

Medicinal and Toilet Preparations (excise duties) Act, 1955 and Rules thereunder 1976

The present Act prescribes uniform rules for whole of the country regarding duty leviable on such preparations. Alcohol may be used in the manufacture of medicines and toilet preparations. The alcohol required for this purpose can be obtained at lower rate of duty than required for drinking as ordinary alcoholic beverages.

This Act extends to the whole of India and provides legal binding on the use of alcohol.

A. Objective

It provides for the levy and collection of duties of excise on medicinal and toilet preparations containing alcohol, opium, Indian hemp, or other narcotic drugs and narcotics.

B. Definitions

Alcohol: Alcohol means ethyl alcohol of any strength and purity having chemical composition C_2H_6OH .

Dutiable goods: It includes the medicinal and toilet preparations specified in the schedule as being subject to the duties of excise levied under this Act.

Medicinal Preparation: It includes the drugs used as a remedy or prescription prepared for internal or external use of human beings or animals and all substances intended to be used for or in treatment, mitigation or prevention of disease in human being or animals.

Toilet Preparation: The preparation intended to be used in the toilet of human body or in perfuming apparel of any description, or any substance intended to cleanse, improve or alter the complexion, skin, hair or teeth, and includes deodorants and perfumes.

Bonded Manufactory: It means the premises or any part of the premises approved and licensed for the manufacture and storage of medicinal and toilet preparations containing alcohol, opium, Indian hemp and other narcotic drugs or narcotics on which duty has not been paid.

Non-bonded manufactory: It means the premises or any part of the premises approved and licensed for the manufacture and storage of medicinal and toilet preparations containing alcohol opium, Indian hemp and other narcotic drugs or narcotics on which duty been paid.

Denatured Spirit or Denatured alcohol: It 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 the approval of the Central Government.

Spirit Store: It is the part of the bonded or non-bonded manufactory used for the storage of alcohol, opium, Indian hemp and other narcotic drugs or narcotics purchased free of duty or at prescribed rates of duty specified in the Schedule to the Act.

Restricted Preparation: These are medicinal preparations which are considered as capable of being misused as ordinary alcoholic beverages.

Unrestricted Preparation: These are medicinal preparations which are considered to be not capable of being, misused as ordinary alcoholic beverages.

Substandard Preparations: It includes:

- (a) A pharmacopoeial preparation in which the amount of any of the various ingredients is below the minimum i.e. requirement.
- (b) A proprietary medicine, not conforming to the formula displayed on the label.

C. Manufacture

Manufacturer gets the rectified spirit required for manufacture of medicinal and toilet preparations from a distillery or a spirit warehouse of the state. If there is a loss of rectified spirit due to the wastage in transit, and if the Excise Commissioner satisfies that the loss is bonafide and due to negligence by the manufacturer, the duty payable in respect of such loss may be waived in full or in part depending on the circumstances.

Permission of State Government is necessary to claim the concessions in duty in case of the issues of rectified spirit made to non-bonded manufactories.

There are two modes of manufacture of medicinal and toilet preparation containing alcohol,

(i)

Manufacture in bond; and

(ii)

Manufacture outside bond.

In the first case, alcohol on which duty has not been paid shall be used under the excise supervision and in case of manufacturer outside bond, only the alcohol on which duty has already been paid shall be used. **Procedure for license:**

Every person, desiring to manufacture Medicinal and Toilet preparation containing alcohol or other narcotic substances is required to obtain a license,

- (1) From the Excise Commissioner in case of a Manufacture in Bond; and
- (2) From the officer as the State Government may authorise in this behalf in case of manufacture outside bond.

The application for grant of license should be submitted in the prescribed form together with prescribed fee (treasury chalan) so as to reach the licensing authority at least two months before the proposed date of the commencement of the manufacture.

Such application should contain the following particulars:

- (1) The name or names and address or addresses of the applicant or applicants.

In case of a firm, the name and address of every partner. In case of a company, its registered name and address, the names and addresses of its Directors, Managers and Managing agents.

- (2) Name and address of the place and the site on which the Bonded or Non-bonded Laboratory is situated or to be constructed.

- (3) The amount of capital proposed to be invested.

- (4) Approximate date from which the applicant desires to start the manufacture if the required license is granted.

- (5) The number and full description of the vats, stills and other permanent apparatus and machinery which the applicant wishes to set up.

- (6) The maximum quantities in L.P. Liters of alcohol and alcoholic content in unfinished and finished preparations are likely to remain in the laboratory at any one time; and Maximum quantities by weight of opium, Indian hemp or other narcotic drug and their content in unfinished and finished preparations are likely to remain in the laboratory at one time.

- (7) In case of Bonded laboratory, whether the proposed bonded manufactory will require the services of a whole-time or part-time excise officer.

- (8) A list of all preparations, that the licensee proposes to manufacture showing,

(i) The percentage or proportion of alcohol in such preparation containing alcohol. (ii) The quantities of opium, Indian hemp or other narcotic drugs in terms of weight in preparations containing these substances.

(9) The kind and number of licences held by the applicant under the Drugs and Cosmetics Act, 1940.

(10) Site and elevation plans of the manufactory building or buildings showing the location of the different rooms with doors and windows therein.

(11) In case of a firm, a true copy of the partnership deed. And in case of a company, the list of the Directors and Managers together with copies of Memorandum of Association and Articles of Association.

On receipt of such application the licensing authority makes the following enquiries:

- (a) The qualifications and experience of the technical persons.
- (b) The equipment of the bonded or non-bonded laboratories,
- (c) Suitability of the proposed building for the establishment of a laboratory.

After satisfying that the applicant is eligible for the issue of a license, the licensing authority (the Excise Commissioner) shall issue a license and approve the plans of buildings submitted along with the application by the applicant. After constructing the buildings and establishing the laboratory as per the approved plans, the planning authority shall verify the plans to ascertain whether the construction is as per the approved plan or not.

In some cases where security is required to be furnished the licensing authority shall fix the amount of such security before granting the license. The security shall be either in cash or in interest bearing securities like Government Promissory Notes, National Savings Certificates, etc.

I.

Bonded Laboratory or Bonded Manufactory

Following are the requirements of the bonded laboratory:

1. A spirit store, (if a distillery or a rectified spirit warehouse from which rectified spirit is made available, is not attached with the laboratory).
2. Room or rooms for the manufacture of medicinal preparations.
3. One or more rooms for the storage of the finished medicinal preparations.
4. A separate room or arrangement for the manufacture of toilet preparations. 5. The storage room for the finished toilet preparations.

6. Accommodation near the entrance for the officer-in-charge with necessary furniture.
7. Every room in the bonded laboratory should bear a board indicating the name of the room and serial number.
8. The pipes from sinks or wash basins in the laboratory should be connected with the general drainage of the laboratory.
9. The arrangements of gas and electric connections should be such that their supply can be cut off at the end of the day's work.
10. Every window in the bonded laboratory would be provided with specific arrangement of malleable iron rods of prescribed dimensions and the window should be covered on the inside with strong wire netting of a mesh not exceeding 25 mm.
11. There shall be only one entrance to the bonded laboratory and one door to each of its compartments. All the doors shall be secured with excise ticket locks in the absence of the officer-in-charge. No alterations in the bonded premises shall be made without the previous orders of the Excise Commissioner.
12. All vessels intended to hold alcohol and other liquid preparations should bear a distinctive serial number and full capacity.
13. The vessels for the storage of alcohol, opium, Indian hemp and other narcotic drugs and all the finished preparations on which duty has not been paid should bear excise ticket locks.

For the manufacture in bonded laboratory, the rectified spirit shall be issued without previous payment of duty subject to the condition that the manufacturer enters into a bond in prescribed form with sufficient security.

Obtaining the rectified spirit from the Distillery or spirit warehouse approved the Excise Commissioner:

The spirit required for the manufacture in bond shall be obtained on an in prescribed form countersigned by the officer in-charge of the laboratory from the approved spirit store or distillery. After receiving the duplicate of indent from the officer in-charge of the bonded laboratory, the distillery or warehouse officer shall issue the spirit under the appropriate permit,

and send the advice portion of such permit to the officer-in-charge. The cost price of such rectified spirit shall be paid by the licensee to the distiller warehouse officer.

Verification and Storage of rectified spirit received: After receiving the rectified spirit, it is verified in volume and strength and entered in the register. Then the spirit is stored in the spirit store.

Issue of the rectified spirit from the spirit store for manufacture:

The licensee should calculate the requirement of spirit on the basis of the formula of the preparation in pharmacopoeia or formula displayed on the label and hand it over to the officer in-charge. Officer-in-charge shall then issue the spirit to the manufacturer. All rectified spirit issued shall be added immediately to the other ingredients of the preparation in presence of the officer-in charge.

The manufacturing vessels like percolators charged with alcohol should bear a label indicating

- (a) The name and batch number of the preparation.
- (b) Description and quantity of alcohol placed in it.
- (e) Date of removal of the preparation and the quantity of such preparation removed.

On completion of the manufacture of a medicinal and toilet preparation, it should be removed to the finished goods store. With the permission of officer-in-charge, the licensee shall take specified quantity of the free sample for analysis in his laboratory.

Storage of finished products:

1. Finished preparations should be stored in bulk in jars or bottles each containing not less than 2,273 ml.
2. The preparations ready for issue may be filled in the containers of not less than 57 ml capacity. In some cases the Excise Officer may authorize issue in smaller containers.
3. Every container should be labeled and the label should contain:
 - (a) Name of the preparation.
 - (b) Batch number.
 - (e) Alcoholic strength; and
 - (d) Name of the manufacture.
4. The label on the container in which the preparation is stored in bulk should in preparation is

stored in bulk should in addition indicate alcoholic content in liters, alcoholic strength and the date of storage. 5. The containers are so arranged on the rack so as to allow ready identifications of each batch.

6. The finished preparations may be stored in a store room for a period of three years or more with the permission of Excise Commissioner.

Issue of preparations from bonded laboratory:

For taking out the preparations from a bonded laboratory, the licensee should apply in prescribed form to Excise Officer-in-charge. After checking the entries and realizing the duty payable, the officer-in-charge shall issue a permit and allow the required quantities to be removed. However, the issue to another bonded warehouse may be made without payment of duty under proper security governed by the rules under this Act.

II.

Non-Bonded Laboratory or Non- Bonded Manufactory

The manufacture and sale in the non-bonded laboratory should be conducted between sunrise and sunset only and on such days and hours as may be fixed by the Excise Commissioner.

Building Arrangements:

1. The portion of the non-bonded laboratory should be separated from the other portion used for other business.
2. There should be separate 'spirit store', laboratory' and finished store' and these should have the windows fitted with malleable iron bars of specific dimensions and the windows should be covered on the inside with strong wire netting of mesh not exceeding 25 mm.
3. There should be only one entrance to the non-bonded manufactory and one door to each of the above-mentioned departments.
4. All the pipes from sinks and wash-basins inside the non-bonded laboratory should be connected with the general drainage system of the premises.
5. The arrangements of gas and electric supply should be such that their supply can be cut off at the end of day's work.
6. There should be separate spirit store for the rectified spirit purchased at different rates

of duty.

7. There should be separate finished stores for medicinal and toilet preparations falling under each item of the schedule to the act e.g., pharmacopoeial preparations with the items like, Aquas, Elixirs, Lotions, spirits etc., and Non-pharmacopoeial preparations. The State Government may relax the provisions in case of small manufacturers whose annual consumption of alcohol is not more than 500 litres and in the case of those who prepare medicinal preparations for dispensing to their patients only and not for sale.

Obtaining the rectified spirit-duty paid:

To obtain the spirit for manufacturing medicinal and toilet preparations from approved distiller or a spirit warehouse, the licensee should send the indent along with treasury chalan (evidence of duty payable) to the officer-in-charge of the distillery. The cost of such rectified spirit shall be paid by the licensee to the distillery or spirit-warehouse-keeper.

The officer-in-charge of the distillery, after satisfying himself that the correct amount of duty has been paid shall order the issue of rectified spirit required together with a permit covering the issue. After entering in the proper register, the spirit so obtained should be transferred to the respective spirit store.

Manufacture and storage of the preparations:

1. The manufacture of preparations from duty paid spirit should be carried out only at the licensed premises.
2. Each preparation should be registered after its manufacture and given a distinctive batch number.
3. All finished preparations should be transferred from the laboratory to the finished store and so arranged that they can be easily checked from the account register.
4. Finished preparations prepared from rectified spirit obtained at different rates of duties should be stored separately in the finished store.
5. The finished preparation stored in bulk should be measured in the storage vessel to the nearest fluid ounce (28.350 ml) and sealed.
6. The quantities from the bulk storage taken out by the manufacturer from time to time should be entered in the stock-card attached thereto. The Excise Officer, without any

previous notice to the manufacturer may take samples at least once a month for analysis.

D. Exemption from Duty

The followings are exempted from duty on medicinal preparations containing alcohol manufactured in India and supplied direct from a bonded manufactory or warehouse. 1. Hospitals and dispensaries under Government or subsidized by the Government (State or Central).

2. Charitable hospitals and dispensaries under local bodies,

3. Medical Stores of Government.

4. Any institution certified by District Medical Officer supplying medicines free to the poor.

The Government has power to exempt any dutiable goods from the levy of the duty in the interest of the trade or in public interest.

E. Classification of Medicinal and Toilet Preparations Containing Alcohol

(A) Allopathic Preparations:

(a) Official allopathic preparations.

(b) Non-official allopathic preparations (Patent and Proprietary Preparations).

(B) Homoeopathic Preparations.

(C) Ayurvedic Preparations.

Medicinal and Toilet preparations are also classified as

(i) Restricted preparations.

(ii) Un-restricted preparations.

Allopathic Preparations:

Official preparations are made according to the formulae given in official books like I.P, B.P, B.P.C., U.S.P., N.F., Veterinary Codex (Government of India) etc.

Non-official allopathic preparations are prepared according to the allopathic system of medicine and conform strictly to the formula displayed on the label. The official and non official preparations, capable of being consumed as ordinary alcoholic beverages are known as 'Restricted Preparations'. Central Government may declare the unrestricted preparations as restricted preparations if they are widely misused.

Proprietary preparation which is newly put in the market is presumed to be a restricted preparation unless declared to be otherwise by the Central Government on the advice of the Standing Committee. Any manufacturer intending to manufacture a new non-official alcoholic preparation should

submit two samples of such preparations with the recipe to the State Government. The State Government, on advice of the Standing Committee, shall declare the class of such preparation, whether restricted or unrestricted.

Homoeopathic Preparations:

American, British and general pharmacopoeias shall be recognized as standard pharmacopoeia for Homoeopathic preparations.

Ayurvedic Preparations:

Ayurvedic preparations containing alcohol may be of two types:

- (1) Those containing self-generated alcohol e.g. Asavas and Aristas.
- (2) Those prepared by distillation or to which alcohol is added at any stage of manufacture.

Duty shall not be levied on Ayurvedic preparation containing self generated alcohol in which the alcoholic content is less than 2 per cent. In case of the preparation, the alcoholic content of which is more than 2% and if it is capable of being consumed as ordinary alcoholic beverages, the duty shall be paid, otherwise not.

Registered Ayurvedic Practitioners are allowed to manufacture and dispense (except by distillation or by addition of alcohol during the process) such preparations are free of duty, provided:

- (a) They take a license.
- (b) Use such preparations only for the patients of the practitioners and not for sale to the general public.
- (c) They should allow Excise Officer to draw samples of such preparations to ensure that the preparations contain only self-generated alcohol; and
- (d) They should maintain accounts of the preparations manufactured or dispensed to the patients together with the names and addresses of the patients. The Ayurvedic preparations may be manufactured in bond or without bond.

F. Warehousing of Alcoholic Preparations The manufacturers or dealers in dutiable goods are allowed to establish bonded warehouses

anywhere in India to deposit dutiable goods. The persons who intend to establish a warehouse should apply in prescribed form along with prescribed fees to Excise Commissioner of State and obtain a license for the purpose from him. The Excise Commissioner may require the licensee to furnish a bond in prescribed form with surety or security, binding him to pay duty on the goods deposited or for removal of such goods to another warehouse or for the due observance of the terms, conditions and requirements of the Act. All such goods brought for warehousing should be produced to the officer-in-charge of the warehouse with the relative transport permit. Before the entry in the warehouse, the goods should be weighed, gauged and assessed to duty and the particulars should be recorded in the register maintained for the purpose. The bonded warehouse should be locked and secured as per the directions of Excise Commissioner.

Goods shall not be removed from any warehouse without payment of duty. Duty shall not be paid for the removal of goods to other warehouse or for export. Goods shall remain in the warehouse in which they are deposited for three years or more as the Excise Commissioner allow.

G. Export of Medicinal and Toilet

Preparations (Alcoholic Preparations):

No duty shall be paid on alcoholic preparations which are exported from India. The preparations can be exported by two methods:

- (1) Duty paid goods shall be exported under claim for rebate of duty.
- (2) Goods (without payment of duty) shall be exported under bond.

I. Export of Duty Paid Goods:

Export of Duty paid goods shall be made under claim for rebate of duty. The owner of the non bonded manufactory or a wholesale dealer who wants to export duty paid goods should give minimum 48 hours' notice to the concerning Excise-Officer to supervise the packing of the goods which are to be exported. The manufacturer or dealer should present the consignment to be exported to the concerning officer who shall send the samples of such dutiable goods to the

Chemical Examiner for analysis to confirm the alcoholic contents of these goods. From the report of Chemical Examiner, the officer shall enter the alcoholic contents (strength) in the duplicate copy of the application which shall be presented to Excise Commissioner by the exporter for claiming rebate of excise duty.

After verifying the application, the officer-in-charge or concerning officer shall get the following particulars noted on the packages:

- (1) Name and address of the consignee.
- (2) Total quantity of the goods packed.
- (3) Description of the goods packed.
- (4) Alcoholic strength of the goods in London-proof (L.P.) liters.
- (5) A Gross weight of each package.

The Officer-in-charge shall then seal each package with his official seal and endorse all the copies of the application specifying the period within which the goods shall be actually exported. The Officer shall return the duplicate to the consignor, who has to enter the number and date of the railway receipt or bill of landing in duplicate copy, after dispatching the goods. The consignor should inform these particulars to the concerning officer for entry in the other copies. On arrival of the goods at the consignee's place (place of export) the goods should be presented to the Customs Collector, Border Examiner etc. for examination, along with duplicate application. After such examination the Customs Collector, Border Examiner such officers of customs may allow export. For obtaining the payment of rebate the exporter should produce to the Excise Commissioner, the duplicate application along with the certificate of the officer who examined the goods. The Excise Commissioner if satisfied from the comparison of duplicate and original application that the claim is in order, he shall sanction the rebate claimed by the exporter.

II. Export under Bond:

The owners of the bonded manufactory or bonded warehouse can export the alcoholic preparations under bond. The exporter should present an application in triplicate to the Excise Officer-in-charge of the bonded laboratory or warehouse, giving the statements that the goods are to be exported by sea or air or by parcel post. The packages of the goods to be exported

should be marked in ink or oil color with the particulars like serial number, owners name and special mark if any and total quantity of the dutiable goods with their alcoholic strength in L.P. liters. On verification of the particulars in the application, the Officer-in-charge also note the following particulars on the packages,

- (1) Name and address of the consignee (to whom the goods are to be exported).
- (2) Description of goods.
- (3) Total quantity of the goods packed.
- (4) Gross weight of the package.

The officer may seal each package with his official seal. The packages can be exported in the same way as that of duty-paid goods.

Inter-State movement of Medicinal and Toilet Preparations under the Act:

Medicinal and Toilet preparation under this Act can be moved from one State to another after payment of duty as per the rules. Such dutiable goods can also be transferred from a bonded warehouse of one State to the bonded warehouse of the other State. The procedure for the same is described in the further paragraph.

Movement of dutiable goods from one Bonded Warehouse to another Bonded warehouse:

When the goods are to be removed from one warehouse to another, the consignor or the consignee should enter into a bond with surety or sufficient (prescribed) security. Such bond shall be furnished to the officer-in-charge of the warehouse of removal or of the warehouse of destination as the case may be. Such bond shall remain valid until the Officer-in-charge of the warehouse of removal has received a re-warehousing certificate (stating that the goods have been re-warehoused) from the Officer-in-charge of warehouse of destination. The consignor should make an application in triplicate for removal of goods from one warehouse to another warehouse to the officer-in-charge of the warehouse together with other necessary information as the Excise Commissioner may require at least 24 hours before the removal of goods.

The officer-in-charge shall take the account of goods and send the duplicate copy after giving remark for removal to the officer-in-charge of the warehouse of destination. And the triplicate copy shall be given to the consignor to send to the consignee.

On arrival of the goods at the destination, the consignee should present such goods along with the triplicate application and the transport permit to the officer-in-charge. Then he shall take account of goods and complete the re-warehousing certificate on the duplicate and triplicate and return the duplicate to the officer-in-charge of the warehouse of removal and the triplicate to the consignee for dispatch to the consignor. The consignor shall then present such triplicate copy of the application together with the warehousing certificate to the officer in-charge of his warehouse within 90 days of the issue of the transport permit to him.

G. Entry, Search and Seizure

An officer authorized by Excise Commissioner shall have free access at reasonable time to any premises, equipment, stocks and accounts of manufacturers and dealers in dutiable goods. Any excise officer authorized in this behalf by the State Government may stop and detain any person carrying or removing any dutiable goods without transport permit or other relevant document required.

Excise Officers, not below the rank of sub-inspectors has power to stop search and seize the vessel or vehicle carrying the dutiable goods. He has also power to enter and search at any time, any premises or land in which he has reason to believe that dutiable goods are stored, manufactured in contravention of the Act and Rules there under. In case of any resistance to entry or search or; seizure he has power to break open any door and remove any other obstacle and open and search into such land or premises.

Such officer may also seize and remove or detain any receptacle, packages or coverings of such goods and animals, vehicles or vessels involved in carrying the goods and the machinery used in the manufacture of such goods. All such searches, seizures etc., made under the Act are in accordance with Criminal Procedure Code.

I. Offences and Penalties

1. (a) Contravention of any of the provisions relating to the terms and conditions of a license granted under this Act; or
- (b) Failure to pay any duty of excise payable under this Act; or
- (c) Failure to supply required information or supplying false information; or
- (d) Attempt to commit or abet any of the above offences.

Punishable with imprisonment up to six months or with fine up to Rs. 2,000/-or with both.

2. Connivance by any owner or occupier of land or by any agent of such owner occupier for any offence against the provisions of this Act, or any rules there under. Punishable with imprisonment up to six months or with fine up to Rs. 500 or both for every offence.

3. Vexations search, seizure by any officer exercising powers under this Act or under the rules made there under.

Punishable with fine up to Rs. 2,000/-.

4. Refusal to perform or withdrawal of one-self from the duty by the Excise Officer without permission of the superior officer.

Punishable with imprisonment up to three months or with fine up to three months pay.

5. Failure to furnish proof of export, within the prescribed period to the satisfaction of Excise Commissioner, by any persons authorized to export dutiable goods in bond.

Punishable with a fine up-to Ra. 2,000/- extent to twice the amount of duty.

6. Of all the offences committed with respect to warehousing.

Punishable with a fine up to Rs. 2,000/- and the goods related to the offences are liable to confiscation.

7. Obstruction to the officers while exercising their powers regarding Entry, Search and Seizure.

Punishable with a fine up to Rs. 500/-.

8. Prosecution: Only the sub-inspector or officer above his rank can institute the prosecution under this Act.

9. Arrests: Only the sub-inspector or officer above his rank can make arrest under this Act.

10. A breach of the rules, where no punishment is provided.

Punishable with a fine up to Rs. 1,000/- and confiscation of the goods.

11. Keeping of stocks of dutiable goods in disorderly manner (not in accordance with the provisions of this Act).

Punishable with a fine up to Rs. 1,000/- 12. Maintaining false accounts of stock of goods in a manufactory or warehouse or not

following the provision of this Act while maintaining such accounts.

Punishable with a fine up to Rs. 2,000/-.

13. Sale of dutiable good except in prescribed containers bearing a label.

Punishable with a fine up to Rs. 1,000/- and confiscation of the goods related with this offence.

14. Disclosure of information by Excise officers learned by him in his official capacity.

Punishable with a fine up to Rs. 1,000/-