

**MEDICINAL & TOILET
PREPARATION ACT 1955
AND RULES THERE
UNDER 1976**

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INTRODUCTION



- This Act provides for the collection of duties of excise on the medicinal and toilet preparations containing **alcohol, Indian hemp and Narcotic drugs.**
- As per Section 19, the Central Govt. has framed the Medicinal and Toilet Preparations (Excise Duties) Rules, 1956.
- This Act was enforced since **1st April 1957** to all over India.



- The Medicinal and Toilet Preparations Act deals with the regulatory problems resulting from the use of alcohol in many medicinal and toilet preparations.
- It significantly assisted in limiting the largescale inter-state smuggling of alcoholic medicinal and toilet preparations that was previously in existence due to different rates of excise duties in various states. This Act made uniform rates of duty applicable in all over the country.

Objectives



- 1) It provides the collections of **tax and duties of excise** on medicinal and toilet preparations having alcohol, narcotic drugs, or narcotics.
- 2) It provides uniformity in the rules and rates of excise duties leviable on these preparations in all over the country.

Definitions Under the Act



- **Alcohol** is ethyl alcohol of any concentration and purity having the chemical composition C_2H_5OH .
- **Excise Officer** is an officer of the Excise Department of any State and includes any person empowered by the collecting Government to exercise all or any of the powers of an excise officer under this Act.
- **Toilet Preparation** is a preparation which is meant to be used in the toilet or in perfuming apparel of any description or any substance intended to cleanse, improve or alter the complexion, hair, skin or teeth and includes deodorants and perfumes.

Definitions Under the Act



- **Bonded Manufactory** is the site recognized and licensed for the manufacture and storage of medicinal and toilet preparations containing alcohol, opium, Indian hemp or other narcotic drugs on which duty has not been paid .
- **Non-Bonded Manufactory** is the site approved and licensed for the manufacture and storage of the medicinal and toilet preparations containing alcohol, opium, Indian hemp and other narcotic drug or narcotics on which duty has been paid.
- **Rectified Spirit:** It means plain undenatured alcohol of strength not less than 50° over proof and includes absolute alcohol.

Licensing



- Manufacture of alcoholic preparations and narcotics or narcotic drugs can be done only by an authorized licensee to whom the license is issued only if he already has the license for manufacturing drugs under the Drugs and Cosmetics Act and Rules.
- An application for the license or for its renewal is made to the Licensing Authority, who is either:
 - 1) **The Excise Commissioner in case of a bonded manufactory or warehouse, or**
 - 2) **An officer authorized by the State Government.**

Licensing



- A list of the preparations that the applicant means to manufacture and/or those he had manufactured in the previous year along with the percentage or amount of alcohol in alcoholic preparations or opium, India hemp or other narcotic drugs in terms of weight in proportions having those substances, stating the Pharmacopoeia under which these preparations are/were planned to be manufactured.
- On receiving the application, the **Licensing Authority can inquiry** about:
 - **1) The qualifications and earlier experience of the personnel in manufacturing,**
 - 2) The equipment of the bonded and non-bonded laboratory,**
 - 3) The applicant's financial status**
 - 4) The suitability of the building where the manufacturing unit must be built.**

Manufacture In Bond and Outside Bond



Manufacture of Alcoholic Preparations

In Bond

- 1) Licence.
- 2) Construction of bonded lab as per law - necessary compartments (raw spirit store manufacturing room, store room for finished goods, and excise staff office).
- 3) Excise duty payable on removal of goods from bonded lab.
- 4) Bonded lab to function under excise staff.
- 5) Suitable for large scale manufacture.

Outside Bond

- 1) Licence.
- 2) Construction of non -bonded lab as per law-necessary compartments (raw spirit store manufacturing room, finished goods store).
- 3) Excise duty payable at the time of spirit purchase.
- 4) No excise staff.
- 5) Suitable for small scale manufacture.

Manufacture In Bond (Bonded Laboratory)



Only one entrance and one door to every compartment should be provided in the bonded factory. The doors should be protected by excise ticket locks, when the officer-in-charge is not available

Provisions required for the bonded laboratory are

- If the manufactory is not situated near the distillery or spirit warehouse, one plain spirit store should be arranged.**
- A large room should be present to manufacture medicinal preparations and separate arrangements should be there for manufacturing toilet preparations.**



- **Separate rooms should be present to stock up the manufactured medicinal and toilet preparations.**
- **In the bonded premises, a room with basic furniture should be present to accommodate the officer-in-charge.**
- **Each window should be fitted with flexible iron rods.**
- **In the licensed premises, all gas and electrical connections should supply gas or electricity effectively, and every regulators or switches can be locked safely after the working hours.**

Licence for Bonded Laboratory



- To manufacture alcoholic preparations and narcotics (or narcotic drugs), an authorized license is needed, which is issued only if the individual already has the license to manufacture drugs as per Drugs and Cosmetics Act and Rules.
- To obtain the license or in order to renew it, an application is forwarded to the Licensing Authority, who may be:
 - 1) The Excise Commissioner, when the license has to be obtained for a bonded manufactory or warehouse, or
 - 2) An officer appointed by the State Government, when the license has to be obtained for non-bonded manufactory or warehouse.

Licence for Bonded Laboratory



Following **particulars** are included in the **application** submitted to obtain license for manufacture of dutiable goods in bond:

- 1) Applicant's name and address, along with the place and site where the manufactory is established or to be constructed. Application for a firm should include:
 - i) The name and address of each partner associated with the firm, and
 - ii) In case of a company, its registered name and address, and also the names and addresses of the directors, managers, and managing agents.
- 2) The amount of the capital to be invested in the project.
- 3) The expected date of starting the manufactory and the statement to inform if the bonded laboratory requires the whole time or part -time service of an Excise Officer, and whether staff quarters will be provided within the manufactory or the surrounding area.

Fees



- The application for license should be accompanied with following fees:

1) When consumption of alcohol is less than 4,000 L.P. liters per annum

Rs. 100.00

2) When consumption is 4,000 L.P. liters or more

Rs. 200.00

3) Manufacture for sale of Ayurvedic or Unani medicines containing self-generated alcohol or containing alcohol produced by distillation

Rs. 25.00

After attaining the application, the **Licensing Authority** may present query for:



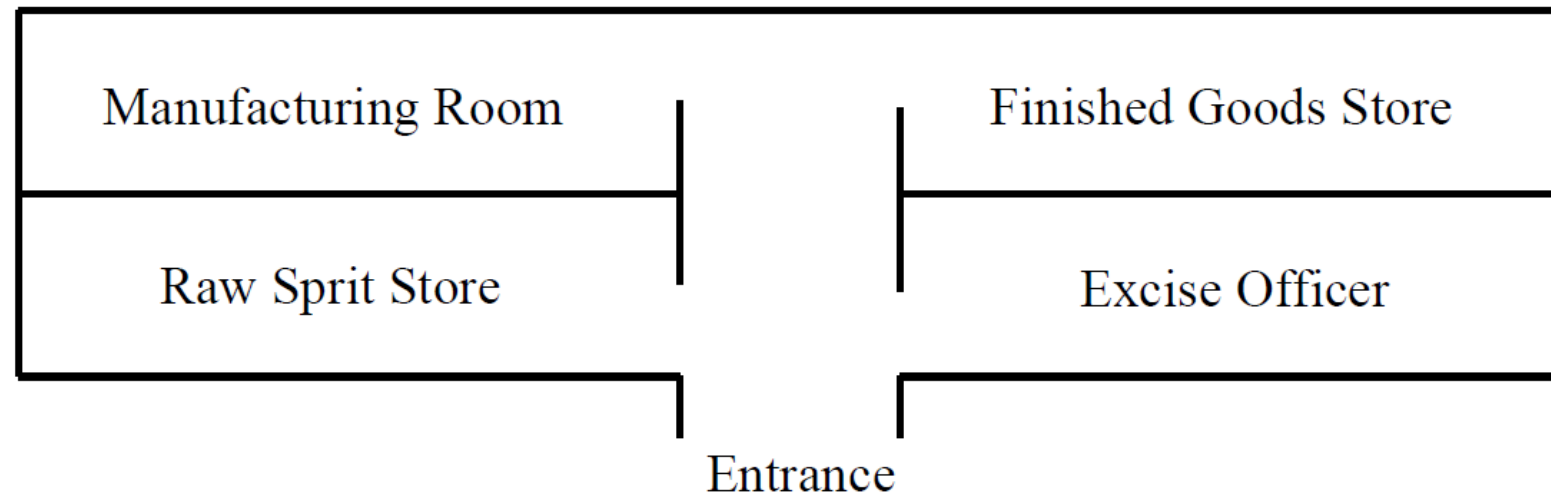
- 1) The qualifications and previous experience of the personnel involved in the manufacturing operations,
- 2) The equipment present in the bonded and non-bonded laboratory,
- 3) Applicant's financial position sustainability, and
- 4) The building where manufacturing is to be carried out.

Design and Construction of Bonded Laboratory



Design and Construction of Bonded Laboratory

A bonded laboratory has the compartments as shown below:



The laboratory should own a single entrance and a single door for each compartment. The laboratory can be opened only when the Excise Officer or in charge is present, and when the officer is unavailable, each door should be secured with excise ticket locks.



- **The sinks pipes of the laboratory should be linked to the drainage system of the premises. Arrangement of the gas and electric connections should allow ease in cutting-off its supply at the end of the working day. Alcohol and other narcotic drugs received under bond should be stored in permanent vessels.**
- **All vessels carrying alcohol and other liquid Preparations should bear a serial number and a statement depicting its full capacity.**
- **At 2.5cm and at 2.5mm, the contents of each vessel should be denoted in tabular form. Excise ticket secured locks are compulsory for vessels having preparations whose duty is pending to be paid .**

Manufacture of Alcoholic Preparations in Bonded Laboratory



- 1) **Procurement of Rectified Spirit:** obtaining rectified spirit to produce medicinal and toilet preparations require attested indent by the officer-in-charge from any distillery or spirit warehouse. As soon as the distillery or spirit warehouse officer receives the duplicate copy of the indent, he should issue the spirit in properly sealed containers. The same should be informed to the office-in-charge.
- 2) **Verification of the Rectified Spirit Received:** At the bonded laboratory, the received consignments of spirit under bond needs to be checked for volume, strength, and the amount entered in the maintained register. The spirit should be stored in the respective store after verification.
- 3) **Issue of the Spirit from the Spirit Store:** The calculated quantity of alcohol can be obtained upon the licensee's request to the officer -in-charge. Manufacturer should keep the other ingredients of the preparation ready and should immediately add alcohol in the presence of the officer -in-charge.



4) Storage of Finished Products: The finished medicinal and toilet preparations should be stored in jars or bottles with capacity of 80 fluid ounce volume. The ready -to-use preparations should be filled in bottles or containers with 2 fluid ounce volume. Permission could be obtained from the Excise Commissioner for filling up of small capacity bottles or containers.

5) Issue of Alcoholic Preparations from the Bonded Laboratory: An application in the prescribed form is sent to the Excise Officer after paying for it, a manufacturer can acquire alcoholic preparations from a bonded laboratory.

6) Deficiencies in Finished Store: A record is prepared and maintained by the officer-in-charge in store for shortages of finished medicinal or toilet preparations. This report should be forwarded to the Excise Commissioner quarterly.



7) Disposal of Sub -Standard Preparations: If the quality of the finished medicinal or toilet preparations have depleted, the manufacturer should destroy it after obtaining permission from the Excise Commissioner. The Excise Commissioner in this case should allow the manufacturer to re - process the preparation (of sub - standard quality).

8) Disposal of Recovered Alcohol: While manufacturing a medicinal or toilet preparation, the alcohol recovered or distilled separately from the mark of such preparation, should be employed in the following manufacture of the same preparation.

9) Remission of Duty in Case of Loss due to Accident: The alcohol lost either accidentally in a bonded manufactory (else by theft) or due to any reason uncontrollable by the licensee is liable to submit the duty with the consent of the Excise Commissioner.

Manufacture Outside Bond (**Non-Bonded Laboratory**)



- The production of medicinal and toilet preparations can be carried out without bond by the manufacturer after availing the respective license. An application for the license in the prescribed form is sent to the officers appointed by the State Government for this purpose.
- The license specifications are same for the manufacturing of medicinal preparations outside bond and in bond. Non –bonded manufactory requires separate premises where only medicinal and toilet preparations will be manufactured.

Licence



- The license required for manufacturing medicinal and toilet preparations without bond can be obtained by giving an application to officers appointed by the State Governments.

The following fee structure should be followed for obtaining a license for non-bonded manufactory:

- a) Consumption of alcohol is 125 L.P. liters or less per annum. ...Rs. 10.00
- b) Consumption of alcohol per annum is more than 125 but less than 500 L.P. liters ...Rs. 25.00
- c) For manufacturing Ayurvedic Unani preparations containing either self-generated alcohol or distilled alcohol. ...Rs. 25.00

Manufacture in Non-Bonded Laboratory



- **Obtaining the Spirit:** Two copies of an application (one to the distiller or the warehouse keeper and the other to the Excise officer -in-charge of the warehouse or the distillery) should be sent for getting spirit, either from a distillery or a spirit warehouse.
- **Manufacture:** The preparations utilizing the duty paid spirit should be manufactured at the authorized premises. After manufacturing the preparations, each one should be assigned a batch number.
- **Storage:** After manufacturing, the finished preparations should be shifted from the laboratory to the finished goods store. Arrangement of these preparations should be such that they allow easy access from the stock register.



- **Sampling:** Samples of 10-15% of the total number of batches manufactured each month should be withdrawn by the Excise Officer (authorized to the non-bonded laboratory) for analysis.
- **Returns:** The manufacturer should keep track on the business transactions in the manufactory. The accounts maintained should be sent to the authorized officer on the 5th of every month.
- **Inspection:** The inspection of the non -bonded laboratory (at least once in a month) should be done by the Excise Commissioner and other Excise Officers authorised in that area.

Export of Alcoholic Preparations



- **In India, the alcoholic preparations are exported duty free. An application in triplicate is submitted by the exporter. This application holds a declaration for the goods to be exported by land, sea, air, or by post parcel to the officer-in-charge or the other concerned officer.**

- 1. Export under Bond**
- 2. Export of Duty Paid Goods**
- 3. Export by Parcel Post**
- 4. Inter-State Transport of Alcoholic Goods**
- 5. Failure to Pay Duty**



1. Export under Bond

The goods should be packed in cases or packages for export from a bonded manufactory or warehouse and the **following details** should be marked in ink or oil colour:

- **Progressive number starting from 1 for each year,**
- **Name of the owner and its special mark (if any), and**
- **Quantity of dutiable goods and their alcoholic content (in L.P. gallons).**

2. Export of Duty Paid Goods

In order to export duty paid goods, the owner of the non -bonded manufactory or a warehouse dealer needs to provide a notice of 48 hours to the concerned officer to supervise the goods packed to be exported.



3. Export by Parcel Post

- After sealing the goods to be exported by post, the exporter needs to present the duplicate copy of application along with relevant packets or packages to the Postmaster at the booking office.

4. Inter-State Transport of Alcoholic Goods

- The inter -state transportation of medicinal and toilet preparations containing alcohol, opium, Indian hemp, or other narcotic drugs is possible once the payment of duty is made. The Excise Commissioner access into a bond with security (to remove goods from time to time) permits to shift goods from one warehouse to another.



5. Failure to Pay Duty

- The authorized officer has power to either continue the bond implemented by the owner or restrain some goods, for which the payment must be done by the owner.
- If the payment is not made within 10 days from the date of detention, the goods held back are sold through public auction or by any possible way ordered by the Excise Commissioner.

Procedures



Many procedures are included in the medicinal and toilet preparations:

- **1) Inspection:** The premises licensed to manufacture or store dutiable goods can be inspected any time. This could be done with or without early notice from the officer authorized by the Excise Commissioner. The building, plant, machinery, etc., are inspected and the records and registers are verified in order to assure the accuracy of returns submitted under these Rules.
- **2) Entry, Search and Seizures:** Excise Officers (superior to sub-inspector) may stop and search any vessel, vehicles, car, etc. or any land, building, enclosed space, vessel, conveyance, etc., at any time. This is done in case of suspicion that manufacturing and storing of dutiable goods is carried against the provisions of the Act and Rules.

Procedures



- **3) Detention and Disposal of Persons and Articles** Excise officers authorized in this behalf by the State Governments can stop and detain an individual who is carrying goods which require a permit for their transport. The permit is required from individuals in possession of dutiable goods. The authorized officers can examine the goods to make sure whether or not they are in conformity with the permit.
- **4) Summons by Excise Officers:** Excise officers (not below the rank of sub - inspectors) can call for any individual to give evidence or produce documents, by serving on him a written notice to this effect. If the summoned individual cannot be found, a copy of the summons may be affixed in the house in which he was living or carrying on with his business

Manufacture of Ayurvedic, Homeopathic, Patent and Proprietary Preparations



- ‘Asavas’ and ‘Aristas’ are the major Ayurvedic formulation types that have self generated alcohol. Recently, the Pharmacopoeias used in many states are known as standard Ayurvedic Pharmacopoeias. Ayurvedic preparations having self generated alcohol in content not more than 2% proof spirit are considered to be non-alcoholic; and thus , are released from the payment of the excise duty.
- American, British and General Pharmacopoeias are considered standard for homeopathic preparations. The Homoeopathic preparations having alcohol are used as ordinary alcoholic beverages, and thus are liable to pay duty prescribed for such preparations.

Patent and Proprietary Preparations



- Allopathic preparations are prepared according to the modern medicine system, and are classified as:
 - 1) Official preparations prepared according to the formulae in the current editions of B.P., B.P.C., I.P., U.S.P., N.F (U.S.), any other pharmacopoeia recognized under the Drugs and Cosmetics Act, 1940 by the Government of India, and Veterinary Codex recognized by the Government of India.
 - 2) Non-official allopathic preparation(proprietary preparation)s prepared according to the allopathic system of medicine and buying the formula on the label l.

Exemption from Duty

- 1. Hospitals and dispensaries under government or Subsidized by the government (state or central)**
- 2. Charitable Hospitals and Dispensaries under local bodies**
- 3. Medical store of government**
- 4. Any Institute certified by District medical officer supplying medicines free to the poor**

Offences and Penalties



Offences	Penalties
1) Non-compliance with conditions of licence and failure to pay duty, or	Imprisonment for up to 6 months or fine of up to ₹200 or both.
2) Failure to supply information asked or supplying false information.	Same as above
3) Attempting or committing or helping commission of any offence.	Same as above
4) Involvement in offences by owners or occupiers of land.	Imprisonment for up to 6 months or fine of up to ₹500 or both.
5) Aggravating search, seizure, etc. by Excise Officer.	Fine of up to ₹ 2000 for every offence.
6) Failure of Excise Officer on duty.	Imprisonment for up to 3 months or fine of up to 3 months' pay or both.
7) Improper keeping of stocks or accounts.	Fine of up to ₹100.
8) Making false entries or tearing pages from stock book.	Fine of up to ₹ 2000 and goods liable to confiscation.



Thank you

