

Chapter-4 | Pharmacy Law & Ethics

Medicinal and Toilet Preparations Act 1955

- This Act was passed in 1955 in regard to collection of tax and excise duties on Medicinal and Toilet Preparations having alcohol, Narcotic drugs or Narcotics and the corresponding rules to the act were passed in 1956.

Definition: The definition and important terms of the Medicinal and Toilet Preparations Act 1955 are as follows-

1. **Alcohol:-** Alcohol is ethyl alcohol of any concentration and purity having the chemical composition C_2H_5OH .
2. **Excise officer:-** It is an officer of the excise department of any state and includes any person empowered by the collecting government to exercise of or any of the powers of an excise officers under this act.
3. **Medicinal preparation:-** Including all drugs which are prescription prepared for external and internal use of human beings or animals in treatment reduction and prevention of disease in human beings or any ones.
4. **Narcotic drugs:-** Those substance which is coca derivative or opium or Indian hemp and shall include any other substance which produced in human beings dependence tolerance and withdrawal of syndrome.
5. **Toilet preparation:-** This act was passed to collect tax and duties of excise imposed on medicinal and Toilet Preparations made up of alcohol and other narcotics drugs.

- **There are two modes of manufacture of medicinal and Toilet Preparations containing alcohol are as follows-**

1. Manufacture In-bond

2. Manufacture outside bond

- In the 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 duties has already be paid shall be used.

1. Manufacture In-bond (Bonded Laboratory) :

- Only one entrance and do to every compartment should be provided in the bonded factory.
- If the manufacturing is not suitable in situated near the distillery of spirit warehouse one plain spirit store should be arranged.
- A large room should be present to manufacture medicinal prepration and separated arrangement should be therefore manufacturing toilet prepration.
- In the bonded premises a room with basic furniture should be present to officers incharge.
- Each window should be fitted with flexible iron rod placed four inches apart depth of 2inches in brick internally covered with strong wire netting or mesh diameter one inches.
- In the manufacturing outside each rooms abroad carrying with specific name and a serial number.
- Each pipe comming from the sink or wash basins in the manufacturing area should be attached to a common drainage system to dispose of the all the waste.

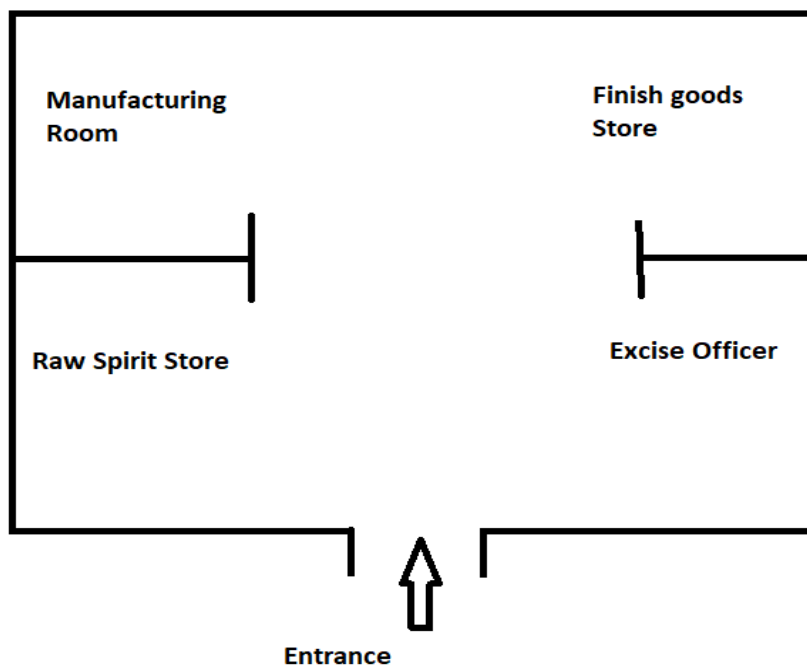


Fig: Bonded Laboratory Design

License for bonded laboratory:

To manufacture alcoholic preparation and narcotics and authorised license is need which is issued only if the individual already has the license to manufactures drugs as per drug and cosmetic act and rules. To obtained the license or in order to renew it and application is forwarded to the license authority who may be -

1. The excise commissioner when the license has to be obtained for a bonded manufacturing.
2. An officer appointed by the state government when the license has to be obtained for non-bonded manufacturing.

2. Manufacture outside bond (Non-bonded laboratory)

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- The production of the Medicinal and Toilet Preparations can be carried out without bond by the manufacturer after availability the respective license. An application for the license in the prescribed form is send to the officers appointed by the state government for this purpose. The license specification are same for the manufacturing of medicinal preparation outside bond and inside bond.
- Non-bonded manufacturing requires separate premises where only Medicinal and Toilet Preparations will be manufactured.

License:

- The license required for manufacturing Medicinal and Toilet Preparations without bond can be obtained by giving an application to officers appointed by the state government.
- The application form and other condition of the license for manufacturing Medicinal Preparation outside bond (Non bond) are the same as those for manufacturing under bond.

The following fee structure should be followed for obtaining a license for non-bonded manufacturing —

- ✓ Consumption of alcohol is 125 L.P litres O less per annum Rs-10
- ✓ Consumptions of Alcohol per annum is more than 125 but less than 500 L.P litres – Rs - 25.
- ✓ For manufacturing ayurvedic unani prepration containg either self generated Alcohol or distilled Alcohol Rs-25.

Offence and Penalties:

- ✓ The offence and related penalties to the medicinal and Toilet Preparations Act are in listed are as follows –

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Sr.	Offences	Penalties
1.	Non-compliance with condition of license and failure to pay duty.	Imprisonment for up to 6 months or fine up to 200 or both.
2.	Failure of excise officer on duty.	Imprisonment for up to 3 months fine up to 2000 or both.
3.	Improper keeping of stocks or accounts	Fine up to 100
4.	Making fake entries or tearing pages from stock books	Fine up to 100
5.	Failure to furnish proof of export within specify period	Fine up to 2000.