### INTRODUCTION TO MEDICINAL AND TOILET PREPARATIONS

- Alcohol has always been a fascinating friend of the mankind.
- However the consumption of alcohol purely for drinking purpose to derive pleasure is the abuse of this liquid.
- Use of alcohol for preparation of medicines is necessity.
- 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.
- This is the reason to take this Act in existence.
- The Excise Duties Act came in force in 1955.
  - For excise duty to be an effective alcohol control measure, duty increases need to increase annually in relation to inflation and income.
  - It has found that increasing the level of a minimum price per unit leads to steep reductions in alcohol consumption and related harms.
- An excise or excise tax is an inland tax. It is different from Customs duties.
  - In other words, an excise is considered an indirect tax.
- In common terminology (but not necessarily in law),
- an excise is distinguished from a sales tax or VAT in three ways:
  - (i) an excise typically applies to a narrower range of products;
  - (ii) an excise is typically heavier, accounting for a higher fraction of the retail price of the targeted products; and
  - (iii) an excise is typically a per unit tax, costing a specific amount for a volume or unit of the item purchased, whereas a sales tax or VAT is an ad valorem tax and proportional to the price of the good.
- In India, an excise is described as an indirect tax levied and collected on the goods manufactured in India.
- The Act is extended throughout India.
- The Excise Duties Act is sometimes referred as "Sin tax" Types of Excise duty Basic Additional Special Excisable Goods
- The term 'excisable goods' means the goods which are specified in the first schedule and the second schedule to the Central Excise Tariff Act, 1985, as being subject to a duty of excise.

## DEFINITIONS

- "Medicinal Preparation"
  - includes all drugs which are 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 the treatment, mitigation or prevention of disease inhuman beings or animals.
- "Toilet preparation" means
  - any preparations, which is intended for use in the toilet of the human body or in perfuming apparel of any description or any substances intended to cleanse, improve or alter the complexion, skin, hair or teeth and includes deodorants and perfumes.
- "Absolute alcohol" means
  - o alcohol confirming to the British Pharmacopoeial specification for dehydrated alcohol
- "Bonded manufactory" 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" 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 been paid

- "Chemical Examiner" means
  - the Chemical Examiner to the State Government and includes such other officer whom the State Government or the Central Government may at any time appoint as Chemical Examiner;
- "Denatured spirit" or "denatured alcohol" 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
- "Duty" means
  - $\circ$  the duty of excise payable under Sec. 3 of the Act
- "Excise Commissioner" means
  - the Head of the Excise administration of a State and includes a Prohibition Commissioner and also an officer designated in any State as Prohibition or Excise Director
- "Finished store" means
  - that portion of a non bonded or bonded manufactory which is set apart for the storage of its finished preparations
- "From" means
  - o a Form appended to the rules
- "Gauge" means
  - to determine the quantity of alcohol or dutiable goods contained in or taken from any cask or receptacle or to determine the capacity of any cask or receptacle
- "Laboratory" means
  - that part of a non-bonded or bonded manufactory in 2 which the actual manufacture of dutiable goods takes place;
- "Manufacturer" means
  - $\circ$  a person to whom a licence has been granted for the manufacture of dutiable goods.
- "Officer –in-charge " means
  - an officer of the Excise Department of any State appointed by the collecting Government to supervise work in a bonded manufactory or a bonded warehouse and includes officers of any other Department similarly appointed;
- "Proper officer" means
  - an Excise Officer in whose jurisdiction the premises of the manufacturer of any dutiable goods, or of any person engaged in the process of manufacture of, or trade in such goods or containers thereof, whether as manufacturer, wholesale dealer, or intended manufacturer or wholesale dealer, are situated;
- "Prove" means
  - $\circ$  to test the strength of alcohol by hydrometer or other suitable instrument;
- "Quarter" means
  - $\circ$  a period of three months beginning with 1st January, 1<sup>st</sup> April , 1<sup>st</sup> July or 1st October;
- "Rectified spirit" means
  - plain un-denatured alcohol of a strength not less than 50.0 over proof and includes absolute alcohol;
- "Rectified preparation" means
  - every medicinal preparation specified in the schedule and includes every preparation declared by the Central Government as restricted preparation under these rules;
- "Unrestricted preparation" means
  - any medicinal preparation containing alcohol but other than a restricted preparation a spurious preparation;
- "Schedule" means
  - the schedule annexed to these rules;
- "Spirit store" means

- that portion of the bonded or non-bonded manufactory which is set apart for the storages of alcohol opium, Indian hemp and other narcotic drugs or narcotic purchased free of duty or at prescribed rates of duty specified in the schedule to the Act;
- "Standard preparation: means
  - $\circ$  a preparation other than a "sub-standards preparation".
- A "sub-standard preparation " is -
  - (a) a pharmacopoeial preparation in which the amount of any of the various ingredients is below the minimum that the pharmacopoeial composition would require , or
  - (b) a proprietary medicine which does not conform to the formula or the list of ingredients disclosed on the label on the container or on the container;
- "Warehouse" means
  - any place or premises licensed licensed under rule 70.

# **OBJECTIVE OF MEDICINAL AND TOILET PREPARATIONS (EXCISE DUTIES) ACT, 1955**

- 1. This is a central Act and thus extends to the whole of India.
- 2. It came into force with effect from 1st of April, 1957.
- 3. This Act provides for the levy and collection of duties of excise on the medicinal and toilet preparations containing alcohol, Indian hemp., narcotic drugs and narcotics which are termed as dutiable goods.
- 4. With the above object, the Act also regulates the manufacture of dutiable goods.
- 5. The Excise duty is collected on the manufacture of such preparations as per the schedule prescribed in the Act.
- 6. By virtue of section 19, the Central Govt. has framed the Medicinal and Toilet Preparations (Excise Duties) Rules, 1956 to carry out the purposes of the Act.

# SCENARIO BEFORE THE ENACTMENT OF MEDICINAL AND TOILET PREPARATIONS

- Before the enactment of the Medicinal and Toilet Preparation (Excise Duties ) Act,1955,
- levy of excise duties on the medicinal and toilet preparations containing alcohol, Indian hemp, narcotic drugs and narcotics was a subject on which the provincial legislature could legislate.
- Various Provincial Government had their own legislature for levy and collection of excise duties on the medicinal and toilet preparations containing alcohol, Indian hemp, narcotic drugs and narcotics.

# CATEGORY OF LICENSES UNDER THE MEDICINAL AND TOILET PREPARATIONS

- 1. L-I:
  - License to manufacture medicinal and toilet Preparations containing alcohol, opium, Indian hemp and other narcotic drugs and narcotics under bond for payment of duty
- 2. L-2:
  - License to manufacture medicinal and toilet Preparations containing alcohol, opium, Indian hemp and other narcotic drugs and narcotics outside bond
- 3. L-3
  - License for Ayurvedic or Unani Practitioner to manufacture Ayurvedic or Unani preparations containing self-generated alcohol for dispensing and not for trade purposes
- 4. L-4:
  - License for a bonded warehouse

# APPLICATION FORMS FOR PROCURING LICENCES

- 1. AL-1
  - (Application form for licences in forms L-1 & L-2 to manufacture goods liable to duty of excise under the Medicinal and Toilet Preparations (Excise Duties ) Act, 1955

- 2. AL-2:
  - Application form for licence in form L-3 to manufacture Ayurvedic or Unani preparations by any Ayurvedic Practitioner
- 3. AL-3:
  - Application form for licence in form L-4 for a bonded warehouse for the storage of excisable goods liable to duty under the Medicinal and Toilet Preparations (Excise Duties ) Act, 1955

# MANUFACTURE OF ALCOHOLIC PREPARATIONS

## Manufacture in-bond:

- 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 preparation.
- **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.
- **5.** List of preparations containing alcohol; licence number issued by Licensing Authority under DCA.
- **6.** Elevation plan, plan of different rooms, details of doors and windows, and quarters for excise staff are to be provided.
- **7.** In case of firm, partnership deal and in case of companies, list of association and latest balanced sheet of the company.
- The Licensing Authority shall enquire into
  - $\circ\;$  the purpose of manufacturing of such formulations containing alcohol and narcotic drugs;
  - o qualifications of the staff employed, previous experience of technical personnel;
  - suitability of the proposal;
  - financial position of the applicant.
- The Licensing Authority shall also look into
  - the equipment, requirement of alcohol and fix an amount of security.
- After satisfying all conditions,
  - the Licensing Authority issues license for one year relating to the premises approved after inspection and for manufacturing of product containing alcohol or narcotic drug.
- Separate licence is issued for each premises and the license is not transferable.
- The licence issued should be displayed properly in the premises.
- Licensing Authority may amend or alter the conditions of licence.
- Renewal of licence
  - should be done before one month of expiry or else 25% extra fee is charged.
- Conviction of violation of provision of the Act is possible under sections 109 or 116 of Indian Penal Code.
- Before cancelling or suspending the licence, sufficient opportunity is given to the licensee to explain his/her position.

#### Ayurvedic Preparations and Homoepathic Preparations

Ayurvedic preparations are of two types:

- 1) Self-generated alcohol containing preparations like Asavas and Aristas
- 2) Prepared by distillation or addition of alcohol.
- Self-generating preparation:
- Containing alcohol was earlier exempted from excise duty.
- However, now all such preparations are chargeable with 4% ad valorem excise duty.
- Those preparations with more than 2% self-generated alcohol and being capable of consumed as a beverage are charged duty of 4% ad valorem.
- **Ayurvedic practitioners** are exempted for license from excise authorities if the samples are being used for their own patients.
  - However, the excise officer should be allowed to take the sample, if required.
- For Homoepathic preparations capable of consumption as ordinary alcoholic beverages, the excise duty of 4% ad valorem is required to be paid.

## Manufacture outside bond:

- The manufacturing and sale operations are restricted only between sunrise and sunset and days and hours as fixed by the Excise Commissioner.
- Essential requirements of Manufactory are:
  - **1.** Separate laboratory spirit store and finished store.
  - **2.** Only one entrance to non-bonded manufactory and one door each to laboratory, spirit store and finished store.
  - **3.** The iron bars in windows should be not less than 19 mm in thickness, set not more than 102 mm apart and fixed in brick construction to the depth of not less than 51 mm. The aperture of wire netting to the window should not exceed 25 mm in diameter.
  - **4.** A separate spirit store for rectified spirit purchased at the specified duty.
  - **5.** All pipes from wash basins and sinks are connected to closed drainage fonning part of general drainage system.
  - 6. All electric and gas connections should be well secured with one cut off switch.
- The State Government may relax conditions of requirements of infrastructure if alcohol consumption is less.
- Alcohol is procured by the manufacturer after payment of excise duty.
- The form for payment of duty is filled up in triplicate,
  - o one copy is to be given to spirit warehouse keeper,
  - $\circ \quad \text{second to officer in charge and}$
  - 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.
- The alcohol purchased cannot be resold.
- Manufacturing, storage and sale of preparations should be carried out only in licensed premises.
- Batch number should be given and separate finished store is provided for alcoholic products.
- All necessary entries of operations carried out are maintained in stock register and the same should be made available for inspection by the excise officer and drug control authority.
- Excise officer may take upto 10% of the preparation for analysis and the same is sent to the chemical examiner.
- 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 this is frequently done by manufacturer, licence may be withdrawn.

# Design and construction of non-bonded lab manufacture in non-bonded lab:

- The following categories of preparations are exempt from excise duty
  - $\circ~$  Hospitals and dispensaries working under the supervision of Central Govt. or a State Govt.
  - Hospitals and dispensaries subsidized by the Central Govt. or State Govt.
  - $\circ\,$  Charitable hospitals and dispensaries under the Administrative control and management of local body.
  - Medical Store depot, Central Govt. or State Govt.
  - Every other institution certified by the principal Medical Officer of the district in which such institution is situated, which distributes drugs to poor for free.

# Following particulars and documents shall have to be furnished to obtain a license to establish a bonded and non-bonded manufactory:

- **1.** Requisite license under the Drugs and Cosmetics Act, 1940 for manufacturing the medicinal products.
- 2. The approved list of the medicinal preparations and their compositions, by the Drug department.
- **3.** Declaration regarding the maximum quantity of alcohol, Indian hemp, narcotic drugs and narcotics in finished and non-finished preparation that are likely to remain in the manufactory at one time.
- **4.** Declaration regarding the number and full description of vats, stills and other apparatus and machinery required for the purpose.
- 5. The proposed amount of capital to be invested.
- 6. The detail of the site.
- 7. The nature of service required (whole-time /part time) of the Excise Officer.
- **8.** Three copies of the B.P.Plan.
- 9. In case of firm following particulars are to be submitted :
  - a. Registration copy of the firm, if registered.
  - b. The partnership deed.
- 10. In case of company, the following particulars are to be submitted :
  - a. A list of directors and managers, as certified by the Registrar of Joint stock companies.
  - b. Memorandum of articles of association.
  - c. The latest balance sheet.
- **11.** The qualification and previous experience of the technical, personnel engaged in the manufacturing operation.
- 12. Financial solvency.
- **13.** Trade License.
- 14. Fire license.
- **15.** I-Tax / P-tax / S-tax clearance certificate.
- **16.** Certificate of physical and mental soundness.
- Before granting of license of bonded manufactory / warehouse, the licensing authority shall fix the amount of security / surety, which is required to be furnished under these rules.
- The security may be furnished in interest bearing securities viz. Government promissory notes, national savings certificate.

# The effective rates of duty on different categories of medical preparations and toilet preparations are as follow:

Description							Rate of duty
a.	Allopathic	medicinal	preparations	containing	alcohol,	Narcotic	16% ad-valorem
	drug or nai	cotics.					

containing alcohol but containing narcotic drugs or narcotics.sale price after abatement ofc. Toilet preparations containing alcohol, narcotic drugs or narcotics.40% of the retail sale priceAyurvedic / Unani / Indigenous system medicinal preparations containing alcohol which are prepared by distillation and to which alcohol is added.6%Ayurvedic / Unani / Indigenous system medicinal preparations containing self-generated alcohol capable of being consumed as ordinary alcoholic beverages.4%Homoeopathic preparations containing alcohol.Rs 20/- per PAC		
c. Toilet preparations containing alcohol, narcotic drugs or narcotics.40% of the retail sale priceAyurvedic / Unani / Indigenous system medicinal preparations containing alcohol which are prepared by distillation and to which alcohol is added.6%Ayurvedic / Unani / Indigenous system medicinal preparations containing self-generated alcohol capable of being consumed as ordinary alcoholic beverages.4%Homoeopathic preparations containing alcohol.Rs 20/- per PAC		16% ad-valorem on the retail
Ayurvedic / Unani / Indigenous system medicinal preparations containing alcohol which are prepared by distillation and to which alcohol is added.6%Ayurvedic / Unani / Indigenous system medicinal preparations containing self-generated alcohol capable of being consumed as ordinary alcoholic beverages.4%Homoeopathic preparations containing alcohol.Rs 20/- per PAC		sale price after abatement of
containing alcohol which are prepared by distillation and to which alcohol is added.4%Ayurvedic / Unani / Indigenous system medicinal preparations containing self-generated alcohol capable of being consumed as ordinary alcoholic beverages.4%Homoeopathic preparations containing alcohol.Rs 20/- per PAC	c. Toilet preparations containing alcohol, narcotic drugs or narcotics.	40% of the retail sale price
alcohol is added.4%Ayurvedic / Unani / Indigenous system medicinal preparations containing self-generated alcohol capable of being consumed as ordinary alcoholic beverages.4%Homoeopathic preparations containing alcohol.Rs 20/- per PAC	Ayurvedic / Unani / Indigenous system medicinal preparations	6%
Ayurvedic / Unani / Indigenous system medicinal4%preparations containing self-generated alcohol capable of being consumed as ordinary alcoholic beverages.4%Homoeopathic preparations containing alcohol.Rs 20/- per PAC	containing alcohol which are prepared by distillation and to which	
preparations containing self-generated alcohol capable of being consumed as ordinary alcoholic beverages.Homoeopathic preparations containing alcohol.Rs 20/- per PAC	alcohol is added.	
consumed as ordinary alcoholic beverages.Homoeopathic preparations containing alcohol.Rs 20/- per PAC	Ayurvedic / Unani / Indigenous system medicinal	4%
Homoeopathic preparations containing alcohol. Rs 20/- per PAC	preparations containing self-generated alcohol capable of being	
	consumed as ordinary alcoholic beverages.	
Avurvedic / Unani / Indigenous system medicinal NII	Homoeopathic preparations containing alcohol.	Rs 20/- per PAC
right vedicy of any magenous system medicinal	Ayurvedic / Unani / Indigenous system medicinal	NIL
preparations containing self-generated alcohol not capable of being	preparations containing self-generated alcohol not capable of being	
consumed as ordinary alcoholic beverages.	consumed as ordinary alcoholic beverages.	

## WAREHOUSING OF ALCOHOLIC PREPARATIONS

- The manufacturers and dealers in alcoholic preparations are allowed to establish warehouses anywhere in India for the purpose of depositing spirituous goods on which duty has not been paid.
- Those wishing to establish such a warehouse should obtain a licence for the purpose from the Excise Commissioner of the State, by making application to him with a fee of Rs.25.

## Movement of goods from one warehouse to other 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 Govt. in this behalf.

### Inter-state transport of alcoholic goods export of alcoholic preparations

• Under bond (directly from a bonded laboratory without payment of duty) under claim for rebate of duty

#### DUTIES OF EXCISE TO BE LEVIED AND COLLECTED ON CERTAIN GOODS

- 1. There shall be levied duties of excise, at the rates specified in the Schedule, on all dutiable goods manufactured in India.
- 2. The duties aforesaid shall be leviable:
  - where the dutiable goods are manufactured in bond, in the State in which such goods are released from a bonded-warehouse for home consumption, whether such State is the State of manufacture or not;
  - where the dutiable goods are not manufactured in bond, in the State in which such goods are manufactured.

#### Explanation:

• Dutiable goods are said to be manufactured in bond within the meaning of this section if they are allowed to be manufactured without payment of any duty of excise leviable under any law for the time being in force in respect of alcohol, [narcotic drug or narcotic] which is to be used as an ingredient in the manufacture of such goods. Subs. by Act 66 of 1976, s. 39

#### **REBATE OF DUTY ON ALCOHOL PREPARATIONS**

• Where alcohol opium, Indian hemp or other narcotic drug or norcotic had been supplied to a manufacturer or any dutiable goods for use as an ingredient of such goods by, or under the authority of, the collecting Government and a duty or excise on the goods so supplied had already been recovered by such Government under any law for the time being in force, the collecting Government shall, on an application being made to it in this behalf, grant in respect of the duty of excise leviable under this Act, a rebate to such manufacturer of the excess, if any, of the duty so recovered over the duty leviable under this Act.

#### CERTAIN OPERATIONS TO BE SUBJECT TO LICENSES

- 1. The Central Government may, by notification in the official Gazette, provide that from such date as may be specified in the notification,
  - no person shall engage in the production or
  - manufacture of any dutiable goods or of any specified component parts or
  - ingredients of such goods or
  - of specified container of such goods or
  - of labels of such containers
  - except under the authority and in accordance with the terms and conditions of license granted under this Act.
- 2. Every license under sub-section (1) shall be granted for such area, if any, for such period, subject to such restrictions and conditions, and in such form and containing such particulars as may be prescribed.

#### OFFENCES AND PENALTIES

### If any person

- 1. contravenes any of the provisions of a notification issued under Sec. 6; or
- 2. evades the payment of any duty of excise payable under this Act; or
- 3. fails to supply any information which he is required by rules made under this Act to supply or (unless with a reasonable belief, the burden of proving which shall be upon him, that the information supplied by him is true) supplies false information; or
- 4. Attempts to commit or abets the commission of any offence mentioned in Cl. (a) or Cl.(b).
- 5. He shall for every such offence be punishable with imprisonment for a term which may extend to six months, or with fine which may extend to two thousand rupees, or with both.

### Officers required assisting Excise Officers

• All officers of Customs and Central Excise, and such other officers of the Central Government as may be specified in this behalf, and all police officers and all officers engaged in the collection of land revenue are hereby empowered and required to assist excise officers in the execution of this Act.

## Owners or occupiers of land to report manufacture of contraband dutiable goods

- Every owner or occupier of land and the agent of any such owner or occupier incharge of the management of that land,
  - if dutiable goods are manufactured thereon in contravention of the provisions of this Act or the rules made thereunder, shall, in the absence of reasonable excuse, be bound to give notice of such manufacture to a Magistrate or to an officer of the Excise, Customs, Police or Land Revenue Department immediately the fact comes to his notice.

#### Failure of excise officers on duty

- Any excise officer who
  - ceases or refuses to perform, or
  - o withdraws himself from, the duties of his office,
  - o unless he had obtained the express written permission of his superior officer or
  - $\circ$   $\;$  has given such superior officer two months' notice in writing of his intention or
  - has other lawful excuse,
- shall be punishable with imprisonment for a term which may extend to three months, or with fine which may extend to three months' pay, or with both.