the alcohol consumed, the pure alcohol content is more 2250 litres per annum	200
	(ii) where, in the alcohol consumed, the pure alcohol content is more than 2250 litres per annum	400
	(b) Medicinal preparations and toiler preparations not containing alcohol, but containing opium, Indian hemp, or other narcotic drug or narcotic	20
	(c) Homoeopathic preparations containing alcohol-	
	(i) where, in the alcohol consumed, the pure alcohol content is less than 2250 litres per annum	200
	(ii) where, in the alcohol consumed, the pure alcohol content is more than 2250 litres per annum	400
	(d) Medicinal preparations in Ayurvedic, Unani or other indigenous systems of medicines containing alcohol and which are prepared by distillation or to which alcohol has been added	50

	(i) where, in the alcohol consumed, the pure alcohol is 70 litres or less per annum	20
	(ii) where, in the alcohol consumed, the pure alcohol is more than 70 litres but less than 280 litres per annum	50
	(iii) where, in the alcohol consumed, the pure alcohol is 280 litres or more per annum	400
	(d) Medicinal preparations in Ayurvedic, Unani or other indigenous systems of medicines containing alcohol and which are prepared by distillation or to which alcohol has been added	50
3	Manufacture of medicinal preparations containing self-generated alcohol in Ayurvedic or Unani or other indigenous systems of medicines by Ayurvedic or Unani practitioners for dispensing for the use of their patients and not for sale to general public	2
4	Bonded warehouse	50
5	Manufacture of medicinal preparations containing alcohol by hospitals, dispensaries and other charitable institutions which are eligible from exemption from duty under rule 7 and which are specifically authorized in this behalf by the State Government or by the Administration in the case of a Union Territory.	NIL]
2	Manufacture outside bond-	
	(a) Allopathic medicinal preparations and toilet preparations containing alcohol-	
	(i) where, in the alcohol consumed, the pure alcohol is 70 litres or less per annum	20
	(ii) where, in the alcohol consumed, the pure alcohol is 280 litres or more per annum	50
	(iii) where, in the alcohol consumed, the pure alcohol is 280 litres or more per annum	400
	(b) Medicinal preparations and toilet preparations not containing opium, Indian hemp or other narcotic drug or narcotic	20
	(c) Homoeopathic preparations containing alcohol-	

Offences and Penalties

OFFENCES	PENALTIES
I. BY LICENSEES	
a) Failure to follow licence conditions/pay duty	Imprisonment up to 6 months or fine up to Rs. 2000
b) Disorderly keeping of stocks or accounts	Fine up to Rs. 2000
c) Illegal sale of dutiable goods	Fine up to Rs. 1000
d) Failure to furnish export proof	Fine up to Rs. 2000
e) Obstruction to officers/ false information	Fine up to Rs. 5000
f) Failure to provide/ maintain weighing or measuring devices	Fine up to Rs. 1000
g) Failure to provide / maintain facilities for locking	Fine up to Rs. 200
II. BY EXCISE OFFICERS	
a) Failure to do duty	Imprisonment up to 3 months or fine or both
b) Vexatious searches / seizures	Fine up to Rs. 2000
c) Disclosure of information	Fine up to Rs. 1000
III. BY PUBLIC	
a) Malicious information	Imprisonment up to 2 years or fine upto Rs. 2000 or both
b) Connivance of owners/ occupiers of land or	Imprisonment up to 6 months or fine upto Rs. 500 or both

Latest amendments

- **Amendment of Article 268 (1) (Duties levied by the union but collected by the States): –**
- Article 268 (1) provides the provision of levy of stamp duty and excise duty on medicinal and toilet preparation by union government and collection by state (In case of State) or by union (In case of union territory).
- Now, the duties of excise on medicinal and toilet preparation has been omitted and same is been amalgamated in GST.

Manufacture in Bond

- **Preparations are deemed to be manufactured in bond when they are manufactured in a premise, licensed or approved for this purpose and on which the duty has not been paid until the finished products are removed from the licensed premises**
- Every person interested in manufacturing preparations containing alcohol or other narcotic substances should obtain a license for the Excise Commissioner of the concerned state
- The application for the license should be submitted in the prescribed form accompanied with the **prescribed fee at least 2 months before the date of commencement of the manufacture**

Licensing

- The particulars required to fill in the application for obtaining the licence are:
- Name and address of the applicant and place and site on which the bonded lab is proposed to be situated
- The amount of the capital proposed to be invested in the venture
- Approximate date from which the applicant desires to commence the manufacture, stating the % of alcohol in each
- **The number and full description of vats, still and other permanent apparatus and the machinery which the applicant wishes to get together with the maximum quantity of alcohol to be used**
- The site and the elevation plans of the manufactory/building, showing the different rooms, doors and windows, along with similar plans for the quarters of the Excise Officer together with relevant records
- The kind and number of each licence under the Drugs and Cosmetics Act held by the applicant
- *In case of a firm, copy of the partnership deed and in the case of companies, the*

list of directors and managers.

- A list of all preparations which the applicant proposes to manufacture and /or those manufactured during the preceding year showing the percentage or proportion of alcohol in preparations or opium, indian hemp or other narcotic drug

Processing of application

- On receipt of application, the licensing authority will enquire into the
 - 1) The qualifications and experience of the technical personnel involved in the manufacture
 - 2) The equipment of the bonded laboratory
 - 3) Suitability of the proposed building for the establishment of bonded laboratory
 - 4) Applicants financial position

MANUFACTURING ROOM		FINISHED GOODS STORE
RAW SPIRIT STORE		EXCISE OFFICER

Conditions of License

- If the Excise commissioner is satisfied with the enquiries made, he may issue directions for license to be issued and approve the plans of the building and equipments
- On completion of the construction, the licensing authority will ascertain whether the construction has been done in accordance with the approved plan
- Separate licenses should be obtained for separate premises of business
- If the licensee desires to **transfer his business to another person**, the transferee should obtain a fresh license which shall be granted free of fee for the residue of the period covered by the original license
- Any transfer in premises should be notified to the licensing authority 10 days in advance and obtain an amended license
- The license is valid for a period of **1 year** and should be renewed thereafter
- The application for renewal should be submitted one month before the due date
- The license should be displayed in a prominent place within the premises
- The licensee should allow his premises and goods to be inspected by the licensing authority
- A visit book should be maintained to enter the remarks of the visiting officers
- All invoices and documents related to the business should be maintained

Design and construction of a bonded laboratory

A bonded lab should consist of the compartments as per the following diagram

1. A Spirit Store
 2. A room for the manufacture of medicinal preparations
 3. One or more rooms for the storage of finished medicinal preparations
 4. If the manufacture of toilet preparations is also carried on, a separate manufacturing room for these togetherwith a separate room for the storage of finished toilet goods
 5. Accommodation , with necessary furniture for the excise officer in charge of the bonded lab, near its entrance
- There should be only one entrance to the lab and only one door for each of its compartments
 - The lab can be opened only in the presence of the excise officer and during his absence, all the doors should besecured with excise ticket locks
 - Every window in the bonded premises should be provided with maleable iron rods, not less than 1.9 cm inthickness and set not more than 10 cm apart
 - The rods should be embodied in brick work to a depth of at least 5 cm and covered on the inside with strong netting or expanded metal of a mesh not more than 2.5 cm in diameter in length
 - Each room in the lab should bear a **board** indicating its serial number and purpose
 - The pipes from sinks inside the laboratory should be connected to the *general drainage* of the premises
 - The **gas** and electric connections in the lab should be arranged in such a way that their supply can be cut off atthe end of a day's work
 - Permanent vessels should be provided for the storage of alcohol and other narcotic substances received underbond
 - **All vessels should bear a distinctive** serial number and a statement of their full capacity
 - **All vessels, containing preparations on which duty has not been paid should be secured with excise ticketlocks.**

Manufacture of preparations in bonded laboratory: The essential steps are :

1. Obtaining raw spirit from distillery without duty
2. Verification of raw spirit by excise officer
3. Storage of raw spirit in raw spirit store
4. Manufacture

5. Storage of finished preparations
6. Issue of preparations from bonded lab

1. Obtaining raw spirit from distillery

- Raw spirit is obtained from a distillery approved by the Excise commissioner
- An indent is sent in the prescribed form, countersigned by the officer in charge of the lab (in Duplicate)
- The distiller will receive the duplicate copy of the indent and issue the spirit in duly sealed containers along with the advice of consignment to the excise officer in charge of the bonded lab
- There should be no wastage of spirit during transportation from the distillery to the lab
- In case there is a loss of contents due to negligence by the manufacturer, the manufacturer will be asked to pay duty on the total loss in the amount of spirit
- However if the Excise commissioner is satisfied that the loss has occurred in spite of all care taken by the manufacturer, he may waive off the duty on the lost spirit

2. Verification and storage of raw spirit

- The consignment of the spirit has to be verified in volume and strength by the Excise officer on its arrival in the bonded lab and the amount entered in the register maintained for the purpose
- The spirit will then be stored in the spirit store

3. Manufacture of alcoholic preparations

- Whenever the manufacturer wants to manufacture any preparation, he must calculate the requirements of the spirit and hand it over to the officer in charge
- The officer will then issue the spirit
- Before requesting for the spirit, all the other ingredients of the preparation should be kept ready
- The spirit is then mixed with the ingredients in the presence of the officer in charge
- The finished product is then moved to the finished goods store, measured and stored in the vessels provided for the purpose
- It should also be entered in a register and given a batch number
- The officer in charge may permit the manufacturer to take a sample upto a max of 250 ml from each batch of the finished preparation, free of duty for determination of its alcoholic strength

- A separate account should be entered for samples used for analysis and any amount left over after analysis should be mixed with the main batch

4. Storage of finished preparations

- All finished preparations should be stored in bulk in jars and bottles, each containing not less than 2.25 litres of the preparation
- Every container should be labeled with the name of the preparation, batch number, strength, date of storage and actual content
- Preparations may be issued in containers not less than 50 ml capacity
- The stored preparations should be entered in a stock ledger which should be updated with manufacture of each batch

5. Issue of finished preparations

- Whenever the manufacture wishes to take out any preparation from the bonded lab, he must present an application to the excise officer and pay duty for it
- The officer will check the entries, realize the duty and allow the preparations to be removed from the bonded lab
- Before issue of preparations, an issue pass has to be written out by the Excise officer

Summary

- Use of alcohol for preparation of medicines is necessary.
- Alcohol used either for drinking or manufacture of perfumes is subjected to higher duties than that of used in medicine preparation.
- The Excise Duties Act came in force in 1955.
- For excise duty to be an effective alcohol control measure, duty increases need to increase annually in relation to inflation and income.
- An **excise** or **excise tax** is an inland tax
- The objective of the Act is to provide for the collection of levy and duties of excise on medicinal and toilet preparations containing alcohol, narcotic drugs or narcotics
- **Alcohol** means ethyl alcohol of any strength and purity having the chemical composition C_2H_5OH
- **Medicinal Preparation** includes all drugs which are a remedy or prescription prepared for internal or external use of human being or animals and all substances intended to be used for or in the treatment, mitigation or prevention of disease in human beings or animals

Narcotic Drugs and Psychotropic Substances Act, 1985

Contents of This Chapter

- Introduction to NDPS act
- Objective of the NDPS Act
- Legal Definitions of different Narcotic and Psychotropic substances
- The NDPS consultative committee
- Prohibition, control and regulation by Central Government
- Prohibition, control and regulation by State Government
- Offences and Penalties

Intended learning outcomes

- **At the end of this lecture, student will be able to**
 - Describe the importance of Narcotic Drugs and psychotropic substances ACT, 1985
 - Illustrate the Objectives of Narcotic Drugs and psychotropic substances ACT, 1985
 - Define the Narcotic and psychotropic substances
 - Describe the Consultative Committee of Narcotic Drugs and psychotropic substances ACT, 1985
 - Illustrate prohibition, control and regulation of Narcotic Drugs and psychotropic substances ACT, 1985
 - Explain the offences and penalties in connection with Narcotic Drugs and psychotropic substances ACT, 1985

Introduction

- India had no legislation regarding narcotics until 1985.
- Cannabis and its derivatives (marijuana, hashish/charas and bhang) were legally sold in India until 1985, and their recreational use was commonplace
- Consumption of cannabis was not seen as socially deviant behaviour, and was viewed as being similar to the consumption of alcohol
- Ganja and charas were considered by upper class Indians as the poor man's intoxicant, although the rich consumed bhang during Holi
- The United States began to campaign for a worldwide law against all drugs, following the adoption of the Single Convention on Narcotic Drugs in 1961
- However, India opposed the move, and withstood American pressure to make cannabis illegal for nearly 25 years

- American pressure increased in the 1980s, and in 1985, the Rajiv Gandhi government succumbed and enacted the NDPS Act, banning all narcotic drugs in India
- State regulation and community tolerance ceased after the enactment of the Narcotic Drugs and Psychotropic Substances Act (NDPS) in 1985, which created a restrictive regime around drugs
- Clampdown on cannabis and opium in the late 1980's purportedly triggered more dangerous use – chasing and injecting heroin and other opioids
- Narcotic Drugs and Psychotropic Substances Act is popular as NDPS Act
- It was passed to tackle an important social problem: drug trafficking

Objectives

- To consolidate and amend the existing laws related to Narcotic Drug
- To make stringent provisions for the control and regulation of operation
- To enhance the penalties for trafficking offences
- To make provisions for the implementation of International Conventions relating to NDPS to which India is a party

Cannabis

- Charas, the separated resin, obtained from the cannabis plant, includes concentrated preparation and resin known as hashish oil or liquid hashish
- Ganja, the flowering fruiting tops of the cannabis plant, excludes the seeds and leaves when not accompanied by the tops
- Any mixture, with or without any neutral material, or any of the above forms of cannabis or any drink prepared from it

Coca Derivatives

- Crude cocaine, any extract of coca leaf, which can be used for manufacture of cocaine
- Ecgonine and all derivatives of ecgonine
- Cocaine, i.e, methyl ester of benzoylecgonine and its salts
- All preparations containing more than 0.1% of cocaine

Controlled substances: means any substance which the Central Government may, having regard to the available information as to its possible use in the production or manufacture of narcotic drugs or Psychotropic substances or to the provisions of any International Convention, by notification in the official gazette, declare to be a controlled substance

Illicit traffic

- Cultivating or gathering any portion of any coca plant

- Cultivating the opium poppy of any cannabis plant
- Engaging in the production, manufacture, possession, sale, purchase, transportation, warehousing, concealment, use or consumption, import or export inter-state, import into India, export from India or transshipment of NDPS
- Dealing in any activities in NDPS other than those referred above
- Handling or letting out any premises for carrying out the above activities

Manufacture

- All processes other than production by which such drugs or substances may be obtained
- Refining of such drugs or substances
- Making or preparation containing such drugs or substances

Manufactured Drugs

- All coca derivatives, medicinal cannabis, opium derivatives and poppy concentrate
- Any other preparation which the Central Government may by notification declare to be a manufactured drug
- **Medicinal Cannabis** or medicinal hemp means any extract or tincture of cannabis
- **Narcotic Drugs** means coca leaf, cannabis, opium straw and includes all manufactured goods

Opium Poppy

- The plant of the species *Papaver somnifera* L. The plant of the any other species of *Papaver* from which opium or any other phenanthrene alkaloid can be extracted

Opium

- The coagulated juice of opium poppy
- Any mixture, with or without any neutral material, of the coagulated juice of the opium poppy

Poppy Straw means all parts of the opium poppy after harvesting whether in their original or cut, crushed or powdered and whether or not juice has been extracted therefrom

Poppy Straw Concentrate means the material arising when poppy straw has entered into a process for the concentration of its alkaloids

Opium Derivatives

- Medicinal opium, that is opium which has undergone the processes necessary to adapt it for medicinal use in powder form or granulated form
- Prepared opium, that is any product of opium designed to transform opium into extract suitable for smoking and other residue remaining after smoking
- Phenanthrene alkaloids, namely **morphine**, **codeine**, thebaine and their salts
- Diacetylmorphine, the alkaloid also known as dia-morphine or **heroin** and its salts

Psychotropic Substances means any substance, natural or synthetic, or any natural material or any salt, or preparation of such substance or material included in the list of psychotropic substances specified in the schedule

Examples of Psychotropic Substances

Antidepressants

amitriptyline (Elavil)
amoxapine (Asendin)
bupropion (Wellbutrin, Wellbutrin SR)
bupropion (Wellbutrin XL)
citalopram (Celexa)
desipramine (Norpramin)
desvenlafaxine (Pristiq, Khedezla) *nonformulary*
doxepin (Sinequan)
duloxetine (Cymbalta)
escitalopram (Lexapro)
fluoxetine (Prozac)
imipramine (Tofranil)
levomilnacipran (Fetzima) *nonformulary*
maprotiline (Ludiomil)
mirtazapine (Remeron, Remeron SolTab)
nefazodone (Serzone) *nonformulary*
nortriptyline (Pamelor, Aventyl)
paroxetine (Paxil, Paxil CR)
protriptyline (Vivactil)
sertraline (Zoloft)
trazodone (Desyrel)

Antipsychotics

aripiprazole (Abilify, Abilify Discmelt)
aripiprazole (Abilify Maintena)
Aripiprazole lauroxil (Aristada) *nonformulary*
asenapine (Saphris)
brexpiprazole (Rexulti®)
chlorpromazine (Thorazine)
clozapine (Clozaril, Fazaclo, Versacloz) Reserve
droperidol (Inapsine) *nonformulary*
fluphenazine (Prolixin)
fluphenazine decanoate (Prolixin D)
haloperidol (Haldol)
haloperidol decanoate (Haldol D)
iloperidone (Fanapt) Reserve
loxapine (Loxitane)
loxapine inhalant (Adasuve) *nonformulary*
lurasidone (Latuda)
molindone *nonformulary*
olanzapine (Zyprexa, Zyprexa Zydis)
olanzapine pamoate (Zyprexa Relprevv) Reserve
paliperidone (Invega)

Licensed cultivation, production and sale of Opium

- **Legal cultivation of opium** for medicinal purposes is carried out in India, only in selected areas, under a license granted for the purpose
- Legal cultivation for medical use is permissible within the ambit of United Nations, Single Convention on Narcotic Drugs 1961
- Some place where opium is grown are Chittourgarh in Rajasthan; Mandsaur, Ratlam, Neemuch in Madhya Pradesh; and Barabanki, Bareilly, Lucknow & Faizabad in Uttar Pradesh.

A. Cultivation of Opium poppy

- Each year the Central Government notifies the selected tracts where such cultivation will be permitted, and the general conditions for eligibility of the licence.
- The essential condition for issue of licence is, fulfillment of **minimum qualifying yield (MQY)** criterion, specified in number of kilogrammes per hectare
- Cultivators who have tendered at least this quantity in the previous year are eligible for licence

- The licence among other conditions, specifies the maximum area in which the opium crop can be sown
- The crop year starts from **1 September and ends on 30 October each year.**
- Officers of **CBN (CENTRAL BOARD OF NARCOTICS)** measure each field and exercise controls to ensure that no excess cultivation takes place
- The licenses are granted by the District Opium officers (DPO)
- The licenses granted by DPO can be cancelled or withdrawn by higher officers
- The DPO will designate one of the licensed cultivators as **Lambardars** who may discharge duties as specified by the Narcotics Commissioner
- If any opium is cultivated without license or under a cancelled license, the crop will be destroyed
- The **extraction** of opium takes place during the months of *February and March*
- Farmers still use the traditional method where they lance each poppy capsule manually with a special blade like tool, a process known as lancing
- The lancing is done in late afternoon or evenings.
- The opium latex which oozes out and congeals in the night is scraped and collected manually the next morning
- Each poppy capsule is given three to four lancements.

B. Production of Opium

- Cultivators during harvesting should take each day's collection to the Lambardar for weighing and entry in records
- The records are jointly attested each day by the Lambardar and the cultivator
- These records may be checked during inspections
- Any discrepancy between quantity produced and quantity entered, could lead to an enquiry and lead to punishment
- All opium produced has to be delivered to the DPO who will weigh, examine and classify the same
- A cultivator who is dissatisfied with the classification can have the opium forwarded to the Government Opium and Alkaloid factory where it will be classified by the factory's general manager
- If the DPO suspects that any opium sent to him is adulterated, he may collect the samples, seal it in the presence of the Lambardar and the cultivator and send it separately to the government factory for analysis
- Adulterated opium is liable for confiscation after giving a hearing to the cultivator

- The price of the opium is fixed from time to time by the central government

C. Manufacture of opium

- Only central govt. can manufacture opium at its two factories at **Ghazipur and Neemuch**

D. Sale of opium

- Sale of opium to the state government or manufacturing chemists can be made only from the factory at Ghazipur
- Manufacturing chemists should obtain a permit from State govt. - three copies of which are sent to the opium factory

Manufacture of manufactured drugs and psychotropic substance

- Manufacture should be conducted in accordance with a license granted by the Narcotics Commissioner or any other officer authorized by the central govt.
- License will be issued only to those persons holding license for the manufacture of drugs under the Drugs and Cosmetics Act 1940
- A security deposit of Rs. 10,000 should be paid
- The quantities manufactured cannot exceed the limits permitted by the licensing authority
- The licensee also has to ensure adequate security in the premises
- 15 days' notice should be to the govt. before commencement of manufacture and one month notice before cessation
- True accounts of all transactions should be maintained and returns submitted to the Narcotics commissioner
- Sale and distribution has to be done in accordance with the rules made by the state government

Administration of NDPS act

1. Narcotics Commissioner
2. The Narcotic Drugs and Psychotropic Substances Consultative Committee
3. Deaddiction centres

The Narcotic Drugs and Psychotropic Substances Consultative Committee

- The Central Government may constitute an advisory committee to advise it on matters related to the act
- The committee shall consist of a Chairman and such other members, *not exceeding twenty*
- It shall meet when required to do so by the Central Government and shall have the power to regulate its own procedure
- The committee may constitute sub-committee/s for the efficient discharge of functions, and

may appoint newmembers

- All rules pertaining to the committee are made by the Central Government
- The members of the Committee shall be appointed by the Central Government
- No member shall be appointed to the Committee unless he or she is willing to serve on it
- Casual vacancies in the Committee, caused due to resignation or otherwise of non-official members, shall be filled from amongst persons of eminence possessing expertise and background in the field of drug abuse prevention; but shall, as far as possible, be sponsored by the Ministries concerned of the Government of Jammu and Kashmir.
- The term of official members of the Committee shall be ex -officio
- The term of non-official members of the Committee shall, unless extended or otherwise, be for a period of
- ***three years.***
- The period of extension shall not be for more than a year at a time, subject, however, to a maximum of 2 years.
- The Minister for Finance or Minister of State in the Ministry of Finance (in-charge of Department of Revenue) shall be the Chairman of the Committee
- If the Chairman is, for any reason, unable to act, the Committee shall choose any other member to act as Chairman for that sitting
- The Committee may appoint Sub-Committees-whether generally or for consideration of any particular matter.

The Sub-Committees, to be appointed for the purpose, shall be as follows:

- a. a Sub-Committee, to be headed by Secretary in the Department of Revenue for looking into the various aspects of enforcement, and
 - b. a Sub-Committee, to be headed by Secretary in the Ministry of Health and Family Welfare for looking into the various aspects of deaddiction treatment, rehabilitation, social reintegration of drug addicts and other connected matters
- The Sub-Committees shall be assisted by the Director General, Narcotic Control Bureau and the Medical Superintendent Safdarjung Hospital, New Delhi, who shall act as Member-Secretaries of the respective Committees
 - The Committee may, if it deems necessary so to do for the efficient discharge of any of its functions, constitute more sub-committees for the purpose, and may appoint to any

such subcommittee, any person (including a nonofficial) who is not a member of the Committee.

Prohibition, Control and Regulation

• The following operations are prohibited under the NDPS Act

- Cultivation of any coca plant or gathering of any portion of coca plant
- Cultivation of opium poppy or any cannabis plant
- Production, manufacture, possession, sale, purchase, transportation, warehousing, consumption, import, export, etc. of any NDPS substances

Power of Central government

1. The Central government may, by rules, permit and regulate:

- The cultivation of or gathering of any portion of coca plant, or the production, possession, sale, purchase, transport, import, export, use or consumption of cocoa leaves
- The cultivation of opium poppy
- The production and manufacture of the opium and production of poppy straw
- Cultivation of cannabis plant for industrial purpose
- The sale of opium and opium derivatives from the Central Government factories for the export from India or sale to the State Government or to manufacturing chemists
- The manufacture, possession, transport, import, import inter-state, export, sale, purchase, consumption or use of Psychotropic substances
- The import into India and export from India and transshipment of Narcotic drugs and Psychotropic substances

2. The central government may by rules, prescribe any other matter required to render effective the control of the Central Government over any of the matter specified above

- The central government may permit, with or without conditions, and on its behalf, the cultivation of any coca plant or gathering of any portion thereof or the production, possession, sale, purchase, transport, import interstate, export interstate, or import into India of coca leaves for use in the preparation of flavouring agents

Power of State Government

1. The state Government may by rules permit or regulate ;

- The possession, transport, import inter-state, export inter-state, warehousing, sale, purchase, consumption and use of poppy straw
- The possession, transport, import inter inter-state, export inter-state, warehousing, sale,

purchase, consumption and use of opium

- The cultivation of any cannabis plant, production, manufacture, possession, transport, import inter inter-state, export inter-state, sale, purchase, consumption and use of cannabis
- The manufacture of medicinal opium or any preparation containing any manufactured drug from materials which the maker is lawfully entitled to possess
- The possession, transport, purchase, sale, import inter-state, export inter-state, use or consumption of manufactured drugs other than prepared opium and of coca leaf and any preparation containing any manufactured drug
- the manufacture and possession of prepared opium lawfully possessed by an addict registered with the State Government on medical advice for his personal consumption

Offences and Penalties

- **Offences punishable with rigorous imprisonment for 10 to 20 years and a fine of not less than one lakh rupees on first conviction and with rigorous imprisonment for 15 to 30 years and a fine of not less than two lakh rupees on second and subsequent conviction :**
 - a. Contravention of provisions of the act or rules
 - b. Embezzlement of opium by cultivator
 - c. Illegal import to India, export from India or transshipment of narcotic drugs and psychotropic substances
 - d. External dealings in narcotic drugs and psychotropic substances
 - e. Allowing use of premises, conveyance etc., for commission of an offence under the Act
 - f. Financing illicit traffic and harbouring offenders

Death penalty for certain offences after previous conviction:

- If any person who has been convicted of the commission of, or attempt to commit, or abetment of, or criminal conspiracy to commit, any of the offences listed above, is subsequently convicted of similar offences with respect to the narcotic drugs or psychotropic substances specified and which is equal to or more than the quantity specified in this behalf, shall be awarded death penalty
- **Offences punishable with rigorous imprisonment upto 5 years and fine upto 50,000 rupees on first conviction and with rigorous imprisonment upto 10 years and fine upto 1 lakh rupees on second and subsequent conviction**
 - a. Contravention of the provisions in the Act or Rules in respect of cannabis plant and cannabis

related to ganja

- **Offences by licenses or their employees punishable with imprisonment upto 5 years or fine or both:**
 - a. Failure without any reasonable cause, to maintain accounts or to submit any return in accordance with the provisions of this Act
 - b. Failure to produce, without any reasonable cause, licence, permit or authorisation on demand by an authorised person
 - c. Keeping of false accounts or making of false statements
 - d. Wilful and deliberate indulgence in breach any of the conditions of licence, permit or authorisation for which no penalty has been provided elsewhere in the Act
- **Offences punishable with imprisonment upto 1 year or fine or both**
 - Illegal possession in small quantities for personal consumption or consumption of cocaine, morphine, diacetyl morphine or any other narcotic drug or psychotropic substances specified in this behalf
- **Offences punishable with imprisonment upto 6 months or fine or both**
 - Illegal possession in small quantities for personal consumption or consumption of substances other than those mentioned above
 - Offences for which no penalty is provided separately in the Act
- **Punishment for attempt to commit offence**
 - Same as that of commitment of the offence itself
- **Punishment for abetment of criminal conspiracy**
 - Same as that of commitment of the offence itself
- **Punishment for preparation of an offence but where circumstances have prevented the commitment of the offence itself**
 - Half of that for the commitment of the offence itself
- **Punishment of offences by companies**
 - The court have been empowered to impose a fine higher than the maximum provided under the Act
 - The reason for imposing such a fine has to be recorded in the judgement
 - Persons who are convicted outside India for similar offences are liable to enhanced punishment for subsequent offences of the same kind in India

Question Bank

Short answers (2 marks):

1. Write about preparation of first register.
2. Mention the offences and penalties in contravention of Pharmacy Act.
3. Differentiate between State and Joint State Pharmacy Council.
4. Define Education Regulation.
5. Mention the ex-officio members of PCI.
6. Define London proof spirit under M&TP Act.
7. Define rectified spirit as per M&TP Act.
8. Write a short note on Central Drugs Standard Control Organization (CDSCO).
9. What is the punishment specified for illegal cultivation of coca plant.
10. What are objectives of NDPS Act?
11. Define cannabis under NDPS Act.
12. State clandestine arrangement.
13. What is the punishment specified for illegal cultivation of coca plant.
14. What are objectives of NDPS Act?
15. Define cannabis under NDPS Act.
16. State clandestine arrangement.
17. Define London proof spirit under M&TP Act.
18. Define rectified spirit as per M&TP Act.
19. Write a short note on Central
20. Drugs Standard Control Organization (CDSCO).

Short essays (5 marks):

1. Write in detail on first register, subsequent register and removal of name from register as per Pharmacy Act.
2. Discuss in detail about manufacture in bonded laboratory.
3. Write a short note on non-bonded laboratory.
4. Explain about ware-housing of alcoholic preparations as per M&TP Act 1995.
5. What are requirements of bonded laboratory?
6. Explain in brief about alcoholic preparations.
7. Write a note on patent and proprietary preparations.
8. Explain in brief about manufacturing of Ayurveda preparations under M&TP Act.
9. Write in brief about manufacturing in non-bonded laboratories.
10. Explain opium-poppy cultivation as per NDPS Act.

11. Define manufactured drug and controlled substances as per NDPS Act
12. Give the offences and penalties under NDPS Act.
13. Write a short note on Narcotic and Psychotropic consultative committee.
14. Describe the manufacture, sale and export of opium under NDPS Act.
15. Define manufactured drugs.
16. Write the operations controlled by central and state government under NDPS Act.
17. Write a note on manufacture of cocaine and morphine.
18. Explain opium-poppy cultivation as per NDPS Act.
19. Define manufactured drug and controlled substances as per NDPS Act
20. Give the offences and penalties under NDPS Act.
21. Write a short note on Narcotic and Psychotropic consultative committee.
22. Describe the manufacture, sale and export of opium under NDPS Act.
23. Define manufactured drugs.
24. Write the operations controlled by central and state government under NDPS Act.
25. Write a note on manufacture of cocaine and morphine.
26. Discuss in detail about manufacture in bonded laboratory.
27. Write a short note on non-bonded laboratory.
28. Explain about ware-housing of alcoholic preparations as per M&TP Act 1995.
29. What are requirements of bonded laboratory?
30. Explain in brief about alcoholic preparations.
31. Write a note on patent and proprietary preparations.
32. Explain in brief about manufacturing of Ayurveda preparations under M&TP Act.
33. Write in brief about manufacturing in non-bonded laboratories.

Long essays (10 marks):

1. Write the constitution and functions of PCI.
2. Explain in detail about Education Regulation (ER) 1991.
3. Write in detail about Education Regulation of State and Joint State Pharmacy Councils.
4. Define Education Regulation. Mention the standards, regulations prescribed for Education Regulation.
5. What are subsequent registers? Mention the qualifications required for entry into first and subsequent registers.
6. Give the design of bonded laboratory. Discuss in detail about manufacturing of alcoholic preparations in bonded laboratory.

7. Give the design of non-bonded laboratory. Discuss in detail about manufacturing of alcoholic preparations under non-bonded laboratory.
8. Define Drug Inspector. Mention the qualifications, degrees and powers of Drug Inspector.
9. Write the objectives of NDPS Act 1985. Discuss briefly about offences and penalties of NDPS Act 1985.
10. What are the objectives of NDPS Act 1985? Give a detailed account on cultivation, production and sale of poppy straw.
11. Write the objectives of NDPS Act 1985. Discuss briefly about offences and penalties of NDPS Act 1985.
12. What are the objectives of NDPS Act 1985? Give a detailed account on cultivation, production and sale of poppy straw.
13. Give the design of bonded laboratory. Discuss in detail about manufacturing of alcoholic preparations in bonded laboratory.
14. Give the design of non-bonded laboratory. Discuss in detail about manufacturing of alcoholic preparations under non-bonded laboratory.
15. Define Drug Inspector. Mention the qualifications, degrees and powers of Drug Inspector.

