

**MEDICINAL AND TOILET  
PREPARATION ACT-1955  
(EXCISE DUTIES ACT)**

- Alcohol is an important industrial solvent excellent preservative, and a therapeutic agent.
- Use of alcohol both medicinal preparations and toilet preparations are necessity
- It is, however, likely to be misused and it could be a drug of addiction (euphoric drink).
- Alcohol used either for drinking or manufacture of perfumes is subjected to higher duties than that of used in medicine preparation
- Affordability of alcohol is to be controlled.

- An Act to provide for the levy and collection of duties of excise on medicinal and toilet preparations containing alcohol, opium, Indian hemp or other narcotic drug or narcotic.

### *Before commencement of the act*

- Some States were rich in production of alcohol, while others were utilizing this as raw material in manufacture of formulations.
- In the absence of uniform excise policy, the price structure of alcohol containing medicines was varying from State to State within the country.

- After the act, the alcohol required for medicinal purpose can be obtained at lower rate of duty than required for drinking as well as ordinary alcoholic beverages.
- The alcohol obtained at lower rate of duty may be misused for drinking purpose. Therefore it is necessary to control the issue and transport of alcohol by forming Medicinal and Toilet Preparations (Excise Duties) *Act, 1955 (passed) and Rules passed in 1956.*

## Objectives of the Act

The Medicinal and Toilet preparation(Excise Duties) Act, 1955 was passed with the following objectives :

- To provide for the collection of levy and duties of excise on medicinal and toilet preparation containing alcohol, narcotic drugs or narcotics
- To provide for uniformity in the rules and rates of Excise duties leviable on such preparation throughout the country.
- To control the alcohol in terms of its issue, transport and use
- To provide exhaustive rules and provisions are provided to cover all types of preparations containing alcohol including homeopathic preparation

# Definitions

# Definitions

- **Alcohol** means ethyl alcohol of any strength and purity having the chemical composition  $C_2H_5OH$
- ***Absolute Alcohol*** - It is alcohol conforming to the British Pharmacopoeial specification for dehydrated alcohol.
- **Toilet Preparation**: It means any preparation used in the toilet of the human body or in perfuming apparel of any description. It also covers substances used to cleanse, improve or alter the complexion, teeth, skin or hair and includes perfumes and deodorants.
- **Bonded Manufactory or Laboratory** - It is the premises approved and licensed for the manufacturing and storage of medicinal and toilet preparations containing alcohol, opium, Indian hemp and other narcotic drugs on which duty has not been paid.



- *Non-bonded Manufactory or Laboratory* - It is the premises approved and licensed for manufacture and storage of preparations containing alcohol, opium and Indian hemp and other narcotic drugs on which duty has been paid •
- *Denatured Spirit or Denatured Alcohol* - Means alcohol of any strength which has been rendered unfit for human consumption by addition of substances, approved by Central Government or by State Government with the approval of Central Government.



- **Rectified spirit** – It means plain undenatured alcohol of strength not less than 50.0° over proof and includes absolute alcohol.
- **Restricted preparation** - These are medicinal preparation which are considered as capable of being misused as ordinary alcoholic beverages specified in the schedule and include every preparation declare by central govt. as restricted preparation.
- **Excise Commissioner** - He/She is the Head of the Excise Commission of a State and includes a Prohibition Commissioner or an officer designated in any State for the purpose.

# Licensing

# Licensing

- Manufacturing of alcoholic and narcotic preparations can only be undertaken under the authority of a license granted for the purpose and such a license is issued only if the requisite license for the manufacture of drugs under Drugs and Cosmetics Act and Rules has been first obtained.
- Application for the license or for its renewal is to be made to Licensing authority who is the excise commission in the case of a bonded manufactory or warehouse and in other cases, such officer as the government may authorize in this behalf.
- The applicant for the license should submitted in the prescribed form accompanied with the prescribed fee, at least two months from the proposed date of commencement of the manufacture

## **Details required in the form**

1. Name and address of the applicant and place and site on which the manufactory is situated is to be constructed. If the applicant be a firm, the name and address of every partner of firm, and if it be a company, its registered name and address, and the names and address of it's directors, managers and managing agents.
2. The amount of the capital proposed to be invested in the venture.
3. Approximately date from which the applicant desires to commence the manufactory and statement whether the bonded laboratory will require the services of a whole time or a time excise officer and whether quarters for the excise staff will be provided within the manufactory or it's vicinity.

4. The number and full description of vats, still and other permanent apparatus and the machine which the applicant wishes to get up together with the maximum quantity of the alcohol at alcohol content in the finished preparation and the maximum quantities by weight of opium Indian hemp or other narcotic drugs or narcotic and their contents in finished and unfinished preparation.
5. The site and elevation plans of the manufactory/building and also similar plans for the quantity of the Excise Officer together with relevant records.
6. The amount in cash or Government Promissory Notes which the applicant is prepared furnish for the due performance of the conditions on which the licence may be granted.

7. The kind and number of each licence under the drug and cosmetic act held by the applicant.
  
8. A list of all preparations which the applicant proposes to manufacture and /or those manufacture during the preceding year showing the percentage or proportion of alcohol in alcohol preparations or opium, Indian hemp or other narcotic drug in terms of weight in proportion containing those substance, quoting the pharmacopoeia under which such preparations were proposed to be manufactured.

**Manufacture**



# Manufacture

- The manufacture of alcoholic and other narcotic drugs can be undertaken only under the authority of a licence granted for purpose.
- Such licence is issued only when the requisite licence for the manufacture of drugs under the drugs and cosmetic act has been first obtained.
- The licence cannot be transferred or sold and has to be exhibited in a conspicuous part of the licensed premises.

- There are two modes of manufacture of medicinal and toilet preparation containing alcohol,
  - Manufacture in bond; and**
  - Manufacture outside bond**
- In first case, alcohol on which duty has not been paid shall be used under the excise supervision and in the case of manufacture outside bond, only the alcohol on which duty has already been paid shall be used.



In Bond	Outside Bond
<ul style="list-style-type: none"> <li>• Licence</li> </ul>	<ul style="list-style-type: none"> <li>• Licence</li> </ul>
<ul style="list-style-type: none"> <li>• Construction of bonded lab as per law [raw spirit store, manufacturing room, store room for finished goods, excise staff office]</li> </ul>	<ul style="list-style-type: none"> <li>• Construction of non-bonded lab as per law [raw spirit store, manufacturing room, store room for finished goods]</li> </ul>
<ul style="list-style-type: none"> <li>• Excise duty payable on removal of goods from bonded lab.</li> </ul>	<ul style="list-style-type: none"> <li>• Excise duties payable at the time of spirit purchase</li> </ul>
<ul style="list-style-type: none"> <li>• Bonded lab to function under excise staff.</li> </ul>	<ul style="list-style-type: none"> <li>• No excise staff</li> </ul>
<ul style="list-style-type: none"> <li>• Suitable for large scale manufacture.</li> </ul>	<ul style="list-style-type: none"> <li>• Suitable for small scale manufacture</li> </ul>

# *Manufacturing In Bond*

## Manufacture in bonded laboratories

- The licence is issued from office of the Excise Commissioner of the State for alcohol. Application should be made two months in advance prior to date of manufacturing along with requisite fee as indicated.
- The application should include:
  1. Name, addresses and site of bonded laboratory if it is a firm name and address of every partner of the firm ;if it is a company its registered name, address of the managing director and directors.
  2. Capital to be invested for bonded appreciation.
  3. Number and description of apparatus, machinery, still and maximum amount of alcohol to remain at one time
  4. Approximate date of starting manufacturing ; requirement of excise officer, either whole time or part time

## *Structures of the Bonded Manufactory*

1. A separate plain spirit store
2. A separate room for manufacturing of medicinal preparations
3. One or more rooms for storage of finished medicinal preparations
4. A separate room for manufacturing of toilet preparations and their storage
5. A room for excise officer In charge near the entrance with furniture.
6. There should be only one entrance to the laboratory, only one door for each of its compartments
7. Each room in bonded laboratory should have a board indicating name and a serial number of the room and the purpose for which it is used, painted in oil color.



8. The bonded laboratory should be opened and closed in presence of excise officer in charge and secured with excise ticket locks.
9. The spirit should be obtained from the government spirit warehouse approved by the Excise Commissioner.
10. The indent should be sent in duplicate in prescribed form countersigned by the officer in charge of the laboratory.
11. Alcohol is issued in duly sealed containers and under intimation to the Excise Officer concerned.



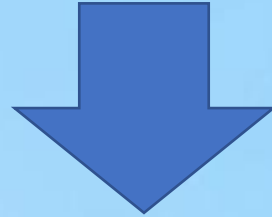
12. The gas and electric supply should be arranged in such a way that they are cut off at the end of day's work from one place.
13. All the regulators or switches should be securely locked.
14. Permanent vessels in bonded laboratory should bear the serial number and statement of full capacity of the vessel.
15. No wastage during transshipment is permissible and for any loss due to negligence of the manufacturer, excise duty has to be paid.

16. Every window should be provided with iron rods not less than 19 mm in thickness set apart at a distance of not more than 102 mm
17. The windows should be covered from inside with strong wire netting, the aperture of which should not exceed 25 mm in diameter.
18. The pipes from sinks in the laboratory should be connected to closed drainage ultimately, forming part of general drainage system.



## *Obtaining of sprit from distillery or sprit warehouse:*

- A distillery or sprit warehouse approved by the excise commissioner supplies the sprit for the manufacture of medical or toilet preparation.



- After receiving the indent the officer-in-charge of bonded laboratory or warehouse officer shall issue the sprit under the appropriate permit.



- No wastage of sprit during its transit from distillery to bonded lab is permitted. The manufacturer is liable to pay duty on any loss of amount of sprit, if some loss occurs due to negligence.

- *Verification and Storage of Alcohol*

- On its arrival in bonded laboratory, alcohol is measured in volume and strength.



- Entries are made in register and stored in spirit store room under excise lock with perfect coordination between excise officer incharge and officer of manufacturing unit.
- The alcohol is issued from spirit store from time to time in accordance with the procedure laid down under Rules.



- *Issue of Alcohol from Store*

- • The manufacturer should calculate requirement of alcohol and hand it over to the excise officer who shall issue the same from the spirit store



- The spirit so issues has to be immediately mixed with other ingredients of the preparation in presence of excise officer.



*The percolators or vessels should be labelled with*

1. The name and batch number of the product
2. Description and quantity of alcohol used
3. Date of manufacture and quantity of preparation removed.

As soon as the mfg of preparation has been completed it should be immediately removed to the finished good store, measured and stored in vessels provided. Details of preparation should be entered in the register

- *Sampling:*

- On completion of medical or toilet preparation, the manufacturer may be permitted to take free sample of each quantity as the officer-in-charge consider necessary for analysis and determination of its alcoholic strength.
- Any quantity left over after the analysis should be returned to finished goods store and mixed with the main bulk of the batch.
- The excise officer-in-charge also withdraw 2 Samples from each batch. each not more than 150 ml.



- One may be sent to chemical examiner and other kept under excise ticket lock.
- After the receipt of the report from the chemical examiner the duplicate sample should be returned to the finished goods store.
- If the chemical examiner declares the strength more than 3 over proof the strength declared by the manufacturer or has been declared to be spurious.

## *Storage of Finished Product:*

- Finished medicinal or toilet preparations may be transferred from the finished store. The goods are arranged in such a way that they can be easily checked from the stock store.
- All finished preparation should be stored in bulk in jars or bottles, each containing not less than 2.5 (80fl.oz) ltr. of the preparation.
- Every container should be labeled with the
  1. Name of Preparation .
  2. Strength
  3. Date of storage,
  4. Actual content in bulk liters.
- Ready for use preparation may be filled in bottles or containers of not less than 50ml. (2fl. oz)

- ***Issue of Alcoholic Preparation from Bonded Laboratories:***

- The manufacturer makes application to excise officer and pays excise duty or it can be adjusted against any advance duty payed by him. Only on payment of calculated duty, the goods containing alcohol and narcotic drugs are permitted to be taken out of bonded laboratory by the excise officer
- Dutiable goods cannot be delivered from the Bonded laboratory or a bonded warehouse before 6.00 am and after 6.00p.m on all working days. No goods are taker out on Sunday or any other proceeding holidays.
- **Exemptions:**
- *The preparations supplied to Government hospitals, dispensaries and charitable hospitals, and institutions which supply medicines to poor as certified by the district medical officer are exempted from payment of excise duties.*

- **Important facts**

## 1- Wastage of Sprit during Manufacturing:

- The permissible percentage of wastage of alcohol during the manufacture of a particular medicine or toilet preparation is fixed the state Govt. from time to time.
- Any wastage exceeding the permissible limit and not properly accounted the manufacturer will be libel to pay the duty on the excess wastage along with any penalty prescribed by the excise commissioner.

## 2- Disposal of Sub-standard preparations:

- A finished medicinal or toilet preparation which have deteriorated in quality may be destroyed by the manufacturer with the permission of the Excise Commissioner.
- He (Excise commissioner) may allow a manufacturer to reprocess a sub-standard preparation If he get satisfied that the deterioration of the preparation was due to reason beyond the control of the manufacturer, he may exempt the excise duty on the preparation

### **3-Disposal of recovered alcohol:**

- Alcohol which is recovered during the manufacture may be used in the manufacture of subsequent batches of some preparation. A separate account should be maintained for it.
- If recovered alcohol declared by the manufacturer to be unfit for consumption shall be destroyed by him in the presence of excise officer-in-charge, on submission of written application

### **4-Remission of duty in case of loss due to accident:**

- In cases of any accidental loss of alcohol in a bonded laboratory (other than theft) due to reason beyond the control of the manufacturer, the duty on the alcohol so lost shall be remitted with the approval of Excise Commissioner

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*Manufacturing Outside*  
*Bond (Non-bonded*  
*Manufactory)*

## *A. Issue of license*

1. Manufacturer has to apply for license to excise commissioner of state
2. Pay prescribed fee to treasury and attach the challan with the application
3. Elevation plan and list of equipments submit with the application
4. The amount of capital proposed and quantity of alcohol needed are informed to licensing authority.
5. Details of constitution of firm
6. If the application is feasible, issue the license



## *B. Structures of the out-Bonded Manufactory*

1. Separate laboratory spirit store and finished store.
2. Only one door to each compartments
3. Separate Manufacturing and finished products rooms
4. Window should provide with 19 mm thick malleable iron rods, set 102 mm apart and covered strong wire net with mesh size not exceeding 25 mm.
5. All pipes from wash basins and sinks are connected to closed drainage forming part of general drainage system.
6. Cut-off gas and electric connections after each day's work
7. Alteration in the building allow only with the permission of Excise commissioner
8. The State Government may relax conditions of requirements of infrastructure if alcohol consumption is less.

### *C. Rectified spirit- procurement*

- Alcohol is procured by the manufacturer after payment of excise duty.
- The form for payment of duty is filled up in triplicate, one copy is to be given to **spirit warehouse keeper**, second to **officer in charge** and third to be **retained by the licensee**.
- The duty for alcohol purchased is to be paid to Government treasury and challan enclosed.
- Thereafter, the treasury officer sends an advice to officer incharge. Sealed containers are required to be used for procurement and storage of alcohol.

## Rate of duty

- a) Allopathic preparations containing alcohol which is not consumable:  
Rs. 10/L
  - b) Allopathic preparations containing alcohol which is consumable: Rs.  
20/L
  - c) Other Allopathic preparations s: Rs. 80/L
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- The alcohol purchased cannot be resold.

## *D. Manufacture*

- The manufacturing and sale operations are restricted only between sunrise and sunset and days and hours as fixed by the Excise Commissioner. Manufacture in licensed premise only
- After preparation, assign batch numbers and enter the consumption in register
- After preparation, transfer it to store
- They must store as per the duty of alcohol
- Maintain stock card

## *E. Sampling*

- Excise officer take the samples and forward to Chemical Examiner for analysis
- - If the chemical examiner of government gives the report that alcohol content is more than what is claimed, the penalty charged is 10 times or maximum of Rs. 2000/- per batch.
- If it occur frequently, License may cancelled

## *F. Inspection*

- Inspected by excise officer
- They inspect at least one in a month
- The state govt can also appoint other officers for this purpose

**WAREHOUSING OF**  
**ALCOHOLIC**  
**PREPARATIONS**

## Warehousing of alcoholic preparations

- Manufacturers and dealers in alcoholic preparations are allowed to establish warehouses anywhere in India for the purpose of depositing goods on which duty has not been paid.
- They should obtain a licence from Excise Commissioner of the State, by making application in form B-2 with a fee of Rs. 25.
- The Excise Commissioner, before granting a licence to any person, may require him to furnish a bond in the prescribed form with security, in cash or kind,
  - binding him to pay duty in the issue of goods deposited in his warehouse or
  - for their safe transport to another warehouse.

**Purpose of bonding**



- All goods, received at the warehouse, should be covered by valid transit permits and should, on their arrival, be produced to the Excise officer-in-charge of the warehouse.
- The goods should also be weighed and gauged in the presence of Excise officer-in-charge of the warehouse and the duty chargeable calculated.
- After that, all particulars (description and quantity of goods, marks and number of packages, number and date of permit and the amount of duty leviable should be recorded in the proper register

- No goods should be removed from the warehouse without the payment of duty, unless they are removed for the purpose of export from India or transfer to another bonded warehouse.
- If any goods are destroyed or lost in the warehouse due to some avoidable reasons, the Excise commissioner may remit the duty thereon provided a notice is given to the officer in charge of the warehouse immediately

- The warehouse owner may separate, pack or repack the goods and make necessary alterations for preservation, sale or disposal of goods with sanction of proper officer.
- No goods, other than the dutiable ones, can be deposited in a licensed warehouse.
- The Excise Commissioner may direct as to how the warehouse should be locked and secured, but the licensee shall be responsible for the safety of the goods in the warehouse at all times.

## **Movement of Goods from One Warehouse to Another**

- When warehoused goods are desired to be removed from one warehouse to another, the consignor or the consignee of the goods should enter into a bond with the Excise Commissioner and furnish security to the extent of at least twice the amount of duty payable on such goods.
- Such a bond shall remain valid, until the officer-in-charge of the warehouse, from which goods were removed, has received a certificate from the officer-in-charge of the warehouse of destination to say that the goods have been re-warehoused.
- The Excise Commissioner may, however, permit a person to transmit goods from one warehouse to another on furnishing a general bond with such security as the Excise Commissioner may prescribe.

- For the removal of goods from one warehouse another, the consignor must present an application (in triplicate) to the officer-in-charge at least 24 hours in advance.
- The officer may then take account of the goods and allow them to be removed from the warehouse. He must send the duplicate copy of the application to the officer-in-charge of the destination warehouse and give a transport permit to the consignor.
- On the arrival of the goods at the warehouse of destination, the consignee should present them to the Excise officer-in. charge, together with the transport permit and the triplicate copy of the application.
- The officer may take account of and gauge the goods and calculate the duty payable on them. Such particulars should then be recorded in the register maintained for the purpose and the goods deposited in the warehouse.

- After the goods have been deposited, the officer-in-charge may issue a re-warehousing certificate to the consignee, and return to him, the triplicate copy of the original application with due endorsement.
- The consignor shall then present to the officer in-charge of his warehouse the triplicate copy of the application, together with the rewarehousing certificate, from the officer-in-charge of the warehouse of destination, within 90 days of the issue of the transport permit to him.
- If the consignor fails to do so, the officer-in-charge may demand duty from him, which should be paid within 10 days of the demand.

- Goods may be kept in a warehouse for a maximum period of 3 years from the date of their deposit or for such extended periods, as may have been permitted by the Excise Commissioner.
- On the expiry of three years or the extended period, if any, the goods must be removed from the warehouse



## **B. Returns**

- The licensee must, within 7 days of the expiry of each month. submit details of the transactions made in the warehoused goods and such other details, as may be prescribed by the State Government in this behalf

## **C. Inter-State Transport of Alcoholic Goods**

- Alcoholic and other preparations can be moved from one State to another only after payment of the duty on the same.
- They may, however, be transferred, under bond, from a bonded warehouse in one state to a warehouse in another State, without payment of duty.
- The procedure required to be followed, in the movement of dutiable goods from one warehouse to another, has been discussed above.

*Manufacture of Ayurvedic,*  
*Homeopathic and patent and*  
*proprietary preparations*

# **Ayurvedic preparations**

# Ayurvedic preparations

Ayurvedic preparations containing alcohol are generally of two types:

- i. Those containing self-generated alcohol, such as 'Asavas' and 'Aristas' and
  - ii. Those which are either prepared by distillation or to which alcohol is added at any stage of the manufacture.
- Ayurvedic preparations containing self-generated alcohol, in which the **alcohol contents does not exceed 2% proof spirit**, are deemed to be non-alcoholic for the purposes of this Act and are, therefore exempt from the payment of excise duty.

- Preparations containing **more than 2% alcohol but which are not capable of being consumed** as ordinary alcoholic beverage are also exempt from excise duty.
- **The preparations which can be consumed as alcoholic drinks are liable to duty of Rs. 1.00 per liter.**
- However, Ayurvedic practitioners, registered under any law for the time being in force, allowed to manufacture and dispense such preparations free of duty, provided they take a license from the Excise authorities and use such preparations only for their patients.

- The practitioner however required to allow excise officers to take samples of the preparations manufactured by them and also maintain accounts of the quantities manufactured and dispensed to the patients, together with the name and addresses of the patients.
- Ayurvedic preparations, which are either made distillation or to which alcohol is added at any stage of their manufacture, are treated as preparations capable of being used as ordinary alcoholic beverages and hence are liable to a duty of Rs. 30 per L.P. liter. They may be manufactured in bond or without bond.

# Homeopathic preparations



# Homeopathic preparations

- All homeopathic preparation containing alcohols are classified as being capable of being consumed as ordinary alcoholic beverages and attract duties
- Prescribes for such class preparations falling under the category of restricted preparations

# **Patent and Proprietary Preparations**

# Patent and Proprietary Preparations

Allopathic preparations containing alcohol can be categorised into 2 categories

- i. Official preparations made according to the formulae given in the B.P.C., I.P., U.S.P., the National Formulary of the United States or Veterinary Codex etc. approved by the Government or any other pharmacopoeia recognised under the Drugs and Cosmetics Act, 1940.
- ii. (ii) Non-Official Allopathic preparations also known as proprietary preparations.

All official and non-official preparations, which are capable of being consumed as ordinary alcoholic beverages, are known as "**Restricted preparations**" and are listed in the Schedule to the Act.

All other standard preparations and proprietary preparations which are not capable of being consumed as alcoholic beverages are referred to as '**Unrestricted preparations**'.

Any of the unrestricted preparations, if widely misused, may be declared to be restricted preparations by the Central Government, either on the request of the State Government or on its own or on the advise of the Standing Committee.

- Any new proprietary preparation containing alcohol is deemed to be a restricted preparation, until it has been declared to be otherwise by the Central Government on the advice of the Standing Committee.
- Any manufacturer, wanting to manufacture a proprietary preparation, should submit two samples of the same together with its formula to the State Government.
- The State Government which, after seeking the advice of the Standing Committee, will declare whether the sample is to be classified as a restricted or as an unrestricted preparation.

The Standing Committee consists of:

- i. The Drugs Controller of India.
- ii. The Chief Chemist, Central Revenues laboratory.
- iii. One pharmacologist nominated by the Central Government.
- iv. The adviser in Indigenous System of Medicine, Ministry of Health

- The committee advises the Central Government on all matters connected with the technical aspects of administration of the Act and the Rules and particularly whether a preparation is to be treated as a genuine medicinal or toilet preparation for the purpose of the Act,
- And if so whether it would be treated or continue to be treated as a restricted or unrestricted preparation.

Thank You