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MEDICINAL AND TOILET PREPARATIONS (EXCISE DUTIES)  
ACT, 1955

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## **MEDICINAL AND TOILET PREPARATIONS (EXCISE DUTIES) ACT, 1955 LEARNING OBJECTIVES**

### **The objectives of the Act.**

- The procedure of getting license for manufacturing medicinal and toilet preparations.
- The bonded and non-bonded manufacturing process of alcoholic preparations.
- The export process of alcoholic preparations.
- The offences and penalties of the Act.

### **INTRODUCTION**

Alcohol has excellent solvent properties apart from its preservative mechanism and hence it has found a very important role in the manufacturing of drugs and medicines. Drinking alcohol is an abuse whereas its usage in toilet preparations may be considered as a luxury. For this reason, alcohol, which is used either for drinking or for the manufacture of toilet preparations such as perfumes, is subject to a much higher rate of excise duty than that used for the manufacture of medicinal preparations which cannot be used as ordinary alcoholic beverages. Prior to the enactment of this act, each state in India had an Excise manual and a set of rules of its own. Thus, differences existed in the rates of excise duty for the same item in different states, leading to large scale inter-state smuggling of such preparations. The Act was passed mainly to curb this evil and repealed the laws in force in any state prior to the commencement of this Act. However, any state rules not inconsistent with this Act are still valid and have the same force as if they have been made by an authority in this behalf under this Act.

The Medicinal and Toilet preparations Act was passed in the year 1955 and the Rules were passed in 1956. The Act extends to the whole of India and came into force on 1st April 1957.

### **OBJECTIVES OF THE ACT**

This Act was passed with the following objectives:

- (i) To provide the collection of levy and duties of excise on medicinal and toilet preparations containing alcohol, narcotic drugs or narcotics.
- (ii) 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** alcohol conforming to the British Pharmacopoeial specifications for dehydrated alcohol.

**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 for use in the toilet of the human or in perfuming apparel of any description, or any substance intended to cleanse, improve or alter 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.

**Patent or Proprietary medicines means** any medicinal preparation which bears either on itself or on its container or both, a name which is not specified in a monograph in a Pharmacopoeia, formulary or other publications notified in this behalf by the Central Government in the Official Gazette, or which is a brand name or any other mark such as a symbol, monogram, label, signature or invented words or any writing which is used in relation to that medicinal preparation for the purpose of indicating or so as to indicate a connection in the course of trade between the preparation and some person having the right either as proprietor or otherwise to use the name or mark with or without any indication of the identity of that person.

**Denatured alcohol or Denatured spirit means** alcohol of any strength which has been made 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 strength not less than 50.0° over proof and includes absolute alcohol.

**London proof spirit means** that mixture of ethyl alcohol and distilled water which at the temperature of 51°F weighs exactly 12/13th parts of an equal measure of distilled water at the same temperature.

**Restricted preparation means** every medicinal and toilet preparation specified in the Schedules 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.

## **LICENSING PROCEDURE**

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 manufacture of drugs under the 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 in the case of a bonded manufactory or ware house and in other cases, such officer as the State government may authorize in this behalf. A separate application is to be made if more than one kind of license is desired. Where the applicant has more than one place of business, he should obtain a separate license in respect of each such place of business. The application for the license should be submitted in the prescribed form accompanied by the prescribed fee, at least two months before the proposed date of commencement of the manufacture.

The following particulars are required to be submitted in the application for obtaining a license to manufacture dutiable goods in or outside bond:

- 1.** Name and address of the applicant and place and site on which the manufactory is situated or to be constructed. If the applicant is a firm, the name, and address of every partner of the firm, and if it is a company, its registered name, and address, and the names and addresses of its directors, managers, and managing agents.
- 2.** The amount of capital proposed to be invested in the venture.
- 3.** Approximate date from which the applicant desires to commence the manufactory and the statement whether the bonded laboratory will require the services of a whole-time or part time excise officer and whether quarters for the excise staff will be provided within the manufactory.
- 4.** The number and full description of vatts, still and other permanent apparatus and the machinery which the applicant wishes to get up together with the maximum quantity of alcohol and alcohol content in the finished preparations and the maximum quantities by weight of opium, Indian hemp or other narcotic drugs or narcotic and their contents in finished and unfinished preparations.
- 5.** The site and elevation plans

of the manufactory/building and also similar plans for the quarter of the Excise Officer together with relevant records.

6. The amount in cash or Government Promissory Notes which the applicant is prepared to furnish for the due performance of the conditions on which the license may be granted.

7. The kind and number of each license under the Drugs and Cosmetics Act held by applicant.

8. 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 alcoholic preparations or opium, Indian hemp or another narcotic drug in terms of weight in proportion containing those substances, quoting the pharmacopoeia under which such preparations were proposed to be manufactured.

**On receipt of the application, the Licensing Authority may enquire into the following:**

(i) The qualifications and previous experience of technical personnel engaged in the manufacturing operations.

(ii) The equipment of the bonded and non-bonded laboratory.

(iii) The soundness of the applicant's financial position.

(iv) Suitability of the proposed building for the establishment of the manufacturing unit.

The license cannot be sold or transferred. It should be exhibited in a conspicuous part of the licensed premises. Where a licensee sells or transfers his business to another person, the purchaser or the transferee has to obtain a fresh license but for the residue of the period covered by the license, it is issued free of cost. A licensee can enter into partnership after obtaining the prior sanction of the licensing authority and his license

is then suitably amended. If a partnership is dissolved, every partner is required to send a report of dissolution to the licensing authority within ten days. If a licensee desires to transfer his business to new premises he can do so by informing the licensing authority at least fifteen days in advance, specifying the address of the premises, and getting his license suitably amended.

A license can be revoked, or suspended by the licensing authority if the licensee or an other in his employment is found to have committed a breach of the prescribed conditions or any of provisions of the act or rules, or has been convicted of an offence; after giving him a reasonable opportunity of showing cause against the action proposed to be taken.

The license remains valid for a period of one year and should be renewed thereafter. The application for renewal should be submitted at least one month before the commencement of the year to which it relates.

The licensee also provides a Visit Book paged and stamped by any officer empowered by the Excise commissioner in this behalf, in which the visiting officers may record any remarks when inspecting the licensed premises. On termination of the period of the license, the licensee has to deliver the Visit Book, the account and the license to such officer as directed by the licensing authority. All invoices, cash memoranda, permits and other documents relating to the consignments received and dealt with licensee are to be preserved for a year after the year to which they relate.

## **MANUFACTURE**

Manufacture of alcoholic and other narcotic drugs can be undertaken only under the authority a license granted for the purpose. Such license is issued only when the requisite license for the manufacture of drugs under the Drugs and Cosmetics Act has been first obtained. The license cannot be transferred or sold and has to be exhibited in a conspicuous part of the licensed premises. Manufacture of medicinal and toilet preparations containing alcohol is permitted both 'in bond' as well as 'outside bond'.

### **Manufacture in Bond**

Preparations are deemed to be manufactured in the bond when they are manufactured in the premises, that are licensed or approved for this purpose and on which excise duty is not paid until the finished products are removed from the licensed premises. Rectified spirit is issued for the purpose only if manufacturer enters into a bond with sufficient security towards due payment of the duty.

**A bonded laboratory should have the following provisions:**

1. A spirit store unless the laboratory is attached to a distillery or a spirit warehouse.
2. A large room for the manufacture of medicinal preparations and separate arrangement for the manufacture of toilet preparations.
3. There should be one or more separate rooms for the storage of finished medicinal or toilet preparations.
4. Accommodation with necessary furniture for the officer-in-charge of the bonded laboratory near its entrance.
5. Malleable iron rods not less than 1.9 cm in thickness, set not more than 10 cm apart, embodied in brick work to a depth of at least 5 cm and covered on the inside with strong wire netting or expanded metal of a mesh not more than 2.5 cm in diameter or length, in every window of the bonded laboratory.
6. A board outside every room bearing the name and a serial number of the room.
7. All pipes from sinks inside the laboratory, connected with the general drainage system of the premises.
8. Provisions for cutting off the gas and electric supply to the laboratory at the end of the day's work. There should be only one entrance to the laboratory and only one door for each of its compartments. The laboratory can be opened only in the presence of the Excise officer-in-charge and during his absence, all the doors should be secured with excise ticket locks. Addition or alteration to the permanent fixture in the



premises can be made only with the previous permission of the Excise Commissioner. The permanent vessels for the storage of alcohol, narcotic drugs and narcotics received under bond and all the finished products on which duty has not been paid should be secured with excise ticket locks. All vessels intended to hold alcohol and liquid preparations should bear a distinctive serial number and their full capacity distinctly and indelibly marked on them. Manufacture of Alcoholic Preparations in Bond:

### **1. Procurement of Spirit from a Distillery or Spirit Warehouse:**

Rectified spirit required for the manufacture of medicinal and toilet preparations can be obtained on an indent counter signed by the officer-in-charge of the laboratory, from any approved distillery or spirit warehouse either situated in the same State or in another State. The officer of the distillery warehouse, on receipt of the duplicate copy of the indent, shall issue the spirit in duly sealed containers and send advice of the consignment to the Excise officer-in-charge of the bonded laboratory.

### **2. Verification and Storage of Spirit Received:**

Consignments of spirit received at the laboratory have to be verified in volume and strength by the Excise officer and then stored in the Spirit Store from where it can be issued from time to time to the manufacturer, according to his requisition.

### **3. Issue of Spirit from the Spirit Store for Manufacture:**

Calculated quantities of spirit can be obtained by the manufacturer on a requisition to the officer in-charge who shall then issue the same from the Spirit Store. The spirit so issued has to be immediately mixed with other ingredients of the preparation in the presence of the officer-in-charge. The percolators or other vessels charged with the spirit should be labeled with the following particulars:

- (a) Name and Batch number of preparation.
- (b) Description and quantity of alcohol put in it.
- (c) Date of removal of preparation and the quantity of such preparation removed.

As soon as the manufacture of preparation has been completed, it should be removed to the finished goods store, measured and stored in the vessels provided for the purpose. Details of the preparation should also be entered in a register and it should be given a Batch number. The Excise officer-in-charge may permit the manufacturer to take a sample of not more than 250 ml for analysis purpose, free of duty. A separate account must be maintained by the manufacturer regarding the number of samples used by him for analysis and any amount left over after analysis should be mixed with the main bulk of the batch.

#### 4. Storage of Finished Product:

All finished preparations should be stored in bulk in jars or bottles, each containing not less than 2.25 litres of the preparation. Every container should be labeled with the name of the preparation of its batch number, strength, date of storage and the actual content in bulk litres. The containers should be so arranged in suitable racks so as to allow ready identification of each batch. A record of all deficiencies in bulk content of finished preparations should be kept by the officer-in-charge and Excise Commissioner quarterly. If the Excise Commissioner is satisfied that the deficiency reported was due to some unavoidable reasons, he may remit the duty payable. Otherwise, such loss is subject to levy of duty at a penal rate which shall not be more than double the prescribed rates.

#### 5. Issue of Alcoholic Preparations from Bonded Laboratories:

Alcoholic preparations from a bonded laboratory can be taken out by the manufacturer by making an application to the officer-in-charge and after payment of the excise duty. Duty

is payable even on Physician's free samples. However, preparations issued to a bonded warehouse or for export to a place outside India or to institutions authorized to receive duty free preparations may be issued without the payment of duty.

#### Disposal of Substandard Preparations:

A finished medicinal or toilet preparation if suspected to have deteriorated in quality may be destroyed by the manufacturer with the permission of the Excise Commissioner. The Excise Commissioner may also allow the manufacturer to reprocess a sub-standard preparation. The Excise Commissioner shall waive the duty on the alcoholic content of the preparation so destroyed, if he is satisfied that the deterioration of the preparation or its improper manufacture was due to reasons beyond the control of the manufacturer.

**Disposal of Recovered Alcohol:**

Alcohol recovered in the course of production of a medicinal or toilet preparation may be for subsequent production of the same preparation, provided, such alcohol is collected and accounted separately. Where the alcohol recovered from a preparation liable to duty at the lower rate is sought to be used in the manufacture of a preparation subject to a higher rate of duty, the duty on the preparation so manufactured shall be collected after determining the spirit strength of the preparation. An account of recovered alcohol shall be maintained by the officer-in-charge in the prescribed form. Recovered alcohol unfit for the consumption shall be destroyed by the manufacturer in the presence of officer-in-charge. No rebate of duty shall however, be allowed on recovered alcohol so destroyed.

**Wastage of Spirit during Manufacture:**

The permissible percentage of wastage of alcohol during the manufacture of a particular medicinal or toilet preparation is fixed by the State Government from time to time. Any wastage exceeding the permissible limit and not properly accounted for shall be charged with the duty together with such penalty not exceeding the duty leviable thereon as the Excise Commissioner may deem fit.

**Remission of Duty In Case of Loss Due to Accident:**

In case of any accidental loss of alcohol in bonded manufactory (except on account of

theft), the Excise commissioner may remit the duty on the alcohol so lost, if he is advised by the Excise Officer in-charge of the laboratory that the loss was beyond the control of the Manufacturer.

#### **4.5.2 Manufacture Outside Bond**

Preparations are deemed to be manufactured outside bond when they are manufactured in a premise, licensed or approved for this purpose and where duty paid spirit is used for the preparation. The manufacture and sale in a non-bonded laboratory have to be conducted between sunrise and sunset on days and hours fixed for this purpose by the Excise Commissioner.

##### **1. Receiving Duty Paid Spirit:**

Rectified spirit can be obtained from any distillery or spirit warehouse on an indent prepared in triplicate. The original copy is sent to the distiller or spirit warehouse keeper, the duplicate is sent to the officer in-charge of the distillery or spirit warehouse and triplicate is retained by the licensee. The duty should be paid to the Government Treasury and a challan in token of such payment should be enclosed along with the duplicate copy of the indent being sent to the officer-in charge of the distillery or spirit warehouse. The treasury officer sends advice to the officer-in-charge of the distillery or the spirit warehouse who shall issue the spirit together with a permit covering the issue. The spirit so brought into the non- bonded manufactory has to be immediately transferred to the spirit store and the necessary accounts written up in the prescribed register. The manufacturer cannot sell or transfer the rectified spirit obtained by him. In any case, the quantity of rectified spirit in the possession of the manufacturer should not exceed the limit fixed by the licensing authority.

##### **2. Manufacture, Storage, and Sale:**

The manufacture, storage, and sale should be carried out in the licensed premises only. Each preparation should be registered and bear a distinctive batch number. All

finished preparations should be transferred from the laboratory to the 'finished store' and be so arranged that the checking of stock of every batch of preparation from the register is facilitated. Preparations stored in bulk should be measured into the storage vessel to the nearest fluid ounce and sealed. The quantities taken out from time to time should be entered in the stock card maintained for the purpose.

### **3. Sampling:**

Without previous notice to the manufacturer, the excise Sam officer shall take samples of not less than 10% and not more than 15% of the total number of preparations from the finished stocks at least once every month. These samples are forwarded to the chemical examiner for the verification of alcohol contents thereof. If the report of the chemic examiner differs by more than 3° proof strength as declared by the manufacturer, the manufacturer is liable to a penalty at the rate of 10 times the difference in duty on the quantity so manufactured but not exceeding ` 2000. The frequent occurrence of such offence shall be ground for the cancelation of the license held by the manufacturer. All samples are to be taken by the excise officer personally and in the presence of the manufacturer or his authorized agent. Every sample (8 fluid ounces or as fixed by the Excise Commissioner) should be taken in duplicate and the cork of each bottle should be fixed with an officer's personal seal. The label of the bottle should be signed by the officer taking the sample. The manufacturer can also affix his seal and sign the labels. Duplicate samples are to be preserved carefully under lock and key and returned promptly to the manufacturer when needed no more. The manufacturer is not entitled to any compensation for the samples taken for analysis.

### **4. Returns:**

The manufacturer should maintain up-to-date and proper accounts of the transactions of a business in his manufactory and deliver them to the proper officer by the 5th of each month. The manufacturer is also required to furnish a list of all his employees who are required to enter non-bonded manufactory, to the Excise Commissioner and only such persons should be allowed to enter the laboratory.

**5. Inspection:**

The non-bonded laboratory can be inspected by the Excise Commissioner and other having jurisdiction over the area in which the manufactory is situated. It shall be inspected at once every month by the proper Excise officer. The State Government may authorize inspection of the non-bonded establishment by any officer of Prohibition, Land Revenue or Medical and Public Health Departments.