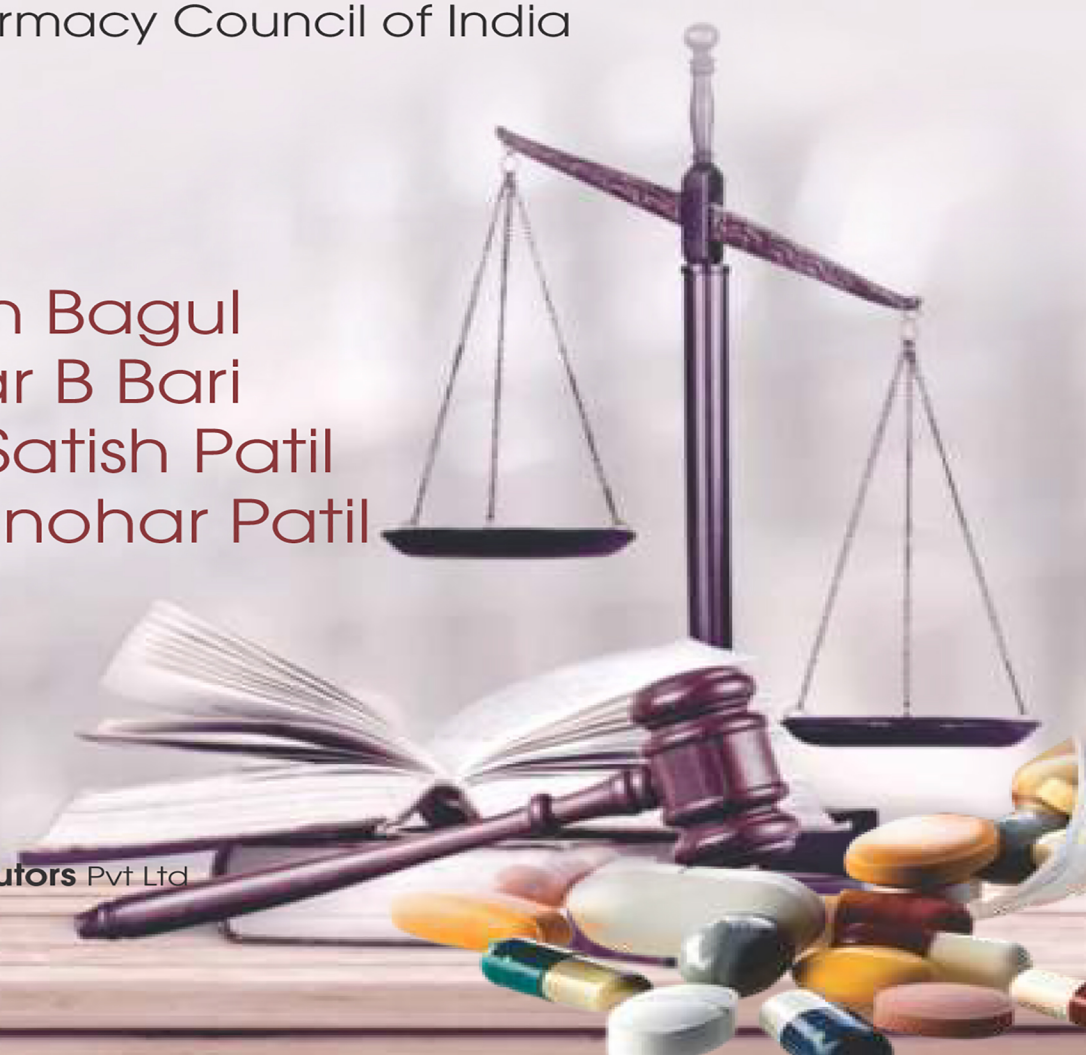
# Textbook of Pharmaceutical Jurisprudence

Course Code **BP505T**

*for* Fifth Semester Bachelor of Pharmacy

As per the latest syllabus prescribed by
Pharmacy Council of India

Vishal Suresh Bagul
Sanjaykumar B Bari
Rajeshwari Satish Patil
Deepak Manohar Patil



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**Vishal Suresh Bagul** M Pharm
Assistant Professor, Department of Pharmacognosy
HR Patel Institute of Pharmaceutical Education and
Research, Shirpur, Dhule, Maharashtra

**Sanjaykumar B Bari** M Pharm PhD
Principal and Professor, Department of Pharmaceutical Chemistry
HR Patel Institute of Pharmaceutical Education and
Research, Shirpur, Dhule, Maharashtra

**Rajeshwari Satish Patil** M Pharm
Assistant Professor, Department of Pharmacognosy
RC Patel Institute of Pharmaceutical Education and
Research, Shirpur, Dhule, Maharashtra

**Deepak Manohar Patil** M Pharm
Assistant Professor, Department of Quality Assurance
HR Patel Institute of Pharmaceutical Education and
Research, Shirpur, Dhule, Maharashtra



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**Corporate Office:** 204 FIE, Industrial Area, Patparganj, New Delhi-110092; Ph: +91-11-49344934; Fax: +91-11-49344935; Website: www.cbspd.com; www.eduport-global.com; E-mail: eresources@cbspd.com; marketing@eduport-global.com

**Head Office:** CBS PLAZA, 4819/XI Prahlad Street, 24 Ansari Road, Daryaganj, New Delhi-110002, India.; Ph: +91-11-23289259, 23266861, 23266867; Fax: 011-23243014; Website: www.cbspd.com; E-mail: publishing@cbspd.com; eduportglobal@gmail.com.

***Branches***

- **Bengaluru:** Seema House 2975, 17th Cross, K.R. Road, Banasankari 2nd Stage, Bengaluru - 560070, Kamataka Ph: +91-80-26771678/79; Fax: +91-80-26771680; E-mail: bangalore@cbspd.com
- **Chennai:** No.7, Subbaraya Street Shenoy Nagar Chennai - 600030, Tamil Nadu Ph: +91-44-26680620, 26681266; E-mail: chennai@cbspd.com
- **Kochi:** 36/14 Kalluvilakam, Lissie Hospital Road, Kochi - 682018, Kerala Ph: +91-484-4059061-65; Fax: +91-484-4059065; E-mail: kochi@cbspd.com
- **Mumbai:** 83-C, 1st floor, Dr. E. Moses Road, Worli, Mumbai - 400018, Maharashtra Ph: +91-22-24902340 - 41; Fax: +91-22-24902342; E-mail: mumbai@cbspd.com
- **Kolkata:** No. 6/B, Ground Floor, Rameswar Shaw Road, Kolkata – 700014 Ph: +91-33-22891126 - 28; E-mail: kolkata@cbspd.com

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*to*
*my father Late Suresh Bagul*
*& grandmother*



*Late Lilabai Wasaikar*
*—Mr Vishal S Bagul*

# Preface

It gives us immense pleasure to present *Textbook of Pharmaceutical Jurisprudence* in a new form for pharmacy graduates.

With increasing interest in the field of pharmacy, the book on pharmaceutical jurisprudence is specially intended for the degree and diploma students.

The main objective of this book is to help the reader by providing adequate material of syllabus along with MCQs in manner that will prove useful to them. Each chapter contains concise material and the number of questions on each topic has been kept on higher side to provide rigorous practice. We are sure that the added topics will provide value-added information to readers. There may be a few mistake and deficiencies, we will be grateful to the readers if they point them out and revert with their suggestions.

We would like to thank Mr YN Arjuna and team of CBS Publishers & Distributors for publishing this book and extending the passionate cooperation from management of Shirpur Education Society for providing the necessary resources and motivation. Our sincere thanks to all our well-wishers for their support.

**Vishal Suresh Bagul**
**Sanjaykumar B Bari**
**Rajeshwari Satish Patil**
**Deepak Manohar Patil**

# Pharmaceutical Jurisprudence

**Course Code: BP505T** **45 Hours**

**Scope:** This course is designed to impart basic knowledge on important legislations related to the profession of pharmacy in India.

**Objectives:** Upon completion of the course, the student shall be able to understand:

1. The pharmaceutical legislation and their implications in the development and marketing of pharmaceuticals.
2. Various Indian Pharmaceutical Acts and Laws.
3. The regulatory authorities and agencies governing the manufacture and sale of pharmaceuticals.
4. The code of ethics during the pharmaceutical practice.

## UNIT I — 10 Hours

**Drugs and Cosmetics Act, 1940 and its Rules, 1945:** Objectives, Definitions, Legal definitions of schedules to the Act and Rules, Import of drugs—classes of drugs and cosmetics prohibited from import, Import under license or permit. Offences and penalties. Manufacture of drugs—prohibition of manufacture and sale of certain drugs, conditions for grant of license and conditions of license for manufacture of drugs, manufacture of drugs for test, examination and analysis, manufacture of new drug, loan license and repacking license.

## UNIT II — 10 Hours

**Drugs and Cosmetics Act, 1940 and its Rules, 1945:** Detailed study of Schedule **G, H, M, N, P, T, U, V, X, Y,** Part XII B, Sch F & DMR (OA) Sale of Drugs: Wholesale, retail sale and restricted license. Offences and penalties labeling and packing

of drugs: General labeling requirements and specimen labels for drugs and cosmetics, list of permitted colors. Offences and penalties. Administration of the Act and Rules—Drugs Technical Advisory Board, Central Drugs Laboratory, Drugs Consultative Committee, government drug analysts, licensing authorities, controlling authorities, drug inspectors.

**UNIT III** **10 Hours**

**Pharmacy Act, 1948:** Objectives, Definitions, Pharmacy Council of India; its constitution and functions, Education Regulations, State and Joint State Pharmacy Councils; constitution and functions, registration of pharmacists, offences and penalties.

**Medicinal and Toilet Preparation Act, 1955:** Objectives, definitions, licensing, manufacture in bond and outside bond, export of alcoholic preparations, manufacture of Ayurvedic, Homeopathic, patent and proprietary preparations. Offences and penalties.

**Narcotic Drugs and Psychotropic Substances Act, 1985 and Rules:** Objectives, definitions, authorities and officers, Constitution and Functions of Narcotic and Psychotropic Consultative Committee, National Fund for Controlling the Drug Abuse, Prohibition, Control and Regulation, opium poppy cultivation and production of poppy straw, manufacture, sale and export of opium, offences and penalties.

**UNIT IV** **08 Hours**

**Study of Salient Features of Drugs and Magic Remedies Act and its Rules:** Objectives, definitions, prohibition of certain advertisements, classes of exempted advertisements, offences and penalties.

**Prevention of Cruelty to Animals Act, 1960:** Objectives, Definitions, Institutional Animal Ethics Committee, CPCSEA guidelines for breeding and stocking of animals, performance of experiments, transfer and acquisition of animals for experiment, records, power to suspend or revoke registration, offences and penalties.

**National Pharmaceutical Pricing Authority: Drugs Price Control Order (DPCO) 2013.** Objectives, definitions, sale

prices of bulk drugs, retail price of formulations, retail price and ceiling price of scheduled formulations, national list of essential medicines (NLEM).

## UNIT V 07 Hours

**Pharmaceutical Legislations:** A brief review, introduction, study of drugs enquiry committee, Health Survey and Development Committee, Hathi Committee and Mudaliar Committee.

**Code of pharmaceutical ethics:** Definition, pharmacist in relation to his job, trade, medical profession and his profession, pharmacist's oath.

**Medical Termination of Pregnancy Act**

**Right to Information Act**

**Introduction to Intellectual Property Rights (IPR)**

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Chapter

1

# Drugs and Cosmetics Act, 1940 and its Rules, 1945

- The Drugs and Cosmetics Act was passed in **10th April 1940.**
- 1940**—Drugs and Cosmetics Act**
- 1945**—Rules under the Act**

## OBJECTIVES

- To regulate the **import, manufacture, distribution** and **sale** of drugs and cosmetics through licensing.
- To regulate the **manufacture** and **sale** of **Ayurvedic, Siddha** and **Unani** drugs.
- **Manufacture, distribution** and **sale** of drugs and cosmetics by **qualified persons** only.
- To prevent **substandard** in drugs.
- To establish **Drugs Technical Advisory Board** (**DTAB)** and **Drugs Consultative Committees (DCC)** for **allopathic** and **allied drugs** and **cosmetics.**

## DEFINITIONS UNDER THE ACT

### Drugs

- A medicine or other substance which has a physiological effect when **ingested** or otherwise **introduced into the body**.
- All medicines for **internal** or **external** use of **human beings** or **animals** and all substances intended to be used for or in the **diagnosis, treatment, mitigation** or **prevention** of any disease or disorder in human beings or animals, including preparations applied on human body for the purpose of repelling insects like mosquitoes.

### *Cosmetic: Section 3 (a)*

Any article intended to be **rubbed, poured, sprinkled** or **sprayed** on, or introduced into, or otherwise applied to, the human body or any part thereof for **cleansing, beautifying, promoting attractiveness**, or altering the appearance, and includes any article intended for use as a component of cosmetic.

### *Ayurvedic, Siddha or Unani Drug: Section 3 (aaa)*

It includes all medicine intended for **internal** or **external** use for or in the **diagnosis, treatment, mitigation** or **prevention** of disease or disorder in **human beings** or **animals** and manufactured in accordance with the formula described in the authoritative books of **Ayurvedic, Siddha or Unani system** of medicine, specified in first schedule.

### *Misbranded Drugs: Section 17*

- If it is so **coloured, coated, powdered** or **polished** that damage is concealed; or
- If it is made to appear of **better or greater therapeutic value** than it really is; or
- If it is not **labelled** in the **prescribed manner**.

### *Adulterated Drug: Section 17 (a)*

- If it consists, in whole or in part, of any **filthy, putrid** or **decomposed** substance; or
- If it contains any harmful or toxic substance which may render it injurious to health.

### *Spurious Drugs: Section 17 (b)*

- If it is imported under a name which belongs to another drug; or
- Which purport to be the product of a manufacture of which it is not truly a product.

### *Inspector: Section 3 (e)*

- In relation to Ayurvedic, Siddha or Unani drug, an Inspector appointed by central or state government under Section 33 *(g)*.

### *Government Analyst (Bench Chemist): Section 3 (c)*

In relation to Ayurvedic, Siddha and Unani drugs, a person appointed by central government or state government under Section 33 *(f)*.

### *Manufacture: Section 3 (f)*

In relation to any drug or cosmetic, it includes any process or part of a process for **making, altering, or namenting, finishing, packing, labelling,** breaking up or otherwise treating or adopting any drug or cosmetic with a view to its sale or distribution but does not include the **compounding** or **dispensing** of any drug, or the packing of any drug or cosmetic, in the ordinary course of retail business.

### *Patent or Proprietary Medicine: Section 3 (h-ii)*

A drug which is a remedy or prescription presented in a form ready for internal or external administration of human beings or animals and which is not included in the edition of the Indian Pharmacopoeia for the time being or any other pharmacopoeia authorized in this behalf by the central government

## APPENDIX

**Appendix I:** Data to be submitted along with the application for permission to market a new drug.

**Appendix II:** Format for submission of clinical trial reports.

**Appendix III:** Requirements for animal clinical trials and marketing a new drug.

**Appendix IV:** Number of animals for long-term toxicity studies.

**Appendix V:** Patient consent form for participation in Phase I clinical trial.

**Appendix VI:** Four groups of fixed dose combinations and their data requirements.

## SCHEDULES TO THE ACT

### First Schedule

**List of Ayurvedic, Siddha and Unani books.**

- **Ayurvedic book**
  Example: Charak Samhita, Sushruta Samhita and Arka Prakasha
- **Siddha book**
  Example: Siddha Vaidya Thirattu and Bhogar Pulippani
- **Unani book**
  Example: Karabadin Quadri and Al Karabadin.

### Second Schedule

Standards to be complied with imported drug and by drugs manufactured for sale, sold, stocked or exhibited for sale or distributed.

| SCHEDULES TO THE RULE | |
|---|---|
| **Schedule A** | List of model forms that are to be used under the Rules like making applications for the licenses, issue and retrieval of licenses. |
| **Schedule B** | Fees to be paid for test or analysis at the CDL (central drugs laboratory)/state government analyst. |
| **Schedule C** | List of **biological products** whose import, sale, distribution and manufacture are governed by special provisions, e.g. insulin, vaccine for parenteral injections, etc. |
| **Schedule C1** | List of **other special products** whose **import, sale, distribution and manufacture** are governed by special provisions, e.g. fish liver oil, adrenaline, vitamins, etc. |
| **Schedule D** | List of drugs exempted for the provisions of **import of drugs**, e.g. oats, ginger, etc. |
| **Schedule E** | List of **poisonous substance** under the **Ayurvedic, Siddha and Unani** systems of medicine, e.g. nux-vomica, etc. |
| **Schedule F (i)** | Space, equipment and supplies required for a **Blood Bank.** |
| **Schedule F (ii)** | Minimum **requirement for grant of license** to procure blood components from whole human blood. |

| | |
|---|---|
| **Schedule F1** | Standards for **surgical dressings.** |
| **Schedule F2** | Standards for **sterilized dressings** |
| **Schedule F3** | Standards for **ophthalmic preparations** |
| **Schedule G** | List of substances that are required to be used only under **medical supervision.** |
| **Schedule H** | List of **prescription drugs** |
| **Schedule J** | Disease or aliments which a drug **may not** purport to prevent or cure. |
| **Schedule K** | Drugs exempted from certain provisions relating to the **manufacture of drugs.** |
| **Schedule M** | **Good manufacturing practices (GMP**) requirements of factory premises, plants and equipment. |
| **Schedule M1** | Requirements of factory premises for **manufacture of homeopathic preparations.** |
| **Schedule M2** | Requirements of factory premises for **manufacture of cosmetics**. |
| **Schedule M3** | Requirements of factory premises for **manufacture of medical devices.** |
| **Schedule N** | List of minimum requirements of **efficient running of pharmacy**. |
| **Schedule O** | Standard of **disinfectant fluids**. |
| **Schedule P** | **Life period** of drug |
| **Schedule P1** | **Pack sizes** of drug |
| **Schedule Q (i)** | List of **dyes, colors** and **pigment** permitted in **cosmetics** and **soaps.** |
| **Schedule Q (ii)** | List of **colors permitted in soaps.** |
| **Schedule R** | Standards for **condoms** made of rubber latex intended for single use and other mechanical **contraceptives.** |
| **Schedule S** | Standards of **cosmetics**. |
| **Schedule T** | Requirements of factory premises and hygienic conditions for **Ayurvedic** and **Unani** drugs. |
| **Schedule U** | Particulars to be shown in manufacturing, raw materials and analytical records of **drug.** |

| | |
|---|---|
| **Schedule U1** | Particulars to be shown in manufacturing, raw materials and analytical records of **cosmetics**. |
| **Schedule V** | Standards for **patent** or **proprietary medicines.** |
| **Schedule W** | List of drugs to be marketed under **generic names only**. |
| **Schedule X** | List of drugs whose **import, manufacture and sale** are governed by **special provisions**. |
| **Schedule Y** | Requirements and guidelines on **clinical trials** for **import and manufacture of new drugs.** |

## IMPORT OF DRUGS

Bring (goods or services) into a country from abroad for sale.

No any drug, the **manufacture, sale** or **distribution** of which is **prohibited** in the country of origin, shall be imported under the same name or under any other name except for the purpose of **examination**, **test of analysis**.

### Prohibition of Import of Certain Classes of Drugs and Cosmetics

#### *Misbranded Drugs and Cosmetics*

- If it is not labeled in the prescribed manner.
- If it contains a **color** which is not prescribed
- If it is **not labelled** in the prescribed manner

#### *Adulterated Drugs and Cosmetics*

- If it contains any **harmful or toxic substance** which may render it injurious to health.
- If any substance has been mixed therewith so as to reduce its quality or strength.
- If it bears or contains any harmful for purposes of coloring only, a colour other than one which is prescribed.

#### *Spurious Drugs or Cosmetics*

- If it is imported under a name which belongs to another drug; or
- Which purport to be the product of a manufacture of which it is not truly a product.

- If it is imported under a name which belonging to another cosmetics.

### *Drugs of Substandard Quality*

No any drug shall be imported unless it complies with the standard of **strength, quality, and purity** if any, and the test prescribed in the rule shall be applicable for determining whether any such imported drug complies with the said standard.

Provided further that the licensing authority shall not allot the import of any drug having **<60%** residual shelf-life period as on the date of import.

Drugs whose manufacture, sale/distribution are prohibited in original country, except for the purpose of test, examination and analysis.

Patent/proprietary medicines whose true formula is not disclosed.

Packing and labeling of imported drug and cosmetic: No drug shall be imported unless it is packed in conformity with rule in Part IX and X and further conform to the standard laid down in Part XII.

**Packing and labeling of imported homoeopathic medicine:** No homoeopathic medicine shall be imported unless it is packed and labelled in conformity with the rules in Part IX-A.

Specially cosmetics product which contains more than 2 ppm arsenic, 20 ppm lead, 100 ppm heavy metals.

## Import of the Biological Drugs (C/C1)

### *Conditions to be Fulfilled*

- Licensee must have **adequate facility** for the **storage**.
- Licensee must maintain a record of the sale.
- Licensee must allow an inspector to inspect premises and to check the records.
- Licensee must furnish the sample to the authority.
- Licensee must not sell drugs from which sample is withdrawn and he is advised not to sale, and recall the batch from the market.

### Import of the Schedule X Drugs (Narcotic Drugs and Psychotropic Substances)

***Conditions to be Fulfilled***

- Licensee must have adequate **storage facility.**
- Applicant must be **reputable** in the occupation, trade or business.
- The license **granted even** before should **not be suspended or cancelled.**
- The licensee has **not been convicted any offence** under the Drugs and Cosmetics Act or Narcotic Drugs and Psychotropic Substances Act.

### Drugs Imported for Examination, Test or Analysis

***Conditions to be Fulfilled***

- License is necessary under Form 11
- Must use imported drugs **only for said purpose** and at the place specified in the license.
- Must keep the **record** with respect to quantities, name of the manufacturer and date of import.
- Must **allow an inspector** to inspect the premises and check records.

### Drugs Imported for Personal use

***Conditions to be Fulfilled***

- Up to 100 average doses may be imported without any permit, provided it is part of passenger's luggage.
- More than 100 doses imported with license. Apply on Form 12 (*a*) and 12 (*b*).
- Drugs must be bonafied personal use.
- Drugs must be declared to the custom collectors if so directed.

### Import of Drugs without License

- Substances **not used for medicinal purpose**
- Drugs in Schedule C1 required for manufacturing and not for medicinal use.
- Substances which are **both drugs and foods** such as:
  – Condensed/powdered milk
  – Malt

– Lactose
– Oats
– Predigested foods: Ginger, pepper, cumin, cinnamon.

### Import of Drugs under License or Permit

The following classes of drugs can be imported under the license or permit granted by LA

1. Drugs specified in Schedule C and C1 except those specified in Schedule X
2. Drugs specified in Schedule X
3. Small quantities of drugs imported for the purpose of examination, test or analysis.
4. Drugs for personal use covered by the prescription of registered medical practitioner.
5. Any new drug

An application for import license must be made to the proper authority in prescribed form and license remains valid up to **31st December** of the year, following the year it was granted unless it was suspended earlier.

Aggrieved party has the right to appeal in High Court against an order of the Drugs Controller of India canceling the import license granted to him.

- A separate license is necessary in respect of drugs from each manufacturer.
- A separate license is necessary in respect to drug manufactured in each premises when a single manufacturer abroad has more than one factory.
- A single application may be made and single license may be issued in respect of import of more than one drug or class of drugs manufactured by same manufacturer.
- A change in constitution of licensed firm must be informed to the LA.

### Conditions of Import License

1. Manufacturer must observe at all times the undertaking given by him or on his behalf on Form 9.
2. The license must allow any authorized inspector to enter any premises where the imported substance is stocked to

inspect the means, if any, employed for testing the substances 7 to take samples.

3. Maintained records of all sales of imported substances showing particulars of substances and persons to whom it is sold and such records must be open for inspection.

## Places through which Drugs may be Imported in India

**Table 1.1:** Places and their sources for importation

| *Place* | *Sources* |
|---|---|
| Ferozpur cantonment and Amritsar railway station | In respect to drugs imported by rail across the border with Pakistan |
| Runagate, Bongaon and Mohiassan railway stations | In respect to drugs imported by rail across the border with Bangladesh |
| Raxaul | In respect to drugs imported by road and rail connecting India and Nepal |
| Chennai, Kolkata, Mumbai, Cochin and Kandla | In respect to drugs imported by sea into India |
| Chennai, Kolkata, Mumbai, Delhi, Ahmedabad and Hyderabad | In respect to drugs imported by air into India |

## Offences and Penalties

**Table 1.2:** Offences and penalties related to Import

| *Offences* | *Penalties* |
|---|---|
| Import of spurious OR adulterated drug OR drug which involves risk to human beings or animals OR drug not having therapeutic values | **3 years** imprisonment and **₹ 5000** fine on **first conviction**<br>**5 years** imprisonment OR **₹ 1000** fine OR **both** for **subsequent conviction** |
| Contravention (an action which offends against a law) of the provision | **6 months** imprisonment OR **₹ 500** fine for **first conviction**<br>**1 year** imprisonment OR **₹ 1000** fine OR **both** for **subsequent offence** |

### Application of Laws Relating to Sea and Customs

The customs collector and other officers authorized in this behalf by the central government may detain any imported packages which he suspects to contain any drug or cosmetic the import of which is prohibited under this act, and report such detention to the Drugs Controller, India and if necessary forward any package or sample to central drugs laboratory for analysis.

## MANUFACTURE OF DRUG

Manufacture in relation to any drug or cosmetic, includes any process or part of process for making, altering, ornamenting, finishing, packing, labeling, braking up or otherwise treating any drug or cosmetic with a view to its sale and distribution but does not include the compounding or dispensing of any drug or packing of any drug in ordinary course of retail business.

### Following Licenses are Provided for Manufacture of Drugs under D&C Act

1. License for manufacture of **Schedule C and C1** drugs
2. License for manufacture of **Schedule X** drugs
3. Drugs specified in **Schedule C, C1** and **X**
4. Drugs for the purpose of **examination, test or analysis**
5. **Loan** licenses
6. **Repacking** licenses
7. **Blood** products
   - Repacking is also a manufacturing for the purpose of the Act.
   - If drugs are manufactured in more than one set of premises, a separate application is to be made and separate license shall be issued in respect of each such premises.
   - Licenses for manufacture or sale or distribution of drugs are granted or renewed by **Central License Approving Authority** (CLAA) appointed by the central government.

- CLAA can delegate his power of signing licenses to any other person under his control with approval of the central government.

### Prohibition for the Manufacture and Sale of Certain Drugs

From the date notified by the state government, no person shall himself manufacture for sale or distribution or sell or distributed. Any drug which is not of standard quality or is misbranded, adulterated or spurious:

- If any cosmetic which not of standard quality or is misbranded, adulterated or spurious.
- If any patent or proprietary medicine whose formulae are not disclosed on label or the container.
- If any drug which purports to cure, mitigate or prevent any disease specified in Schedule J.
- If any cosmetic containing any ingredient which may render it unsafe or harmful for use.
- If any drug or cosmetic in contravention of this Act or Rules thereunder.
- If any drug or cosmetic which has been imported or manufactured in contravention of the provisions of this Act or Rules thereunder or in contravention of the conditions of a license.
- Every person not being manufacturer of a drug or cosmetic or his agent for the distribution shall if so required disclose to the inspector the name, address and other particulars of the person from whom he procured the drug or cosmetic.

### Manufacture of Drugs Specified in Schedule C, C1 and X

- Application for the license of manufacturing drugs specified in Schedule C, C1 excluding those specified in Schedule X should be made to the CLAA in Form 27 and for manufacture of drugs specified in Schedule C, C1 and X in Form 27 (*b*). Respective licenses are issued in Form 28 and 28 (*b*).

- Application for including any additional drug in the license should be accompanied by a fee of ₹ 50 for each drug subject to a maximum of ₹ 500.
- Conditions for the grant of license: Before the grand of license, the following conditions must be complied by the applicant.

The manufacture will be conducted under the active direction of a competent technical staff consisting at least one person who is a full time employee and **who is:**

1. A graduate in pharmacy/pharmaceutical chemistry of a recognized university with at least 18 months practical experience after graduation in manufacture of drugs to which this license applies.
2. A graduate in science of a recognized university who passed in degree with chemistry or microbiology as principal subject and had at least 3 years' experience in the manufacture of drugs to which the license applies.
3. A graduate in medicine of a recognized university with at least 3 years' experience in manufacture of relevant drugs; or
4. A graduate in chemical engineering of a recognized university with at least 3 years' experience in manufacture of relevant drugs.

- The factory conditions must comply with the conditions prescribed in Schedule M and M3.
- Applicant should provide adequate space, plant and equipment for any or all manufacturing operations as prescribed in Schedule M and M3.
- Applicant should provide adequate staff, premises and laboratory equipment for carrying out such tests for strength, quality and purity of substances as required under the Rules.
- Adequate facilities for the storage of manufactured drugs should be provided.
- License in Form 28 and 28 (*b*) remains valid for a period of 5 years on and from the date on which it is issued.
- If application for renewal is made before its expiry, or application made within 6 months of expiry, after

payment of additional fee, the license shall continue to be valid.

- License shall deemed to have expired if the application for its renewal is not made within 6 months of its expiry.
- **Large volume parenteral** means the sterile solutions indented for parenteral administration with a volume of 100 ml or more in one container of the finished dosage form indented for single usage.

### Manufacture of Drugs other than those Specified in Schedule C and C1

- Application for the grand or renewal of license for the manufacture of drugs other than those specified in Schedule C, C1 and X for manufacture of Schedule X drugs in Form 24 (*f*). Respective licenses are issued in Form 25 and 25 (*f*).
- Application for grand/renewal of such license shall be made for up to 10 items in each category in Form 24 (*a*) accompanied by fee of ₹ 6000 and an inspection fee of ₹ 1500 and license shall be issued in Form 25 (*a*).
- Additional fee of ₹ 300 per item is payable for each additional item. License in Form 25 or 25 (*f*) remains valid for a period of 5 years on and from the date on which it is issued.
- If application for renewal is made before its expiry, or application made within 6 months of expiry, after payment of additional fee, the license shall continue to be valid.
- License shall deemed to have expired if the application for its renewal is not made within 6 months of its expiry.

### Manufacture of Drugs for Examination, Tests or Analysis

- License is necessary for the manufacture of any drug in small quantity for the purpose of examination, test or analysis.
- If a person proposing to manufacture does not hold license (i) to manufacture drugs other than those specified

in Schedule C, C1 and X, or (ii) to manufacture drugs specified in Schedule C, C1 in respect to such drugs; he should obtain license in Form 29.

- If drug is not recognized as safe for use, license in Form 29 is only granted after producing no objection certificate from LA appointed by central government.
- License remains valid for a period of one year time.
- Drugs to be kept in containers bearing labels indicating the purpose for which it has been manufactured.
- If the drugs are to be supplied, it should bear label stating name and address of manufacturer, scientific name of substance and purpose for which it has been manufactured.

### Conditions for License

1. Drugs to be used exclusively for the purpose for which they are manufactured
2. Licensee to allow inspector to inspect the premises and satisfy himself that only examination, test or analysis is being conducted.
3. Licensee to keep record of quantity of drugs manufactured and supplied to any person.
4. Licensee to maintain inspection book to enable inspector to record his impression and defects noticed.
5. Licensee must comply with any rules made subsequently and of which the LA has given him NLT one month's notice.

### Manufacture of New Drugs

- Defined as a drug the composition of which is such that it is not generally recognized among experts as safe for use under conditions recommended.
- Suggested on the label and includes any drug the composition of which is such that the drug as a result of investigations for determining its safety for use under such conditions, is so recognized but which has not otherwise than during course of such investigations, been used to any large extend for any appreciable length of time under the said conditions.

- Provisions applicable for the manufacture of new drugs whether classifiable under Schedule C and C1 or otherwise.
- No new drug can be manufactured unless prior approval has been taken.
- Applicant to produce all documentary and other evidence relating to the standards of quality, purity, strength and such other information as may be required including the results of therapeutic trials carried out on the new drug.
- While applying for a license to manufacture a new drug, or its preparations an applicant should produce along with his application evidence that the drug has already been approved.

## Loan Licenses

### *Definition*

A person (applicant) who does not have his own arrangements (factory) for manufacture but who wish to avail the manufacturing facilities owned by another licensee. Such licenses are called loan licenses

- Issued for the manufacture for sale or distribution of drugs other than those specified in Schedule C, C1 and X.
- Application for license is made in Form 24 (*a*) and the license is issued in Form 25 (*a*).
- Inspector shall check into all the portions of the plant and shall also inquire in professional qualification for the technical staff employed.
- Licensee is required to test each batch of raw materials and finished products and the records must be maintained for a period of 5 years from the date of manufacture. (2 years in case of drugs having expiry date, from the date of expiry.)
- Loan license is deemed to be cancelled or suspended if license owned by loan licensee, whose manufacturing facilities are been availed by licensee is cancelled or suspended.

## Repacking Licenses

### *Definition*

Process of breaking up any drug from a bulk container into small packages and labeling with a view to their sale and distribution

- Repacking license are granted for breaking up of any drug other than those specified in Schedule C, and C1, on application to LA in Form 24 (*b*) and license is issued in Form 25 (*b*) subject to satisfying the following conditions:
  - Factory conditions must specify conditions prescribed in Schedule M.
  - Applicant must have in his premises adequate facilities for the testing of drugs which is separate from the repacking unit
  - License must be kept at licensed premises and produced on request of DI.
  - The label on repacked drugs should mention the name and address of the licensee and his license number preceded by the word 'Reg. Lic. No.
  - The license remains valid up to 31st December of the year, following the year in which it is grated.

## Offences and Penalties

**Table 1.3:** Offences and penalties related to manufacturing

| *Offences* | *Penalties* |
|---|---|
| Manufacture of any spurious drugs | 1–3 years imprisonment and ₹ 5000 fine.<br>2–6 years imprisonment and ₹ 10000 fine on **subsequent** conviction |
| Manufacture of adulterated drugs | 1 year imprisonment and ₹ 2000 fine<br>2 years imprisonment and ₹ 2000 fine for subsequent conviction |
| Manufacture of drugs in contravention of the provisions | Imprisonment up to 3 months and ₹ 500 fine<br>Imprisonment up to 6 months and ₹ 1000 fine on **subsequent conviction** |

## DETAIL STUDY OF SCHEDULE M (M1 AND M2)

- Good manufacturing practices (GMP).
- Guidelines are meant to assure the quality of drugs.
- Draft of GMP was prepared in 1975 and finalized and implemented in 1988.
- **Part I** deals with good manufacturing practices relating to factory premises.
- **Part II** deals with plant and equipment for the manufacture of drugs.

## PART I FACTORY PREMISES

### GENERAL REQUIREMENTS

- Location of factory and its surroundings should ensure freedom from contamination due to sewage drain, etc. and obnoxious odors or fumes, or large quantity of soot, dust or smoke.
- **Factory building** should be constructed to ensure production of drugs under hygienic conditions.
- Operations such as manufacturing, processing, packing labeling and testing should be carried out in such a way that mix up and cross contamination are prevented.
- Premises should be constructed and maintained as to prevent entry of insects and rodents, interior surface should be smooth and free from cracks and permit easy cleaning disinfection. Adequate lighting, ventilation and humidity must be maintained. Drainage systems should be underground, the sanitary fitting and electrical fixtures in the manufacture area must be concealed. Water used must be free of pathogenic micro-organisms and of drinkable quality. Waste water should be treated before disposal.
- There should be a validated system for the treatment of water so as to produce purified water confirming to IP specification. Water should be stored in tanks and freedom from microbial growth must be ensured. The tanks should be cleaned periodically and the records should be maintained.
- Provisions should be made for the roper storage of the materials awaiting disposal. The disposal of sewage and effluents shall be as required under the Environmental Pollution Control Board while all biomedical waste must be

destroyed as per the rules of Biomedical Waste Management and Handling Rules.

### Warehousing Area

- Adequate areas shall be designed and provided with proper bins, racks and platforms for the storage and warehousing of all materials and products, machine and equipment, etc. Warehousing area must be clean, dry and maintained within acceptable temperature limits. Storage areas should have appropriate housekeeping and rodents, pests and vermin control procedures and records should be maintained. Active raw materials and excipients must require separate sampling and warehousing area.
- Regular check should be made to ensure adequate steps taken against spillage, breakage and leakage of containers.

### Production Area

- Should be designed to allow the production preferably in uni-flow and with logical sequence of operations.
- The equipment and materials must be placed orderly and the movement of personnel must be restricted to avoid cross-contamination.
- Separate dedicated self-containing facilities should be made available for the production of sensitive pharmaceutical products like penicillin or biological preparations with live microorganisms.
- Pipe works, electrical fittings, ventilations, openings and similar service lines must be designed to avoid creation of recesses.
- Service lines shall preferably identified by colors and nature of supply and direction of flow shall be indicated.

### Quality Control Area

- It should be independent of production area and divided into separate sections for physiochemical, biological, microbiological and radioisotope analysis.
- Laboratories shall be designed to avoid mix ups and cross-contamination. Separate instrument room with adequate area shall be provided for sensitive and sophisticated instruments employed for analysis.

- Suitable storage space shall be provided for test samples, retained samples, reference standards, reagents and records.

### *Personnel*

- Manufacture/testing shall be conducted under the direct supervision of competent technical staff and head of quality control laboratory shall be independent of manufacturing unit.
- Personnel in quality control and quality control operations shall be suitably qualified and experienced and appropriate training must be given to them in the duties and responsibilities assigned to them.

### *Health, Clothing and Sanitation of Workers*

- All personnel coming to contact with products and raw materials should be free from contagious diseases and should undergo periodic health checkup. Just before entry to manufacturing area, room with facility for personnel cleanliness should be provided.
- Prior to employment, personnel shall undergo medical examination and shall be free from TB, skin and other communicable/contagious diseases.
- Periodical medical examination at least once a year may be necessary.
- All persons prior to and during the employment shall be trained in practices that ensure personnel hygiene.
- Persons handling β-lactam antibiotics shall be tested for penicillin sensitivity before employment and those handling sex hormones, cytotoxic substances and other potent drugs shall be periodically examined for adverse effects.
- Direct contact shall be avoided between unprotected hands of personnel and raw materials, intermediate, or finished unpacked products.
- All persons should wear clean body coverings.
- Smoking, eating, drinking, chewing or keeping plants or food and personnel medicines shall not be permitted in production, laboratory storage and other areas.

### *Ancillary Areas*

- Rest and refreshment rooms should be separate and should not lead directly to the manufacturing area.

- Facilities for changing, storing of clothes and for washing and toilet purposes should be provided and must be adequate for the number of users.

### *Sanitation in Manufacturing Premises*

- Manufacturing area should not be utilized for any other purposes and should be maintained clear and in orderly manner free from accumulated waste, dust, debris, etc. A routine sanitation program must be exercised.
- Production areas shall be well lit, particularly where visual online controls are carried out.

### *Raw Materials*

All raw materials must be:

- Purchased from approved sources under valid purchase vouchers, possibly from producers directly.
- Identified and their containers examined for damage and assigned control number.
- There shall be separate areas for materials under test, approved and rejected.
- All incoming materials shall be quarantined immediately after receipt or processing.
- Materials must be stored in such a way that first in/first expiry, first out principle can be applied.
- Only raw materials released by QC department and which are within their shelf-life shall be used.

### *Sterile Products*

- Separate enclosed areas provided with air locks, dust free, ventilated with air supply through HEPA filters are recommended.
- Routine microbial counts of area are necessary during manufacturing operation.
- Design of area must avoid possibility of mix-up between sterile and nonsterile products.
- Access to manufacturing area must be restricted to authorized personnel only.

### *Working Space*

- Adequate working space and adequate room for orderly placement of equipment and materials should be provided

to eliminate mix-up between different drugs and cross contamination.
- Separate space should be provided in storage area for "under test", "approved", and "rejected", materials.

### *Medical Services*

Manufacturer must provide facilities for:
- Adequate facilities for first aid.
- Medical examination of workers at time of employment and periodic checkup there after once in a year.
- Facilities for vaccination or other exigencies.

### *Equipment*

Equipment used for manufacture must be constructed, designed, installed and maintained to:
- Achieve operational efficiency to attain the desired quality.
- Prevent physical, chemical or physiochemical change through surface contact.
- Prevent contact of any substances required for operation of equipment such as lubricants.
- Facilitate thorough cleaning whenever necessary.
- Minimize any contamination of any drugs and their containers during manufacture.

### *Master Formula Records*

- The licensee has to maintain master formula records.
- Relating to all manufacturing procedures for each product, the master formula record must have:
  - Patent or proprietary name of product along with generic name, strength and dosage form, description or identification of final containers, packaging materials.
  - Labels and closures to be used.
  - Identity, quality and quantity of each raw material to be used.
  - Description of all equipment and vessels and the size used in the process.
  - Manufacturing and control instructions along with parameters for critical steps such as mixing, drying, blending, sieving, and sterilizing the product.

- Theoretical yield to be expected from the formulation
- Detailed instructions and precautions to be taken in manufacture, storage of drugs and of semi-finished products and the requirements in process quality control tests and analysis to be carried out during each stage of manufacture.

### *Batch Manufacturing Records*

Licensee has maintain batch manufacturing records for each batch of drugs as per Schedule U. It has provide complete account of manufacturing history of each batch showing that it has been manufactured, tested and analyzed in accordance with manufacturing procedures and written instructions as per master formulae.

### *Manufacturing Operations and Control*

All manufacturing operations must be carried out under the supervision of competent technical staff. Critical steps in the process related to selection, weighing and measuring of raw materials must be done under the direct supervision of competent technical staff.

### *Product Containers and Closures*

Has complied with pharmacopoeial requirements. Suitable test methods, cleaning and sterilization procedures should be used to assure that components, closures and other component part of drug packages are suitable and they are not reactive, additive, absorptive or leach to an extent that significantly affects the quality or purity of the drug.

### *Labels and other Printed Materials*

Printed labels and packaging materials including leaflets have be handles and accounted to ensure that they do not become intermixed. Prior to issue, they should be examined and released as satisfactory for use by quality control personnel.

### *Distribution of Records*

Records for the distribution of each batch of drug should be maintained in order to facilitate prompt and complete recall of the batch if necessary.

### *Quality Control System*

*Principal duties of quality control department are:*

- Prepared detailed instruction for carrying out each tests and analysis.
- To release or reject (i) each batch of raw material, (ii) semi-finished products if necessary, (iii) packaging and labeling materials and final containers, (iv) each batch of finished products ready for distribution.
- Evaluate adequacy of conditions under which raw materials, semifinished products and finished products are stored.
- Evaluate quality and stability of finished products.
- To establish, and when necessary revise, control procedures and specifications.
- To examine returned products as to whether such products be released, reprocessed or destroyed.

## PART IA

***Specific requirements for manufacture of sterile products. parenteral preparations (small volume injectables and large volume parenterals) and sterile ophthalmic preparations.***

### Introduction

- Following implementation of these WHO good manufacturing practices (GMP) guidelines within the context of the WHO Prequalification of Medicines Programme, clarifying, editorial modifications have been proposed.
- These changes were adopted for maintenance purposes. In order to ease reading the full guideline has been reproduced again as an Annex to the current report of the WHO Expert Committee on specifications for pharmaceutical preparations.

### WHO Good Manufacturing Practices for Sterile Pharmaceutical Products

1. General considerations
2. Quality control
3. Sanitation
4. Manufacture of sterile preparations
5. Sterilization

6. Terminal sterilization
7. Aseptic processing and sterilization by filtration
8. Isolator technology
9. Blow/fill/seal technology
10. Personnel
11. Premises
12. Equipment
13. Finishing of sterile products

### *General Considerations*

- The production of sterile preparations should be carried out in clean areas, entry to which should be through airlocks for personnel and/or for equipment and materials. Clean areas should be maintained to an appropriate standard of cleanliness and supplied with air that has passed through filters of the required efficiency.
- The various operations of component preparation (such as those involving containers and closures), product preparation, filling and sterilization should be carried out in separate areas within the clean area. These areas are classified into four grades (*see* Section 4).

*Manufacturing operations are divided here into two categories:*

- First, those where the product is terminally sterilized; and
- Second, those which are conducted aseptically at some or all stages.

### *Quality Control*

- The sterility test applied to the finished product should only be regarded as the last in a series of control measures by which sterility is assured. The test should be validated for the product(s) concerned.
- Samples taken for sterility testing should be representative of the whole of the batch but should, in particular, include samples taken from parts of the batch considered to be most at risk of contamination. For example:
- Products that have been filled aseptically, samples should include containers filled at the beginning and end of the batch and after any significant interruption of work; for products

that have been heat sterilized in their final containers, consideration should be given to taking samples from that part of the load that is potentially the coolest.

- The sterility of the finished product is assured by validation of the sterilization cycle in the case of terminally sterilized products, and by "media simulation" or "media fill" runs for aseptically processed products. Batch-processing records and, in the case of aseptic processing, environmental quality records, should be examined in conjunction with the results of the sterility tests.
- The sterility test procedure should be validated for a given product. Pharmacopoeial methods should be used for the validation and performance of the sterility test. In those cases where parametric release has been authorized in place of sterility testing special attention should be paid to the validation and the monitoring of the entire manufacturing process.
- For injectable products the water for injection and the intermediate, if appropriate, and finished products should be monitored for endotoxins, using an established pharmacopoeial method that has been validated for each type of product. For large volume infusion solutions, such monitoring of water or intermediates should always be done, in addition to any tests required by an approved monograph for the finished product. When a sample fails a test, the cause of the failure should be investigated and necessary action should be taken. Alternative methods to those in the pharmacopoeias may be used if they are validated, justified and authorized.

### *Sanitation*

- The sanitation of clean areas is particularly important. They should be cleaned frequently and thoroughly in accordance with an approved written programme. Where disinfectants are used, more than one type should be employed. Monitoring should be regularly undertaken to detect contamination or the presence of an organism against which the cleaning procedure is ineffective. Interactions between different cleaning materials should be validated. Appropriate cleaning validation should be carried out to ensure disinfectant residuals can be detected and are removed by the cleaning process.

- Disinfectants and detergents should be monitored for microbial contamination; dilutions should be kept in previously cleaned containers and should only be stored for defined periods unless sterilized. Disinfectants and detergents used in Grade A and B areas should be sterile before use.
- A disinfectant programme should also include a sporicidal agent since many common disinfectants are ineffective against spores. The effectiveness of cleaning and disinfectant procedures should be demonstrated.
- Fumigation of clean areas may be useful for reducing microbial contamination in inaccessible places.

### *Manufacture of Sterile Preparations*

Clean areas for the manufacture of sterile products are classified according to the required characteristics of the environment. Each manufacturing operation requires an appropriate level of environmental cleanliness in the operational state to minimize the risks of particulate or microbial contamination of the product or materials being handled.

*For the manufacture of sterile pharmaceutical preparations, four grades of clean areas are distinguished as follows:*

**Grade A:** The local zone for high-risk operations, e.g. filling and making aseptic connections. Normally such conditions are achieved by using a unidirectional airflow workstation. Unidirectional airflow systems should provide a homogeneous air speed of 0.36–0.54 m/s (guidance value) at a defined test position 15–30 cm below the terminal filter or air distributor system. The velocity at working level should not be less than 0.36 m/s. The uniformity and effectiveness of the unidirectional airflow should be demonstrated by undertaking airflow visualization tests.

**Grade B:** In aseptic preparation and filling, this is the background environment for the Grade A zone.

**Grades C and D:** Clean areas for carrying out less critical stages in the manufacture of sterile products or carrying out activities during which the product is not directly exposed (i.e. aseptic connection with aseptic connectors and operations in a closed system).

*A unidirectional airflow and lower velocities may be used in closed isolators and glove boxes.*

- In order to reach the B, C and D air grades the number of air changes should be appropriate for the size of the room and the equipment and personnel present in it.
- High efficiency particulate air (HEPA) filters should be subjected to an installed filter leakage test in accordance with ISO 14644–3 (3) at a recommended interval of every 6 months, but not exceeding 12 months. The purpose of performing regular leak tests is to ensure the filter media, filter frame and filter seal are free from leaks. The aerosol selected for HEPA leak testing should not support microbial growth and should be composed of a sufficient number or mass of particles.

**Table 1.4:** Maximum permitted airborne particle concentrate

| *Grade* | *Maximum permitted number of particles per $m^3$ greater than or equal to the tabulated size* | | | |
|---|---|---|---|---|
| | *At rest* | | *In operation* | |
| | *0.5 µm* | *5.0 µm* | *0.5 µm* | *5.0 µm* |
| A | 3520 | 20 | 3520 | 20 |
| B | 3520 | 29 | 352000 | 2900 |
| C | 352000 | 2900 | 3520000 | 29000 |
| D | 3520000 | 29000 | Not defined | Not defined |

- The "at rest" state is the condition where the installation is complete with equipment installed and operating in a manner agreed upon by the customer and supplier, but with no personnel present.
- The "in operation" state is the condition where the installation is functioning in the defined operating mode and the specified number of personnel is present. The areas and their associated environmental control systems should be designed to achieve both the "at rest" and "in operation" states.

### *Terminally Sterilized Products*

- Components and most products should be prepared in at least a Grade D environment to ensure low microbial

bioburden and particulate counts prior to filtration and sterilization. Where the product is at unusual risk of microbial contamination (e.g. because it actively supports microbial growth, must be held for a long period before sterilization, or is necessarily processed mainly in open vessels), the preparation should generally be done in a Grade C environment.

- The filling of products for terminal sterilization should generally be done in at least a Grade C environment.
- Where the product is at unusual risk of contamination from the environment (e.g. because the filling operation is slow, the containers are wide-necked or are necessarily exposed for more than a few seconds before sealing), the filling should be done in a Grade A zone with at least a Grade C background.
- The preparation and filling of ointments, creams, suspensions and emulsions should generally be done in a Grade C environment before terminal sterilization.

### *Aseptic Preparation*

- Components after washing should be handled in at least a Grade D environment. The handling of sterile starting materials and components, unless subjected to sterilization or filtration through a microorganism-retaining filter later in the process, should be undertaken in a Grade A environment with a Grade B background.
- The preparation of solutions which are to be sterile-filtered during the process should be undertaken in a Grade C environment (unless a closed system is used, in which case a Class D environment may be justifiable). If not sterile-filtered (therefore an aseptic manipulation) the preparation of materials and products should be undertaken in a Grade A environment with a Grade B background.
- The handling and filling of aseptically prepared products, as well as the handling of exposed sterile equipment, should be undertaken in a Grade A environment with a Grade B background.
- The transfer of partially closed containers, as used in freeze-drying, before stoppering is completed, should be undertaken either in a Grade A environment with a Grade B background or in sealed transfer trays in a Grade B environment.

### Processing

- Precautions to minimize contamination should be taken during all processing stages, including the stages before sterilization.
- In general preparation containing live microorganism should not be made nor should container be filled in areas used for the processing of other pharmaceutical products.
- Validation of aseptic processing should include a process simulation test using a nutrient medium (media fill). Selection of the nutrient medium should be made based on dosage form of the product and selectivity, clarity, concentration and suitability for sterilization of the nutrient medium.

## PART IB

***Specific requirements for manufacture of oral solid dosage forms (tablets and capsules).***

- In this article we will discuss about manufacturing process. Read: Documentations, requirements and other formalities to start solid dosage form manufacturing company.
- Solid dosage form is well accepted and most popular dosage form in pharmaceutical industry. Accuracy in dose and easy to take like advantage give it popularity among professionals and patients. Today we are going to discuss about manufacturing of solid dosage form, i.e. tablet and capsule.

### Technical Staff

- Manufacturing chemist
- Analytical chemist
- Quality assurance manager
- Production supervisors

### Non-technical Staff

- Machine operators
- Helpers

### Section Required

- Mixing, granulation and drying section
- Tablet punching section

- Coating (film coating and sugar coating) section
- Capsule filling section (in case of capsule)
- Packaging section

### Machinery used

Weighing machines and testing equipment (e.g. electronic balance, hardness tester, friability and disintegrated test apparatus, tablet inspection units, dissolution test apparatus etc.), disintegrator and shifter, mixer (mass/rapid/planetary mixer), granulator, drier (trey/fluid bed drier), rotatory (tablet compression machine)—single or multi-punch, punches and dies (as per tablet size/s), packaging machines (blister/strip/alu-alu, etc.) and testing equipment, coating and polishing pan (in case of coated tablets), capsule filling machine.

### Tablet Manufacturing

*Tablet manufacturing process involves following steps:*

- Dispensing of ingredients
- Sizing
- Blending
- Formulation
- Milling and granulation
- Drying
- Final blending:
  - Tablet compression
  - Coating
  - Packaging

*Three processes are used to manufacture tablet dosage form:*

- Direct compression
- Wet granulating
- Dry granulating

#### *Direct Compression Method*

This method is used for tablet compression only if powder/s is easily compressible and does not require any additional requirement for compression. All powders are mixed and directly compressed into tablet punching machine for making

a tablet. Powdered should be blended together and should remain in mixed form.

### *Wet Granulating Method*

Widely used method for making tablets if powders used are not easily compressible or floppy in nature or do not mix well then wet granulating process is used. Wet granulating method follows following steps:

- Mixing of active ingredients and excipients
- Preparation of binding material
- Addition or mixing of mixed powders and binding solution
- Sieved or milled to convert into granules
- Drying and sieve again
- Mix disintegrant, glidant and lubricant into it.

### *Dry Granulating Method*

- If the material used is sensitive to heat or volatile in nature then we have to compress tablet without use of heat and solvents. There are two basic procedures used in dry granulating method. One is to form a pack or compact by compression and then sieved or milled to convert into granules.
- In dry granulation, one method is to recompress powder into slugs and milled to form granules and second method is to form compacts through pressure. Compaction of powder is accomplished by rolling powder under pressure.

**Method used for manufacturing tablet is depended at raw material nature used for making tablets. Wet granulating method is widely accepted and used to compress raw material into tablet form**.

### *Procedure for Tablet Manufacturing*

**Dispensing:** Each ingredient including active ingredient/s should be accurately dispenses as per dose. It is one of the critical steps and any type of formulation. Weighing and measuring should be done under technical supervision.

**Sizing:** If all ingredients are of equal size, it becomes easier to mix all of them. Sizing is an important part in tablet manufacturing. Reduce all ingredients to equal size for better flow property and easy mixing.

**Blending:** Blend all powders to make a uniform and homogeneous mixer.

**Formulation:** Mix this mixture with binding agent.

**Pre-milling:** Now above formulation passed through mills or sieves to form granules.

**Drying:** Granules need to be dried for a particular time period in trey dry or fluid bed drier.

**Milling:** Again pass through this mixture into mills and sieve it.

**Final blending:** Blend above granules finally with disintegrants, lubricates and glidants.

**Rotary machine:** Next step is to compress these granules into tablet form. Rotary machine contains punch and die. Size and shape of punch and die may vary according to your need. Compression is crucial for tablet manufacturing. It should not be low or high. If it will be low, tablet will not have hardness. If compression is high then tablet dissolution time will be affected. Granules or powder is flowed toward dye; fill the space obtained by vacuum in die. After filling of die, punch compression is obtained to convert powder or granules into tablet.

**Coating pan:** If tablets need to be coated then a coating material is prepared and sprayed at tablets in coating pan till desired coating film is obtained.

*Tablets defect that should be consider during manufacturing:*

- Weight variation
- Friability variation
- Capping and molting
- Sticking and picking
- Laminating
- Double press
- Chipping

*Test during and after manufacturing:*

- Weight variation
- Hardness

- Dissolution time
- Friability testing
- Assay

*Principles of capsule filling machines:*

- Positioned all incoming capsules into upright position
- Separate cap and body of capsule shell
- Attained pre-determined volume
- Fill powder/granules/pallets in capsule shell body
- Remove excess material
- Rejoined cap and body of capsule shell
- Polishing of capsule shell
- Eject capsule from machine
- Packaging

**Preparation for filling hard gelatin capsules:** At large scale and small scale generally filling of capsule could be divided into following steps:

- Developing and preparing the formulation and selecting the capsule size
- Filling the capsule shells
- Capsule sealing (optional)
- Cleaning and polishing the filled capsules.

## PART IC

***Specific requirements for manufacture of oral liquids (syrups, elixirs, emulsions, and suspensions).***

Oral liquids are homogeneous liquid preparations, usually contains a solution, an emulsion or a suspension of one or more active ingredients in a suitable liquid base. They are prepared for oral administration either as such or after dilution. They may contain other substances such as suitable dispersing, solubilizing, wetting, emulsifying, stabilizing, suspending, thickening agents and antimicrobial substances for preservation.

### Building and Equipment

- The premises and equipment shall be designed, constructed and maintained to suit the manufacturing of oral liquids.

The layout and design of the manufacturing area shall strive to minimize the risk of cross-contamination and mix ups.

- Manufacturing area shall have entry through double door air-lock facility. It shall be made fly proof by use of flycatcher and/or 'air curtain'.
- The production area shall be cleaned and sanitized at the end of every production process. Tanks, containers, pipework and pumps shall be designed and installed so that they can be easily cleaned and sanitized. Equipment design shall be such as to prevent accumulation of residual microbial growth or cross-contamination.
- Stainless steel or any other appropriate material shall be used for parts of equipment coming in direct contact with the products. The use of glass apparatus shall be minimum.
- Arrangements for cleaning of containers, closures, and droppers shall be made with the help of suitable machines/devices equipped with high pressure air, water, and steam jets.
- The furniture used shall be smooth, washable and made of stainless steel or any other appropriate material which is scratch proof, washable and smooth.

### Purified Water

The chemical and microbiological quality of purified water used shall be specified and monitored routinely. The microbiological evaluation shall include testing for the absence of pathogens and shall not exceed 100 CFU/ml (as per Appendix 12.5 of IP 1996).

### Manufacturing

- Manufacturing personnel shall wear wherever required non-fiber shedding clothing to prevent contamination of the product.
- Materials likely to shed fiber-like gunny bags, or wooden pallets shall not be carried into the area, where products or cleaned-containers are exposed.
- Care shall be taken to maintain the homogeneity of the emulsion by use of appropriate emulsifier and suspensions by use of appropriate stirrer during filling. Mixing and filling

processes shall be specified and monitored. Special care shall be taken at the beginning of the filling process, after a stoppage due to any interruption and at the end of the process to ensure that the product is uniformly homogenous during the filling process.

- The primary packaging area shall have an air supply which is filtered through 5 µm filters. The temperature of the area shall not exceed 30°C.
- When the bulk product is not immediately packed, the maximum period of storage and storage conditions shall be specified in the master formula. The maximum period of storage time of a product in the bulk stage shall be validated.

## PART ID

***Specific requirements for manufacture of topical products, i.e. external preparations (creams, ointments, pastes, emulsions, lotions, solutions, dusting powders and identical products).***

**Note:** The general requirements as given in Part I of this Schedule relating to requirements of good manufacturing practices for premises and materials for pharmaceutical products shall be complied with, mutatis mutandis, for the manufacture of topical products, i.e. external preparations (creams, ointments, pastes, emulsions, lotions, solutions, dusting powders and identical products used for external applications). In addition to these requirements, the following specific requirements shall also be followed, namely:

1. The entrance to the area where topical products are manufactured shall be through a suitable airlock. Outside the airlock, insectocutors shall be installed.
2. The air to this manufacturing area shall be filtered through at least 20 µm air filters and shall be air-conditioned.
3. The area shall be fitted with an exhaust system of suitable capacity to effectively remove vapors, fumes, smoke or floating dust particles.
4. The equipment used shall be designed and maintained to prevent the product from being accidentally contaminated with any foreign matter or lubricant.

5. Suitable cleaning equipment and material shall be used in the process of cleaning or drying the process equipment or accessories used.
6. Water used in compounding shall be purified water IP.
7. Powders, whenever used, shall be suitably sieved before use.
8. Heating vehicles and a base-like petroleum jelly shall be done in a separate mixing area in suitable stainless steel vessels, using steam, gas, electricity, solar energy, etc.
9. A separate packing section may be provided for primary packaging of the products.

## PART IE

### *Specific requirements for manufacture of metered-dose inhalers (MDI)*

**Note:** The general requirements as given in Part I of this Schedule relating to requirements of good manufacturing practices for premises and materials for pharmaceutical products shall be complied with, mutatis mutandis, for the manufacture of metered-dose inhalers (MDI). In addition to these requirements, the following specific requirements shall also be followed.

### General

Manufacture of metered-dose inhalers shall be done under conditions which shall ensure minimum microbial and particulate contamination. Assurance of the quality of components and the bulk product is very important. Where medicaments are in suspended state, uniformity of suspension shall be established.

### Building and Civil Works

- The building shall be located on a solid foundation to reduce risk of cracking walls and floor due to the movement of equipment and machinery.
- All building surfaces shall be impervious, smooth and non-shedding. Flooring shall be continuous and provided with a cover between the floor and the wall as well as between the wall and the ceiling. Ceiling shall be solid, continuous and preceded a cone with the walls. Light fittings and air-grills

shall be flush with the ceiling. All service lines requiring maintenance shall be erected in such a manner that these are accessible from outside the production area.

- The manufacturing area shall be segregated into change rooms for personnel, container preparation area, bulk preparation and filling area, quarantine area and spray testing and packing areas.
- Secondary change rooms shall be provided for operators to change from factory clothing to special departmental clothing before entering the manufacturing and filling area.
- Separate area shall be provided for de-cartooning of components before they are air washed.
- The propellants used for manufacture shall be delivered to the manufacturing area distribution system by filtering them through 2 μm filters. The bulk containers of propellants shall be stored, suitably identified, away from the manufacturing facilities.

### Environmental Conditions

- Where products or clean components are exposed, the area shall be supplied with filtered air of Grade C.
- The requirements of temperature and humidity in the manufacturing area shall be decided depending on the type of product and propellants handled in the facility. Other support areas shall have comfort levels of temperature and humidity.
- There shall be a difference in room pressure between the manufacturing area and the support areas and the differential pressure shall be not less than 15 pascals (0.06 inches or 1.5 mm water gauge).
- There shall be a written schedule for the monitoring of environmental conditions. Temperature and humidity shall be monitored daily.

### Garments

- Personnel in the manufacturing and filling section shall wear suitable single piece-garment made out of non-shedding, tight weave material. Personnel in support areas shall wear clean factory uniforms.

- Gloves made of suitable material having no interaction with the propellants shall be used by the operators in the manufacturing and filling areas. Preferably, disposable gloves shall be used.
- Suitable department-specific personnel protective equipment like footwear and safety glasses shall be used wherever hazard exists.

### Sanitation

- There shall be written procedures for the sanitation of the MDI manufacturing facility. Special care should be taken to handle residues and rinses of propellants.
- Use of water for cleaning shall be restricted and controlled. Routinely used disinfectants are suitable for sanitizing the different areas. Records of sanitation shall be maintained.

### Equipment

- Manufacturing equipment shall be of closed system. The vessels and supply lines shall be of stainless steel.
- Suitable check weights spray testing machines and labeling machines shall be provided in the department.
- All the equipment shall be suitably calibrated and their performance validated on receipt and thereafter periodically.

### Manufacture

- There shall be an approved master formula records for the manufacture of metered-dose inhalers. All propellants, liquids and gases shall be filtered through 2 µm filters to remove particles.
- The primary packing material shall be appropriately cleaned by compressed air suitably filtered through 0.2 µm filter. The humidity of the compressed air shall be controlled as applicable.
- The valves shall be carefully handled and after de-cartoning, these shall be kept in clean, closed containers in the filling room.
- For suspensions, the bulk shall be kept stirred continuously.
- In-process controls shall include periodical checking of weight of bulk formulation filled in the containers. In a

two-shot-filling process (liquid filling followed by gaseous filling), it shall be ensured that 100% check on weight is carried out.

- Filled containers shall be quarantined for a suitable period established by the manufacturer to detect leaking containers prior to testing, labelling and packing.

### Documentation

In addition to the routine good manufacturing practices documentation, manufacturing records shall show the following additional information:

1. Temperature and humidity in the manufacturing area.
2. Periodic filled weights of the formulation.
3. Records of rejections during online check weighing.
4. Records of rejection during spray testing.

## PART IF

***Specific requirements of premises, plant and materials for manufacture of active pharmaceutical ingredients (bulk drugs).***

**Note:** The general requirements as given in Part I of this Schedule relating to requirements of good manufacturing practices for premises and materials for pharmaceutical products shall be complied with, mutatis mutandis, for the manufacture of active pharmaceutical ingredients (bulk drugs). In addition to these requirements, the following specific requirements shall also be followed.

### Buildings and Civil Works

Apart from the building requirements contained in Part I, the active pharmaceutical ingredient facilities for manufacture of hazardous reactions, β-lactam antibiotics, steroids and steroidal hormones/cytotoxic substances shall be provided in confined areas to prevent contamination of the other drugs manufactured.

The final stage of preparation of a drug, like isolation/filtration/drying/milling/sieving and packing operations shall be provided with air filtration systems including pre-filters and finally with a 5 µm filter. Air handling systems with

adequate number of air changes per hour or any other suitable system to control the airborne contamination shall be provided. Humidity/temperature shall also be controlled for all the operations wherever required.

Air filtration systems including pre-filters and particulate matter retention air filters shall be used, where appropriate, for air supplies to production areas. If air is re-circulated to production areas, measures shall be taken to control recirculation of floating dust particles from production. In areas where air contamination occurs during production, there shall be adequate exhaust system to control contaminants.

Ancillary area shall be provided for boiler house. Utility areas like heat exchangers, chilling workshop, store and supply of gases shall also be provided.

For specified preparation like manufacture of sterile products and for certain antibiotics, sex hormones, cytotoxic and oncology products, separate enclosed areas shall be designed. The requirements for the sterile active pharmaceutical ingredient shall be in line with the facilities required for formulations to be filled aseptically.

### Sterile Products

Sterile active pharmaceutical ingredient filled aseptically shall be treated as formulation from the stage wherever the process demands like crystallization, lyophilisation, filtration, etc. All conditions applicable to formulations that are required to be filled aseptically shall apply mutatis mutandis for the manufacture of sterile active pharmaceutical ingredients involving stages like filtration, crystallization and lyophilisation.

### Utilities/Services

Equipment like chilling plant, boiler, heat exchangers, vacuum and gas storage vessels shall be serviced, cleaned, sanitized and maintained at appropriate intervals to prevent malfunctions or contamination that may interfere with safety, identity, strength, quality or purity of the drug product.

### Equipment Design, Size and Location

Equipment used in the manufacture, processing, packing or holding of an active pharmaceutical ingredient shall be of

appropriate design, adequate size and suitably located to facilitate operations for its intended use and for its cleaning and maintenance.

If equipment is used for different intermediates and active pharmaceutical ingredients, proper cleaning before switching from one product to another becomes particularly important. If cleaning of a specific type of equipment is difficult, the equipment may need to be dedicated to a particular intermediate or active pharmaceutical ingredient.

*The choice of cleaning methods, detergents and levels of cleaning shall be defined and justified. Selection of cleaning agents (e.g. solvents) should depend on:*

a. The suitability of the cleaning agent to remove residues of raw materials, intermediates, precursors, degradation products and isomers, as appropriate.
b. Whether the cleaning agent leaves a residue itself;
c. Compatibility with equipment construction materials like centrifuge/filtration, dryer/fluid bed dryer, rotocone proton dryer, vacuum dryer, frit mill, multi-mill/jet mills/ sewetters cut sizing;
d. Test for absence of intermediate or active pharmaceutical ingredient in the final rinse.

Written procedures shall be established and followed for cleaning and maintenance of equipment, including utensils used in the manufacture, processing, packing or holding of active pharmaceutical ingredients. These procedures shall include but should not be limited to the following:

a. Assignment of responsibility for cleaning and maintaining equipment.
b. Maintenance and cleaning program schedules, including where appropriate, sanitizing schedules.
c. A complete description of the methods and materials used to clean and maintain equipment, including instructions for dis-assembling and reassembling each article of equipment to ensure proper cleaning and maintenance
d. Removal or obliteration of previous batch identification.
e. Protection of clean equipment from contamination prior to use.

f. Inspection of equipment for cleanliness immediately before use.
g. Establishing the maximum time that may elapse between completion of processing and equipment cleaning as well as between cleaning and equipment reuse.

Equipment shall be cleaned between successive batches to prevent contamination and carry-over of degraded material or contaminants unless otherwise established by validation.

As processing approaches the final purified active pharmaceutical ingredient, it is important to ensure that incidental carry over between batches does not have adverse impact on the established impurity profile. However, this does not generally hold good for any biological, active pharmaceutical ingredient where many of the processing steps are accomplished aseptically and where it is necessary to clean and sterilize equipment between batches.

### In-process Controls

*In-process controls for chemical reactions may include the following:*

a. Reaction time or reaction completion;
b. Reaction mass appearance, clarity, completeness or pH solutions;
c. Reaction temperature;
d. Concentration of a reactant;
e. Assay or purity of the product;
f. Process completion check by TLC/any other means.

*In-process controls for physical operations may include the following:*

a. Appearance and color
b. Uniformity of the blend
c. Temperature of a process
d. Concentration of a solution
e. Processing rate or time
f. Particle size analysis
g. Bulk/tap density
h. pH determination
i. Moisture content.

### Product Containers and Closures

- All containers and closures shall comply with the Pharmacopoeial or any other requirement, suitable sampling methods, sample sizes, specifications, test methods, cleaning procedures and sterilization procedures, when indicated, shall be used to assure that containers, closures and other component parts of drug packages are suitable and are not reactive, additive, adsorptive or leachable to an extent that significantly affects the quality or purity of the drug.
- The drug product container shall be re-tested or re-examined as appropriate and approved or rejected and shall be identified and controlled under a quarantine system designed to prevent their use in manufacturing or processing operations for which these are unsuitable.
- Container closure system shall provide adequate protection against foreseeable external factors in storage/transportation and use that may cause deterioration or contamination of the active pharmaceutical ingredient.
- Bulk containers and closures shall be cleaned and, where indicated by the nature of the active pharmaceutical ingredient, sterilized to ensure that they are suitable for their intended use.
- The container shall be conspicuously marked with the name of the product and the following additional information concerning:
  a. quality and standards, if specified;
  b. Manufacturing license number/drug master file number (whichever applicable), batch number;
  c. Date of manufacture and date of expiry;
  d. Method for container disposal (label shall give the methodology, if required);
  e. Storage conditions, if specified and name and address of the manufacturer, if available.

Areas for different operation of active pharmaceutical ingredients (bulk drugs) section shall have appropriate areas which may be suitably partitioned for different operations.

## DETAIL STUDY OF SCHEDULE H AND H1

- These are drugs which cannot be purchased **over-the-counter** without the prescription of a qualified doctor.
- Another provision needs to be followed is that, only the required amount of medications mentioned in the prescription can be dispensed.
- It is a class of prescription drugs which cannot be purchased over-the-counter the present list included 536 drugs.

## SCHEDULE H (*See* Rules 65 and 97) PRESCRIPTION DRUGS

1. Abacavir
2. Abciximab
3. Acamprosate calcium
4. Acebutol hydrochloride
5. Aclarubicin
6. Albendazole
7. Alclometasone dipropionate
8. Actilyse
9. Acyclovir
10. Adenosine
11. Adrenocorticotrophic hormone (ACTH)
12. Alendronate sodium
13. Allopurinol
14. Alphachymotrypsin
15. Alprazolam
16. Alprostadil
17. Amantadine hydrochloride
18. Amifostine
19. Amikacin sulphate
20. Amiloride hydrochloride
21. Amineptine
22. Aminoglutethimide
23. Aminosalicylic acid
24. Amiodarone hydrochloride
25. Amitriptyline
26. Amlodipine besylate
27. Amoscanate
28. Amoxopine
29. Amrinone lactate
30. Analgin
31. Androgenic anabolic, oestrogenic and progestational substances
32. Antibiotics
33. Apraclonidine
34. Aprotinin
35. Organic compound of arsenic
36. Arteether
37. Artemether
38. Artesunate
39. Articaine hydrochloride
40. Atenolol 2
41. Atracurium besylate injection
42. Atorvastatin
43. Auranofin
44. Azathioprine
45. Aztreonam
46. Bacampicillin
47. Baclofen
48. Balsalazide
49. Bambuterol
50. Barbituric acid
51. Basiliximab
52. Benazepril hydrochloride
53. Benidipine hydrochloride

54. Benserazide hydrochloride
55. Betahistine dihydrochloride
56. Bethanidine sulphate
57. Bezafibrate
58. Bicalutamide
59. Biclotymol
60. Bifonazole
61. Bimatoprost
62. Biperiden hydrochloride
63. Biphenyl acetic acid
64. Bitoscanate
65. Bleomycin
66. Primonidine tartrate
67. Bromhexine hydrochloride
68. Bromocriptine mesylate
69. Budesonide
70. Bulaquine
71. Bupivacaine hydrochloride
72. Bupropion
73. Buspirone
74. Butenafine hydrochloride
75. Butorphanol tartrate
76. Cabergoline
77. Calcium dobesilate
78. Candesartan
79. Capecitabine
80. Captopril
81. Carbidopa
82. Carbocisteine
83. Carboplatin
84. Carboquone
85. Carisoprodol
86. L-carnitine
87. Carteolol hydrochloride
88. Carvedilol
89. Cefadroxyl
90. Cefatoxime sodium
91. Cefazolin sodium
92. Cefdinir
93. Cefepime hydrochloride
94. Cefetamet pivoxil
95. Cefpirome
96. Cefpodoxime poxetil
97. Ceftazidime pentahydrate
98. Ceftizoxime sodium
99. Cefuroxime
100. Celecoxib
101. Centchroman
102. Centbutindole
103. Centpropazine
104. Cetirizine hydrochloride
105. Chlordiazepoxide
106. Chlormezanone
107. Omitted vide GSR 790 (E) dated 29.10.2009
108. Chlorpromazine
109. Chlorzoxazone
110. Ciclopirox olamine
111. Cimetidine
112. Cinnarizine
113. Ciprofloxacin hydrochloride monohydrate/lactate
114. Cisplatin
115. Citalopram hydrobromide
116. Clarithromycin
117. Clavulanic acid
118. Clidinium bromide
119. Clindamycin
120. Clobazam
121. Clobetasol propionate
122. Clobetasone 17-butyrate
123. Clofazimine
124. Clofibrate
125. Clonazepam
126. Clonidine hydrochloride
127. Clopamide
128. Clopidogrel bisulphate
129. Clostebol acetate
130. Clotrimazole

131. Clozapine
132. Codeine
133. Colchicine
134. Corticosteroids
135. Cotrimoxazole
136. Cyclandelate
137. Cyclosporins
138. Daclizumab
139. Danazole
140. Dapsone
141. Desloratadine
142. Desogestrol
143. Dexrazoxane
144. Dextranomer
145. Omitted vide GSR 790 (E) dated on 29.10.2009
146. Dextropropoxyphene
147. Diazepam
148. Diazoxide
149. Diclofenac sodium/potassium/ acid 3
150. Dicyclomin hydrochloride
151. Didanosine
152. Digoxin
153. Dilazep hydrochloride
154. Diltiazem
155. Dinoprostone
156. Diphenoxylate, its salts
157. Dipivefrin hydrochloride
158. Di-sodium pamidronate
159. Disopyramide
160. Docetaxel
161. Domperidone
162. Donepezil hydrochloride
163. Dopamine hydrochloride
164. Dothiepin hydrochloride
165. Doxapram hydrochloride
166. Doxazosin mesylate
167. Doxepin hydrochloride
168. Doxorubicin hydrochloride
169. Drotrecogin-alpha
170. Ebastine
171. Econozole
172. Efavirenz
173. Enalapril meleate
174. Enfenamic acid
175. Epinephrine
176. Epirubicine
177. Eptifibatide
178. Ergot, alkaloids of whether hydrogenated or not, their homologoues, salts
179. Esomeprazole
180. Estradiol succinate
181. Estramustine phosphate
182. Etanercept
183. Ethacridine lactate
184. Ethambutol hydrochloride
185. Ethamsylate
186. Ethinyloestradiol
187. Ethionamide
188. Etidronate disodium
189. Etodolac
190. Etomidate
191. Etoposide
192. Exemestane
193. Famciclovir
194. Famotidine
195. Fenbendazole
196. Fenofibrate
197. Fexofenadine
198. Finasteride
199. Flavoxate hydrochloride
200. 5-fluorouracil
201. Fludarabine
202. Flufenamic acids
203. Flunarizine hdrochloride
204. Fluoxetine hydrochloride
205. Flupenthixol

206. Fluphenazine enanthate and decanoate
207. Flurazepam
208. Flurbiprofen
209. Flutamide
210. Fluticasone propionate
211. Fluvoxamine maleate
212. Formestane
213. Fosfestril sodium
214. Fosinopril sodium
215. Fossphenytoin sodium
216. Fotemustine
217. Gabapentin
218. Galanthamine hydrobromide
219. Gallamine, its salts, its quaternary compound
220. Gancyclovir
221. Ganirelix
222. Gatifloxacin
223. Gemcitabine
224. Gemfibrozil
225. Gemtuzumab
226. Genodeoxycholic acid
227. Gliclazide
228. Glimepiride
229. Glucagon
230. Glycopyrrolate
231. Glydiazinamide
232. Goserelin acetate
233. Granisetron
234. Guanethidine
235. Gugulipid
236. Halogenated hydroxyquinolines
237. Haloperidol
238. Heparin
239. Hepatitis B vaccine
240. Hyaluronidase
241. Hydrocorisone 17-butyrate
242. Hydrotalcite
243. Hydroxizine
244. Ibuprofen
245. Idebenone
246. Indapamide
247. Imipramine
248. Indinavir sulphate
249. Indomethacin
250. Insulin human
251. Interferon
252. Intravenous fat emulsion
253. Iobitridol
254. Iohexol
255. Iopamidol 4
256. Iomeprol
257. Iopromide
258. Irbesartan
259. Irinotecan hydrochloride
260. Iron preparation for parenteral use
261. Isepamicine
262. Isocarboxazid
263. Isoflurane
264. Isonicotinic acid hydrazine and other hydragine derivatives of isonicotinic acid
265. Isosorbide dinitrate/ mononitrate
266. Isotretinoin
267. Isoxsuprine
268. Itopride
269. Ketamine hydrochloride
270. Ketoconazole
271. Ketoprofen
272. Ketorolac tromethamine
273. Labetalol hydrochloride
274. Lacidipine
275. Lamivudine
276. Lamotrigine
277. Latanoprost
278. Lefunomide

279. Lercanidipine hydrochloride
280. Letrozole
281. Leuprolide acetate
282. Levamisole
283. Levarterenol
284. Levobunolol
285. Levocetirizine
286. Levodopa
287. Levofloxacin
288. Levovist
289. Lidoflazine
290. Linezolid
291. Lithium carbonate
292. Lofepramine decanoate
293. Loperamide
294. Lorazepam
295. Losartan potassium
296. Loteprednol
297. Lovastatin
298. Loxapine
299. Mebendazole
300. Mebeverine hydrochloride
301. Medroxyprogesterone acetate
302. Mefenamic acid
303. Mefloquine hydrochloride
304. Megestrol acetate
305. Meglumine iocarmate
306. Melagenina
307. Melitracen hydrochloride
308. Meloxicam
309. Mephenesin, its esters
310. Mephentermine
311. Meropenem
312. Mesterolone
313. Metaxalone
314. Methicillin sodium
315. Methocarbamol
316. Methotrexate
317. Metoclopramide
318. Metoprolol tartrate
319. Metrizamide
320. Metronidazole
321. Mexiletine hydrochloride
322. Mianserin hydrochloride
323. Miconazole
324. Midazolam
325. Mifepristone
326. Milrinone lactate
327. Miltefosine
328. Minocycline
329. Minoxidil
330. Mirtazapine
331. Misoprostol
332. Mitoxantrone hydrochloride
333. Mizolastine
334. Moclobemide
335. Mometasone furoate
336. Montelukast sodium
337. Morphazinamide hydrochloride
338. Mosapride
339. Moxifloxacin
340. Mycophenolate mofetil
341. Nadifloxacin
342. Nadolol
343. Nafarelin acetate
344. Nalidixic acid
345. Naproxen
346. Narcotic drugs listed in Narcotic Drugs and Psychotropic Substances Act, 1985
347. Natamycin
348. Nateglinide
349. N-butyl-2-cyanoacrylate
350. Nebivolol
351. Nebumetone
352. Nelfinavir mesylate
353. Netilmicin sulphate
354. Nevirapine
355. Nicergoline
356. Nicorandil

357. Nifedipine
358. Nimesulide
359. Nimustine hydrochloride
360. Nitrazepam 5
361. Nitroglycerin
362. Norethisterone enanthate
363. Norfloxacin
364. Octylonium bromide
365. Ofloxacin
366. Olanzapine
367. Omeprazole
368. Ornidazole
369. Orphenadrine
370. Orthoclone sterile
371. Oxazepam
372. Oxazolidine
373. Oxcarbazepine
374. Oxethazaine hydrochloride
375. Oxiconazole
376. Oxolinic acid
377. Oxprenolol hydrochloride
378. Oxybutynin chloride
379. Oxyfedrine
380. Oxymetazoline
381. Oxyphenbutazone
382. Oxytocin
383. Ozothine
384. Paclitaxel
385. Pancuronium bromide
386. Pantoprazole
387. Para-aminobenzene sulphonamide, its salts and derivatives
388. Parp-aminosalicylic acid, its salts, and derivatives
389. Parecoxib
390. Paroxetine hydrochloride
391. D-penicillamine
392. Pentazocine
393. Pentoxifylline
394. Pepleomycin
395. Phenelzine sulphate
396. Phenobarbital
397. Phenothiazine, its salts and derivatives
398. Phenylbutazone
399. Pimozide
400. Pindolol
401. Pioglitazone hydrochloride
402. Piracetam
403. Piroxicam
404. Pituitary gland, active principles of, not otherwise specified in this schedule and their salts
405. Polidocanol
406. Polyestradiol phosphate
407. Poractant alpha
408. Praziquantel
409. Prednimustine
410. Prednisolone stearoylglycolate
411. Prenoxdiazine hydrochloride
412. Promazine hydrochloride
413. Promegestone
414. Propafenon hydrochloride
415. Propanolol hydrochloride
416. Propofol
417. Protriptyline hydrochloride
418. Pyrazinamide
419. Pyrvinium
420. Quetiapine fumerate
421. Quinapril
422. Quinidine sulphate
423. Rabeprazole
424. Racecadotril
425. Raloxifene hydrochloride
426. Ramipril hydrochloride
427. Ranitidine
428. Rauwolfia, alkaloids of, their salts, derivatives of the alkaloids or Rauwolfia

429. Reboxetine
430. Repaglinide
431. Reproterol hydrochloride
432. Rilmenidine
433. Riluzone
434. Risperidone
435. Ritonavir
436. Ritodrine hydrochloride
437. Rituximab
438. Rivastigmine
439. Rocuronium bromide
440. Ropinirole
441. Rosoxacin
442. Rosiglitazone meleate
443. Salbutamol sulphate
444. Salicyl-azo-sulphapyridine
445. Salmon calcitonin
446. Saquinavir
447. Satranidazole
448. Secnidazole
449. Septopal beads and chains
450. Serratiopeptidase
451. Sertraline hydrochloride
452. Sibutramine hydrochloride
453. Sildenafil citrate
454. Simvastatin
455. Sirolimus
456. Sisomicin sulphate
457. S-neominophagen
458. Sodium picosulphate
459. Sodium cromoglycate
460. Sodium hyaluronate
461. Sodium valproate
462. Sodium and maglumine iothalamates
463. Somatostatin 6
464. Somatotropin
465. Sotalol
466. Sparfloxacin
467. Spectinomycin hydrochloride
468. Spironolactone
469. Stavudine
470. Sucralfate
471. Sulphadoxine
472. Sulphamethoxine
473. Sulphamethoxypyridazine
474. Sulphaphenazole
475. Sulpiride
476. Sulprostone hydrochloride
477. Sumatriptan
478. Tacrine hydrochloride
479. Tamsulosin hydrochloride
480. Trapidil
481. Tegaserod maleate
482. Teicoplanin
483. Telmisartan
484. Temozolamide
485. Terazosin
486. Terbutaline sulphate
487. Terfenadine
488. Terizidone
489. Terlipressin
490. Testosterone undecanoate
491. Teratolol hydrochloride
492. Thalidomide
493. Thiacetazone
494. Thiocolchicoside
495. Thiopropazate, its salts
496. Thymogene
497. Thymosin-alpha 1
498. Tiaprofenic acid
499. Tibolone
500. Timolol maleate
501. Tinidazole
502. Tizanidine
503. Tobramycin
504. Tolfenamic acid
505. Topiramate
506. Topotecan hydrochloride
507. Tramadol hydrochloride

508. Tranexamic acid
509. Tranylcypromine, its salts
510. Trazodone
511. Tretinoin
512. Trifluperazine
513. Trifluperidol hydrochloride
514. Triflusal
515. Trimetazidine dihydrochloride
516. Trimipramine
517. Tripotassium dicitrato bismuthate
518. Tromantadine hydrochloride
519. Urokinase
520. Valsartan
521. Vasopressin
522. Vecuronium bromide
523. Venlafaxine hydrochloride
524. Verapamil hydrochloride
525. Verteporfin
526. Vincristine sulphate
527. Vinblastine sulphate
528. Vindesine sulphate
529. Vinorelbine tartrate
530. Xipamide
531. Zidovudine hydrochloride
532. Ziprasidone hydrochloride
533. Zoledronic acid
534. Zolpidem
535. Zopiclone
536. Zuclopenthixol

### Schedule H1

- The schedule H1 drugs were mainly allocated to restrict the selling of antibiotics through over-the-counter (OTC) sales, after it was noted that any number of these drugs could be bought from pharmacies across India without any limitations.
- Irrational prescribing of antibiotics and other drugs by doctors and chemists lacking a registered pharmacist has contributed to the increasing antibiotics resistance and tolerance of psychotropic. In response to these serious issues, antibiotic forums, scientific meetings and symposiums were conducted by medical fraternity and various educational institutions.
- As a result, the Government of India issued a gazette notification, GSR 588 (E) dated on 30. 08. 2013 regarding Schedule H1 drugs which show the importance of this Schedule.
- The Schedule H1 drug includes 3rd and 4th generation antibiotics, antituberculosis drugs and certain habit-forming drugs like psychotropic drugs.
- To dispense these drugs two main criteria have to be followed strictly.

- The drug supplied under the Schedule H1 specification should be recorded in a **separate register at the time of supply, mentioning the name and address of the prescriber, name of the patient, and the name of the drug along with the quantity supplied.** This register has to be maintained confidentially up to three years and should be open for inspection.
- The Schedule H1 drugs should be labeled with the **symbol Rx in red**, clearly displayed on the left top corner of the drug label. The label should also bear the following words in a box with a red border.
- The Schedule H1 drug list, however, shows no limitation of using the drugs as topical or for external use such as in ophthalmic, ear or nose preparations.
- It is a known fact that a gazette notification alone will not help. Apart from this several measures have to be executed by the respective authorities at all levels.
- Alprazolam, balofloxacin, buprenorphine, capreomycin, cefdinir, cefditoren, cefepime, cefetamet, cefexime, cefoperazone, ceftizoxime, ceftriaxone, chlordiazepoxide, clofazimine, codeine, diphenoxylate, nitrazepam, pentazocine, prulifloxacin, pyrazinamide, ribabutin, rifampicin, tramadol, zolpidem.

## DETAIL STUDY OF SCHEDULE T

### GOOD MANUFACTURING PRACTICES FOR AYURVEDIC, SIDDHA AND UNANI MEDICINES

- Raw materials used in the manufacture of drugs are authentic, of prescribed quality and are free from contamination.
- The manufacturing process is as has been prescribed to maintain the standards.
- Adequate quality control measures are adopted.
- The manufactured drug which is released for sale is of acceptable quality.
- To achieve the objectives above each licensee shall evolve methodology and procedures for following the prescribed

process of manufacture of drugs which should be documented as a manual and kept for reference and inspection.

## DETAIL STUDY OF SCHEDULE G

- The Drugs and Cosmetics Rules, 1945 contains provisions for classification of drugs under given schedules and there are guidelines for the storage, sale, display and prescription of each schedule.
- The Rule 67 details the conditions of licenses. The Rule 97 contains the labeling regulations.
- List of substances included in Schedule G is as below:
- Aminopterin
- L-Asparaginase
- Bleomycin
- Busulphan; its salts
- Carbutamide
- Chlorambucil; its salts
- Chlorothiazide and other derivatives of 1, 2, 4-benzothiadiazine
- Chlorpropamide; its salts
- Chlorthalidone and other derivatives of chlorobenzene compound.
- Cisplatin
- Cyclophosphamide; its salts
- Cytarabine
- Daunorubicin
- Di-isopropyl fluorophosphate
- Disodium stilboestrol diphosphate
- Doxorubicin hydrochloride
- Ethacrynic acid; its salts
- Ethosuximide
- Glibenclamide
- Hydantoin; its salts; its derivatives, their salts
- Hydroxyurea
- Insulin: all types
- Lomustine hydrochloride
- Mercaptopurine; its salts
- Metformin; its salts

- Methsuximide
- Mustine; its salts
- Paramethadione
- Phenacemide
- Phenformin; its salts
- 5-Phenylhydantoin; its alkyl and aryl derivatives; its salts
- Primadone
- Procarbazine hydrochloride
- Quinethazone
- Sarcolysine
- Sodium-2-mercaptoethanesulfonate, tamoxifen citrate
- Testolactone
- Thiotepa
- Tolbutamide
- Tretamine; its salts
- Troxidone

### Antihistaminic Substances and Salts of their Derivatives

- Antazoline
- Bromodiphenhydramine
- Buclizine
- Chlorcyclizine
- Chlorpheniramine
- Clemizole
- Cyproheptadine
- Diphenhydramine
- Diphenylpyraline

## DETAIL STUDY OF SCHEDULE N

*List of minimum equipment for the efficient running of a pharmacy.*

### Entrance

The front of a pharmacy shall bear an inscription "Pharmacy" in front.

### Premises

- The premises of a pharmacy shall be separated from rooms for private use. The premises shall be well built, dry, well lit and ventilated and of sufficient dimensions to allow the goods in stock especially medicaments and poisons to be kept in a clearly visible and appropriate manner.
- The area of the section to be used as dispensing department shall be not less than 6 square meters for one pharmacist working therein with additional 2 square meters for each additional pharmacist. The height of the premises shall be at least 2.5 meters.
- The floor of the pharmacy shall be smooth and washable. The walls shall be plastered or tiled or oil painted so as to maintain smooth, durable and washable surface devoid of holes, cracks and crevices.
- A pharmacy shall be provided with ample supply of good quality water.
- The dispensing department shall be separated by a barrier to prevent the admission of the public.

### Furniture and Apparatus

- The furniture and apparatus of a pharmacy shall be adapted to the uses for which they are intended and correspond to the size and requirements of the establishment.
- Drugs, chemicals, and medicaments shall be kept in a room appropriate to their properties and in such special containers as will prevent any deterioration of the contents or of contents of containers kept near them. Drawers, glasses and other containers used for keeping medicaments shall be of suitable size and capable of being closed tightly to prevent the entry of dust.
- Every container shall bear a label of appropriate size, easily readable with names of medicaments as given in the pharmacopoeias.
- A pharmacy shall be provided with a dispensing bench, the top of which shall be covered with washable and impervious material like stainless steel, laminated or plastic, etc.
- A pharmacy shall be provided with a cupboard with lock and key for the storage of poisons and shall be

clearly marked with the work 'poison' in red letters on a white background.

- Containers of all concentrated solution shall bear special label or marked with the works "To be diluted".

A pharmacy shall be provided with the following minimum apparatus and books necessary for making of official preparations and prescriptions.

### Apparatus

- Balance, dispensing, sensitivity 30 mg.
- Balance, counter, capacity 3 kg, sensitivity 1 gm.
- Beakers, lipped, assorted sizes
- Bottles, prescription, ungraduated assorted sizes
- Corks assorted sizes and tapers.
- Cork, extractor
- Evaporating dishes, porcelain.
- Filter paper
- Funnels, glass
- Litmus paper, blue and red
- Measure glasses cylindrical 10 ml, 25 ml, 100 ml and 500 ml
- Mortars and pestles, glass
- Mortars and pestles, Wedgwood.
- Ointment pots with bakelite or suitable caps.
- Ointment slab, porcelain
- Pipettes, graduated, 2 ml, 5 ml and 10 ml
- Ring, stand (retort) iron, complete with rings.
- Rubber stamps and pad
- Scissors
- Spatulas, rubber or vulcanite
- Spatulas, stainless steel.
- Spirit lamp
- Glass stirring rods
- Thermometer, 0°C to 200°C
- Tripod stand
- Watch glasses
- Water bath
- Water distillation still in case eye drops and eye lotions are prepared.

- Weights, metric, 1 mg to 100 gm
- Wire gauze
- Pill finisher, boxwood
- Pill machine
- Pill boxes
- Suppository mould

### Books

- The Indian Pharmacopoeia (Current Edition)
- National Formulary of India (Current Edition)
- The Drugs and Cosmetics Act, 1940
- The Drugs and Cosmetics Rules, 1945
- The Pharmacy Act, 1948
- The Dangerous Drugs Act, 1930

### General Provisions

- A pharmacy shall be conducted under the continuous personal supervision of a registered pharmacist whose name shall be displayed conspicuously in the premises.
- The pharmacist shall always put on clean white overalls.
- The premises and fittings of the pharmacy shall be properly kept and everything shall be in good order and clean.
- All records and registers shall be maintained in accordance with the laws in force.
- Any container taken from the poison cupboard shall be replaced therein immediately after use and the cupboard locked. The keys of the poison cupboard shall be kept in the personal custody of the responsible person.
- Medicaments when supplied shall have labels conforming to the provisions of laws in force.

## DETAIL STUDY OF SCHEDULE P

The life period of drugs and the storage conditions of drugs are covered in this Schedule. Between the date of production and the date of expiry, the duration should be measured in months.

**Table 1.5:** Life period of drug

| *Drugs* | *Drugs life period (months)* | *Drugs storage* |
|---|---|---|
| Ampicillin trihydrate | 30 | In a cool place |
| Ampicillin sodium | 36 | In a cool place |
| Adriamycin | 30 | In a cool place |
| Ampicillin | 36 | In a cool place |
| Colistin sulphate | 60 | Protected from light |
| Nystatin | 36 | At temp not exceeding 5ºC |
| Penicillin tablet | 18 | In a cool place |

### Schedule P1

The pack size of drugs is specified in this schedule. It lists the medication names, as well as the dose type and pack size. Other than the pack sizes mentioned in this schedule, no other pack sizes should be noted.

**Table 1.6:** Pack sizes of drug

| *Drugs* | *Dosage forms* | *Pack size* |
|---|---|---|
| Aspirin (low dose) | Tablets | 14 tabs |
| Albendazole | Suspension | 10 ml |
| Atenolol | Tablet | 14 tabs |
| Catalin | Ophthalmic drops | 15 ml |
| Ciclopirox olamine | Vaginal cream | 30 gm |
| Haloperidol | Oral solution | 15 ml |
| Isoniazid | Syrup | 200 ml |

## DETAIL STUDY OF SCHEDULE U

The particulars to be shown in the manufacturing record, record of raw material and analytical record of drug.

### Substances other than Parenteral in Preparations in General

1. Serial number.
2. Name of the product.

3. Reference of master formula records.
4. Lot/batch size.
5. Lot/batch number.
6. Date of commencement of manufacture and date of completion of manufacture and the assigned date of expiry.
7. Name of all ingredients, specifications and quantities required for the lot/batch size and quantities actually used. All weighing and measurements shall be carried out by a responsible person and initiated by him and shall be counter-checked and signed by the competent technical staff under whose personal supervision the ingredients are used for manufacture.
8. Control numbers of raw materials used in the formulations.
9. Date, time and duration of mixing.
10. Details of environmental controls like room temperature, relative humidity.
11. Date of granulation, wherever applicable.
12. Theoretical weight and actual weight of granules/powder blend.
13. Records of in-processes controls (periodically whenever necessary).
    a. Uniformity of mixing.
    b. Moisture content of granules/powder in case of tablet/capsules.
    c. pH of solution in case of liquid.
    d. Weight variation.
    e. Disintegration time.
    f. Hardness.
    g. Friability test
    h. Leak test in case of strip packing.
    i. Filled volume of liquids.
    j. Quantity of tablets/capsules in the final container.
    k. Content of ointment in the filled containers.
14. Date of compression in case of tablets/date of filling in case of capsules.
15. Date of sealing/coating/polishing in case of capsules/tablets wherever applicable.

16. Reference to analytical report number stating the result of test and analysis.
17. Separate records of the disposal of the rejected batches and of batches withdrawn from the market.
18. The theoretical yield and actual productions yield and packing particulars indications the size and quantity of finished packing.
19. Specimen of label/strip, carton with batch coding information like batch number, date of manufacturing, date of expiry, retail price as applicable, stamped thereon and inserts used in the finished packing.
20. Signature with date of competent technical staff responsible for the manufacture.
21. Counter-signature of the head of the testing units or other approved person in-charge of testing for having verified the batch records and for having released the batch for sale and distribution, the quantity released and date of release.
22. Date of release of finished packing and quantity released for sale and distribution.
23. Quantity transferred to warehouse.
24. For hypodermic tablets and ophthalmic preparations which are required to be manufactured under aseptic conditions, records shall be maintained indicating the precautions taken during the process of manufacture to ensure that aseptic conditions are maintained.

### Parenteral Preparations

1. Serial number
2. Name of the product
3. Reference of the master formula record
4. Batch/lot size.
5. Batch no. and/or lot no.
6. Date of commencement of manufacture and date of completion.
7. Name of all ingredients, specifications and quantity required for the lot/batch size and quantity actually used. All weighing and measurements shall be carried out by a

responsible person and initialed by him and shall be counter-signed by the technical staff under whose personal supervision the stocks are issued and by another competent technical staff under whose supervision the ingredients are used for manufacture.

8. Control numbers of raw materials used in the formulation.
9. Date, time and duration of mixing.
10. Details of environmental controls like temperature, humidity, microbial count in the sterile working areas.
11. pH of the solution, wherever applicable.
12. Date and method of filtration.
13. Sterility test, reference on bulk batch wherever applicable.
14. Record of check on volume filled.
15. Date of filling.
16. Records of tests employed: (a) to ensure that sealed ampoules are leak-proof. (b) To check the presence of foreign particles. (c) Pyrogen test, wherever applicable. (d) Toxicity tests wherever applicable.
17. Records of checking of instruments and apparatus of sterilization (indicators).
18. Records of cleaning and sterilization of containers and closure, if necessary, sterilized including particulars of time, temperature and pressure employed. Such records should be marked to relate to the sterilized.
19. Number and size of containers filled and quantity rejected.
20. The theoretical yield and actual yield and the percentage yield thereof.
21. Reference of analytical report numbers stating whether of standard quality or otherwise.
22. Specimen of labels, cartons, etc. with batch coding information like batch number, date of manufacture, date of expiry, as applicable, stamped thereon, and inserts used in the finished packings.
23. Signature with date of the component technical staff responsible for manufacture.
24. Particulars regarding the precautions taken during the manufacture to ensure that aseptic conditions are maintained.

25. Counter-signature of head of the testing unit or person in-charge of testing for having verified the documents and for having released the product for sale and distribution, the quantity released and date of release.
26. Records for having transferred to warehouse giving packings and quantities.
27. Separate records of the disposal of the rejected batches and of all batches withdrawn from the market.
28. Records of reprocessing if any and particulars of reprocessing.

### *Records of Raw Materials*

Records in respect of each raw material shall be maintained indicating the date of receipt, invoice number, name and address of manufacturer/supplier, batch number, quantity received, pack size, date of manufacture, date of expiry, if any, date of analysis and release/rejection by quality control, analytical report number, with special remarks, if any quantity issued, date of issue and the particulars of the name and batch numbers of products for the manufacture of which issued and the proper disposal of the stocks.

*Tablets and capsules*

1. Analytical report number.
2. Name of the sample.
3. Date of receipt of sample.
4. Batch/lot number.
5. Protocols of tests applied.
   a. Description.
   b. Identification.
   c. Uniformity of weight.
   d. Uniformity of diameter (if applicable).
   e. Disintegration test (time in minutes).
   f. Any other tests.
   g. Results of assay.
6. Signature of the analyst.
7. Opinion and signature of the approved analyst.

*Parenteral preparations*

1. Analytical report number.
2. Name of the sample.
3. Batch number.
4. Date of receipt of samples.
5. Number of containers filled.
6. Number of containers received.
7. Protocols of tests applied.
   a. Clarity.
   b. pH wherever applicable.
   c. Identification.
   d. Volume in container.
   e. Sterility:
      i. Bulk sample wherever applicable
      ii. Container sample.
   f. Pyrogen test, wherever applicable.
   g. Toxicity test, wherever applicable.
   h. Any other tests.
   i. Results of assay.
8. Signature of the analyst.
9. Opinion and signature if the approved analyst.

*Pyrogen test*

1. Test report number.
2. Name of the sample.
3. Batch number.
4. Number of rabbits used.
5. Weight of each rabbit.
6. Normal temperature of each rabbit.
7. Mean initial temperature of each rabbit.
8. Dose and volume of solution injected into each rabbit and time of injection.
9. Temperature of each rabbit noted at suitable intervals.
10. Maximum temperature.
11. Response.

12. Summed response.
13. Signature of the analyst.
14. Opinion and signature of the approved analyst.

*Toxicity test*

1. Test report number.
2. Name of the sample.
3. Batch number.
4. Number of mice used and weight of each mouse.
5. Strength and volume of the drugs injected.
6. Date of injection.
7. Results and remarks.
8. Signature of analyst.
9. Opinion and signature of the approved analyst.

*For other drugs*

1. Analytical report number.
2. Name of the sample.
3. Batch/lot number.
4. Date of receipt of sample.
5. Protocol of tests applied.
   a. Description.
   b. Identification.
   c. Any other tests.
   d. Results of assay.
6. Signature of the analyst.
7. Opinion and signature of the approved analyst.

*Raw materials*

1. Serial number.
2. Name of the materials.
3. Name of the manufacturer/supplier.
4. Quantity received.
5. Invoice/challan number and date.
6. Protocols of tests applied.

*Container, packing materials, etc.*

1. Serial number.
2. Name of the item.
3. Name of the manufacturer/supplier.
4. Quantity received.
5. Invoice/challan number and date.
6. Results of tests applied.
7. Remarks.
8. Signature of the examiner.

## DETAIL STUDY OF SCHEDULE V

Patent or proprietary medicines containing vitamins intended for prophylactic, therapeutic or pediatric use shall bear on label the words "For Prophylactic Use", "For Therapeutic Use" or "For Pediatric Use" as the case may be. In the cases of pediatric preparations the age of the infant or the child for whose use it is intended, shall be given in addition to the particulars required to be given under these rules.

### Tablets

Medicines should fulfill the needs for tablets as given in the IP. The nature of coating and the permitted colors should be added on the label. Nature of tablets (uncoated, sugar coated, or film coated) should be given on the label.

### Capsules

Medicines should fulfill the requirements for capsules as given in the IP. The capsules should be free from distortion, discoloration, and other physical defects such as leakage of powder from joints, pinholes or cracks.

### Liquid Oral Dosage Forms

On shaking, emulsions and suspensions should disperse. Homogeneous solutions should have no sediments. Net content of the product in the container should not be less than the volume mentioned on the label. The ethanol content of pharmaceutical products should be between 90 and 110% of the labelled contents.

### Injections

Medicines should fulfill the needs for injections as given in the IP.

### Ointments

Medicines should fulfill the needs for ointments as given in the IP.

- The content of active ingredients, other than vitamins, enzymes, and antibiotics, should be between 90 and 110% of the labelled content. In dry formulations of antibiotics, the limit should be 90–130% of the labelled contents. In liquid antibiotics, the limit should be 90–140% of the labelled contents.
- All patent or proprietary medicines having aspirin should undergo free salicylic acid test, the limit of which should be 0.75%.
- Patent or proprietary medicines to be tested under the provisions of rule 121 A for pyrogen should be tested by injecting into rabbits in doses not below to that for the humans depending on the body weight of a 60 kg human.
- In injectable patent or proprietary medicines, the test for freedom from toxicity should be conducted as given in the IP.

## DETAIL STUDY OF SCHEDULE X

**Schedule X** is a class of prescription drugs in **India** appearing as an appendix to the **Drugs and Cosmetics Rules** introduced in 1945. These are drugs which cannot be purchased over-the-counter without the prescription of a qualified doctor. Also, the retailer has to preserve the **prescription** for a period of two years.

**Table 1.7:** The list of Schedule X drugs

| *Amobarbital* | *Methylphenobarbital* |
|---|---|
| Amphetamine | Cyclobarbital |
| Methylphenidate | Pentobarbital |
| Barbital | Dexamphetamine |
| Ketamine | Phenmetrazine |
| Phencyclidine | Glutethimide |
| Methamphetamine | Meprobamate |

## DETAIL STUDY OF SCHEDULE Y

Requirements and guidelines for permission to import and/or manufacture of new drugs for sale or to undertake clinical trials.

**Table 1.8:** List of licenses for permission

| *Rule* | *Permission for* |
|---|---|
| 122 A | To **import new drug** |
| 122 B | To **manufacture new drug** |
| 122 D | To import or manufacturing **fixed dose combination** |
| 122 DA | To conduct **clinical trials for new drug/investigation of new drug** |
| 122 DAA | Definition of **clinical trails** |
| 122 E | Definition of **new drug** |

### Requirements and Guidelines on Clinical Trials for Import and Manufacture of New Drug

1. Application for permission
2. Clinical trial
3. Studies in special population
4. Post-marketing surveillance
5. Special studies: BA/BE studies

### Application for Permission

It shall made in **Form 44** accompanied with following data in accordance with appendices, namely:

- Chemical and pharmaceutical information
- Animal pharmacology data
- Animal toxicology data
- Human clinical pharmacology data
- Regulatory status in other countries
- Prescribing information
- Form 12 to import study drug for examination, test or analysis.

## Clinical Trial

### *Approval for Clinical Trials*

CT on a new drug shall be initiated only after permission by licensing authority and approval from EC.

### *Responsibilities of Sponsor*

- Implementing and maintaining QA
- Submit status report to the licensing authority periodically
- SAE should be reported to the licensing authority within 14 calendar days.

### *Responsibilities of Investigator*

- Ensure adequate medical care is provided to the subject.
- SAE and unexpected AE should be reported to the sponsor within 24 hours and to the EC within 7 working days.

### *Informed Consent*

- Freely given informed written consent
- Provide information about the study verbally
- Non-technical and understandable language.

### *Responsibilities of Ethics Committee*

- Approval trial protocol to safeguard RSW of all trial subjects and to protect RSW of all vulnerable subjects
- Conduct ongoing review of the trials.

### *Human Pharmacology (Phase I)*

Safety and tolerability—objective.

### *Therapeutic Exploratory Trials (Phase II)*

- To evaluate the effectiveness of a drug for particular indication
- To determine the short-term side effects and risk associated with the drug
- To determine the dose and regimen for phase III trials.

### *Therapeutic Confirmatory Trials (Phase III)*

- Demonstration of therapeutic benefit
- Drug is safe and effective for use and provides an adequate basis for marketing approval.

### *Post-marketing Trials (IV)*

- Performed after drug approval and related to the approved indication.
- Includes drug–drug interaction, dose-response or safety studies, mortality/morbidity studies.

### *Studies in Special Population*

- Geriatrics
- Pediatrics
- Pregnant or nursing women.

### *Post-marketing Surveillance*

- Closely monitored new drugs clinical safety
- PSUR—to report all relevant new information
- PSUR shall be submitted every 6 months for the first 2 years.

### *Special Studies: BA/BE Studies*

- Conducted according to the guidelines for BA and BE studies.
- Evaluation of the effect of food on absorption of following oral administration.

## SALE OF DRUG

- Drugs and Cosmetics Act and the Rules made thereunder restrict the sale of drug only by license. That is only licensed person are eligible to sell the drug by wholesale or retail and to compound or dispense the drug.
- The license can be obtained from licensing is required for different types of sale drug like wholesale, retail, motor vehicle or vendor sale.

- If drugs are sold or stocked for sale at more than one place, separate licenses are to be obtained in respect of each such place.

### Retail Sale

*For retail sale, two types of licenses are issued:*

i. General licenses

ii. Restricted licenses

### Restricted License

Granted to those dealers who do not engage the services of a qualified person and only deal with such classes of drugs whose sales can be affected without qualified person and vendors who do not have fixed premises.

### Wholesale of Biological (C/C1)

- Adequate premises, with **greater than 10 meter area**, with proper storage facility**.**
- Drugs sold **only to retailer having license.**
- Premises should be in-charge of competent person who is **registered pharmacist**.
- **Records** of purchase and sale.
- Records preserved for 3 years from date of sale.
- License should **display on premises.**

### *Wholesale from other than Specified in C/C1 and X*

- All the conditions as discussed in for biological.
- Compounding is made by or under the direct and personal **supervision of a qualified person.**

### *Classes of Drugs Prohibited to be Sale*

- Misbranded, spurious, adulterated and drugs not of standard quality
- Patent/proprietary drugs with undisclosed formula
- Expired drugs.

- Drugs used for consumption by government schemes such as, Armed Forces.
- Physician's samples.

### Supply of Schedule C Drug

- Serial number of the entry
- Date of supply and date of expiry
- Name and address of the purchaser
- Name and quantity of drug supplied
- Name of the manufacturer
- Batch number of the drug supplied
- Signature of the qualified person

### Supply of Schedule H Drug

- Schedule H drug should be sold against the prescription of registered medical practitioner.
- They should not be dispensed more than once, unless mentioned in the prescription.
- Date of supply and opening and closing stocks of drug on that day and relevant bill numbers.
- Name of drug, its manufacturer and batch number.
- Name and address of purchaser.
- Date of prescription, name and address of the registered medical practitioner.
- Signature of the qualified person.

### Supply of Schedule X Drug

- Schedule X drug shall be kept in a separate cupboard under lock and key.
- Schedule X drug is supplied only against the prescription of registered medical practitioner in duplicate, one copy of which is retained by the licensee and preserved for two years.
- Date of purchase/transaction.
- Quantity received, name, address, and license number of the supplier.
- Batch no. or lot no.

### Offences and Penalties

**Table 1.9:** Offences and penalties in the sale of drug

| *Offences* | *Penalties* |
|---|---|
| Anyone sell, stocks, exhibits for sale or distribute any misbranded or adulterated or spurious drug without proper license | Less than **one year** but may extend up to **10 years imprisonment. First conviction 2 to 10 years** with fine on **subsequent convictions** |
| Anyone who sells, exhibits for sale or distributes any drug in contravention of the Act and Rules | **5 years** imprisonment and **₹ 2000 fine** or both on **first conviction** **10 years** imprisonment and **₹ 5000** fine or both for **subsequent conviction** |

## LABELING AND PACKING OF DRUGS

### Drugs

- Articles intended for use in diagnosis, cure, mitigation, treatment, or prevention of disease
- Articles (other than food) intended to affect the structure or function of the body; and
- Articles intended for use as components in any of the above.

### Types of Drugs

#### *Over-the-counter (OTC) or Nonprescription Drugs*

**Examples:** Aspirin, acetaminophen, cough medicine.

#### *Prescription Drugs*

**Examples:** Blood pressure medicines, blood thinners, antibiotics, eye drops.

**For all medicines, you must read and follow the directions!**

### Labeling

- Labeling has been defined to include the display of written material.
- On the immediate container of a drug presenting vital prescription information.

- Any printed matter on a drug's containers or wrappers, and
- Any promotional or other material "accompanying such article."
- Classified as labeling are brochures, mailing pieces, detailing pieces.
- Literature reprints, reference publications containing manufacturer supplied data, and similar literature disseminated to physicians.

## Prescription Label

- Patient name and address
- Prescriber's name
- Drug name

**Drug Facts**

***Active ingredients (in each tablet)*** ***Purpose***
Chlorpheniramine maleate 2 mg ..... Antihistamine

***Uses*** Temporarily relieves these symptoms due to hay fever or other upper respiratory allergies:
■ Sneezing ■ Runny nose ■ Itchy, watery eyes ■ Itchy throat

***Warnings***
**Ask a doctor before use if you have**
■ Glaucoma ■ A breathing problem such as emphysema or chronic bronchitis
■ Trouble urinating due to an enlarged prostate gland

**Ask a doctor or pharmacist before use if you are** taking tranquilizers or sedatives

**When using this product**
■ You may get drowsy ■ Avoid alcoholic drinks
■ Alcohol, sedatives, and tranquilizers may increase drowsiness
■ Be careful when driving a motor vehicle or operating machinery
■ Excitability may occur, especially in children

**If pregnant or breastfeeding,** ask a health professional before use.
**Keee out of reach of children.** In case of overdose, get medical help or contact a Poison Control Center right away.

***Directions***

| | |
|---|---|
| Adults and children 12 years and over | Take 2 tablets every 4 to 6 hours; not more than 12 tablets in 24 hours |
| Children 6 years to under 12 years | Take 1 tablet every 4 to 6 hours; not more than 6 tablets in 24 hours |
| Children under 6 years | Ask a doctor |

***Other information:*** Store at 20–25°C (68–77°F) ■ Protect from excessive moisture

***Inactive ingredients***: D&C yellow no. 10, lactose, magnesium stearate, microcrystalline cellulose, pregelatinized starch

**Fig. 1.1:** Labeling manner of drug
*Reference:* US Food and Drug Administration (www.fda.gov)

- Pharmacy name and date filled
- Special precautions/instructions

### Precautions for Prescription Medicines

- Tell physician of previous problems/allergies
- Keep list of all medicines currently using
- Understand directions
- Discuss side effects/interactions
- Store properly
- Never take drugs in the dark
- Flush old drugs
- Keep in labeled containers
- Do not use expired medicines

### Medication Label a System of Information

- Primary container labels (state regulated, FDA requirements)
- Auxiliary labels (warning labels) (industry-generated, not standardized)
- Consumer medication information (CMI) (industry-generated)
- Medication guides—prescription only for providers (28 developed by FDA)
- Patient package information (PPI)—for provider (written by manufacturer approved by FDA).

### Regulation Requirements

- Cosmetic ingredient declaration regulations apply only to retail products intended for home use.
- Products used exclusively by beauticians in beauty salons and labeled **"For professional use only"**.
- Cosmetic samples are not required to include the ingredient declaration. Must state the distributor, list the content's quantity, and include all necessary warning statements.
- Regulations require ingredients to be listed on product labels in descending order by quantity.
- Based on the amount used, an ingredient such as water is usually found at the beginning of the product's ingredient listing.

- Color additives and fragrances, used in small amounts, are normally seen at the end of the ingredient listing.
- FDA regulates only the labeling that appears on cosmetic products themselves. Unfair and deceptive advertising that appears in magazines, in newspapers, or on television falls under the authority of the Federal Trade Commission.

### Label Content

- Source, ingredients
- Uses: Symptoms the medicine is approved to treat
- Warnings: Directions: Recommended daily dosage and frequency. Follow this strictly. Other information: Additional information such as proper storage.
- Storage conditions
- Contraindications
- Drug interaction
- Adverse effects
- Details of manufacturer, distributor

## ADMINISTRATION OF THE ACT AND RULES

### A1. Drugs Technical Advisory Board (DTAB)

The central government appoints the Drugs Technical Advisory Board.

**Function:** To advice the central and state governments on technical matters.

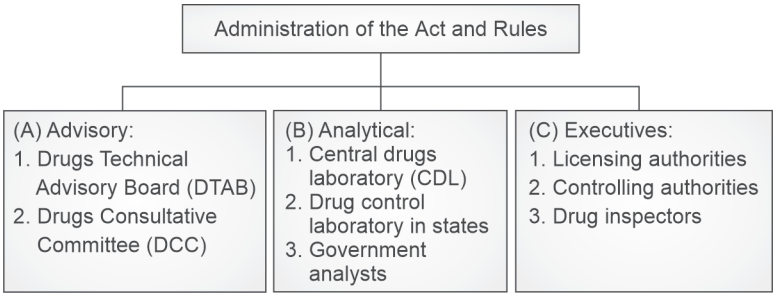



**Fig. 1.2:** Administration of the Act and Rules

### Constitution

#### *A. Ex-officio Member*

1. The Director General of Health services.
2. The Member of Drug Controller of India.
3. The Director of the central Drug Laboratory, Calcutta.
4. The Director of Central Research Institute, Kausali
5. The Director of the Indian Veterinary Research Institute
6. The Director of Central Drug Research Institute, Lucknow
7. The President of PCI
8. The President of MCI.

#### *B. Nominated Member*

1. 2 person from in-charge of the drug control in the states.
2. 1 person from pharmaceutical industry
3. 2 government analysts.
4. 1 teacher in pharmacy, pharmaceutical chemistry or pharmacognosy on the staff of a university or affiliated college elected by the executive committee of **PCI.**
5. 1 teacher in medicine or therapeutics on the staff of a university or affiliated college elected by the executive committee of **MCI.**
6. 1 pharmacologist, elected by the Governing Body of the Indian Council of Medical Research.
7. 1 person elected by the Central Council of Indian Medical Association.
8. 1 person elected by Council of the Indian Pharmaceutical Association.

### A2. Drug Consultative Committee (DCC)

This is an advisory committee constituted by central government.

### Functions

- To advice the central and state governments and the DTAB on any matter to secure uniformity throughout India in administration of the Act.

- The Drugs Consultative Committee shall meet when required.
- Has power to regulate its own procedure.

### Constitution

- 2 representative of central government nominated by central government, and
- 1 representative of each state government nominated by the concerned government.

There is separate **'The Ayurvedic, Siddha and Unani Drug Consultative Committee'** constituted under Section 33 D of the Act.

### B1. Central Drug Laboratory (CDL)

Established in **Calcutta**, under the control of a director appointed by the central government.

#### *Functions*

- **Analysis or test** of samples of drugs/cosmetics sent by the custom collectors or courts.
- Analytical **QC** of the imported samples. Collection, storage and distribution of **internal standards.**
- Preparation of **reference standards** and their maintenance.
- Maintenance of **microbial cultures.**
- **Any other duties** entrusted by central government.
- Acting as an **appellate authority** in matter of disputes.

### B2. Drug Control Laboratories in State

- Every state has a laboratory for analysis and testing of the drug and cosmetics manufactured or sold or to be sold within the respective areas.
- Drug samples sent by the drug inspector are analyzed in these laboratories.

*The laboratory has the following divisions:*

- Pharmaceutical chemistry division
- Immunology division

- Pharmacology division
- Pharmacognosy division
- Food division
- Ayurvedic division

### B3. Government Analyst

In relation to Ayurvedic, Siddha and Unani drugs, a person appointed by central government or state government under Section 33 F.

These officers are appointed by the central or state government and perform the duties.

### Qualification of Government Analyst

Persons having qualification for appointment as government as govermental analysis for allopathic drugs.

Having a degree in medicine, Ayurvedic, Siddha or Unani system and not less than three-year postgraduate experience in the analysis of drugs in a laboratory under control of a government analyst.

### Duties

- The government analyst shall cause to be analyzed or tested such samples or drugs and cosmetics as may be sent to him by inspectors.
- A government analyst shall from time to time forward reports to the government giving the result of analytical work and research with a view to their publication.

### C1. Licensing Authority

- Each state government appoints licensing authorities to issue licenses for manufacturing, distribution, and sale of drug or cosmetics for specified area.
- The licensing authorities have the power to issue or refuse licenses.
- The decision of licensing authority may be appealed before the state or central government as the case may be.

### Qualification

- Graduate in Pharmacy or Pharmaceutical Chemistry or in Medicine with specialization in clinical pharmacology or microbiology from a university established in India by law.
- Experience in the manufacture or testing of drugs a minimum period of five years, provided that the requirements as to the academic qualification shall not apply to those inspectors.

### Duties

- To inspect all establishments licensed for the sale of drugs within the area assigned to him.
- To satisfy himself that the conditions of the licenses are being observed.
- To procure and send for test or analysis, if necessary, imported packages.
- To investigate any complaint.
- To make such enquiries and inspections as may be necessary to detect the sale of drugs in contravention to the Act.
- To maintain a record of all inspections made and action taken by him in the performance of his duties.

### C2. Controlling Authority

- All inspector appointed by the central government shall be under the control of an officer appointed in this behalf by the central government.
- All inspector appointed by the state government shall be under the control of an officer appointed in this behalf by the state government.

### Qualification

- Graduate in Pharmacy or Pharmaceutical Chemistry or in Medicine with specialization in clinical pharmacology or microbiology from a university established in India by law.
- Experience in the manufacture or testing of drugs or enforcement of the provisions of the Act for a minimum period of five years.

### C3. Drug Inspector

- A person to be appointed as a drug inspector should have no financial interest in the import, manufacture or sale of the drug and cosmetics.
- Drug inspector is a Public Servant under Section 21 of Indian Penal Code.

### Qualification

- Persons having qualification for appointment as government as governmental analysis for allopathic drugs.
- Having a degree in Ayurvedic, Siddha or Unani system and not less than three-year postgraduate experience in the analysis of drugs in a laboratory under control of:
  - A government analyst.
  - A chemical examiner.
  - Head of an institution specially approved for this purpose.

#### *Power*

*Inspect:*

i. Any premises where in any drug or cosmetic is being manufactured.

ii. Any premises where in any drug or cosmetic is being sold, or stocked or exhibited or offered for sale, or distributed.

*Take samples of any drug or cosmetic:*

i. Which is being manufactured or being sold or is stocked or exhibited or offered for sale, or is being distributed.

ii. From any person who is in the course of conveying, delivering or preparing to deliver such drug or cosmetic to a purchaser or a consignee.

## SELF-ASSESSMENT EXERCISE

### MCQs

**1. The Drugs and Cosmetics Act was passed in _____.**

a. 10th April 1945
b. 10th April 1940
c. 10th April 1943
d. 10th April 1941

**2. Drugs and Cosmetics Rules under the Act in _____.**

a. 1940 b. 1945
c. 1943 d. 1942

**3. The Act was passed with the main objective to _____.**

a. Register pharmacist
b. Raise the status of profession of pharmacy
c. Regulate the import, manufacture, distribution and sale of drugs and cosmetics
d. None of the above

**4. The Act consists of _____ no. of chapters.**

a. 2 b. 5
c. 4 d. 3

**5. The Rules of the Act are divided into _____ parts.**

a. 10 b. 13
c. 20 d. 23

**6. How many schedules in D and C Act?**

a. 1 b. 2
c. 3 d. 4

**7. How many schedules to the rules?**

a. 10 b. 15
c. 20 d. 27

**8. Standards for medical device is prescribed under Schedule _____.**

a. F1 b. R1
c. M1 d. S1

**9. If a drug contains a colour other than prescribed it is termed as _____.**

a. Spurious drug b. Bulk drug
c. Misbranded drug d. Adulterated drug

**10. If a drug is not labeled in a prescribed manner it is termed as _____.**

a. Spurious drug b. Bulk drug
c. Misbranded drug d. Adulterated drug

**11. If a drug is imported under a name which belongs to another drug it is termed as _____.**

a. Spurious drug b. Bulk drug
c. Misbranded drug d. Adulterated drug

**12. Premises which have a qualified person and engage in compounding of drugs is:**

a. Drug store
b. Pharmacy
c. Chemist and druggist
d. None of these

**13. Premises licensed for sale of drugs which have a qualified person but where drugs are not compounded against premises are called _____.**

a. Drug store b. Pharmacy
c. Chemist and druggist d. None of these

**14. Substance which has a physiological effect when ingested or otherwise introduced into the body is called as _____.**

a. Drugs b. Medicine
c. Compounds d. Material

**15. Misbranded drugs come under Section _____.**

a. 17 b. 17 *(a)*
c. 17 *(b)* d. 3

**16. Adulterated drugs come under Section _____.**

a. 17 b. 17 *(a)*
c. 17 *(b)* d. 3

**17. If it consists, in whole or in part, of any filthy, putrid or decomposed substance is called as _____.**

a. Spurious drug
b. Bulk drug
c. Misbranded drug
d. Adulterated drug

**18. Spurious drugs come under Section _____.**

a. 17 b. 17 *(a)*
c. 17 *(b)* d. 3

**19. Inspector in relation to Ayurvedic, Siddha or Unani drug, an inspector appointed by central or state government under Section _____.**

a. 33 *(c)* b. 33 *(d)*
c. 33 *(f)* d. 33 *(g)*

**20. Inspectors come under Section _____.**

a. 3 *(c)* b. 3 *(d)*
c. 3 *(e)* d. 3 *(g)*

**21. Manufacture means:**

a. Any process or part of a process for making, altering
b. Namenting, finishing, packing, labelling, breaking up
c. Otherwise treating or adopting any drug or cosmetic
d. All of the above

**22. Patent or proprietary medicine comes under Section _____.**

a. 1
b. 2
c. 3
d. 4

**23. Schedule first from the D and C Act, 1940 and its Rules, 1945**

a. List of drug books
b. List of Ayurvedic, Siddha and Unani books
c. List of homeopathy book
d. List of medicine

**24. Standards to be complied with imported drug and by drugs manufactured for sale, sold, stocked or exhibited for sale or distributed under Schedule:**

a. First schedule b. Second schedule
c. Third schedule d. None of these

**25. List of poisonous substance under the Ayurvedic, Siddha and Unani systems of medicine present in Schedule _____.**

a. C b. D
c. E d. F

**26. Drugs exempted from certain provisions relating to the manufacture of drugs come under Schedule _____.**

a. H b. I
c. J d. K

**27. List of permitted dyes and coal tar colours in cosmetics come under Schedule _____.**

a. O b. P
c. Q d. R

**28. List of drugs which are habit forming, psychotropic and other drugs likely to be misused for addictive purposes come under Schedule _____.**

a. W b. X
c. V d. U

**29. Requirement and guidelines for clinical trials come under Schedule _____.**

a. W b. X
c. V d. Y

**30. Import means what?**

a. To bring into India b. To bring out of India
c. Both a and b d. None of these

**31. Import license is granted for the import of drugs specified in Schedule _____.**

a. C b. C1
c. X d. C, C1 and X

**32. For the import of drugs specified in Schedule C and C1, the license shall be granted in:**

a. Form 11
b. Form 10
c. Form 10 *(a)*
d. Form 10 *(b)*

**33. If it is not labeled in the prescribed manner of formulation is called as _____.**

a. Adulterated drugs and cosmetics
b. Spurious drugs or cosmetics
c. Misbranded drugs and cosmetics
d. None of these

**34. If it contains any harmful or toxic substance which may render it injurious to health is known as:**

a. Adulterated drugs and cosmetics
b. Spurious drugs or cosmetics
c. Misbranded drugs and cosmetics
d. None of these

**35. What is mean by adulterated drugs and cosmetics?**

a. If any substance has been mixed therewith so as to reduce its quality or strength.
b. It contains any harmful for purposes of coloring only, a colour other than one which is prescribed.
c. Both a and b
d. None of these

**36. Spurious drugs mean what?**

a. Any substance has been mixed therewith
b. Drugs imported under a name which belongs to another drug
c. Both a and b
d. None of these

**37. Which conditions to be fulfilled with import of the biological drugs?**

a. Licensee must have adequate facility for the storage
b. Licensee must maintain a record of the sale
c. Licensee must furnish the sample to the authority
d. All of the above

**38. Import of Schedule X drugs include:**

a. Narcotic drugs and psychotropic substances
b. Biological drugs
c. Adulterated drugs
d. None of these

**39. For the import of small quantities of drugs a license is granted in _____.**

a. Form 11 b. Form 10
c. Form 10 *(a)* d. Form 10 *(b)*

**40. The importer shall use the substances imported for the purpose of examination, test or analysis in the space specified in _____.**

a. Token b. License
c. Agreement d. None of these

**41. _____ can enter with or without notice at the premises where substances are kept for import.**

a. Drug controller b. Government analyst
c. Inspector d. Manufacturer

**42. The _____ shall keep and report the records of import to licensing authority.**

a. Manufacturer b. Distributor
c. Exporter d. Importer

**43. Drugs may be imported for personal use, if the quality of single dose so imported shall not exceed _____ doses.**

a. 25 b. 50
c. 75 d. 100

**44. Drugs may be imported for personal use, if _____ directs and declares that drug is for personal use.**

a. Licensing authority b. Customs authority
c. Excise office d. Importer

**45. Drugs may be imported for personal use, if that drug shall from the part of _____ bonafied baggage.**

a. Passenger b. Inspector
c. Importer d. Manufacturer

**46. Drugs may be imported for personal use, if more than 100 doses imported with license apply on Form ____.**

a. 11 b. 10
c. 12 d. 13

**47. Licensee must not sell drugs from which sample is withdrawn and he is advised not to sale, and _____ the batch from the market.**

a. Stop b. Run
c. Publish d. Recall

**48. Import of drugs without license include:**

a. Substances used for medicinal purpose
b. Substances not used for medicinal purpose
c. Both a and b
d. None of these

**49. After detaining the imported drugs or cosmetics, officer report it to _____.**

a. Customs collector b. Drug Controller of India
c. Importer d. Exporter

**50. Identify the classes of drugs which are not prohibited for import in India:**

a. Misbranded drugs b. Standard drugs
c. Adulterated drugs d. Spurious drugs

**51. Identify the classes of drugs which are prohibited for import in India:**

a. Expired drugs
b. Patent and proprietary medicine of which formula is not disclosed
c. Drugs for disease mentioned in Schedule J
d. All of the above

**52. Identify the classes of drugs which are not prohibited for import in India:**

a. Drug which has not claimed therapeutic value
b. Drugs claimed therapeutic value

c. Drugs causing risk or injurious to human body or animal
d. Drugs not intended for import

**53. Import license is valid for three years from date of its issue unless it is _____.**

a. Suspended
b. Cancelled
c. Terminated
d. All of the above

**54. No license is required for import of _____.**

a. Drugs
b. Cosmetics
c. Medicines
d. Crude drugs

**55. Identify the classes of cosmetics which are prohibited if contains:**

a. More than 2 ppm of arsenic
b. 20 ppm of lead
c. 100 ppm of heavy metals
d. All of the above

**56. If the importer gives an undertaking in writing not to dispose of the cosmetic, he shall _____ the consignment.**

a. Destroy
b. Export
c. Import
d. Return

**57. Manufacturer must observe at all times the undertaking given by him or on his behalf on _____.**

a. Form 7
b. Form 8
c. Form 9
d. Form 10

**58. Which state in respect to drugs imported by air into India?**

a. Chennai, Kolkata
b. Mumbai, Delhi
c. Ahmedabad, Hyderabad
d. All of the above

**59. Import of spurious OR adulterated drug OR drug which involves risk to human beings or animals OR drug not having therapeutic values punishable with _____.**

a. 3 years imprisonment and ₹ 5000 fine on first conviction
b. 5 years imprisonment OR ₹1000 fine OR both for subsequent conviction
c. Both a and b
d. None of these

**60. Contravention (an action which offends against a law of the provision in import of drugs punishable with _____.**

a. 6 months imprisonment OR ₹ 500 fine OR both for first conviction
b. 1 year imprisonment OR ₹ 1000 fine for subsequent offence
c. Both a and b
d. None of these

**61. Drugs imported into India by sea which placed are involved?**

a. Chennai
b. Calcutta
c. Mumbai
d. All of the above

**62. The drugs are prohibited to manufacture for sale under Section _____.**

a. 15
b. 17
c. 18
d. 20

**63. Which of the following drugs are prohibited to manufacture for sale under Section 18 of the Act?**

a. Any drug or cosmetic which is not of a standard quality
b. Any patent or proprietary medicine, whose formula with the quantities, is not disclosed.
c. Any ingredient which may render it unsafe or harmful for use
d. All of the above

**64. If drugs are manufactured in more than one set of premises, it required _____.**

a. A separate application
b. separate license shall be issued
c. Both a and b
d. None of these

**65. Licenses for manufacture or sale or distribution of drugs are granted or renewed by _____.**

a. State License Approving Authority
b. Central License Approving Authority
c. Government Authority
d. License Authority

**66. Central License Approving Authority (CLAA) appointed by the _____.**

a. Central government
b. State government
c. Government Authority
d. License Authority

**67. CLAA can delegate his power of signing licenses to any other person under his control with approval of the _____.**

a. Central government b. State government
c. Government Authority d. License Authority

**68. Allopathic drugs having own premises come under Schedule _____.**

a. P b. M
c. X d. N

**69. Application for the license of manufacturing drugs specified in Schedule C, C1 excluding those specified in Schedule X should be made to the CLAA in_____.**

a. Form 25 b. Form 27
c. Form 23 d. Form 28

**70. The manufacture of drugs specified in Schedule C, C1 and X in _____.**

a. Form 25 b. Form 27 *(a)*
c. Form 27 *(b)* d. Form 28

**71. Application for including any additional drug in the license should be accompanied by a fee of _____ for each drug subject to a maximum of ₹ 500.**

a. ₹ 25 b. ₹ 50
c. ₹ 75 d. ₹ 100

**72. License in Form 28 and 28B remains valid for a period of _____ on and from the date on which it is issued.**

a. 3 years b. 5 years
c. 7 years d. 9 years

**73. License shall deem to have expired if the application for its renewal is not made within _____ of its expiry.**

a. 3 months b. 6 months
c. 9 months d. 12 months

**74. Application for grand/renewal of such license shall be made for up to 10 items in each category in _____.**

a. Form 24 *(a)* b. Form 24 *(b)*
c. Form 24 *(c)* d. Form 24 *(d)*

**75. How many fees required for application for grand/ renewal of such license shall be made for up to 10 items in each category in Form 24 *(a)*?**

a. 60 b. 600
c. 6000 d. 60000

**76. How many inspection fees required for license issued in form 25 *(a)*?**

a. 1000 b. 2000
c. 2500 d. 1500

**77. _____ is necessary for the manufacture of any drug in small quantity for the purpose of examination, test or analysis.**

a. License b. Permission
c. Grant d. Forms

**78. If a person proposing to manufacture does not hold license it includes:**

a. To manufacture drugs other than those specified in Schedule C, C1 and X
b. To manufacture drugs specified in Schedule C, C1 in respect to such drugs
c. He should obtain license in Form 29
d. All of the above

**79. If drug is not recognized as safe for use, license in _____ is only granted after producing no objection certificate.**

a. Form 29 b. Form 23
c. Form 28 d. Form 25

**80. If drug is not recognized as safe for use, license in Form 29 is only granted after producing no objection certificate from LA appointed by _____.**

a. Central government b. State government
c. Government Authority d. License Authority

**81. License remains valid for a period of _____ year time in manufacture of any drug in small quantity for the purpose of examination, test or analysis.**

a. 5 b. 3
c. 2 d. 1

**82. A person (applicant) who does not have his own arrangements (factory) for manufacture but who wish to avail the manufacturing facilities owned by another licensee is called as _____.**

a. Factory license b. Manufacturing license
c. Loan license d. None of these

**83. Licensee is required to test each batch of raw materials and finished products and the records must be maintained for a period of _____ from the date of manufacture.**

a. 3 years b. 4 years
c. 5 years d. 6 years

**84. Application for loan license is made in Form _____ and the loan license is issued in Form _____.**

a. 24 *(a)* b. 25 *(a)*
c. Both a and b d. None of these

**85. Process of breaking up any drug from a bulk container into small packages and labelling with a view to their sale and distribution is called as _____.**

a. Factory license b. Repacking license
c. Loan license d. None of these

**86. Repacking license must be kept at licensed premises and produced on request of _____.**

a. Director
b. Controller
c. Drug inspector
d. Commissioner

**87. Before a license in Form _____ is granted or renewed.**

a. 21 *(b)*
b. 28 *(c)*
c. 25 *(c)*
d. 20 *(a)*

**88. Manufacture of any spurious drugs punishable with:**

a. 1–3 years imprisonment and ₹ 5000 fine.
b. 2–6 years imprisonment and ₹ 10000 fine on subsequent conviction
c. Both a and b
d. None of these

**89. Manufacture of adulterated drugs punishable with:**

a. 1 year imprisonment and ₹ 2000 fine
b. 2 years imprisonment and ₹ 2000 fine for subsequent conviction
c. Both a and b
d. None of these

**90. Manufacture of drugs in contravention of the provisions punishable with:**

a. Imprisonment up to 3 months and ₹ 500 fine
b. Imprisonment up to 6 months and ₹ 1000 fine on subsequent conviction
c. Both a and b
d. None of the above

**91. Provisions applicable for the manufacture of new drugs whether classifiable under _____.**

a. Schedule C and C1
b. Schedule X and X1
c. Schedule M and M1
d. Schedule P and P1

**92. The drugs are hormonal preparations consist in which of schedule?**

a. Schedule I
b. Schedule G
c. Schedule H
d. Schedule M

**93. What caution should be mentioned in drug label?**

a. It is dangerous to take this preparation except under medical supervision
b. To be sold by retail on the prescription of a registered medical practitioner
c. Both a and b
d. None of these

**94. _____ is the drug also comes under the purview of Narcotic Drugs and Psychotropic Substances Act, 1985.**

a. Schedule I
b. Schedule G
c. Schedule H
d. Schedule M

**95. Which warning should be mentioned in drug label?**

a. It is dangerous to take this preparation except under medical supervision
b. To be sold by retail on the prescription of a registered medical practitioner only
c. Both a and b
d. None of these

**96. Schedule P is for:**

a. Life period of drugs
b. Drugs marketed under generic name only
c. Minimum equipment needed for retail pharmacy
d. Disease that a drug should not claim to cure

**97. Schedule T is for:**

a. Life period of drugs
b. Factory premises and hygienic conditions for Ayurvedic and Unani drugs
c. Minimum equipment needed for retail pharmacy
d. Disease that a drug should not claim to cure

**98. Schedule W is for:**

a. Life period of drugs
b. Drugs marketed under generic name only
c. Minimum equipment needed for retail pharmacy
d. Disease that a drug should not claim to cure

**99. Schedule N is for:**

a. Life period of drugs
b. Drugs marketed under generic name only
c. Minimum equipment needed for retail pharmacy
d. Disease that a drug should not claim to cure

**100. Schedule J is for:**

a. Life period of drugs
b. Drugs marketed under generic name only
c. Minimum equipment needed for retail pharmacy
d. Disease that a drug should not claim to cure

**101. License to sell drugs specified in Schedule C and C1 is given in Form _____.**

a. 19 b. 18
c. 21 d. 24

**102. Requirements of factory premises cover under Schedule _____.**

a. M b. V
c. N d. O

**103. Standard for disinfectant fluids under Schedule _____.**

a. M b. V
c. N d. O

**104. Standard for cosmetic under Schedule _____.**

a. S b. V
c. N d. O

**105. Requirements of factory premises for manufacture of medical devices are for Schedule _____.**

a. M b. M1
c. M2 d. M3

**106. Which part of schedule includes with plant and equipment for the manufacture of drugs?**

a. Part I
b. Part II
c. Part III
d. Part IV

**107. The license has maintained:**

a. Master formula record
b. Labels and closures
c. Identity, quality and quantity
d. None of these

**108. Licensee has maintained batch manufacturing records, records of raw materials and analytical drugs:**

a. Schedule S
b. Schedule V
c. Schedule U
d. Schedule O

**109. The Schedule _____ drugs were mainly allocated to restrict the selling of antibiotics through over-the-counter (OTC) sales.**

a. B
b. D
c. H
d. H1

**110. The Schedule H1 drug includes:**

a. 3rd and 4th generation antibiotics
b. Anti-tuberculosis drugs
c. Psychotropic drugs
d. All of the above

**111. The Schedule P1 is:**

a. Life period of drugs
b. The labeled potency period of the drug
c. Pack sizes of drugs
d. None of these

**112. _____ contains various regulations and requirements for manufacture of Ayurvedic, Siddha and Unani products.**

a. Schedule P
b. Schedule Q
c. Schedule R
d. Schedule T

**113. _____ describes the standards for patent or proprietary medicines.**

a. Schedule U
b. Schedule V
c. Schedule R
d. Schedule T

**114. Patent or proprietary medicines containing vitamins for _____ use.**

a. Prophylactic
b. Therapeutic
c. Paediatric use
d. All of the above

**115. In which type of schedule, the drugs which cannot be purchased over the counter without the prescription of a qualified doctor?**

a. Schedule U
b. Schedule V
c. Schedule X
d. Schedule T

**116. Which of the following is schedule X drug?**

a. Phenometrazine
b. Glutethimide
c. Meprobamate
d. All of the above

**117. _____ Schedule describes requirements and guidelines on clinical trials for import and manufacture of new drugs.**

a. U
b. Y
c. X
d. T

**118. In Schedule Y (Rule 122A) for:**

a. To manufacture new drugs
b. To import new drugs
c. Definition of clinical trials
d. None of these

**119. Form _____ is for to import study drug for examination, test or analysis.**

a. 10
b. 11
c. 12
d. 13

**120. In which type of clinical trial phase to evaluate the effectiveness of a drug for particular indication?**

a. Phase I
b. Phase II
c. Phase III
d. Phase IV

**121. Schedule F is containing:**

a. Regulations and standards for running a blood bank
b. Regulations and standards for bacterial vaccines, viral vaccines, antisera and diagnostic agents
c. Regulations and standards for surgical dressing
d. Regulations and standards for umbilical tapes

**122. Schedule F1 is containing:**

a. Regulations and standards for running a blood bank
b. Regulations and standards for bacterial vaccines, viral vaccines, antisera and diagnostic agents
c. Regulations and standards for surgical dressing
d. Regulations and standards for umbilical tapes

**123. Schedule FF is containing:**

a. Regulations and standards for running a blood bank
b. Regulations and standards for bacterial vaccines, viral vaccines, antisera and diagnostic agents
c. Regulations and standards for ophthalmic preparations
d. Regulations and standards for umbilical tapes

**124. Schedule F2 is containing:**

a. Regulations and standards for running a blood bank
b. Regulations and standards for bacterial vaccines, viral vaccines, antisera and diagnostic agents
c. Regulations and standards for surgical dressing
d. Regulations and standards for umbilical tapes

**125. Schedule F3 is containing:**

a. Regulations and standards for running a blood bank.
b. Regulations and standards for bacterial vaccines, viral vaccines, antisera and diagnostic agents
c. Regulations and standards for surgical dressing
d. Regulations and standards for umbilical tapes

**126. From stockist to shopkeeper is called as _____.**

a. Retail sale
b. Wholesale
c. Restricted sale
d. None of these

**127. Which retail sale, type of licenses is issued for retail sale?**

a. General licenses
b. Restricted licenses
c. Both a and b
d. None of these

**128. What is the full form of RDL?**

a. Retail drug list
b. Retail drug license
c. Retail dose license
d. Regulation drug license

**129. Which type of conditions for whole sale license?**

a. Area shall not be less than 10 sq.m.
b. Sale can be made either by a registered pharmacist
c. License shall be displayed in a prominent place
d. All of the above

**130. Inspection book shall be maintained in Form _____.**

a. 34
b. 35
c. 36
d. 37

**131. Restricted licences in Forms _____ and _____.**

a. 10 (*a*) and 11 (*a*)
b. 11 (*a*) and 12 (*a*)
c. 20 (*a*) and 21 (*a*)
d. 21 (*a*) and 22 (*a*)

**132. Supply of Schedule C drug includes:**

a. Serial number of the entry and date of supply
b. Name and address of the purchaser
c. Name and quantity of drug supplied and name of the manufacturer
d. All of the above

**133. Supply of Schedule H drug includes:**

a. Drug should be sold against the prescription of registered medical practitioner
b. Name of drug, its manufacturer and batch number
c. Signature of the qualified person.
d. All of the above

**134. Supply of Schedule X drug includes:**

a. Drug shall be kept in a separate cupboard under lock and key
b. Date of purchase/transaction
c. Both a and b
d. Name and address of purchaser

**135. Anyone sell, stocks, exhibits for sale or distribute any misbranded or adulterated or spurious drug without proper license shall be punished with:**

a. Imprisonment not less than one year but may extend up to 10 years
b. Imprisonment not less than one year but may extend up to 10 years on first conviction and 2 to 10 years with fine on subsequent convictions.
c. Imprisonment not less than one year but may extend up to 20 years
d. None of these

**136. Anyone who sells, exhibits for sale or distributos any drug in contravention of the Act and Rules shall be punished with:**

a. Imprisonment up to 5 years. Or fine both on first conviction and up to 10 years with fine on subsequent convictions
b. Imprisonment not less than one year but may extend up to 10 years on first conviction and 2 to 10 years with fine on subsequent convictions
c. Imprisonment not less than one year but may extend up to 20 years
d. None of these

**137. Failure to not keeping records of sale in the specified manner punishable with:**

a. Fine up to ₹ 500
b. Imprisonment up to 3 years or fine up to ₹ 1000 or both
c. Imprisonment for 3–5 years and fine of not less than ₹ 5,000
d. None of these

**138. Label should be:**

a. Printed or written in indelible ink
b. Appear in a conspicuous manner on the label of the innermost container of any drug
c. Both a and b
d. None of the above

**139. Articles intended for use in diagnosis, cure, mitigation, treatment, or prevention of disease is called as _____.**

a. Medicine
b. Compound
c. Drug
d. Substances

**140. Full form of OTC is called as _____.**

a. Over-the-counter
b. Open the counter
c. Over the class
d. Open the class

**141. Over-the-counter drug is also called as _____.**

a. Prescription drugs
b. Labelled drugs
c. Packed drugs
d. Nonprescription drugs

**142. "Labelling" has been defined as:**

a. Include the display of written material
b. On the immediate container of a drug presenting vital prescription information,
c. Any printed matter on a drug's containers or wrappers
d. All of the above

**143. Labeling classifies as:**

a. Brochures
b. Mailing pieces
c. Detailing pieces
d. All of the above

**144. Prescription label consist of:**

a. Patient name and address
b. Prescribers name
c. Drug name
d. All of the above

**145. Precautions for prescription medicine includes:**

a. Tell physician of previous problems/allergies
b. Keep list of all meds currently using
c. Both a and b
d. None of these

**146. What precautions are give to medicine?**

a. Flush old drugs
b. Keep in labeled containers
c. Do not use expired medicines
d. All of the above

**147. Primary container labels regulated by:**

a. State b. Central
c. Nation d. None of these

**148. Auxiliary labels are also called as _____.**

a. Primary container labels
b. Warning labels
c. Manufacture label
d. None of these

**149. Full form of CMI:**

a. Consumer market information
b. Consumer medication information
c. Customer market information
d. Customer medication information

**150. Medication guides—prescription and patient package information for:**

a. Consumer b. Patient
c. Provider d. None of these

**151. Products used exclusively by beauticians in beauty salons and labeled:**

a. For internal use only
b. For external use only
c. For professional use only
d. For topical use only

**152. The labeling that appears on cosmetic products themselves. Unfair and deceptive advertising that appears in magazines, in newspapers, or on television falls under the authority of the:**

a. Federal trade commission
b. FDA
c. State government
d. Central government

**153. Recommended daily dosage and frequency is known as _____.**

a. Contraindications
b. Drug interaction
c. Directions
d. Adverse effects

**154. _____ is/are the section telling you what to avoid and who should not use this.**

a. Drug interaction
b. Warnings
c. Directions
d. Adverse effects

**155. Label content:**

a. Source, ingredients
b. Drug interaction
c. Directions
d. All of the above

**156. Advisory committee consists of:**

a. Drugs Technical Advisory Board
b. Drugs Consultative Committee
c. Both a and b
d. None of these

**157. Analytical committee consists of:**

a. Central drugs laboratory
b. Drug control laboratory in states
c. Government analysts
d. All of the above

**158. Executives committee consists of:**

a. Licensing authorities
b. Controlling authorities
c. Drug inspectors
d. All of the above

**159. The _____ appoints the Drugs Technical Advisory Board.**

a. State government
b. Central government
c. Both a and b
d. None of these

**160. What is the function of DTAB?**

a. To advice the central government on technical matters
b. To advice the state government on technical matters
c. Both a and b
d. None of these

**161. How many members in nominated committee in DTAB?**

a. 5 b. 8
c. 9 d. 10

**162. How many members in ex-officio committee in DTAB?**

a. 5 b. 8
c. 9 d. 10

**163. The Central Drug Laboratory is located in _____.**

a. Mumbai b. Calcutta
c. Kausali d. Lucknow

**164. Central Research Institute located in _____.**

a. Mumbai b. Kausali
c. Lucknow d. Both b and c

**165. Indian Veterinary Research Institute located in _____.**

a. Mumbai b. Calcutta
c. Izatnagar d. Lucknow

**166. The pharmacologist, elected by the Governing Body of the:**

a. Indian Medical Association
b. Indian Pharmaceutical Association
c. Indian Council of Medical Research
d. None of these

**167. The Central Drug Laboratory is separate 'The Ayurvedic, Siddha and Unani Drug Consultative Committee' constituted under Section _____ of the Act.**

a. 33 (*a*) b. 33 (*b*)
c. 33 (*c*) d. 33 (*d*)

**168. Central Drug Laboratory established in Calcutta, under the control of a Director appointed by the _____.**

a. State government
b. Central government
c. Both a and b
d. None of these

**169. What is the function of CDL?**

a. Analysis or test of samples of drugs/cosmetics
b. Analytical QC of the imported samples
c. Preparation of reference standards and their maintenance
d. All of the above

**170. Every state has a laboratory for analysis and testing of the drug and cosmetics manufactured or sold or to be sold within the respective areas is known as _____.**

a. Drug control laboratories
b. Indian Veterinary Research Institute
c. Central Research Institute
d. None of these

**171. Drug control laboratories in state consist of following:**

a. Pharmaceutical chemistry division
b. Immunology and pharmacology division
c. Pharmacognosy and food division
d. All of the above

**172. Government analyst in relation to Ayurvedic, Siddha and Unani drugs, a person appointed by central government or state government under Section _____.**

a. 33 (*d*)
b. 33 (*f*)
c. 33 (*e*)
d. 33 (*c*)

**173. What are the duties of government analyst?**

a. Analysed or tested such samples or drugs and cosmetics as may be sent to him by inspectors
b. Time to time forward reports to the government giving the result of analytical work
c. Both a and b
d. None of these

**174. Licencing authority appointed by the central and state governments _____ for the import, manufacture, sale, distribution, etc. of any drug or cosmetic.**

a. For the grant
b. For the renewal of a licence
c. Both a and b
d. None of these

**175. Each state government appoints _____ to issue licenses for manufacturing, distribution, and sale of drug or cosmetics for specified area.**

a. Government analyst
b. Drug control laboratories
c. Licensing authorities
d. None of these

**176. The licensing authorities have the power to:**

a. Issue or refuse licenses
b. May be appealed before the state or central governments
c. Both a and b
d. None of these

**177. What is the qualification of licensing authorities?**

a. He must be a graduate in pharmacy or pharmaceutical chemistry
b. Graduate in medicine with specialization in clinical pharmacology microbiology
c. Experience in the manufacture or testing of drugs a minimum period of five years
d. All of the above

**178. What are the duties of licensing authorities?**

a. To inspect all establishments licensed for the sale of drugs
b. To investigate any complaint.
c. To maintain a record of all inspections
d. All of the above

**179. All drug inspectors appointed by the Central Government or the State Government Act are under the control of an officer appointed by respective governments referred to as:**

a. Government analyst
b. Drug control laboratories
c. Licensing authorities
d. Controlling authority

**180. What is the qualification of controlling authority?**

a. Experience in the manufacture or testing of drugs
b. Enforcement of the provisions of the Act for a minimum period of five years
c. Both a and b
d. None of these

**181. A person to be appointed as a _____ should have no financial interest in the import, manufacture or sale of the drug and cosmetics.**

a. Licensing authorities
b. Controlling authority
c. Drug inspector
d. Government analyst

**182. Drug inspector is a Public Servant under Section _____ of Indian Penal Code.**

a. 20
b. 21
c. 19
d. 18

**183. What is the qualification of drug inspector?**

a. Persons having a degree in Ayurvedic, Siddha and Unani system
b. Person not less than three years postgraduate experience in the analysis of drugs
c. Both a and b
d. None of these

**184. What are the duties of drug inspector?**

a. To inspect
b. Take samples of any drug or cosmetic
c. For entering and searching any place, person or vehicle, etc.
d. All of the above

**ANSWERS**

| | | |
|---|---|---|
| **1. b** | **2. b** | **3. c** |
| **4. b** | **5. d** | **6. b** |
| **7. d** | **8. b** | **9. d** |
| **10. c** | **11. a** | **12. b** |
| **13. c** | **14. a** | **15. a** |
| **16. b** | **17. d** | **18. c** |
| **19. d** | **20. c** | **21. d** |
| **22. c** | **23. b** | **24. b** |
| **25. c** | **26. d** | **27. c** |
| **28. b** | **29. d** | **30. a** |
| **31. d** | **32. b** | **33. c** |
| **34. a** | **35. c** | **36. b** |
| **37. d** | **38. a** | **39. a** |
| **40. b** | **41. c** | **42. d** |
| **43. d** | **44. b** | **45. a** |
| **46. c** | **47. d** | **48. b** |
| **49. b** | **50. b** | **51. d** |
| **52. b** | **53. d** | **54. b** |

| | | |
|---|---|---|
| **55. d** | **56. d** | **57. c** |
| **58. d** | **59. c** | **60. c** |
| **61. d** | **62. c** | **63. d** |
| **64. c** | **65. b** | **66. a** |
| **67. a** | **68. c** | **69. b** |
| **70. c** | **71. b** | **72. b** |
| **73. b** | **74. a** | **75. c** |
| **76. d** | **77. a** | **78. d** |
| **79. a** | **80. a** | **81. d** |
| **82. c** | **83. c** | **84. c** |
| **85. b** | **86. c** | **87. b** |
| **88. c** | **89. c** | **90. c** |
| **91. a** | **92. b** | **93. a** |
| **94. c** | **95. b** | **96. a** |
| **97. b** | **98. b** | **99. c** |
| **100. d** | **101. d** | **102. a** |
| **103. d** | **104. a** | **105. d** |
| **106. b** | **107. a** | **108. c** |
| **109. d** | **110. d** | **111. c** |
| **112. d** | **113. b** | **114. d** |
| **115. c** | **116. d** | **117. b** |
| **118. b** | **119. b** | **120. b** |
| **121. a** | **122. b** | **123. c** |
| **124. c** | **125. d** | **126. b** |
| **127. c** | **128. b** | **129. d** |
| **130. b** | **131. c** | **132. d** |
| **133. d** | **134. c** | **135. b** |
| **136. a** | **137. b** | **138. c** |
| **139. c** | **140. a** | **141. d** |
| **142. d** | **143. d** | **144. d** |
| **145. c** | **146. d** | **147. a** |

**148. b** **149. b** **150. c**
**151. c** **152. a** **153. c**
**154. b** **155. d** **156. c**
**157. d** **158. d** **159. b**
**160. c** **161. d** **162. b**
**163. b** **164. d** **165. c**
**166. c** **167. d** **168. b**
**169. d** **170. a** **171. d**
**172. c** **173. c** **174. c**
**175. c** **176. c** **177. d**
**178. d** **179. d** **180. c**
**181. c** **182. b** **183. c**
**184. d**

## SHORT QUESTIONS

1. What are the objectives of Drugs and Cosmetics Act, 1940?
2. What do you understand by CDL under Drugs and Cosmetics Act?
3. What are the classes of drugs prohibited from being sold?
4. Write a note on Drugs Consultative Committee (DCC).
5. What are the qualifications and duties required to be a government analyst?
6. Write a note on Licensing Authority.
7. Write in short on loan license and repacking license.
8. Write penalties and offences related import.
9. Write penalties and offences related sale of drug.
10. Write penalties and offences related manufacturing of drug.
11. Write prohibition for the manufacturing and sale of certain drug.

## LONG QUESTIONS

1. Write in detail about imports of drugs.
2. Which are the Acts and Rules that regulate manufacturing export and clinical research of Drugs and Cosmetics in India?
3. How many schedules do the D and C Act have, elaborate it in details?
4. Which is prohibited as per D and C Act, 1940?
5. What is the minimum qualification to be appointed as drug inspector as per Drugs and Cosmetics Act, 1940?
6. Write detail study of Schedule M and M1.
7. Write detail study of Schedule H and X.
8. Write detail study of Schedule P and V.
9. Write detail administration bodies with their constitution and function.

Chapter

2

# Pharmacy Act, 1948

## AN ACT TO REGULATE THE PHARMACY PROFESSION

### DEFINITIONS UNDER THE ACT

**Pharmacy Act—An Act to Regulate the Profession of Pharmacy**

***Registered Pharmacist***

A person whose name is for the time being entered in the register of the state in which he or she is for the time being residing or carrying on his profession or business of pharmacy.

### OBJECTIVES

- To regulate the pharmacy education in the country for the purpose of **registration** as a pharmacist under the Pharmacy Act.
- They also regulate the **profession and practice** of pharmacy.
- Maintaining control over the persons entering the pharmacy profession.

### THE PHARMACY COUNCIL OF INDIA

- The first Pharmacy Council of India **(PCI)** constituted by central government in 1949.
- It is reconstituted every 5 years.

### *Constitution*

It consists of three different types of members:

1. Elected member
2. Nominated member
3. Ex-officio member

### *Elected Members*

- 6 members elected by **University Grant Commission (UGC).** There is at least one teacher of each of the pharmacy, **pharmaceutical chemistry**, **pharmacognosy** and **pharmacology**.
- One member, elected by **Medical Council of India.**
- One member, elected by State Council, who shall be a **registered pharmacist.**

### *Nominated Members*

- 6 members, nominated by the **central government**. Of whom at least 4 shall be persons possessing a degree or diploma in, and practicing pharmacy, or pharmaceutical chemistry.
- A representative of the UGC and a representative of the All India Council for Technical Education (AICTE).
- One member nominated by each state government, who shall be a **registered pharmacist.**

### *Ex-officio Member*

- The Director General of Health Services.
- The Director of Central Drug Laboratory.
- The Drug Controller of India.

### *Executive Committee Consisting of*

- President
- Vice-President
- One members elected by Central Council.

### *The Council Shall Appoint*

- A Registrar who may act as a Secretary.
- Other officer and servants.

## Functions

### *Design of the Educational Pattern*

To frame an **educational structure** for the would be pharmacist and to keep it tuned to the changing needs with passage of time.

The standards of education for pharmacist framed by the council are known as the **Education Regulations** and amongst other things prescribe.

*As*

- Minimum qualification for admission to the course
- Duration of the training and the course of study to be covered.
- Equipment and facilities to be provided by the institutions.
- Giving practical training.
- Holding approved examinations.

### *Approval of Institutions/Withdrawal of Approvals*

- An institution or authority which conducts a course of study or holds an examination for the pharmacists has to apply to the Pharmacy Council of India for approval of the course or the examination.
- The council may depute its inspectors to visit the institution to check whether the prescribed facilities for imparting training or holding examinations are in accordance with the Education Regulations or not.
- It may also require inspectors to attend any examination, to judge its standard without interfering with its conduct.
- If on the report of the inspector, the council is satisfied then it gives approval to it and then the said course or examination shall be deemed to be approved for qualifying for registration as pharmacist under the Act.
- If any approved course of study or examination does not continue to be in conformity with the Education Regulations, then the council withdraws the approval.

## EDUCATION REGULATION

Subject to the provision of Section 10 of the Pharmacy Act, 1948.

- Minimum qualification for admission to the course.
- Nature and period of course of study.

- The subject of examination and the standard attained therein.
- The equipment and facilities to be provided by the institution for the student undergoing approved course of study.
- Condition to be fulfilled by institution giving practical training also by authorities holding approved examinations.

### Duration of the Course

**Pharm D:** The duration of course is 6 academics years
**Phase I:** First, second, third, fourth and fifth years.
**Phase II:** Internship or residency training during sixth year in specialty units. The students are exposed to pharmacy practice or clinical pharmacy service.

### Qualification for Admission

#### *Pharm D: Phase I*

- 10 + 2 examination with physics and chemistry are compulsory subject along with mathematics or biology.
- DPharm. Pass from an institution approved by PCI.
- Seats are reserved for the student belonging to SC, ST and OBC as per norms of government.

#### *Syllabus*

The syllabus for each subject of the above course is given in Appendix A to these regulations.

#### *Examination*

Examination (theory, practical including oral) will be held twice a year. The first shall be annual and the second shall be supplementary examination.

### STATE AND JOINT PHARMACY COUNCILS

- State Pharmacy Council and Joint State Pharmacy Council are also constituted by the state government.
- Two or more states may also enter into an agreement (inter-state agreement) for definite, specified periods to form joint state councils.
- Each state council shall have a President and Vice-President elected by the members from amongst themselves.

- The State Council is also require to constitute an executive committee similar to that of the central council. It should also submit the necessary information and annual report to the state government.

**Table 2.1:** Constitution of State Pharmacy Council and Joint State Pharmacy Council

| *State Pharmacy Council* | *Joint State Pharmacy Council* |
|---|---|
| **Elected members**<br>• **Six** members—by registered pharmacist of the state<br>• **One** member elected by MCI | **Elected members**<br>• Registered Pharmacist—**3 to 5** from each state<br>• Medical council—**1** from each state. |
| **Nominated members**<br>• **Five** members nominated by the state government | **Nominated members**<br>• Govt. nominees—**2 to 4** from each state |
| **Ex-officio members**<br>• Chief Administrative Medical Officer<br>• Officer in-charge of drugs Control Administration of the state<br>• Government analyst | **Ex-officio members**<br>• Chief Administrative Medical Officer<br>• Officer in-charge of Drugs Control Administration<br>• Government analyst from each state |

## REGISTRATION OF PHARMACIST

Names of the registered pharmacist are entered in the registers maintained by the State Council and the Central Council.

### Maintenance of Registers

- The full name and residential address of the registered person.
- The date of his/her first admission to the register.
- His/her qualifications for registration.
- His professional address, and if he is employed by any person, the name of such person.

### Entry and Removal of Names

- After an appointed date, all applications for registration should be addressed to the registrar of the State Pharmacy Council.

- The applicant has the requisite qualifications for registration, he may direct his or her name to be entered in the register.
- Person whose names have been removed from the registers of other state shall not be entitled to registration.
- On payment of the fees, the registrar is required to issue a receipt there of and such receipts are deemed to be proofs of renewal of registration.

### Removal of Names from the Register

A person, whose name has been removed from the register, is required to surrender his certificate of registration to the registrar of the Pharmacy Council concerned.

### Printing of Register

- It is done on the 1st day of April subsequent to the commencement of the Pharmacy (Amendment) Act, 1959.
- Thereafter, each year after the first of April, register will arrange for reprinting showing supplements to the registers.
- These supplements and registers are deemed to be proof that the persons, whose names are contained therein, are registered pharmacists.

**Table 2.2:** Offences and penalties

| *Sr. no* | *Offences* | *Penalties* |
|---|---|---|
| 1. | Falsely claiming to be a registered pharmacist | Fine up to **₹ 500.00** on **first** conviction<br>Fine up to **₹ 1000.00** and/or **6 months imprisonment** of any **subsequent** conviction |
| 2. | Dispensed by unregistered person exception—medical practitioner | **6 months imprisonment** or fine up to range **₹ 1000.00** or **both** |
| 3. | Failure to surrender certificate of registration | Fine up to **₹ 50.00** |
| 4. | Obstructing State Pharmacy Council inspector | **6 months imprisonment** or fine to **₹ 1000** or **both** |

## SELF-ASSESSMENT EXERCISE

### MCQs

**1. The PCI was constituted in:**

a. 1948 b. 1989
c. 1947 d. 1950

**2. The Pharmacy Council reconstituted every _____.**

a. 10 years b. 15 years
c. 5 years d. 20 years

**3. "Registered pharmacist" is the person who should be:**

a. Qualified in pharmacy courses
b. Knowledge of compounding and dispensing of drug
c. Trained in any government registered medical dispensing, etc.
d. All of the above

**4. In nominated member of Central Council six members nominated by**

a. State government b. MCI
c. Central government d. AICTE

**5. The inspector report to the _____ after inspection.**

a. Central Council b. State Council
c. Central government d. Joint State Council

**6. In elected members of State Pharmacy Council member elected from amongst themselves by registered pharmacist:**

a. 5 members b. 4 members
c. 6 members d. 2 members

**7. Minimum training required to be a pharmacist:**

a. 100 hours b. 500 hours
c. 300 hours d. 800 hours

**8. Executive Committee consisting of:**

a. The Director General of Health Services
b. The Director of Central Drug Laboratory

c. The Drug Controller of India
d. President

**9. Penalties for making false claims to be a registered pharmacist should include:**

a. Fine up to ₹ 500.00 on first conviction
b. 6 months imprisonment or fine to ₹ 1000 or both
c. Fine up to ₹ 50.00
d. 6 months imprisonment or fine up to range ₹ 1000.00 or both

**10. Approval to new pharmacy institute given by:**

a. DCI b. MCI
c. PCI d. AICTE

**11. Which of the following Act regulates the profession of pharmacy?**

a. Pharmacy Act b. Poison Act
c. Patent Act d. D and C Act

**12. Which of the following is objective of Pharmacy Act?**

a. To provide uniform education and training to those persons willing to enter the pharmacy profession.
b. To maintain control over the persons of the pharmacy profession by registering them as registered pharmacists in every State and Union Territories.
c. Both a and b
d. None of these

**13. Pharmacy Act extends to the whole of India except the state:**

a. Rajasthan b. Assam
c. Jammu & Kashmir d. Himachal Pradesh

**14. Who was the first chemist in India?**

a. Bathgate b. Aristotle
c. Galen d. Ramanujan

**15. Central register maintained by:**

a. Central Council b. MCI
c. AICTE d. State Council

**16. "Registered pharmacist" is the person who should be:**

a. Qualified in pharmacy courses
b. Knowledge of compounding and dispensing of drug
c. Trained in any government registered medical dispensing, etc.
d. All of the above

**17. Ex-officio member of Central Council is:**

a. Officer in-charge of Drug Control Administrative
b. Government analyst of each state
c. Chief medical officer
d. The Drug Controller of India

**18. Function of Central Council is:**

a. Design of the educational pattern
b. Education Regulations
c. Giving practical training
d. All of the above

**19. The inspectors report to the _____ after inspection.**

a. Central Council
b. State Council
c. Central government
d. Joint State Council

**20. The Pharmacy Council of India is required to maintain a register containing name of:**

a. All registered pharmacist
b. Elected member of state
c. Nominated member of Central Council
d. Offences of pharmacy

**21. A person whose name has been removed from the registers of other state shall:**

a. Again register in other state
b. On specific penalty they can registered
c. Not entitled to registration
d. None of these

**22. Upon entry of the name of person in the register, the "Registrar" is required to issue to him a:**

a. Prize
b. Application form
c. Receipt
d. Certificate

**23. Removal of name from the register in condition:**

a. If his name has been entered in register by error
b. If he has been convicted of an offence in any professional
c. If he does not get renewal of his registration
d. None of these

**24. Joint State Pharmacy Council is:**

a. Many states council decide to make an individual council
b. Two or more state governments can agree that the State Council of one state is to serve
c. The PCI elected this council
d. None of these

**25. Offences of Pharmacy Act are:**

a. Falsely claiming to be a registered pharmacist
b. Failure to surrender certificate of registration
c. Dispensed by unregistered person
d. All of the above

**ANSWERS**

| | | |
|---|---|---|
| **1. a** | **2. c** | **3. d** |
| **4. c** | **5. a** | **6. c** |
| **7. b** | **8. d** | **9. a** |
| **10. c** | **11. a** | **12. c** |
| **13. c** | **14. a** | **15. a** |
| **16. d** | **17. d** | **18. d** |
| **19. a** | **20. a** | **21. c** |
| **22. d** | **23. c** | **24. a** |
| **25. d** | | |

## SHORT QUESTIONS

1. Write a note on Pharmacy Act in their function and constitution of PCI.
2. Discuss in short registration of pharmacist.
3. Give the objective of Pharmacy Act.
4. Write down registration of pharmacist.
5. Write the constitution of Pharmacy Council of India.
6. Explain the functions of State and Joint State Pharmacy Council of India.
7. Write a short note on Education Regulations by PCI.

## LONG QUESTIONS

1. Write definition, objective of Pharmacy Act and function, constitution of Pharmacy Council of India.
2. Write constitution and function of Pharmacy Act and State Pharmacy Council as well as Joint State Pharmacy Council.

Chapter

3

# Medicinal and Toilet Preparation Act, 1955 and Rules thereunder 1976

## INTRODUCTION

- This Act provides for the Draft and collection of duties of excise on the medicinal and toilet preparations containing alcohol, Indian hemp. Narcotic drugs or narcotics which are termed dutiable goods.
- With the above object, the Act also regulates the manufacture of dutiable goods.
- The excise duty is collected on the manufacture of such preparations as per the schedule prescribed in the Act.
- By virtue of Section 19, the central government has framed the Medicinal and Toilet Preparations (Excise Duties) Rules, 1956 to carry out the purposes of the Act.
- Before the enactment of the Medicinal and Toilet Preparations (Excise Duties) Act, 1955, Draft of excise duties on the medicinal and toilet preparations containing alcohol, Indian hemp, narcotic drugs or 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 or narcotics.

## OBJECTIVES

- Levy and collection of duties of excise on medicinal and toilet preparation containing alcohol, opium, Indian hemp, or other narcotic drugs and narcotics.
- Curb all irregularities of previous Act.

## DEFINITIONS UNDER THE ACT

**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 being 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 substances 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 has 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 **"opium".**

1. The capsules of the poppy (*Papaver somniferum* L), whether in their original form or cut, crushed or powdered and whether or not juice has been extracted therefrom;
2. The spontaneously coagulated juice of such capsules which has not been submitted to any manipulations other than those necessary for packing and transport; and
3. Any mixture, with or without neutral materials of any of the above forms of opium, and includes and derivative of opium.

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

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

**Standard preparations:** A pharmacopoeial preparation in which the amount of any of the various ingredients is below the minimum, i.e. requirement of proprietary medicines, not conforming to the formula displayed on the label.

**Manufacture**

- There are two modes of manufacture of medicinal and toilet preparation containing alcohol:
  - Manufacture in bond; and
  - Manufacture outside bond

In 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 duty has already been paid shall be used.

**Licensing procedure**

For the preparation containing alcohol and narcotic substances

1. From the Excise Commissioner in case of manufacture in bond.
2. From the office as the state government may authorize in/this behalf in case of manufacture outside bond. Applied with prescribed fee and format.

**Details required**

- Name and address of applicant
- Place/site of the bonded laboratory
- If applicant is a firm then name and address of partners
- If applicant is a company then name and address of directors, managers and managing agents and registration number of company.
- Amount of capital proposed
- Number and full description of vats, stills and other apparatus and machinery.
- Maximum quantity of alcohol remain at one time in the form of finished and unfinished preparations.
- Approximate date of starting production
- Statement indicating that excise officer required full time or part time.
- Site and elevation plant of laboratory building
- In case of firm copy of partnership deed
- In case of company list of directors, managers copies of memorandum of association, articles of association and latest balance sheet.
- On receiving application licensing authority verify
  1. Qualification and experience of technical staff
  2. Equipment
  3. Suitability of proposed building
  4. Soundness of applicant financial position.

## 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)
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.
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.

### NON-BONDED LABORATORY/ 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 arrangement:
  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 cored 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 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 rated 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 preparation.

## 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.

## EXPORT OF MEDICINAL AND TOILET 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.

### 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's of the goods which are to be exported.

### EXPORTS 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 ware house, giving the statements that the goods are to be exported by sea or air or by parcel post.

### IDEAL REQUIREMENTS

- Spirit store
- Room for manufacturing of medicinal preparations.
- Room for storage of finished preparations.
- Room for manufacturing and storage of toilet preparations
- Accommodations for excise officer with furniture.

## Offences and Penalties

**Table 3.1:** Offences and penalties in their Act

| *Sr. no.* | *Offences* | *Penalties* |
|---|---|---|
| 1. | a. Contravenes any of the provisions of a notification issued under Section 6; **or** | Fine up to ₹ **500.00** on **first** conviction |
| | b. Evades the payment of any duty of excise payable under this Act; **or** | |
| | c. Fails to supply any information which he is required by Rules made under this Act to supply, **or** | **6 months imprisonment** of any **subsequent** conviction |

*(Contd…)*

**Table 3.1:** Offences and penalties in their Act *(Contd...)*

| *Sr. no.* | *Offences* | *Penalties* |
|---|---|---|
| | d. Attempts to commit or abets the commission of any offence mentioned in Cl. (a) or Cl. (b) | |
| 2. | Dispensed by unregistered person exception-medical practitioner | **6 months imprisonment** or fine up to range **₹ 1000.00** or **both** |
| 3. | Failure to surrender certificate of registration | Fine up to **₹ 50.00** |
| 4. | Obstructing State Pharmacy Council Inspector | **6 months imprisonment** or fine to **₹ 1000** or **both** |

## SELF-ASSESSMENT EXERCISE

### MCQs

**1. Medicinal and Toilet Preparations Act was passed in ____.**

a. 1945 b. 1996
c. 1985 d. 1955

**2. The Act was passed with the main objective to:**

a. Regulate the production of narcotics
b. Collect duties of excise on medical and toilet preparation containing alcohol, opium, Indian hemp, etc.
c. Achieve adequate distribution
d. None of these

**3. The Medicinal and Toilet Preparations Act was passed in the year 1955 and the Rules were passed in _____.**

a. 1945 b. 1956
c. 1985 d. 1955

**4. The Medicinal and Toilet Preparations Act extends to the whole of India and came into force on _____.**

a. 1st June 1957 b. 1st April 1957
c. 1st May 1957 d. 1st July 1957

**5. The medicinal and toilet preparations specified in the Schedule as being subject to the duties of excise levied under the Act is called as _____.**

a. Non-dutiable goods
b. Dutiable goods
c. Suitable goods
d. None of these

**6. What is mean by medicinal preparation?**

a. The drugs used as a remedy
b. Prescription prepared for internal or external use of human being or animals
c. All substances intended to be used for or in treatment, mitigation or prevention of disease in human being or animals
d. All of the above

**7. _____ is the preparation intended to be used in the toilet of human body or in perfuming apparel of any description.**

a. Medicinal preparation
b. Toilet preparation
c. Dutiable goods
d. Non-dutiable goods

**8. Bonded manufactory means:**

a. The premises or any part of the premises approved
b. Licensed for the manufacture and storage of medicinal
c. Toilet preparations containing alcohol, opium, Indian hemp, and other narcotic drugs or narcotics on which duty has not been paid
d. All of the above

**9. 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 is called as _____.**

a. Medicinal preparation
b. Toilet preparation

c. Bonded manufactory
d. Non-bonded manufactory

**10. The 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:**

a. Denaturated spirit
b. Denatured alcohol
c. Both a and b
d. Non-bonded manufactory

**11. Opium consists of:**

a. The capsules of the *Papaver somniferum L.*
b. Any mixture, with or without neutral materials of any of the above forms of opium, and includes and derivative of opium
c. Both a and b
d. None of these

**12. _____ is the part of the bonded or non-bonded manufactory used for the storage of alcohol, opium, Indian hemp, and other narcotic drugs.**

a. Denaturated spirit
b. Spirit store
c. Denatured alcohol
d. Non-bonded manufactory

**13. Restricted preparation means:**

a. These are medicinal preparations
b. They are considered as capable of being misused as ordinary alcoholic beverages
c. Both a and b
d. None of these

**14. The medicinal preparations which are considered to be not capable of being, misused as ordinary alcoholic beverages are known as _____.**

a. Unrestricted preparation
b. Restricted preparation

c. Standard preparation
d. Alcoholic preparation

**15. A proprietary medicines, not conforming to the formula displayed on the label and pharmacopoeial preparation in which the amount of any of the various ingredients is below the minimum is called as _____.**

a. Unrestricted preparation
b. Restricted preparation
c. Standard preparation
d. Alcoholic preparation

**16. In Medicinal and Toilet Preparations Act on the receiving application licensing authority verify:**

a. Qualification and experience of technical staff
b. Equipment
c. Suitability of proposed building
d. All of the above

**17. Which of the following are the requirements of the bonded laboratory?**

a. A separate room or arrangement for the manufacture of toilet preparations
b. The storage room for the finished toilet preparations
c. A spirit stores
d. All of the above

**18. 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 is the requirement of:**

a. Bonded laboratory
b. Bonded manufactory
c. Both A and B
d. Non-bonded laboratory

**19. Find odd one out with reference to the MTP Act, 1955:**

a. Azithromycin tablet
b. Deodorant and perfumes
c. Skin products
d. Hair products

**20. Name the medical preparations which are considered as capable of being misused as ordinary alcoholic beverages:**

a. Unrestricted preparations
b. Restricted preparations
c. Asava
d. Arista

**21. Finished medicinal preparations should be stored in bulk:**

a. Not less than 2250 ml
b. Not less than 57 ml
c. Not more than 1 litre
d. Not more than 1500 ml

**22. Failure to supply information asked or giving false information under MTP (ED) Act is:**

a. Punishable with imprisonment up to six months or with fine up to ₹ 200 or with both
b. Punishable with fine ₹ 2,00,000
c. Punishable with imprisonment of six years
d. Punishable with imprisonment up to one month

**23. A person who desires to manufacture medicinal and toilet preparation must obtain a license from:**

a. Excise commissioner
b. Drugs Controller of India
c. Central Drug Licencing Authority
d. Police commissioner

**24. The bonded laboratory requires the services of:**

a. Excise officer
b. Drug analyst
c. Drug inspector
d. Officer-in-charge

**25. The working hours for non-bonded laboratory are fixed by:**

a. Drug inspector
b. Drug analyst
c. Excise commissioner
d. Officer-in-charge

**26. The non-bonded manufactory can be operated:**

a. Throughout the day
b. During sunrise and sunset
c. In the afternoon
d. Public holidays

**27. _____ is required to be paid on alcoholic preparations which are exported from India.**

a. Ware house
b. No duty
c. Payment of duty
d. None of these

**28. The owner of the non-bonded manufactory or a wholesale dealer who wants to export duty paid goods should give minimum _____ notice.**

a. 30 hours
b. 45 hours
c. 48 hours
d. 50 hours

**29. Which type of 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?**

a. Export of duty paid goods
b. Export under bond
c. Export non-bonded
d. None of these

**30. Failure to furnish proof of export within the prescribed period to the satisfaction of excise commissioner in MTP Act is punishable by:**

a. Punishable with fine up to ₹ 1000 extent to twice the amount of duty
b. Punishable with fine up to ₹ 200 extent to twice the amount of duty
c. Punishable with fine up to ₹ 2000 extent to twice the amount of duty
d. Punishable with fine up to ₹ 3000 extent to twice the amount of duty

**31. Obstruction to extensive search, seizure by any officer exercising powers under this act punishable with:**

a. Punishable with fine up to ₹ 1000
b. Punishable with fine up to ₹ 200
c. Punishable with fine up to ₹ 2000
d. Punishable with fine up to ₹ 3000

**32. Involvement by any owner for any offence against the provisions of this Act is:**

a. Punishable with 6-month imprisonment with fine up to ₹ 500 or both
b. Punishable with fine up to ₹ 1000 extent to twice the amount of duty
c. Punishable with fine up to ₹ 2000 extent to twice the amount of duty
d. Punishable with fine up to ₹ 200

**33. Contravenes any of the provisions of a notification in MTP Act issued under _____.**

a. Section 5 b. Section 6
c. Section 7 d. Section 4

**34. Which types of Ayurvedic preparations which contain self-generated alcohol?**

a. Asava
b. Arista
c. Both a and b
d. None of these

## ANSWERS

| | | |
|---|---|---|
| **1. d** | **2. b** | **3. b** |
| **4. b** | **5. b** | **6. d** |
| **7. b** | **8. d** | **9. c** |
| **10. c** | **11. c** | **12. b** |
| **13. c** | **14. a** | **15. c** |
| **16. d** | **17. d** | **18. c** |
| **19. a** | **20. a** | **21. a** |
| **22. a** | **23. a** | **24. d** |
| **25. c** | **26. b** | **27. b** |
| **28. c** | **29. b** | **30. c** |
| **31. c** | **32. a** | **33. b** |
| **34. c** | | |

## SHORT QUESTIONS

1. Discuss in detail about manufacture in bonded laboratory.
2. Write a short note on non-bonded laboratory.
3. Explain about ware-housing of alcoholic preparations as per MTP Act, 1995.
4. What are requirements of bonded laboratory?
5. Explain in brief about manufacturing of Ayurveda preparations under MTP Act.
6. Explain in brief about manufacturing in non-bonded laboratories.
7. Write a note on patent and proprietary preparations.

## LONG QUESTIONS

1. Give the design of bonded laboratory. Discuss in detail about manufacturing of alcoholic preparations in bonded laboratory.
2. Give the design of non-bonded laboratory. Discuss in detail about manufacturing of alcoholic preparations in non-bonded laboratory.
3. Define drug Inspector. Mention the qualifications, degrees and powers of drug inspector.

Chapter

4

# Narcotic Drugs and Psychotropic Substances Act, 1985 and Rules

## HISTORY

- The statutory control over narcotic drugs was being exercised under the Opium Act, 1857, the Opium Act, 1878 and the Dangerous Drugs Act, 1930.
- India had no legislation regarding narcotics until 1985. Cannabis smoking in India has been known since at least 2000 BC and is first mentioned in the Atharvaveda, which dates back a few hundred years BC.

## INTRODUCTION

- An Act to consolidate and amend the law relating to narcotic drugs, to make stringent provisions for the control and regulation of operations relating to Narcotic Drugs and Psychotropic Substances.
- NDPS Act, as it is known popularly, is meant to face a very important social problem: drug trafficking (deal or trade). This is also one of the special Acts that has come before the courts very frequently and having a large number of conflicting judgments confusing the general public.
- Act bill issued by President Giani Zail Singh on 16 September 1985, and came into force on 14 November 1985.

## OBJECTIVES

- To consolidate and amend the existing law relating to narcotic drug.

- To make stringent provision for control and regulation of operations relating to Narcotic Drugs and Psychotropic Substances.
- To considerably enhance penalties particularly for trafficking offences.
- To make provisions for implementations of International Convention relating to Narcotic Drugs and Psychotropic Substances to which India is party.

## DEFINITIONS UNDER THE ACT

### Cannabis (Hemp)

a. **Charas**, that is, the separated resin, in whatever form, whether crude or purified, obtained from the cannabis plant and also includes concentrated preparation and resin know as hashish oil or liquid hashish;

b. **Ganja,** that is, the flowering or fruiting tops of the cannabis plant (excluding the seeds and leaves when not accompanied by the tops), by whatever name they may be know or designated; and

c. **Any mixture**, with or without any neutral material, of any of the above forms of cannabis or cannabis or an drink prepared therefrom.

### Coca Derivative

a. **Crude cocaine**, that is, any extract of coca leaf which can be used, directly or indirectly, for the manufacture of cocaine;

b. Ecgonine and all the derivatives of ecgonine from which it can be recovered;

c. Cocaine, that is, methyl ester of benzoyl-ecgonine and its salts; and

d. All preparations containing more than 0.1% of cocaine.

### Manufacture

In relation to Narcotic Drugs and Psychotropic Substances, includes:

1. All processes other than production by which such drugs or substances may be obtained;

2. Refining or transformation of such drugs or substances;
3. Making of preparation containing such drugs or substances.

### Manufactured Drug

a. All coca derivatives, medicinal cannabis, opium derivative and poppy straw concentrate;
b. Any other narcotic substance or preparation which the central government may, having regard to the available information as to its nature or to a decision, if any, under any International Convention, by notification in the official gazette, declare to be a manufactured drug.

### Opium Derivative

i. Medicinal opium
ii. Prepared opium
iii. Phenanthrene alkaloids such as morphine, codeine, thebaine and their salts
iv. Diacetyl morphine (heroin) and its salts
v. All preparation containing more than 0.2% of morphine or any amount of diacetyl morphine.

### Opium Poppy

a. The plant of the species *Papaver somniferum L.*; and
b. The plant of any other species of Papaver from which opium or any phenanthrene alkaloid can be extracted and which the central government may, by notification in the official gazette, declare to be opium poppy for the purposes of this Act.

### Psychotropic Substance

Means any substance, natural or synthetic, or any natural material or any salt or preparation of such substance or material included in the list of psychotropic substances specified in the Schedule.

### Controlled Substance

Means any substance which the central government may, having regard to the available information as to its possible use

in the production or manufacture of Narcotic Drugs and Psychotropic Substances or to the provisions of any International Convention, by notification in the official gazette, declare to be a controlled substance.

## ILLICIT TRAFFIC/PREVENTION OF ILLICIT TRAFFIC IN NARCOTIC DRUGS AND PSYCHOTROPIC SUBSTANCES

i. Cultivating any coca plant or gathering any portion of coca plant;
ii. Cultivating the opium poppy or any cannabis plant;
iii. Engaging in the production, manufacture, possession, sale, purchase, transportation, warehousing, concealment, use or consumption, import inter-state, export inter-state, import into India, export from India or transhipment, of Narcotic Drugs and Psychotropic Substances;
iv. Dealing in any activities in Narcotic Drugs and Psychotropic Substances other than those referred to in sub-Clauses (i) to (iii); or
v. Handling or letting out any premises for the carrying on of any of the activities referred to in sub-Clauses (i) to (iv), other than those permitted under this Act, or any Rule or order made or any condition of any license, term or authorization issued, thereunder, and includes:
    1. Financing, directly or indirectly, any of the aforementioned activities;
    2. Abetting or conspiring in the furtherance of or in support of doing any of the aforementioned activities; and
    3. Harboring persons engaged in any of the aforementioned activities.

## AUTHORITIES AND OFFICERS

### Central Government to Take Measures for Preventing and Combating Abuse of and Illicit Traffic in Narcotic Drugs, etc.

- Co-ordination of actions by various officers, state government and other authorities under this Act, or under any other law for time being in force relating to the enforcement of provision of this Act.

- Obligations under the International Convention.
- Assistance to concerned authorities in foreign countries and concerned international organization regarding prevention and suppression of illicit traffic in narcotic drugs and psychotropic substances.
- Identification, treatment, education, after care, rehabilitation and social re-interaction of addicts.
- Such other matters for effective implementation of this Act and preventing and combating the abuse of Narcotic Drugs and Psychotropic Substances and illicit traffic therein.

### Officers of Central Government

Under the provision of this Act, the central government may appoint Narcotic Commissioner and such other officers as it think fit. Performs the function relating to:

1. Supervision of cultivation of opium poppy
2. Production of opium
3. Other functions as may be instructed by central government committee.

## THE NARCOTIC DRUGS AND PSYCHOTROPIC SUBSTANCES CONSULTATIVE COMMITTEE

The central government may constitute, by notification in the official gazette, an advisory committee to be called "The Narcotic Drugs and Psychotropic Substances Consultative Committee" (hereafter in this section referred to as the committee) to advise the central government on such matters relating to the administration of this Act as are referred to it by that government from time to time.

## PROHIBITION, CONTROL AND REGULATION

Prohibition of certain operations as per Section 8: No person shall:

- Cultivate any coca plant or gather any portion of coca plant; or
- Cultivate the opium poppy or any cannabis plant; or
- Produce, manufacture, possess, sell, purchase, transport, warehouse, use, consume, import inter-state and export inter-state, import into India, export from India or tranship any Narcotic drugs and Psychotropic Substances, except for medical or scientific purposes and in the manner and to the

extent provided by the provisions of this Act or the rules or orders made thereunder.

### Power of Central Government to Permit, Control and Regulate

Subject to the provisions of Section 8, the central government may, by Rules.

#### *Permit and Regulate*

i. The cultivation, or gathering of any portion (such cultivation or gathering being only on account of the central government) of coca plant, or the production, possession, sale, purchase, transport, import inter-state, export inter-state, use or consumption of coca leaves;
ii. The cultivation (such cultivation being only on account of central government) of the opium poppy;
iii. The production and manufacture of opium and production of poppy straw;
iv. The sale of opium and opium derivatives from the central government factories for export from India or sale to state government or to manufacturing chemists;
v. The manufacture of manufactured drugs (other than prepared opium) but not including manufacture of medicinal opium or any preparation containing any manufactured drug from materials which the maker is lawfully entitled to possess;
vi. The manufacture, possession, transport, import inter-state, export inter-state, sale, purchase, consumption or use of psychotropic substances;
vii. The import into India and export from India and transshipment of Narcotic Drugs and Psychotropic Substances;
viii. Prescribe any other matter requisite to render effective the control of the central government over any of the matters specified in Clause (*a*).

#### *In Particular and without Prejudice to the Generality of the Foregoing Power, such Rules may*

a. Empower the central government to fix from time to time the limits within which licenses may be given for the cultivation of the opium poppy;

b. Require that all opium, the produce of land cultivated with the opium poppy, shall be delivered by the cultivators to the officers authorized in this behalf by the central government;

c. Prescribe the forms and conditions of licenses for cultivation of the opium poppy and for production and manufacture of opium; the fees that may be charged therefor; the authorities by which such licenses may be granted, withheld, refused or cancelled and the authorities before which appeals against the order of withholding, refusal or cancellation of licenses shall lie;

d. Prescribe that opium shall be weighed, examined and classified according to its quality and consistence by the officers authorized in this behalf by the central government in the presence of the cultivator at the time of delivery by the cultivator;

e. Empower the central government to fix from time to time the price to be paid to the cultivators for the opium delivered;

f. Provide for the weighment, examination and classification, according to the quality and consistence, of the opium received at the factory and the deductions from or additions (if any) to the standard price to be made in accordance with the result of such examination; and the authorities by which the decisions with regard to the weighment, examination, classification, deductions or additions shall be made and the authorities before which appeals against such decisions shall lie;

g. Require that opium delivered by a cultivator, if found as a result of examination in the central government factory to be adulterated, may be confiscated by the officers authorized in this behalf;

h. Prescribe the forms and conditions of licenses for the manufacture of manufactured drugs, the authorities by which such licenses may be granted and the fees that may be charged therefor;

i. Prescribe the forms and conditions of licenses or permits for the manufacture, possession, transport, import inter-

state, export inter-state, sale, purchase, consumption or use of psychotropic substances, the authorities by which such licenses or permits may be granted and the fees that may be charged therefor;

j. Prescribe the ports and other places at which any kind of Narcotic Drugs and Psychotropic Substances may be imported into India or exported from India or transshipped; the forms and conditions of certificates, authorizations or permits, as the case may be, for such import, export or transshipment; the authorities by which such certificate, authorizations or permits may be granted and the fees that may be charged therefor.

### Power to Control and Regulate Controlled Substances

1. If the central government is of the opinion that, having regard to the use of any controlled substance in the production or manufacture of any Narcotic Drugs and Psychotropic Substances, it is necessary or expedient so to do in the public interest, it may, by order, provide for regulating or prohibiting the production, manufacture, supply and distribution thereof and trade and commerce therein.
2. Without prejudice to the generality of the power conferred by subsection (1), an order made thereunder may provide for regulating by licenses, permits or otherwise, the production, manufacture, possession, transport, import inter-state, export inter-state, sale, purchase, consumption, use, storage, distribution, disposal or acquisition of any controlled substance.

### Power of State Government to Permit, Control and Regulate

Subject to the provisions of Section 8, the state government may, by Rules.

#### *Permit and Regulate*

i. The possession, transport, import inter-state, export inter-state, warehousing, sale, purchase, consumption and use of poppy straw.

ii. The possession, transport, import inter-state, export inter-state, sale, purchase, consumption and use of opium;
iii. The cultivation of any cannabis plant, production, manufacture, possession, transport, import inter-state, export inter-state, sale, purchase, consumption or use of cannabis (excluding charas).
iv. The manufacture of medicinal opium or any preparation containing any manufactured drug from materials which the maker is lawfully entitled to possess;
v. The possession, transport, purchase, sale, import inter-state, export inter-state, use or consumption of manufactured drugs other than prepared opium and of coca leaf and any preparation containing any manufactured drug;
vi. The manufacture and possession of prepared opium from opium lawfully possessed by an addict registered with the state government on medical advice for his personal consumption;
vii. Prescribe any other matter requisite to render effective the control of the state government over any of the matters specified in Clause (*a*).

## OFFENCES AND PENALTIES

1. Punishment for contravention in relation to poppy straw.
2. Punishment for contravention in relation to coca plant and leaves.
3. Punishment for contravention in relation to prepared opium.
4. Punishment for contravention in relation to opium poppy and opium.
5. Punishment for embezzlement (illegal disposal) of opium by cultivator.
6. Punishment for contravention in relation to cannabis plant and cannabis.
7. Punishment for contravention in relation to manufactured drugs and preparation.
8. Punishment for contravention in relation to psychotropic substances.

9. Punishment for illegal import into India, export from India or transshipment of Narcotic Drugs and Psychotropic Substances.
10. Punishment for external dealings in narcotic drugs and psychotropic substances in contravention of provision of this Act.
11. Punishment for allowing premises, etc. to be used for commencement of an offence.

    Punishable with rigorous imprisonment for a term which shall not be less than 10 years but which may extend to 20 years and shall also be liable to fine which shall not be less than one lakh rupees but which may extend to two lakh rupees. The court may, for reasons to be recorded in the judgment, impose a fine exceeding two lakh rupees (for offences are 1, 2, 3, 4, 5, 6, 7, 8, 9, 10, 11).
12. Punishment for certain acts by licensee or his servants.

    Imprisonment up to three years or fine or both (12).
13. Punishment for illegal possession in small quantity for personal consumption of any Narcotic Drugs and Psychotropic Substances or consumption of such drugs or substance.

    Where the Narcotic Drugs and Psychotropic Substances possessed or consumed isv cocaine, morphine, diacetyl-morphine or any other narcotic drug or any psychotropic substance with imprisonment for a term which may extend to one year or with fine or with both; and where the Narcotic Drugs and Psychotropic Substances possessed or consumed is other than those specified in or under the previous point, with imprisonment for a term which may extend to six months or with fine or with both (13).
14. Punishment for attempt to commit offences.
15. Punishment for abetment and criminal conspiracy.

    (14, 15) Punishment given in Section 116 of Indian Penal Code (45 of 1860).
16. Enhanced punishment for certain offences after previous conviction.

    Rigorous imprisonment for a term which shall not be less than 15 years but which may extend to 30 years and shall also be liable to fine which shall not be less than one lakh fifty thousand rupees but which may extend to three lakh rupees (16).
17. Punishment for offence for which no punishment is provided under this Act.

    Imprisonment up to six months or fine or both (17).

## SELF-ASSESSMENT EXERCISE

### MCQs

**1. The term "Narcotic" means:**

a. An addictive drug
b. An opiate
c. Both a and b
d. None of these

**2. Narcotic Drugs and Psychotropic Substances Act was passed in _____.**

a. 1970 b. 1857
c. 1985 d. 1999

**3. Section 2, Clause (*b*) of Control of Narcotics Substances Act, 1997 defines:**

a. Narcotic substances
b. Assets
c. Various classes of criminals
d. None of these

**4. The main object of this Act was:**

a. To consolidate and amend the law relating to narcotic drugs
b. To make stringent provisions for the control and regulation of operation relating to Narcotic Drugs and Psychotropic Substances
c. Both a and b
d. None of these

**5. A personal habitual to regular consumption of any Narcotic Drugs and Psycotropic Substances is known as _____.**

a. Guardian b. Narcotic
c. Addict d. None of these

**6. Cannabis includes:**

a. Charas
b. Ganja
c. Both a and b
d. None of these

**7. Coca derivatives include:**

a. Preparation containing less than 0.1% of cocaine
b. Preparation containing less than 0.2% of morphine
c. Preparation containing more than 0.1% of cocaine
d. Preparation containing more than 0.2% of morphine

**8. Opium means:**

a. Coagulated juice of opium poppy
b. Its mixture excluding preparation contains less than 0.2% cocaine
c. Both a and b
d. None of these

**9. Opium derivatives include:**

a. Preparation containing more than 0.2% of morphine
b. Preparation containing less than 0.2% of morphine
c. Preparation containing more than 0.2% of cocaine
d. Preparation containing less than 0.2% of cocaine

**10. Opium derivatives include:**

a. Medicinal and prepared opium
b. Phenanthrene alkaloids such as morphine, codeine, thebaine and their salts
c. Diacetyl morphine and its salts
d. All of the above

**11. Diacetyl morphine is also known as _____.**

a. Hemp
b. Cannabis
c. Charas
d. Heroin

**12. Medicinal cannabis is also known as _____.**

a. Opium
b. Heroin
c. Hemp
d. Ganja

**13. Opium poppy includes:**

a. Plant of *Papaver somniferum*
b. Plant of *Erythroxylum coca*
c. Plant of *Erythroxylum truxillense*
d. Plant of *Nux vomica*

**14. Coca derivatives include:**

a. Ecgonine
b. Cocaine
c. Both a and b
d. None of these

**15. When did the Narcotic Drugs and Psychotropic Substances Act, 1985, come into force?**

a. 01 April 1986
b. 01 March 1986
c. 14 November 1985
d. 23 April 1985

**16. Which Section of the Narcotic Drugs and Psychotropic Substances Act, 1985 deals with the power of the central government to permit, control, and regulate?**

a. Section 12
b. Section 9
c. Section 14
d. Section 20

**17. Which Section of the Narcotic Drugs and Psychotropic Substances Act, 1985 deals with power of central government to permit, control and regulate?**

a. Section 16
b. Section 14
c. Section 13
d. Section 18

**18. Section 25 of the Narcotic Drugs and Psychotropic Substances Act, 1985 deals with:**

a. Punishment for embezzlement of opium by cultivator
b. Punishment for allowing premises, etc. to be used for commission of an offence
c. Punishment for contravention in relation to psychotropic substances.
d. Punishment for contravention in relation to poppy straw

**19. Punishment for contravention in relation to manufactured drugs and preparations, is provided in Section ___ of the Narcotic Drugs and Psychotropic Substances Act, 1985.**

a. 24
b. 22
c. 21
d. 23

**20. The Narcotic Drugs and Psychotropic Substances Consultative Committee consists of:**

a. 20 members
b. 30 members
c. 40 members
d. 50 members

**21. Section 8 of this Act:**

a. Permits certain operations
b. Prohibits certain operations
c. Regulate certain operations
d. None of these

**22. Section 9 of this Act:**

a. Permits certain operations
b. Prohibits certain operations
c. Regulate certain operations
d. None of these

**23. Punishment for contravention in relation to Ganja is:**

a. Rigorous imprisonment NLT 10 years which may extend to 20 years and fine which shall not be NLT 1 lakh which may extend to 2 lakh rupees
b. Rigorous imprisonment NLT 10 years which may extend to 20 years and fine which shall not be NLT 1 lakh which may extend to 2 lakh rupees
c. Rigorous imprisonment 5 years and fine up to ₹ 50000
d. Rigorous imprisonment NLT 5 years or fine up to ₹ 50000.

**24. Punishment for failure to produce license or keeping false accounts is:**

a. Imprisonment up to 10 years or fine or both
b. Imprisonment up to 3 years or fine
c. Imprisonment up to 10 years or fine
d. Imprisonment up to 3 years or fine or both

**25. Punishment for illegal possession of small quantity of cocaine, morphine, diacetyl morphine, etc. for personal consumption is:**

a. Imprisonment up to 5 years or fine or both
b. Imprisonment up to 1 year or fine or both
c. Imprisonment up to 5 years
d. Imprisonment up to 1 year

**26. As per the Narcotic Drugs and Psychotropic Substances Act, Ganja means:**

a. Flowering and fruiting tops of *Cannabis sativa*
b. Flowering and fruiting tops, leaves and seeds of *Cannabis sativa*
c. Roots of *Cannabis sativa*
d. All parts of *Cannabis sativa*

**27. What is means by separated resin?**

a. Ganja
b. Charas
c. Any mixture
d. None of these

**28. _____ is methyl ester of benzoyl-ecgonine and its salts.**

a. Charas
b. Ganja
c. Cocaine
d. Morphine

**29. Phenanthrene alkaloids include:**

a. Morphine
b. Codeine
c. Thebaine
d. All of the above

**30. Narcotic commissioner shall perform the functions relating to:**

a. The supervision of cultivation of opium poppy
b. The supervision of production of opium
c. Other functions as may be entrusted to him by central government
d. All of the above

**31. Offence: Punishment for contravention related to poppy straw:**

a. Rigorous imprisonment NLT 10 years which may extend to 20 years and fine which shall not be NLT 1 lakh which may extend to 2 lakh rupees
b. Rigorous imprisonment NLT 15 years which may extend to 20 years and fine which shall not be NLT 1 lakh which may extend to 2 lakh rupees
c. Imprisonment up to 5 years with fine up to 50000 rupes
d. All of the above

**32. The scientific name of coca leaf:**

a. Hemp
b. Desomorphine
c. Erythroxylon
d. All of the above

**33. NDPS Act provides licensing system to regulate _____ of Narcotic Drugs and Psychotropic Substances.**

a. Manufacturing
b. Cultivation
c. Transportation
d. All of the above

**34. Extract or tincture of cannabis is called as _____.**

a. Medicinal opium
b. Medicinal hemp
c. Medicinal cannabis
d. Both b and c

**35. Under the provision of NDPS Act the central government may appoint:**

a. Drug control officer
b. Drug inspector
c. Narcotic commissioner
d. Police commissioner

**36. The Opium Act was come on _____.**

a. 1878
b. 1857
c. 1956
d. 1945

**37. _____ means any substance which the central government may, having regard to the available information as to its possible use in the production or manufacture of Narcotic Drugs and Psychotropic Substances.**

a. Psychotropic substances
b. Controlled substance
c. Narcotic substances
d. None of these

**38. _____ punishment for illegal possession in small quantity for personal consumption of any Narcotic Drugs and Psychotropic Substances or consumption of such drugs or substance.**

a. Imprisonment for a term which may extend to 1 year or with fine or with both
b. Imprisonment for a term which may extend to 6 months or with fine or with both

c. Imprisonment for a term which may extend to 3 months or with fine or with both
d. None of these

**39. Punishment given in Section 116 of Indian Penal Code (45 of 1860) for:**

a. For attempt to commit offences
b. For abetment and criminal conspiracy
c. Both a and b
d. None of these

## ANSWERS

| | | |
|---|---|---|
| **1. c** | **2. c** | **3. b** |
| **4. c** | **5. c** | **6. c** |
| **7. c** | **8. c** | **9. a** |
| **10. d** | **11. d** | **12. c** |
| **13. a** | **14. c** | **15. c** |
| **16. b** | **17. a** | **18. b** |
| **19. c** | **20. a** | **21. b** |
| **22. a** | **23. c** | **24. d** |
| **25. b** | **26. a** | **27. b** |
| **28. c** | **29. d** | **30. d** |
| **31. a** | **32. c** | **33. d** |
| **34. d** | **35. c** | **36. a** |
| **37. b** | **38. b** | **39. c** |

## SHORT QUESTIONS

1. What is the NDPS Act?
2. What is the objective of the NDPS Act?
3. Define the following terms: Addict, cannabis, coca derivative, an opium derivative, opium poppy, manufacture, manufactured drug, psychotropic substance.

4. What are the different operations controlled by central and state governments under NDPS?
5. What is the difference between Narcotic Drugs and Psychotropic Substances?

## LONG QUESTIONS

1. Write a brief account on the prevention of illicit traffic in Narcotic Drugs and Psychotropic Substances.
2. Explain in detail prohibition, control, and regulation.
3. Write about offences and penalties under the dangerous Drugs Act of NDPS.

Chapter

5

# Study of Salient Features of Drugs and Magic Remedies Act and its Rules

## OBJECTIVES

*The Act has been passed with the aim:*

1. To control certain types of the advertisements relating to drugs;
2. To prohibit certain kinds of advertisements relating to magic remedies which falsely claim and mislead public; and
3. To provide for matters related therewith.

## DEFINITIONS UNDER THE ACT

### Advertisement

*It includes:*

1. Any notice, circular, label, wrapper or otherwise such document; and
2. Any announcement made orally or by means of producing or transmitting light, sound or smoke.

### Magic Remedy

It includes a Talisman, Mantra, Kavacha, and any other charm claiming to possess miraculous powers:

1. For diagnosis, treatment and prevention of any disease in human beings or animal; or
2. For affecting or altering the structure or organic function of the body of human beings or animal.

### Drugs

1. A medicine for the internal or external use of human beings or animals.
2. A substance intended for the diagnosis, cure, mitigation, treatment or prevention of disease in human beings or animals.
3. Any article, other than food, intended to affect or influence in any way the structure or any organic function of the body of human beings or animals.
4. Any articles used as a component of any medicine.

### Registered Medical Practitioner

*It means any person:*

- Who holds a qualification granted by an authority specified in, or notified under Section 3 of the Indian Medical Degrees Act, 1916 (7 of 1916) specified in the Schedules to the Indian Medical Council Act, 1956 (102 of 1956); or
- Who is entitled to be registered as a medical practitioner under any law for the time being in force; in any state to which this Act extends relating to the registration of medical practitioner.

## CLASSES OF PROHIBITED ADVERTISEMENTS

### Prohibition of Advertisement of Certain Drugs for Treatment of Certain Diseases and Disorders

Subject to the provisions of this Act, no person shall take any part in the publication of any advertisement referring to any drug in terms, which suggest or are calculated to lead to the use of, that drug for:

a. The procurement of miscarriage in women or prevention of conception in women; or
b. The maintenance or improvements of the capacity of human beings for sexual pleasure; or
c. The correction of menstrual disorder in women; or
d. The diagnosis, cure, mitigation, treatment or prevention of any disease, disorder or condition specified in the Schedule, or any other disease, disorder or condition (by whatsoever name called) which may be specified in the Rules made under this Act.

### Advertisements of Magic Remedies for the Treatment

Of certain diseases and disorders which claim to the efficacious for any of the purposes specified in 1 as above.

### Prohibition of Misleading Advertisements Relating to Drugs

Subject to the provisions of this Act, no person shall take any part in the publication of any advertisement relating to a drug if the advertisement contains any matter which:

a. Directly or indirectly gives a false impression regarding the true character of the drug; or
b. Makes a false claim for the drug; or
c. Is otherwise false or misleading in any material particular.

### Prohibition of Advertisement of Magic Remedies for Treatment of Certain Diseases and Disorders

No person carrying on or purporting (claim) to carry on the profession of administering magic remedies shall take any part in the publication of any advertisement referring to any magic remedy which directly or indirectly claims to be efficacious for any of the purposes specified in **Section 3**.

### Prohibition of Import into, and Export from India of Certain Advertisement

No person shall import into, or export from, the territories to which this Act extends any document containing and advertisement of the nature referred to in Section 3, or Section 4, or Section 5, and any documents containing any such advertisement shall be deemed to be goods of which the import or export has been prohibited under Section 19 of the Sea Customs Act, 1878 (8 of 1978), and all the provisions of that Act shall have effect accordingly, except that Section 183, thereof shall have effect as if for the word "shall" therein the word "may" were substituted.

### Classes of Exempted Advertisements

**Provisions for savings, under this Act:** The following classes of advertisements are not prohibited under this Act. It

means nothing in this Act is applicable to these types of advertisements:

1. Any sign board or notice displayed by a registered medical practitioner on his premises indicating that treatment for any disease, disorder or condition specified in section 3; the Schedule or the rules made under this Act, is undertaken in those premises; or
2. Any treatise or book dealing with any of the matter specified in Section 3 from a bonafied scientific or social standpoint; or
3. Any advertisement relating to any drug sent confidentially in the manner prescribed under Section 16 only to a registered medical practitioner; or
4. Any advertisement relating to a drug printed or published by the government; or
5. Any advertisement relating to a drug printed or published by any person with the previous sanction of the government granted prior to the commencement of the Drugs and Magic Remedies (Objectionable Advertisement) Amendment Act, 1963 (42 of 1963).
6. Advertisement relating to the drugs which comply with the required conditions as follows:
   a. Leaflets or literature along with packing of drugs or advertisements of drugs in medicinal, pharmaceutical, scientific and technical journals.
   b. Therapeutic index or price list published by licensed manufacturer, importer or distributor of drug (under the D & C Act, 1940) or medical literature distributed by medical representatives.

## OFFENCES AND PENALTIES

1. Contravention of any of the provision of this Act or Rules thereunder:
   a. Punishable with imprisonment up to six months or with fine or with both on first conviction.
   b. Punishable with imprisonment up to one year or with fine on subsequent conviction.

2. In case of contravention of the provisions of the Act by a company, every person who, at the time of the commission of the offence, was in-charge and responsible for the conduct of company business shall be deemed to be guilty and liable for the punishment.
   - However, such person is not liable for punishment if he proves that the offence was committed without his knowledge or that he has taken all the precautions to prevent the commission of such offence.

## SELF-ASSESSMENT EXERCISE

### MCQs

**1. The Drugs and Magic Remedies Act came from:**

a. 1st January 1995 b. 1st April 1995
c. 1st January 1996 d. 1st April 1996

**2. The Drugs and Magic Remedies Act was implemented in:**

a. 1960 b. 1965
c. 1963 d. 1962

**3. It includes all the notices, labels, circulars, wrappers or other documents and all the announcements made orally or by means of producing or transmitting light, sound or smoke is called as _____.**

a. Magic remedy b. Advertisement
c. Magic labels d. None of these

**4. Magic remedy means:**

a. Talisman, mantra
b. Kavacha
c. Any other charm claiming to possess miraculous powers
d. All of the above

**5. Drug is:**

a. A medicine for the internal or external use of human beings or animals
b. An article used as a component of any medicine
c. Both a and b
d. None of these

**6. Any person who holds a qualification granted by an authority specified in, or notified under Section 3 of the Indian Medical Degrees Act, 1916 (7 of 1916) specified in the Schedules to the Indian Medical Council Act, 1956 (102 of 1956) is called as _____.**

a. Practitioner
b. Philosopher
c. Registered medical practitioner
d. None of these

**7. Which of following is classes of exempted advertisements?**

a. Any advertisement relating to a drug printed or published by the government
b. Any of the matter specified in Section 3 from a bonafide scientific or social standpoint
c. Both a and b
d. None of these

**8. Which of the following classes of prohibited advertisements?**

a. Prohibition of advertisement of certain drugs for treatment of certain diseases and disorders
b. Advertisements of magic remedies for the treatment
c. Prohibition of misleading advertisements relating to drugs
d. All of the above

**9. Which offences and penalties are used in Drugs and Magic Remedies Act?**

a. Punishable with imprisonment up to 6 months or with fine or with both on first conviction
b. Punishable with imprisonment up to 1 year or with fine on subsequent conviction
c. Both a and b
d. None of these

**ANSWERS**

| | | |
|---|---|---|
| **1. b** | **2. c** | **3. b** |
| **4. d** | **5. c** | **6. c** |
| **7. c** | **8. d** | **9. c** |

## SHORT QUESTIONS

1. Define "Magic remedies" under the Drugs and Magic Remedies Act, 1954.
2. Define "Advertisement" as per the Drugs and Magic Remedies Act, 1954.
3. What is the objective of the Drugs and Magic Remedies Act, 1954?
4. Write a note on the classes of exempted advertisements.
5. Give offences and penalties under the Drugs and Magic Remedies Act, 1954.

## LONG QUESTIONS

1. Give certain classes of drugs are prohibited for sale, distribution, and exhibition.
2. Write classes of advertisements that are prohibited to be advertised under the DMR Act, 1954.

Chapter

6

# Prevention of Cruelty to Animals Act, 1960

## OBJECTIVES

- To prevent the infliction of unnecessary pain or suffering on animal as well as to prevent cruelty to animal.
- To amend the law relating to the prevention of cruelty to animal.

## DEFINITIONS UNDER THE ACT

**Animal:** This term included any living creature except human being.

**Cruelty:** It is not defined under this Act but it roughly means the infliction of unnecessary pain or suffering.

## ANIMAL WELFARE BOARD OF INDIA

This board is established by **central government** in **1962** under the **Section 4.** The board consists of 28 members who serve for a period of 3 years. The central government nominates one of the members to be its Chairman and another member to be its Vice-Chairman.

The central government may appoint secretary of the board. Headquarter of this board is at Chennai.

## OBJECTIVES

- To promote animal welfare in general
- To protect animals from unnecessary pain or suffering in particulars.

### Functions

- To prevent the cruelty to animals and advice the central government regarding the amendments.
- To advice the central government on making of rules with the object of preventing unnecessary pain or suffering to animal.
- To suggest the government any improvements in the design of vehicle so as to lessen the burden on draught animals.
- To encourage by any financial assistance formation of rescue homes, animal shelters.
- To advice the government on medical care and attention to be provided in animal hospitals.
- To advice the government in such other matters relating to animal welfare.

### Experimentation of Animals

New discovery of physiological knowledge, biological production of vaccines, sera, hormones, etc.

### Committee Constitution

#### *Nominated Members*

- ICMR—two members
- ICAR—two members
- CSIR—two members
- University giving medical/veterinary degree—two members
- Person actively engaged in animal welfare activities—five non-official members.

#### *Elected Members*

- One member from Lok Sabha
- One member from Rajya Sabha

### Role of Committee

- Head of institution is responsible for experiments conducted in premise/outside the premise individual who conduct the experiment.

- Conduct the experiments under the influence of anaesthetics as well as possible.
- If animals during the experiments injured beyond recovery should be destroyed while under the influence of anaesthetic.
- Avoid the experiments on animals if books, models, films are sufficient in colleges/hospitals.
- Avoid large animals if same results can be obtained from smaller animals.
- The experiments on animals are not performed merely to have practice.
- Animals used for experimentation are properly looked before and after the experiment.
- Proper record regarding experimentation on animals should maintained.

### ENTRY AND INSPECTION

- The committee may authorize any of its office to inspect any institution/place where such experiments are being carried out.
- Such officers have power
  a. To enter at any reasonable time and inspect the place/institution.
  b. To require any person to produce the respective record.

### PROHIBITION OF EXPERIMENTATION OF ANIMALS

- On report/recommendation of the concerned officer committee may prohibit the institute/individual from carrying experiments on animals for specific period or indefinitely.
- In some cases committee may allow such institute/individual to carry on the experiments subject to certain condition.

### OFFENCES AND PENALTIES

- Treating animals cruelly is punishable with fine NLT ₹ 10 which may extend to ₹ 50 on first conviction.
- On subsequent conviction within 3 years of previous offence, it is punishable with fine NLT ₹ 25 which may

extend to ₹ 100 or imprisonment of 3 months or with both.

- Preforming operation like Phooka or any other operation to improve lactation which injurious to health of animal is punishable with fine up to ₹ 1000 or imprisonment up to 2 years or with both. Animal may be forfeited by the government.
- Contravention of any order of committee or breach of law imposed by committee is punishable with fine up to ₹ 200.

## SELF-ASSESSMENT EXERCISE

### MCQs

**1. The Prevention of Cruelty to Animals Act was enacted in the years _____.**

a. 1940 b. 1950
c. 1960 d. 1970

**2. Animal Welfare Board of India constituted under the prevention of cruelty to animals at situated in:**

a. New Delhi b. Mumbai
c. Kolkata d. Chennai

**3. According to the Prevention of Cruelty to Animals Act, 1960 _____ members are actively engaged in the promotion of animal welfare is nominated by central government.**

a. Five b. Six
c. Two d. One

**4. Animal Welfare Board is established by:**

a. State government b. State council
c. Central council d. Central government

**5. Cruelty to animals includes:**

a. Not giving food
b. Causing pain
c. Keeping in very small cage
d. All of the above

**6. For registration of breeders the permission has to be taken from:**

a. Committee for the purpose of control and supervision of experiments on animals
b. Central government
c. Institutional Animal Ethics Committee
d. None of these

**7. For treating animal cruelty how much fine has to be imposed for first instance?**

a. ₹ 50
b. ₹ 100
c. ₹ 150
d. ₹ 200

**8. Supreme court banned Jallikattu under which of the following Acts?**

a. The Prevention of Cruelty to Animals Act, 1960
b. The Prevention of Cruelty to Animals Act, 1970
c. Environment Prevention Act
d. None of these

**9. Which of the following is function of Animal Cruelty Act?**

a. To prevent the cruelty to animals and advice the central government regarding the amendments
b. To advice the government in such other matters relating to animal welfare
c. To encourage by any financial assistance formation of rescue homes, animal shelters
d. All of the above

**10. How many elected members are come in experimentation of animals committee?**

a. 2 b. 3
c. 4 d. 5

**11. How many non-official members are come in experimentation of animals committee?**

a. 2 b. 3
c. 4 d. 5

**12. Which type of officer power for entry and inspection committee?**

a. To enter at any reasonable time and inspect the place/ institution
b. To require any person to produce the respective record
c. Both a and b
d. None of these

**13. Contravention of any order of committee or breach of law imposed by committee is punishable with fine up to:**

a. ₹ 100
b. ₹ 200
c. ₹ 300
d. ₹ 500

**14. Following is true for "Animal Welfare Board of India":**

a. Protecting animals from being subjected to unnecessary pain or suffering
b. Established by the central government
c. To advised the central government on the making of Rules under this Act
d. All of the above

**15. The full form of IAEC is:**

a. Institution animal ethics corporation
b. Institution animal ethics committee
c. Institution animal education committee
d. None of these

**ANSWERS**

| | | |
|---|---|---|
| **1. c** | **2. d** | **3. a** |
| **4. d** | **5. d** | **6. a** |
| **7. a** | **8. a** | **9. d** |
| **10. a** | **11. d** | **12. c** |
| **13. b** | **14. d** | **15. b** |

## SHORT QUESTIONS

1. What is the objective of the Animal Cruelty Act?
2. What are the objectives and functions of the Animal Welfare Board of India?
3. Write a note on the committee constitution and its role.
4. Give offences and penalties under the Prevention of Cruelty to Animals Act, 1960.

## LONG QUESTION

1. What is the objective of the Animal Cruelty Act and give offences and penalties under the Prevention of Cruelty to Animals Act, 1960?

Chapter

7

# National Pharmaceutical Pricing Authority: Drugs Price Control Order (DPCO) 2013

## HISTORY

- Drugs (Display of Prices) Order 1962
- Drugs (Control of Prices) Order 1963

In 1966, parliament members felt that manufacturers charging high rate on drugs

↓

To control on high drug rates, DPCO 1966 was passed under Section 3 of Essential Commodities Act, 1955

↓

DPCO 1966 replaced by DPCO 1970

↓

In 1974, Hathi Committee was formed and submitted its reports in 1975

↓

DPCO 1970 replaced by DPCO 1979

↓

DPCO 1979 replaced by DPCO 1987

↓

DPCO 1987 replaced by DPCO 1995

↓

Finally DPCO 1995 replaced by DPCO 2013

Brought price of 348 essential drugs (all formulations) mentioned in NLEM against only 74 drugs and their formulation of DPCO 1995.

## INTRODUCTION

- Drugs play an important role in the health of both people and the economy of a country.
- People and governments willing to spend money on drugs for many reasons so, it must be safe, effective and of good quality and used appropriately. Problems relating to drug safety and efficacy exist in many places around the world today in developing and developed countries.
- This means, that development, production, importation, exportation and subsequent distribution of drugs must be regulated to ensure that they meet prescribed standards. Therefore, effective drug regulation is required to ensure the safety, efficacy and quality of drugs as well as accuracy and appropriateness of the drugs.

## OBJECTIVES

- To achieve adequate production and distribution.
- To ensure availability of essential medicines at reasonable price.
- To meet the goals of employment and shared economic growth of all.
- To provide sufficient opportunity for innovation and competition to support the growth of industry.
- Promoting the rational use of drug in the country to encourage cost-effective production with economic sizes.
- To ensure availability at reasonable prices of essential and life-saving medicine of good quality.

## DEFINITIONS UNDER THE ACT

### API or Bulk Drug

It means any pharmaceutical, chemical, biological or plant product including its salts, esters, isomers, analogues and derivatives, conforming to standards specified in D & C Act, 1940 and used as such or as an ingredient in any formulation.

### Ceiling Price

Price fixed by government for scheduled formulation accordance with the provisions of this order.

### Formulation

Medicine processed out or containing one or more bulk drugs with/without pharmaceutical aid for internal/external use for/in diagnosis, treatment, mitigation or prevention of disease in human/animals. (Not include Ayurvedic, Sidhha, Unani, Tibbi and Homeopathic system of medicine.)

### New Drug

Means a formulation launched by an existing manufacturer of a drug of specified dosage and strength as listed in NLEM by combining the drug with another drug listed/not listed in the NLEM or formulation launched by changing the strength, dosage or both of the drug listed in NLEM.

### Retail Price

Means the price fixed by government for a new drug.

### Scheduled Formulation

Means any formulation, included in first schedule whether referred as generic version or brand name.

### Nonscheduled Formulation

Means a formulation, the dosage and strength of which are not specified in first schedule.

### MRP

Ceiling price or retail price plus local taxes or duties as applicable, at which the drug shall be sold to the ultimate consumer or where such price is mentioned on the pack.

MRP of scheduled formulation = Ceiling price + local taxes.

MRP of new drug = Retail price + local taxes.

### NLEM

Means national list of essential medicines, 2011 published by the Ministry of Health and Family Welfare as updated or

revised from time to time and included in the first schedule of this order by government through a notification in the official gazette.

### Pharmacoeconomics

Means a scientific discipline that compares the therapeutic value of one drug/drug therapy to another.

- Manufacturer, distributor, dealer (wholesaler or retailer)

## SCHEDULED FORMULATION

### Calculation of Ceiling Price of Scheduled Formulation

$$P(c) = P(s)\ (1 + m/100),$$

where

M = % Margin to retailer 16%

P(s) = Average price to retailer of the schedule formulation for the same strength and dosage of the medicine.

- **If the other strength or dosage forms of the same schedule formulation are available in the list of schedule formulation then the average price to retailer shall be calculated as under**

$$P(s) = Pm\ [(1 - (Pi + Pi2 + \ldots)/N*100)],$$

where

Pm = Price to retailer of highest priced schedule formulation under consideration.

Pi = % Reduction in average price to retailer of other strength and dosage forms in the list of schedule formulations.

N = Number of such other strength or dosage forms or both in the list of schedule formulations.

### Retail Price of Formulation

*Formula for calculation:*

$$RP = (MC + CC + PM + PC) \times (1 + MAPE/100) + ED,$$

where

RP = Retail price

MC = Material cost

CC = Conversion cost

PM = Packaging material cost
PC = Packing charges
ED = Excise duty
MAPE = Maximum allowable post-manufacturing expenses.

### MARGIN TO RETAILER

16% to retailer allowed while fixing the ceiling prices of scheduled formulation and retail prices of new drug.

### PRICING OF SCHEDULED FORMULATION COVERED UNDER DPCO 1995

- Fixed and notified up to 31st May 2012 and shall remain effective 30th May 2013, can be revised by manufacturer as per annual wholesale price index.
- Fixed and notified after 31st May 2012 and shall remain effective for 1 year from the date of notification, can be revised by manufacturer as per annual wholesale price index.

Same criteria applicable to scheduled formulation which are in DPCO 1995 but not in first schedule of this order.

### PRICE OF FORMULATION LISTED IN NLEM

Manufacturer shall fix the price of formulation (branded or generic) equal or below to ceiling price.

### PRICE OF SCHEDULED FORMULATION FOR EXITING MANUFACTURER

- If selling on higher than ceiling than government reduce up to ceiling price.
- If formulation available in market before the publication of ceiling price manufacturer should revise within 45 days.

### REVISION OF CEILING PRICE OF SCHEDULED FORMULATION

- Government may revise on the basis of WPI before 1st April of every year and notify on 1st day of April every year.
- Manufacturer may increase the MRP on WPI basis once in every year. Inform the government. Within 15 days about it in Form 2.

## NONSCHEDULED FORMULATION

### Monitoring the Prices of Nonscheduled Formulations

No manufacturer increases the MRP of drug more than 10% of MRP during preceding 12 months and where the increase is beyond 10% of MRP it shall reduce the same to the level of 10% for next 12 months.

### Display of Price of Nonscheduled Formulation and Price List

- The MRP of the formulations must be printed with the words "maximum retail price" or "including of all taxes".
- Every manufactures must issue a price list/supplementary price list to the dealers, SDC and government indicating changes time to time.
- Every dealer/retailer must display the price list on a conspicuous part of premises.

## SCHEDULED AND NONSCHEDULED FORMULATION

### Sale Price of the Formulations

- No selling of formulation at price exceeding pricelist/MRP.
- No selling of loose quantity at price exceeding pro-rata price.

### Power of Entry, Search and Seizure

Any gazette offices of central/state government can enter and search, seize any drug along with container, package or covering and seize any documents.

### Power to Review

- Any person aggrieved by any notification may apply to government for review within 30 days of the publication/notification.
- No selling at price exceeding the ceiling/retail price till the decision.

### Exemptions

*The provisions of Act not applicable to*

New drug patented under IPA 1970, for a period of 5 years from its commercial production in the country.

### WITHOUT APPROVAL OF GOVERNMENT

- Manufacturer should not increase retail price of drug.
- Manufacturer should not marketed new formulation.
- No person shall sell imported scheduled formulation.

### FIXATION OF PRICE UNDER CERTAIN CIRCUMSTANCES

- If any manufacturer of bulk drug fails to submit the application for fixation or revision of price or fails to give information within specified time period.
- Then government fix price of the bulk drug.

### SCHEDULES RELATED WITH DPCO 1995

#### First Schedule

- Divided in 27 sections
- First schedule includes 74 bulk drugs.
- Penicillin, tetracycline, vitamins A, $B_1$, $B_2$, C and E, insulin, etc.

#### Second Schedule

**Different forms included:**

- *Form 1:* Application for price fixation/revision of a new drug formulation related to **NLEM.**
- *Form 2:* Proforma for submission of revised prices for scheduled formulations.
- *Form 3:* Proforma for quarterly return in respect of production/import and sale of NLEM drugs.
- *Form 4:* Proforma for the submission of the details in respect of discontinuation of the production and import of scheduled formulations.
- *Form 5:* Form of price list.

#### Types of Pharmaceutical Company

- **Category A:** Large-sized unit with turnover exceeding ₹ 6 crores per annum.
- **Category B:** Medium-sized unit turnover between ₹ 1 and 6 crore per annum.
- **Category C:** Other units with turnover of less than ₹ 1 crore per annum.

## SELF-ASSESSMENT EXERCISE

### MCQs

**1. The drug price control order (DPCO) is issued by the government under _____.**

a. Section 1 b. Section 2
c. Section 3 d. Section 4

**2. DPCO 1987 was replaced by:**

a. 1990 b. 1995
c. 1997 d. 2000

**3. Drug price control order was passed with the aim to:**

a. Achieve adequate production
b. Secure or regulate equitable distribution
c. Maintain and increase the supplies of bulk drugs and formulations
d. All of the above

**4. While fixing the price of bulk drugs government shall take into consideration post tax return of:**

a. 10% b. 12%
c. 14% d. 20%

**5. While fixing the price of bulk drugs government shall take into consideration return of _____ on capital employed.**

a. 12% b. 20%
c. 18% d. 22%

**6. _____ % margin to retailer allowed while fixing the ceiling prices of scheduled formulation and retail prices of new drug.**

a. 10 b. 12
c. 16 d. 15

**7. A manufacturer who starts production of scheduled bulk drug he has to furnish details to government within ____.**

a. 10 days b. 15 days
c. 30 days d. 60 days

**8. Formula for calculating retail price of formulation is:**

a. RP = (MC + CC + PM + PC) + (1 × MAPF/100) + ED
b. RP = (PM + PC + CC) + (1 × MAPF/100) + ED
c. RP = (MC + PC) + (1 × MAPF/100) + ED
d. RP = (CC + PM + PC) + (1 × MAPF/100) + ED

**9. If the other strength or dosage forms of the same schedule formulation are available in the list of schedule formulation then the average price to retailer shall be calculated as under:**

a. P(s) = Pm (1–(Pi + Pi2 +…)/N*100)
b. P(s) = Pm (1–(/N*100))
c. P(s) = (1–(Pi + Pi2+…)/N*100)
d. P(s) = Pm (1–(Pi + Pi2 +…)/N*)

**10. The latest drug price control order is:**

a. 2011 b. 1995
c. 2015 d. 2013

**11. What is full form of MAPM?**

a. Maximum allowable post manufacturing
b. Minimum allowable post manufacturing
c. Maximum allowable product manufacturing
d. None of the above

**12. How many sections are divided into schedule drugs?**

a. 20 b. 25
c. 27 d. 29

**13. First schedule includes _____ bulk drugs.**

a. 75 b. 74
c. 76 d. 77

**14. Schedule II consists how many forms?**

a. 5 b. 4
c. 3 d. 8

**15. Who has power to fix ceiling price of scheduled?**

a. State government b. State council
c. Central council d. Central government

**16. Which type of form involved in price list?**

a. Form 3 b. Form 4
c. Form 5 d. Form 6

**17. Which type of pharmaceutical company consists large-sized unit with turnover exceeding ₹ 6 crores per annum?**

a. Category A b. Category B
c. Category C d. Category D

**18. Which type of pharmaceutical company consists medium-sized unit turnover between ₹ 1 and 6 crore per annum?**

a. Category A b. Category B
c. Category C d. Category D

**19. Which type of form involved proforma for the submission of the details in respect of discontinuation of the production and import of scheduled formulations?**

a. Form 3 b. Form 4
c. Form 5 d. Form 6

**20. Any person aggrieved by any notification may apply to government for review within _____ of the publication/ notification.**

a. 15 days b. 30 days
c. 45 days d. 60 days

**21. If formulation available in market before the publication of ceiling price manufacturer should revise within _____.**

a. 15 days b. 30 days
c. 45 days d. 60 days

## ANSWERS

| | | |
|---|---|---|
| **1. c** | **2. b** | **3. d** |
| **4. c** | **5. d** | **6. c** |
| **7. b** | **8. a** | **9. a** |
| **10. d** | **11. a** | **12. c** |
| **13. b** | **14. a** | **15. d** |
| **16. c** | **17. a** | **18. b** |
| **19. b** | **20. b** | **21. c** |

## SHORT QUESTIONS

1. What is the objective of DPCO 1987?
2. Define the following terms under DPCO: API, new drug, formulation, scheduled formulation.
3. Give the formula which is used to calculate the retail price of formulation and the drugs (price control) order 1979.

## LONG QUESTIONS

1. Write about the pricing of drugs in bulk and revision of prices of drugs.
2. What do Schedule I, Schedule II, and Schedule III, to the drugs (price control) orders prescribe?
3. Write down power to fix the retail price of the scheduled formulation and the ceiling price of the scheduled formulation.
4. Define the following terms under DPCO: API, new drug, formulation, scheduled formulation, ceiling price, a national list of essential medicines, manufacturer, distributor, dealer, wholesaler, net worth, leader price, pharmacoeconomics.

Chapter

8

# Pharmaceutical Legislations

Pharmaceutical law is a hybrid piece of legislation that addresses both social and economic issues.

## PURPOSE OF PHARMACEUTICAL LEGISLATION

To ensure that the patients receive drugs of required quality, tested and evaluated for safety and efficacy for their intended result.

## INTRODUCTION

- At the end of the 19th century and early 20th century use of allopathy system increases.
- Drugs of natural origin: Veg, mineral oil and animals
- At that time, profit became main motive than service
- Overdose of quinine
- Using croton oil in eye instead of atropine solution
- In adequate dispensing and selling
- Excellent dumping of drugs
- Drugs are badly adultered
- Instead of quinine, chalk tablets are used
- Drugs like satonine were badly adultered
- Potent drugs like antimony, arsenic and digitalis marketed without any standards.
- Leading article published by Indian Medical Gazette (1927–1929).

*"India become a land of quacks, of quacks doctors, quack medicine mongers, quacks dentists, quacks of medicines, quacks of opticians, quack of faith healers". There was practically no legislation to control on drugs as well as on the pharmacy profession.*

## ORIGIN AND NATURE OF PHARMACEUTICAL LEGISLATION IN INDIA

- Earlier, the allopathic system of medicine was brought by Britisher's to our country and allopathic medicines were mainly imported.
- To have some control on the import, the British Rulers introduced:
  - The Indian Merchandise Marks Act, 1889.
  - The Sea Customs Act, 1898.
  - Indian Tariff Act, 1894.
  - The Opium Act, 1878.
  - Poison Act, 1919
- They were not comprehensive enough to control the chaotic and deplorable conditions in the drugs trade and industry.

## DRUGS ENQUIRY COMMITTEE

- On representation from the Indian people, the Viceroy appointed a committee on 11th August 1930, under the chairmanship of Col. RN Chopra.
- This committee also called its Viceroy Committee/RN Chopra Committee/Drug Enquiry Committee.
- The report was published in 1931.

### Aspects

1. To enquire into the extent to which drugs and chemicals of impure quality or defective strength, particularly those recognized by the British Pharmacopoeia are imported, in the public interest, of controlling such importation, manufacture and sale and to make recommendations.
2. Recommendations to overcome the above.
3. The enquire into the necessity of legislation to restrict the profession of pharmacy to duly qualified persons and to make recommendations.

## Recommendations

1. A central law to control drugs and pharmacy profession.
2. Setting up of test laboratories in all states to control the quality of production of drugs and pharmaceuticals and a control laboratory to control the quality of imported drugs and also to act as expert referee in case of disputed samples sent by local governments.
3. Appointment of an advisory board to advise the government in making rules to carry out the objects of the Act.
4. Setting up of courses for training in pharmacy minimum qualification for registration.
5. **Registration of every patent and proprietary** medicines of undisclosed formula manufactured in India or imported from outside the country.
6. The crude single drugs as well as compounded medicines used in **indigenous system of treatment** should be brought under control.
7. The **drugs industry in India should be developed**.
8. Gradual reduction of **manufacturing in medical**.
9. **Stores depot.**
10. **Compilation of an Indian Pharmacopoeia.**
11. The **Cinchona Department** should cultivate Cinchona.

## Scope and Objectives

- Drug Bill was introduced in 1940 in legislative assembly, and Drug Bill 1940 was passed, which came to force in 1947. Since then Drugs and Cosmetics Act was amended many times and at present it covers the provisions related to drugs, cosmetics, Ayurvedic, including Unani and Homeopathic medicines.
- The present Drugs and Cosmetics Act is an improved version of *the Drugs and Cosmetics Act, 1940.* The main objective of this Act was to regulate the import, manufacture, distribution and sale of drugs and cosmetics in India.
- The central government made several rules entitled the *Drugs and Cosmetics Rules, 1945.* These Act and Rules were amended from time to time.
- The Pharmacy Act, 1948 was passed with the main objective to regulate the profession of pharmacy in India.

- In 1954, the Drug and Magic Remedies Act was passed with the main aim to control certain types of advertisements related to drug and to prohibit certain types of advertisements related to magic remedies.
- Medicinal and Toilet Preparations (Excise Duty) Act, 1955 was passed providing for the levy and collection of duties of excise on medicinal and toilet preparations containing alcohol, opium Indian hemp or other narcotic drugs.
- Central government implemented Drug Price Control Order 1987.
- In 1985, the Narcotic Drugs and Psychotropic Substances Act, was passed. The main objective of this Act was to consolidate and amend the laws relating to Narcotic Drugs and Psychotropic Substances.

### MUDALIAR COMMITTEE

- In 1959, Healthy Survey and Planning Committee appointed Chairman—**Dr A Lakshmanswamy Mudaliar.**
- Recommended the inclusion of indigenous systems of medicine under the purview of the Drugs and Cosmetics Act.

### HATHI COMMITTEE

- Important milestone in pharmaceutical legislation history is Hathi Committee appointed Chairman—**Jaisukh Lal Hathi**.
- This committee covered all the aspects of licensing, price control, imports, role of foreign sector quality control.

### *Other Acts*

**These were included**

1. Prevention of food Adulteration Act, 1954 and Rules.
2. The Industries (Development and Regulations) Act, 1951.
3. The Industrial Employment (Standing Order) Act, 1946 and Rules.
4. Industrial Dispute Act, 1947.
5. Factory Act, 1948.
6. The Indian Patent and Design Act, 1970.
7. The Trade and Merchandise Mark Act, 1958.
8. The Epidemic Disease Act, 1897.
9. Shops and Establishment Act of respective states.

## SELF-ASSESSMENT EXERCISE

### MCQs

**1. Pharmaceutical legislation is:**

a. Social aspects of the society
b. Economic aspects of the society
c. Both a and b
d. None of these

**2. Drug Enquiry Committee was appointed on:**

a. 11th May 1930 b. 11th August 1930
c. 11th August 1945 d. 11th August 1945

**3. Drug Enquiry Committee under the chairmanship of:**

a. Col RN Chopra
b. Sir Joseph Bhore
c. Dr A Lakshmanswamy Mudaliar
d. Jaisukh Lal Hathi

**4. Drug Enquiry Committee also called as _____.**

a. Health Survey Committee
b. Viceroy Committee
c. Chopra Committee
d. Both b and c

**5. Which of the following is the name of advisory boards?**

a. Drugs Technical Advisory Board
b. Drugs Consultative Committee
c. Both a and b
d. Hathi Committee

**6. Mudaliar Committee was appointed in:**

a. June 1930 b. June 1943
c. June 1945 d. June 1959

**7. Mudaliar Committee was appointed under chairmanship of:**

a. Col. RN Chopra
b. Sir Joseph Bhore
c. Dr A Lakshmanswamy Mudaliar
d. Jaisukh Lal Hathi

**8. Mudaliar Committee also called as _____.**

a. Health Survey and Planning Committee
b. Viceroy Committee
c. Chopra Committee
d. None of these

**9. The Mudaliar Committee submitted its report of recommendations in:**

a. 1930 b. 1943
c. 1961 d. 1959

**10. Hathi Committee was set up under the chairmanship of:**

a. Col. RN Chopra
b. Sir Joseph Bhore
c. Dr A Lakshmanswamy Mudaliar
d. Jaisukh Lal Hathi

## ANSWERS

| | | |
|---|---|---|
| **1. c** | **2. b** | **3. a** |
| **4. d** | **5. c** | **6. d** |
| **7. c** | **8. a** | **9. c** |
| **10. d** | | |

## SHORT QUESTIONS

1. Write in brief about the scope and objectives of pharmaceutical legislation in India.
2. Enumerate the recommendations of the Drug Enquiry Committee.

## LONG QUESTIONS

1. Discuss in brief the development of pharmaceutical legislation in India.
2. Give the role of the pharmacist in the health care system in short.

Chapter

9

# Code of Pharmaceutical Ethics

## ETHICS

- Ethics may defined as **'the code of moral principles'** or as **'the science of the moral'**.
- With every profession is associated certain sets of moral principles may it be health-related profession or engineering. Ethics merely mean science of moral duties towards society.

## PHARMACEUTICAL ETHICS

The ethics in relation to pharmacy profession is called pharmaceutical ethics.

## MORALITY

Morality means good conduct or behaviour and consciousness.

## LAW

Law is defined as, the rules of human conduct binding to all persons in a state or nation.

## OBJECTIVE OF CODE OF PHARMACEUTICAL ETHICS

The code of pharmaceutical ethics is formulated by PCI for the guidance of Indian pharmacist. The code of pharmaceutical ethics helps to guide the pharmacist as to how he should conduct himself in relation to:

- His job his trade
- His profession (pharmacy) medical profession

**Table 9.1:** Difference between law and ethics

| *Law* | *Ethics* |
|---|---|
| Rules of human conduct binding all persons in a state or nation | Rules by which a profession regulates actions and sets standards for all its members |
| Law may prevent one from harming others, but it can not force someone to help the needy | Helping the needy is a value attributed by ethics |
| If law is broken the violator is subjected to legal prosecution which may include fine or imprisonment or both depending on the severity of crime committed | If ethics are breached the violator is subjected to loss of professional privilege, e.g. his license may be suspended, he may not be able to enjoy the honor of him being a professional |
| A law is something that you must obey | Ethics expects a sensible and responsible behavior towards society |
| Law prevents pharmacist from selling substandard drugs, but cannot prevent him from selling drugs at a lesser price than his fellow pharmacist | Selling drugs at reasonable rate and not getting into cut throat competition by selling drugs at cheaper rates is a part of ethics |
| Law deals with actions that are punishable | Ethics deals with right or wrong |

## PHARMACIST IN RELATION TO HIS JOB

### Scope of Pharmaceutical Services

- When premises are registered under statutory requirements and opened as a pharmacy, a reasonably comprehensive pharmaceutical service should be provided.
- This involves the supply of commonly required medicines of this nature without undue delay.
- It also involves willingness to furnish emergency supplies at all times.

### Conduct of Pharmacy

- The condition in a pharmacy should be such as to preclude avoidable risk or error or of accidental contamination in the preparation, dispensing and supply of medicines.

- The appearance of the premises should reflect the professional character of the pharmacy.
- It should be clear to the public that the practice of pharmacy is carried out in the establishment.
- Signs, notices, descriptions, wording on business, stationary and related indications, should be restrained in size, design and terms.

### Handling of Prescriptions

- When a prescription is presented for dispensing. It should be received by a pharmacist without any discussion or comment over it regarding the merits and demerits of its therapeutic efficiency.
- The pharmacist should not even show any expression on his face of alarm or astonishment upon the receipt of a prescription; as such things may cause anxiety in patients or their agents and may lose their faith on physician.
- Any question on a prescription should be answered with every caution and care; it should neither offend a patron nor should it disclose any information, which might have been intentionally, withheld from him.
- It is not within the privilege of a pharmacist to add, omit or substitute any ingredient or alter the composition of a prescription without the consent of the prescriber, unless the change is emergent or is demanded purely by the technique of the pharmaceutical art and does not cause any alteration in the therapeutic action of the recipe.
- In case of any obvious error in it due to any omission, incompatibility or over dosage, the prescription should be referred back to the prescriber for correction or approval of the change suggested.
- While such an act is imperative in the best interest of the patient, in no case should it be done in a manner, which may hamper the reputation of the prescriber concerned.
- In matter of refilling prescriptions a pharmacist should solely be guided by the instructions of the prescriber aid he should advise patients to use medicines or remedies strictly in accordance with the intention of the physician as noted on the prescription.

### Handling of Drugs

- All possible care should be taken to dispense a prescription correctly by weighing and measuring all ingredients in correct proportions by the help of scale and measures: Visual estimations must be avoided.
- Always use drugs and medicinal preparations of standard quality available. He should never fill his prescriptions with spurious, substandard and unethical preparations.
- A pharmacist should be very judicious in dealing with drugs and medicinal preparations used for addiction or any other abusive purposes.

### Apprentice Pharmacists

- While in-charge of a dispensary, drugstore or hospital pharmacy where apprentice pharmacists are admitted for practical training, a pharmacist should see that the trainees are given full facilities for their work so that on the completion of their training they have acquired sufficient technique and skill to make themselves dependable pharmacists.
- No certificate or credentials should be granted unless the above criterion is attained and the recipient has proved himself worthy of the same.

## PHARMACISTS IN RELATION TO HIS TRADE

### Price Structure

Prices charged from customers should be fair and in keeping with the quality and quantity of commodity supplied and the labor and skill required in making it ready for use, so as to ensure an adequate remuneration to the pharmacist taking into consideration his knowledge, skill, the time consumed and the great responsibility involved, but at the same time without unduly taxing the purchaser.

### Fair Trade Practices

- No attempt should be made to capture the business of a fellow pharmacist by cut-throat competition, that is, by offering any sort of prizes or gifts or by knowingly charging

lower prices for medical commodities than those charged by fellow pharmacist.

- In case any order or prescription genuinely intended to be served by some dispensary is brought by mistake to another, the latter should refuse to accept it and should direct the customer to the right place.
- Labels, trademarks and other signs and symbols of contemporaries should not be imitated or copied.

### Purchase of Drugs

Drugs should always be purchased from genuine and reputable sources and a pharmacist should always be on his guard not to aid or abet, directly or indirectly the manufacture, possession, distribution and sale of spurious or substandard drugs.

### Hawking of Drugs

- Hawking of drugs and medicinal should not be encouraged nor should any attempt be made to solicit orders for such substances from door to door.
- Self-service' method of operating pharmacies and drug-stores should not be used as this practice may lead to the distribution of therapeutic substances without an expert supervision and thus would encourage self-medication, which is highly undesirable.

### Advertising and Displays

- No display material either on the premises, in the press or elsewhere should be used by a pharmacist in connection with the sale to the public of medicines or medical appliances which is undignified in style or which contains:
- Any offer about refund of money.
- Misleading, or exaggerated statements or claims.
- The word "Cure" in reference to an ailment or symptoms of ill-health.
- A guarantee of therapeutic efficacy.
- An appeal to fear.

## PHARMACIST IN RELATION TO HIS PROFESSION

1. Extend help to fellow pharmacist in emergency need.
2. Should maintain standard of the profession.
3. Should try to weed out corruption in profession and society.
4. He should not be afraid of bringing or causing a miscreant to be brought to book, may be a member of his own profession.
5. Should have up to date knowledge of professional matters.
6. Should have fair knowledge of laws related to his profession.

## PHARMACIST IN RELATION TO MEDICAL PROFESSION

1. **Limitation of professional activities:** Pharmacist under no circumstances takes to medical practice, i.e. diagnosing drug and prescribing medicines. In emergency he can give first aid to the person. Should not recommend a medical practitioner.
2. **Clandestine arrangement:** No pharmacist should enter into the secret arrangement and contract with the physician to offer him any commission or any other advantage.
3. **Liaison with public:** Being a liaison between medical profession and people, a pharmacist will always keep himself updated with the modern development of pharmacy by regular reading of books, magazines, etc.

## PHARMACIST'S OATH

- *At this time, I vow to devote my professional life to the service of all humankind through the profession of pharmacy.*
- *I will consider the welfare of humanity and relief of human suffering my primary concerns.*
- *I will apply my knowledge, experience, and skills to the best of my ability to assure optimal drug therapy outcomes for the patients I serve.*
- *I will keep abreast of developments and maintain professional competency in my profession of pharmacy.*
- *I will maintain the highest principles of moral, ethical, and legal conduct.*

- *I will embrace and advocate change in the profession of pharmacy that improves patient care.*
- *I take these vows voluntarily with the full realization of the responsibility with which I am entrusted by the public.*

## SELF-ASSESSMENT EXERCISE

### MCQs

**1. Ethics is:**

a. Social aspects of the society
b. Science of moral duty
c. Moral principles
d. Both b and c

**2. 'Rules of human conduct binding on all persons in a state or nation' is called as _____.**

a. Ethics
b. Law
c. Codes
d. None of these

**3. Rules by which a profession regulates actions and sets standards for all its members is known as _____.**

a. Ethics
b. Law
c. Codes
d. None of these

**4. The ethics in relation to pharmacy profession is called as _____.**

a. Pharmaceutical ethics
b. Biological ethics
c. Sociological ethics
d. None of these

**5. The code of ethics is prepared by a:**

a. Pharmacist
b. Legislator
c. Court
d. Both a and b

**6. What is the role of pharmacists in relation to his trade?**

a. Price structure
b. Fair trade practices
c. Purchase of drugs
d. All of the above

**7. What is the relation of pharmacist to his profession?**

a. Maintain standard of the profession
b. Extend help to fellow pharmacist in emergency need
c. Try to weed out corruption in profession and society
d. All of the above

**8. What is the relation of pharmacist to medical profession?**

a. Limitation of professional activities
b. Clandestine arrangement
c. Liaison with public
d. All of the above

**9. Which of the following oaths are involved in pharmacy profession?**

a. I will consider the welfare of humanity and relief of human suffering my primary concerns
b. I will maintain the highest principles of moral, ethical, and legal conduct
c. I will embrace and advocate change in the profession of pharmacy that improves patient care
d. All of the above

**10. What is the relation of pharmacist to his job?**

a. Scope of pharmaceutical services.
b. Conduct of pharmacy
c. Handling of prescriptions
d. All of the above

**ANSWERS**

| | | |
|---|---|---|
| **1. d** | **2. b** | **3. a** |
| **4. a** | **5. a** | **6. d** |
| **7. d** | **8. d** | **9. d** |
| **10. d** | | |

## SHORT QUESTIONS

1. Define law and ethics.
2. What is ethics? What is the code of pharmaceutical ethics?
3. Give the difference between law and ethics.
4. What are the ethics of pharmacists in their profession?
5. As per the code of ethics, how should the relationship between pharmacists with physicians be?
6. How a pharmacist should handle the prescription as per pharmaceutical ethics?
7. Explain the role of the pharmacist in the medical profession.

## LONG QUESTIONS

1. Discuss the professional conduct of the pharmacist during his service.
2. Describe the ethics of pharmacists regarding their trade.

Chapter

10

# Medical Termination of Pregnancy Act

## HIGHLIGHTS

The Medical Termination of Pregnancy (MTP) Act in India came into existence in 1971. It was amended in 2003 to facilitate better implementation and increase access for women especially in the private health sector.

The MTP Act overrides the IPC by allowing a woman to get an abortion within the first 12 weeks of pregnancy, provided a registered medical practitioner diagnoses grave danger to the pregnant woman's physical and mental health.

If the foetus is between 12 and 20 weeks old, then the procedure requires permission from two medical practitioners.

The Act also allows abortion if the foetus (developing infant) will be born with severe abnormalities.

## OBJECTIVES

- To improve the maternal health scenario by preventing large number of unsafe abortions.
- Legalizes abortion services.
- Promote access to safe abortion services to women.
- Offers protection to medical practitioners who otherwise would be penalized under the Indian Penal Code (Section 315–316).

## DEFINITIONS UNDER THE ACT

**Guardian:** A person taking care of a minor or mentally ill person.

**Lunatic:** A person who is mentally ill.

**Minor:** A person who under the Provision of the Indian Majority Act, 1875 is to be deemed not to have attained his majority.

**Registered Medical Practitioner (RMP):** A person with recognized medical qualification as under Section 2 of the Indian Medical Council Act, 1956 whose name is entered in State Medical Register and who possesses such experience or training in obstetrics and gynecology as prescribed under Rules to the Act.

### EXPERIENCE OF RMP

- For the RMP registered before the commencement of the Act, a minimum of 3 years professional experience in obstetrics and gynecology is compulsory.
- The RMP has completed six months of house surgency in gynecology and obstetrics.
- If he has experience at any hospital for a period of not less than one year in the practice of obstetrics and gynecology.
- If he has assisted a register medical practitioner in the performance of pregnancy in a hospital established approved hospital.
- He/she permitted to conduct termination of pregnancy only up to 12 weeks of gestation.

### WHEN PREGNANCIES CAN BE TERMINATED BY RMP?

- Act, 1971—the Act provides that pregnancies may be terminated by Registered Medical Practitioner (RMP) possessing experience or training in the gynecology and obstetrics.
- It extends to whole India except Jammu and Kashmir.
- The RMP may terminate a pregnancy when it is not more than 12 weeks old.
- The Registered Medical Practitioner may terminate a pregnancy of in-between 12 to 20 weeks with the opinion of another Registered Medical Practitioner in good faith.

### Conditions

- Continuation of pregnancy is a risk of life for pregnant woman or it can cause grave injury to her physical and mental health.
- Substantial risk that the child, if born, would be seriously handicapped due to physical or mental abnormalities.
- The Registered Medical Practitioner may terminate a pregnancy of a woman who is less than 18 years of age or lunatic, with written consent of her guardian The Registered Medical Practitioner may terminate a pregnancy of a woman who is less than 18 years of age or lunatic, with written consent of her guardian.
- The RMP may terminate pregnancy after judgment of court.

### WHO CAN TERMINATE PREGNANCIES?

- A Medical Termination of Pregnancy Rules, 1975 prescribe the experience or training in gynecology and obstetrics that a Registered Medical Practitioner should have to terminate any pregnancy.
- A Medical Practitioner registered in a state medical register immediately before the commencement of the Act should have not less than 3 years' experience in the practice of gynecology and obstetrics.
- A Medical Practitioner registered in state medical register on after the date of the commencement can terminate the pregnancy.
- In case of Registered Medical Practitioner who holds a post-graduate degree or diploma in gynecology and obstetrics, the experience or training joined during the course of such degree or diploma is considered.

### WHERE CAN TERMINATE PREGNANCIES?

1. A hospital established or maintained by government.
2. A place for the time being approved for the purpose of this Act by government.

### APPROVAL OF PLACES FOR TERMINATION OF PREGNANCIES

The place for termination of pregnancies may be approved only if:

- The government is satisfied that the termination of pregnancies may be done therein under safe and hygienic conditions.

*The following facilities are provided*

- An operation table and instruments for performing abdominal or gynecological surgery.
- Anesthetic equipment, resuscitation equipment and sterilization equipment.
- Drugs and parenteral fluids for emergency use.
- The certificate of approval issue by the committee shall be displaced at the place to be easily visible to person visiting the place.

### OFFENCES AND PENALTIES

- The termination of pregnancy by a person who is not Registered Medical Practitioner shall be deemed to be a punishable offence under **Indian Penal Code.**
- An unauthorized person involved in termination of pregnancy is punishable with **2–7 years imprisonment**.
- Any fine who fails to comply with Rules under the Act or contravenes them may be fined up to ₹ **1000.**

## SELF-ASSESSMENT EXERCISE

### MCQs

**1. The Medical Termination of Pregnancy Act was passed by the parliament in:**

a. 1971
b. 1957
c. 1960
d. 1975

**2. A person having the care of the person of a minor or a lunatic is called as _____.**

a. Guardian
b. Registered Medical Practitioner
c. Lunacy
d. None of these

**3. Section 3 of the Indian Lunacy Act, 1912 assigned for:**

a. Guardian
b. Registered Medical Practitioner
c. Lunacy
d. None of these

**4. What is the full form of RMP?**

a. Registered medical pharmacist
b. Registered Medical Practitioner
c. Regulation medical practitioner
d. None of these

**5. Which of the following circumstances are involved in pregnancies of women may be terminated by Registered Medical Practitioner?**

a. In case of women who are less than 18 years of age
b. Pregnancy which is not more than 12 weeks old
c. Both a and b
d. None of these

**6. What is the experience or training for an RMP to terminate pregnancy?**

a. Experience in the practice of gynecology and obstetrics for not less than three years
b. Six months of house surgery in gynecology and obstetrics
c. Obstetrics in any hospital for not less than one year
d. All of the above

**7. Which offences and penalties are involved in Medical Termination of Pregnancy Act?**

a. Anyone who fails with Rules made under the Act or contravenes them may be fined up to ₹ 1,000
b. Termination of a pregnancy by a person who is not a Registered Medical Practitioner is a punishable offence under the Indian Penal Code
c. Both a and b
d. None of these

## ANSWERS

| | | |
|---|---|---|
| **1. a** | **2. a** | **3. c** |
| **4. b** | **5. c** | **6. d** |
| **7. c** | | |

## SHORT QUESTIONS

1. Write a short note on termination of pregnancy as per MTP Act.
2. Describe the places where pregnancy may be terminated as per MTP Act.
3. Write a short note on role of Chief Medical officer (CMO).
4. Write in short note about offences and penalties.
5. Give the objectives of MTP Act, 1971 and its Rules, 1975.
6. Write in short note about experiences of Registered Medical Practitioner (RMP).
7. When pregnancies can be terminated by Registered Medical Practitioner (RMP)?

## LONG QUESTIONS

1. Write in detail about Medical Termination of Pregnancy Act, 1971 and its Rules, 1975.
2. Explain in detail about rules, regulations, instructions, manuals and records for discharging functions about Medical Termination of Pregnancy Act, 1971 and its Rules, 1975.
3. Give detail on statement of the boards, councils, committees and other bodies.
4. Explain in brief about MTP Act.
5. Mention the circumstances under which pregnancy can be terminated.

Chapter

11

# Right to Information (RTI) Act

## HIGHLIGHTS

The Right to Information Act, 2005 which came fully into effect on 12th October 2005 is one of the most significant legislation enacted by the Parliament in India.

It is a major step towards more accountable and transparent government.

RTI has been approved to provide for setting out the practical authority of right to information for citizens to secure access to information under the control of public authorities in order to promote transparency and accountability.

The Act will certainly lead to end the culture of governmental secrecy and fulfill its potential as a truly great democracy.

## DEFINITIONS UNDER THE ACT

**"Appropriate government"** means in relation to a public authority which is established, constituted, owned, controlled or substantially financed by funds provided directly or indirectly:

i. By the central government or the Union Territories administration.

ii. By the state government.

## WHAT IS INFORMATION?

Information means any material in any form including records, documents, memos, e-mails, opinions, advices, press

releases, circulars, orders, logbooks, contracts, reports, papers, samples, models, data material held in any electronic form and information relating to any private body which can be accessed by a public authority under any other law for the time being in force—**Section 2 *(f)*.**

### WHAT IS A PUBLIC AUTHORITY?

"Public authority" means any authority or body or institution of self-government established or constituted:

a. By or under the Constitution;
b. By any other law made by Parliament;
c. By any other law made by State Legislature;
d. By notification issued or order made by the appropriate government, and includes any:
   i. Body owned, controlled or substantially financed;
   ii. Non-government organization substantially financed, directly or indirectly by funds provided by the appropriate government.

### WHAT DOES RIGHT TO INFORMATION MEAN?

*It includes the right to*

i. Inspect works, documents, records.
ii. Take notes, extracts or certified copies of documents or records.
iii. Take certified samples of material.
iv. Obtain information in form of printouts, diskettes, floppies, tapes, video cassettes or in any other electronic mode or through printouts **[Section 2 *(j)*].**

### THE RTI ACT, 2005—PROCESSES

- Application to be submitted in writing or electronically, with prescribed fee, to Public Information Officer (PIO).
- Envisages PIO in each department/agency to receive requests and provide information. Assistant PIO at sub-district levels to receive applications/appeals/complaints. Forward to appropriate PIO. These will be existing officers.
- Information to be provided within 30 days, 48 hours where life or liberty is involved, 35 days where request is given to

Assistant PIO, 40 days where third party is involved and 45 days for human rights violation information from listed security/intelligence agencies.

- Time taken for calculation and intimation of fees excluded from the time frame.
- No action on application for 30 days is a deemed refusal.
- No fee for delayed response.

## RESPONSIBILITIES OF PUBLIC AUTHORITIES

- Appointing PIOs/Assistant PIOs within 100 days of enactment (5(1)).
- Maintaining, cataloguing, indexing, computerising and networking records (4(1)(a)).
- Publishing within 120 days of enactment a whole set of information and updating it every year (4(1)(b)).
- Publishing all relevant facts while formulating important policies or announcing the decisions which affect public (4(1)(c)).
- Providing reasons for its administrative or quasi-judicial decisions to affected persons (4(1)(d)). Providing information suo moto (4(2)).
- Providing information to Information Commission (25(2)).
- Raising awareness, educating and training (26(1)).
- Compiling in 18 months and updating regularly local language guide to information (26(2)(3)).

## PUBLIC AWARENESS AND EDUCATIONAL PROGRAM

- Develop and organize educational programmes to advance the understanding of the public, particularly the disadvantaged, to exercise right to information.
- Government to:
  - Encourage public authorities to participate in programmes; promote timely/effective dissemination of accurate info on activities.
  - Train CPIOs and produce relevant training materials—user guide and related matter.

**PENALTIES**

- Penalties imposable by Information Commission on PIO or officer asked to Assistant PIO.
- For unreasonable delay—₹ 250 per day up to ₹ 25,000.
- For illegitimate refusal to accept application, malafide denial, knowingly providing false information, destruction of information, etc.—fine up to ₹ 25,000.
- Recommendation for departmental action for persistent or serious violations, however, no criminal liability.

## SELF-ASSESSMENT EXERCISE

### MCQs

**1. Right to Information Act comes under _____.**

a. Section 2 b. Section 3
c. Section 4 d. Section 5

**2. Right to Information Act comes in:**

a. 12th October 2005 b. 12th October 2004
c. 12th October 2003 d. 12th October 2006

**3. What is the role of Right to Information Act?**

a. To provide for setting out the practical regime
b. Citizens to secure access to information
c. To promote transparency and accountability
d. All of the above

**4. _____ means in relation to a public authority which is established, constituted, owned, controlled or substantially financed by funds provided directly or indirectly.**

a. State government
b. Appropriate government
c. Central government
d. None of these

**5. What is mean by information?**

a. Any material in any form including records, memos
b. Any material in any form including documents, e-mails
c. Any material in any form including papers, samples
d. All of the above

**6. Any authority or body or institution of self-government established or constituted _____.**

a. Public authority
b. Psychological authority
c. Both a and b
d. None of these

**7. What is meant by Right to Information?**

a. Inspect works, documents, records.
b. Take notes, extracts or certified copies of documents or records
c. Take certified samples of material
d. All of the above

**8. RTI Act, 2005 application to be submitted in writing or electronically with prescribed fee, to _____.**

a. State government
b. Public Information Officer
c. Central government
d. None these

**9. What are responsibilities of public authorities?**

a. Appointing PIOs/Assistant PIOs within 100 days of enactment
b. Maintaining, cataloguing, indexing, computerising and networking records
c. Providing information to Information Commission
d. All of the above

**10. What penalties are taken for unreasonable delay in RTI Act?**

a. Fine up to ₹ 25,000
b. ₹ 250 per day up to ₹ 25,000
c. Up to ₹ 35,000
d. Up to ₹ 45,000

**11. Central Information Commission constituted under _____.**

a. Sub-section (1) of Section 12
b. Sub-section (3) of Section 12
c. Sub-section (2) of Section 5
d. Sub-section (2) of Section 4

**12. "Central Public Information Officer" means the Central Public Information Officer designated under sub-section (1) and includes a Central Assistant Public Information Officer designated as such under _____.**

a. Sub-section (1) of Section 12
b. Sub-section (3) of Section 12
c. Sub-section (2) of Section 5
d. Sub-section (2) of Section 4

## ANSWERS

| | | |
|---|---|---|
| **1. b** | **2. a** | **3. d** |
| **4. b** | **5. d** | **6. a** |
| **7. d** | **8. b** | **9. d** |
| **10. b** | **11. a** | **12. c** |

## SHORT QUESTIONS

1. What is information and objectives of Right to Information Act?
2. What is an Assistant Public Information Officer?
3. Is there any provision for exemption from Disclosure of Information?
4. Whether complaints can be made under this Act? If yes, under what conditions?
5. What is the method of Seeking Information?
6. Is there any organization(s) exempt from providing information under RTI Act?
7. What is the fee for Seeking Information from central government public authorities?

## LONG QUESTIONS

1. Write in detail about Right to Information Act.
2. Explain in detail about rules, regulations, instructions, manuals and records for discharging functions about RTI.
3. Give detail on statement of the boards, councils, committees and other bodies.
4. Explain in brief about public authority.
5. Elaborate in detail about process of RTI Act, 2005.

Chapter

12

# Introduction to Intellectual Property Rights (IPR)

## INTELLECTUAL PROPERTY

It is the term reserved for types of property that result from creations of human mind, the intellect. In short, it is the expression of idea.

## INTELLECTUAL PROPERTY RIGHTS (IPR)

These are legal rights, which result from intellectual activity in industrial, scientific, literary and artistic fields.

## TYPES OF IPR

### Patent

The set of exclusive rights given to an inventor or assignee for limited period of time and in exchange for detailed public disclosure of an invention is called patent.

It is written documents, which is a protection given by government to a inventor for his/her invention, provided the invention satisfies certain condition stipulated in law (Table 12.1).

#### *Why Patent is Necessary?*

- To encourage Research and Development.
- Induces an inventor to disclose his invention.
- Stimulate capital investment—affects economy.
- Encourages technology development.
- Encourages establishment of new industries.

**Table 12.1:** Journey of Indian Patent System

| | |
|---|---|
| 1856 | Protection of Inventions |
| 1859 | Patent monopolies |
| 1872 | Patterns and Design Pollution Act |
| 1888 | The Protection of Inventions Act |
| 1888 | The Inventions and Designs Act |
| 1911 | The Indian Patents and Designs Act |
| 1975 | India joins WIPO (World Intellectual Property Organization) |
| 1999 | India signs TRIPS—Trade-related Aspects of Intellectual Property Rights (after joining WTO—World Trade Organization) |
| 1999, 2002 2004, 2005 | Amendments |

### *How is a Patent Granted?*

The first step in securing a patent is to file a patent application. The application generally contains the title of the invention, as well as an indication of its technical field. It must include the background and a description of the invention, in clear language and enough detail that an individual with an average understanding of the field could use or reproduce the invention. Such descriptions are usually accompanied by visual materials—drawings, plans or diagrams—that describe the invention in greater detail. The application also contains various "claims", that is, information to help determine the extent of protection to be granted by the patent.

### *Who Grants Patents?*

Patents are granted by national patent offices or by regional offices that carry out examination work for a group of countries—for example, the European Patent Office (EPO) and the African Intellectual Property Organization (OAPI). Under such regional systems, an applicant requests protection for an invention in one or more countries, and each country decides whether to offer patent protection within its borders. The WIPO-administered Patent Cooperation Treaty (PCT) provides for the filing of a single international patent application that has the same effect as national applications filed in the

designated countries. An applicant seeking protection may file one application and request protection in as many signatory states as needed.

### *Need of Patent*

- To protect the creativity of the individual
- To protect their invention from being copied
- To reward the inventor.

### *Types of Patent*

1. Independent patent
2. Patent of an addition.

### Trademark

- It is a distinctive sign that identifies certain goods or services as those produced or provided by a specific person or enterprise.
- It may be one or combination of words, letters or numerals.
- It is a proof of ownership and hence provides rights to the proprietor.
- May consist of drawings, symbols, three dimensional signs such as:
  - Shape and packaging of goods
  - Audible signs of music or vocal sounds
  - Fragrances or colors used as distinguishing features
- Provides protection to the owner of the mark by ensuring the exclusive rights to identify.
- Goods or services or authorize someone to use it in return of payment.
- It also helps consumers to identify goods.
- The term of registration is for a term of 10 years.

### Copyright

- Copyright means the legal term describing rights given to creators for their literary and artistic works.
- These works include:
  - Literary works such as novels, poems, plays, reference works, newspapers and computer programs databases.
  - Films, musical competitions and choreography.

  - Artistic works such as drawings, paintings, photographs, sculpture and architecture.
  - Advertisements.
  - Maps and technical drawings.
- Copyright resides in creation hence it is not compulsory to register.
- But, on registration copyright subsists in the work and then creator is the owner of the work.
- The creator may sell the rights for which they receive royalties.
- Except photographs the economic rights have a time limit up to the life of author and 60 years after creator's death.

### Geographical Indication

- Governed by Geographical Indications of Goods Act.
- These are signs used on goods that have a specific geographical origin and possess
- Reputation or quantities due to it.
- The place or origin may be a village or town, a region or a country.
- Agricultural products are its main concern as they typically have qualities which are derived from their place of production and are influenced by local factors such as climate and soil.
- Also, it is an exclusive right to a particular community hence the benefits of its registration are shared by all members of the community.
- Geographical indication is very important for future growth of the tribes or communities or skilled artists associated in developing such products.
- Darjeeling tea is the 1st geographical indication tagged product in India.
- By November, 2015 around 236 products are added to it.

#### *What is WIPO's Role in the Protection of Geographical Indications?*

WIPO administers a number of international agreements that deal partly or entirely with the protection of geographical indications (in particular, the Paris convention and the Lisbon

agreement). WIPO meetings offer Member States and other interested parties the opportunity to explore new ways of enhancing the international protection of geographical indications.

### *What is a "Generic" Geographical Indication?*

If the name of a place is used to designate a particular type of product, rather than to indicate its place of origin, the term no longer functions as a geographical indication. For example, "**Dijon mustard**" a kind of mustard that originated many years ago in the French town of Dijon, has, over time, come to denote mustard of that kind made in many places. Hence, "**Dijon mustard**" is now a generic indication and refers to a type of product, rather than a place.

## INDUSTRIAL DESIGN

- Industrial design refers to creative activity.
- It results in ornamental or formal appearance of a product.
- Design rights refers to novel or optimal design that is accorded to the proprietor of a validly registered design.
- Under TRIPS (Trade Related Aspects of Intellectual Property Rights) minimum standards for protecting industrial designs are given.
- Besides, the purpose of Design Law is to promote and protect the design element of industrial production and also to promote innovative activity in the field of industries.

## ACTS GOVERNING THE VARIOUS IP RIGHTS

1. The Patent Act, 1970.
2. Trade and Merchandise Act, 1958.
3. The Copyright Act, 1957.
4. Geographical Indication of Goods Act, 1999.
5. The Industrial Design Act, 2000.
6. Semiconductor Integral Circuits Layout Design Act, 2000.
7. Biological Diversity Act, 2002.

## SELF-ASSESSMENT EXERCISE

### MCQs

**1. What is the full form of IPR?**

a. Introduction property rights
b. Intellectual property rights
c. International property rights
d. Introduction pharmacy rights

**2. Which of the following is not a type of IPR?**

a. Patent, geographical indication
b. Trademark, industrial design
c. Copyright, trade secret
d. All of the above

**3. The set of exclusive rights given to an inventor or assignee for limited period of time and in exchange for detailed public disclosure of an invention is called _____.**

a. Patent
b. Trademark
c. Copyright
d. Trade secret

**4. The Patent Act in India was implemented in:**

a. 1956
b. 1980
c. 1970
d. 1989

**5. Indian Patent Act was amended in:**

a. March 1999
b. June 1999
c. July 2000
d. August 2006

**6. It is a distinctive sign that identifies certain goods or services as those produced or provided by a specific person or enterprise is called as _____.**

a. Patent
b. Trademark
c. Copyright
d. Trade secret

**7. Trademark should be:**

a. It may be one or combination of words, letters or numerals
b. It is a proof of ownership and hence provides rights to the proprietor
c. It also helps consumers to identify goods
d. All of the above

**8. How many years trademark term of registration is?**

a. 6 years b. 7 years
c. 10 years d. 11 years

**9. The legal term describing rights given to creators for their literary and artistic works is known as _____.**

a. Patent b. Trademark
c. Copyright d. Trade secret

**10. In copyright work includes:**

a. Films, musical competitions and choreography
b. Literary works such as novels, poems, plays, reference works
c. Both a and b
d. None of these

**11. What is the full form of TRIPS?**

a. Trade-related Action of Intellectual Property Rights
b. Trade-related Aspects of Intellectual Property Rights
c. Trade-related Aspects of Introduction Property Rights
d. Trade-related Aspects of Intellectual Position Rights

**12. Copyright Acts come in:**

a. 1958 b. 1957
c. 1959 d. 1955

**13. Which of the following Act come in 1999?**

a. The Patent Act, 1970
b. Trade and Merchandise Act, 1958
c. The Copyright Act, 1957
d. Geographical Indication of Goods Act, 1999

**14. Which of the following Act come in 2000?**

a. Geographical Indication of Goods Act
b. The Industrial Design Act
c. Semiconductor Integral Circuits Layout Design Act
d. Both b and c

**15. Industrial design refers to:**

a. To proprietor of a validly registered design
b. To promote innovative activity in the field of industries
c. Both a and b
d. None of these

## ANSWERS

| | | |
|---|---|---|
| **1. b** | **2. d** | **3. a** |
| **4. c** | **5. a** | **6. b** |
| **7. d** | **8. c** | **9. c** |
| **10. c** | **11. b** | **12. b** |
| **13. d** | **14. d** | **15. c** |

## SHORT QUESTIONS

1. Write a note on different IPR approaches.
2. Enlist types of IPR.
3. Define patent. Enlist need of patent.
4. Write a note on a journey of the Indian Patent System.

## LONG QUESTION

1. Explain the following terms: Trademark, copyright, geographical indications, industrial design.

Chapter

13

# Case Study

## CASE I

**Act:** Narcotic Drugs and Psychotropic Substances

**Case:** Madras High Court (Case no. 446 of 2010 and MP no. 1 of 2011)

**Case title:** Alprazolam worth about ₹ 50,00,000 without any valid permit or license from the government.

**Description:** The case of the prosecution, the appellant was found in possession of the offending drugs, viz. Alprazolam, worth about ₹ 50,00,000 without any valid permit or license from the government.

The appellant stands convicted for the offence under Section 8 (c) r/w. 21 (c) of NDPS Act and sentenced to suffer 10 years rigorous imprisonment and to pay a fine of ₹ 1,00,000, and in default, to undergo 2 years rigorous imprisonment by the learned Special Judge (EC Act Cases), Salem, in his judgement dated on 18.1.2006 and made in CC no. 181 of 2005. Challenging the order of conviction and sentence, the appellant has preferred this Criminal Appeal.

Pending disposal of the appeal, he has filed a petition under Section 389 (1) of Criminal Procedure Code to suspend the sentence imposed on him.

When this petition came up for hearing, Mr TK Sampath, the learned counsel for the appellant has submitted that in so far as the appeal in Crl. A. no. 446 of 2010 is concerned, there is nothing to argue the facts at length, but he is going to confine

his argument only on quantum of sentence. He has also made an endorsement on the reverse of the memorandum of appeal. The learned Additional Public Prosecutor has also conceded to argue the appeal only on quantum of sentence and therefore, with the mutual consent of both the learned counsels, viz. Mr TK Sampath and the Learned Additional Public Prosecutor, the appeal itself is taken up for disposal.

The case of the prosecution, in short is that on 9.3.2005 at about 10.00 am, near second platform of Pallapatti new bus stand, the appellant was found in possession of the offending drugs, viz. Alprazolam, worth about ₹ 50,00,000 without any valid permit or license from the government. Hence, the appellant was charge sheeted by the police under Section 8 (*c*) r/w. Section 22 (*c*) of Narcotic Drugs and Psychotropic Substances Act, 1985.

The prosecution in order to substantiate its case has totally examined 4 witnesses and during the course of their examination Exs. P1 to P12 were marked. Apart from this, the material objects ranging from M. Os. 1, to 5 were also marked. On evaluating the evidences both oral and documentary, the learned Special Judge has found that the appellant guilty convicted and sentenced as aforesaid.

**Result: In the result, the Criminal Appeal is partly allowed. The finding, conviction and sentence recorded by the trial court are modified as detailed below:** The appellant is found guilty under Section 8 (*c*) r/w.21 (*b*) of NDPS Act instead of 8 (*c*) r/w. Section 21 (*c*), convicted thereunder and sentenced to suffer 6 years and 5 months and to pay a fine of ₹ 25,000 and in default to suffer for a further period of one month.

## CASE II

**Case:** Delhi District Court (SC no. : 23/2009 FIR no. : 70/2009)

**Case title:** The appellant was found in possession of 25.1 kilograms Ganja in contravention to the provision of NDPS Act

**Date of filing of Charge Sheet:** 23.04.2009

**Date of taking up matter for the first time:** 16.01.2010

**Date of conclusion of arguments:** 14.05.2011

**Date of judgment:** 21.05.2011

**Description:** Respondent cope with trial for obligating the crime punishable under Section 20 of the Narcotic Drugs and Psychotropic Substances Act, 1985 on the claims that on 24.02.2009 at about 2.45 pm at Platform no. 14, Nizamuddin side, New Delhi Railway Station, he was found in possession of 25.1 kilograms Ganja in contravention to the provision of NDPS Act.

On 24.02.2009 at about 02.45 pm ASI Ashok Kumar, Ct. Vineet Kumar and Ct. Ved Prakash were present at Platform no. 14, Nizamuddin side while patrolling when they saw accused sitting on a bench with a black colour bag and a blue colour trolly bag. Accused could not explain satisfactorily his presence at the spot and thus two bags in his possession were checked and they were found containing Ganja.

Samples were drawn from the Ganja recovered from the two bags. They were sealed and formally seized. FIR was registered on the basis of their prepared by ASI Ashok Kumar. Sealed pulandas of the case property along with the accompanying documents were handed over to Inspector Anil Jaitely, SHO PS New Delhi Railway Station at the police station. After registration of the FIR, investigation was assigned to SI Jagmal Singh, who reached at the spot and completed the proceedings including formal arrest of the accused. Sample pulandas were sent to FSL during investigation and after completion of investigation charge sheet was filed against the accused. Prosecution has examined 9 witnesses.

**Result:** As per the FSL Result Ex. PX-1 and Ex. PX-2, contents of sample pulandas marked S-1 and S-2 were confirmed to be Dried Indian Hemp, i.e. Ganja (Cannabis), which falls under Section 2(iii)(*b*) of NDPS Act. In view of the above observations, discussions and findings, I hold that prosecution has proved beyond all reasonable doubt that accused was in possession of 25.1 kilograms of Ganja, which falls in the commercial quantity as per Entry no. 55 of the Table notified in the NDPS Act vide SO no. 1055(E) on dated 19.10.2001. Accused Suresh Kumar Singh is held guilty and convicted for committing the offence punishable under Section 20 (*b*) (C) of the NDPS Act. Announced in the open Court (Santosh Snehi Mann) of 21st May, 2011 Special Judge, NDPS (Central), Tis Hazari Courts, Delhi.

## CASE III

**Case:** Delhi District Court (CS (OS) 12/2006)

**Case title:** FDA requests removal of all ranitidine products (Zantac) from the market.

**Description:** The US Food and Drug Administration today announced it is requesting manufacturers withdraw all prescription and over-the-counter (OTC) ranitidine drugs from the market immediately. This is the latest step in an ongoing investigation of a contaminant known as N-nitrosodimethylamine (NDMA) in ranitidine medications (commonly known by the brand name Zantac). The agency has determined that the impurity in some ranitidine products increases over time and when stored at higher than room temperatures and may result in consumer exposure to unacceptable levels of this impurity. As a result of this immediate market withdrawal request, ranitidine products will not be available for new or existing prescriptions or OTC use in the US.

"The FDA is committed to ensuring that the medicines Americans take are safe and effective. We make every effort to investigate potential health risks and provide our recommendations to the public based on the best available science. We did not observe unacceptable levels of NDMA in many of the samples that we tested. However, since we do not know how or for how long the product might have been stored, we decided that it should not be available to consumers and patients unless its quality can be assured," said Janet Woodcock, MD, director of the FDA's Centre for Drug Evaluation and Research. "The FDA will continue our efforts to ensure impurities in other drugs do not exceed acceptable limits so that patients can continue taking medicines without concern."

NDMA is a probable human carcinogen (a substance that could cause cancer). In the summer of 2019, the FDA became aware of independent laboratory testing that found NDMA in ranitidine. Low levels of NDMA are commonly ingested in the diet, for example, NDMA is present in foods and in water. These low levels would not be expected to lead to an increase

in the risk of cancer. However, sustained higher levels of exposure may increase the risk of cancer in humans. The FDA conducted thorough laboratory tests and found NDMA in ranitidine at low levels. At the time, the agency did not have enough scientific evidence to recommend whether individuals should continue or stop taking ranitidine medicines, and continued its investigation and warned the public in September 2019 of the potential risks and to consider alternative OTC and prescription treatments.

New FDA analysis and estimation impelled by material from third-party laboratories established that NDMA levels growth in ranitidine even under normal storage conditions, and NDMA has been found to increase expressively in samples stored at greater temperatures, including temperatures the product may be showing to during spreading and handling by consumers. The testing also showed that the older a ranitidine product is, or the longer the length of time since it was manufactured, the greater the level of NDMA. These situations may raise the level of NDMA in the ranitidine product above the suitable daily intake limit.

With today's announcement, the FDA is sending letters to all manufacturers of ranitidine requesting they withdraw their products from the market. The FDA is also advising consumers taking OTC ranitidine to stop taking any tablets or liquid they currently have, dispose of them properly and not buy more; for those who wish to continue treating their condition, they should consider using other approved OTC products. Patients taking prescription ranitidine should speak with their health care professional about other treatment options before stopping the medicine, as there are multiple drugs approved for the same or similar uses as ranitidine that do not carry the same risks from NDMA. To date, the FDA's testing has not found NDMA in famotidine (Pepcid), cimetidine (Tagamet), esomeprazole (Nexium), lansoprazole (Prevacid) or omeprazole (Prilosec).

In light of the current COVID-19 pandemic, the FDA recommends patients and consumers not take their medicines to a drug take-back location but follow the specific disposal instructions in the medication guide or package insert or follow the

agency's recommended steps, which include ways to safely dispose of these medications at home.

The FDA remains its ongoing review, investigation, obedience and pharmaceutical quality efforts across every product area, and will stay to work with drug manufacturers to confirm safe, effective and high-quality drugs for the American public.

The FDA encourages health care professionals and patients to report adverse reactions or quality problems with any human drugs to the agency's Med Watch Adverse Event Reporting Program:

- Complete and submit the report online at www.fda.gov/medwatch/report.htm; or
- Download and complete the form, then submit it via fax at 1-800-FDA-0178.

The FDA, an agency within the US Department of Health and Human Services, protects the public health by assuring the safety, effectiveness, and security of human and veterinary drugs, vaccines and other biological products for human use, and medical devices. The agency also is responsible for the safety and security of our nation's food supply, cosmetics, dietary supplements, products that give off electronic radiation, and for regulating tobacco products.

## CASE IV

**Case:** Patna High Court (Case no.: 8814 of 2017)

**Case title:** The medicines recovered from the house of the petitioner. There is nothing on record that those medicines were not permissible under Drugs and Cosmetic Act.

**Description:** 9-03-2017 This is an application for grant of anticipatory bail for offences punishable under **Sections 467, 468, 471, 420** and **120 (*b*)** of the Indian Penal Code, under **Section 66** of the Information Technology, under **Sections 18 (*a*), 18 (*b*), 18 (*c*), 27 (*c*), 28 (*a*), 27 (*b*),** II, 33 EEC(*b*), 33(1) of the Drugs and Cosmetics Act, 1940 and Sections 3, 4, 5, 7, 9 (*a*) of Magic Remedies Act, 1954.

It has been submitted on behalf of the petitioner that petitioner is a Baidh and it is alleged that some medicines were recovered

from the house of the petitioner. There is nothing on record that those medicines were not permissible under Drugs and Cosmetic Act. He has been made accused in this case when there is nothing against him and other similarly situated person having similar allegation has already been granted bail by this court vide order dated on 02.03.2017, passed in Criminal Miscellaneous no. 8814 of 2017.

**Result:** Having received both sides, in view of the allegation made, let above named petitioner, in the event of arrest or surrender within a period of two weeks from the date of receipt/production of a copy of this order, be enlarged on bail on furnishing bail bond of ₹ 25,000 (twenty-five thousand only) with two sureties of the like amount each to the satisfaction of learned Chief Judicial Magistrate, Nalanda, Biharsharif, in connection with Giriyak PS Case no. 310 of 2016, subject to the conditions as laid down under Section 438 (2) of the Code of Criminal Procedure.

**Medical Termination of Pregnancy Act**

## CASE V

**Case:** Bombay High Court (Case no.: 66 of 2020)

**Case title:** The foetus suffering from open neural tube defect—Spina Bifida/Meningomyelocele to terminate the pregnancy.

**Description:** It is the case of the petitioner that she is into 26th week of pregnancy. In the medical examination conducted on 21.12.2019 it was revealed and confirmed that the fetus Deshmane (PS) 1/12 2 wp-66-2020 is suffering from open neural tube defect—spina bifida/meningomyelocele +. The petitioner has stated in her petition that she desired to terminate the pregnancy, but, she was barred from doing so because the pregnancy had exceeded the statutory period of 20 weeks provided under the Medical Termination of Pregnancy Act, 1971 (hereinafter referred to as 'MTP Act'). We have heard Mr Niranjan Deshpande, learned counsel for the petitioner. Learned counsel for the petitioner relied on a few judgments passed by the Hon'ble Supreme Court, as well as, passed by a Division Bench of this Court dealing with the issue of granting permission for termination of pregnancy even after a statutory period of 20 weeks, provided under the MTP Act was over.

Considering the ratio laid down in these judgments, the petitioner was directed to approach the Medical Board in Sir JJ Group of Hospitals, Mumbai for examination. The Medical Board was directed to conduct Deshmane (PS) 2/12 3 wp-66-2020 the examination and submit its report. Accordingly, the medical examination was conducted and the report of the Board was submitted to this court.

When pregnancies may be terminated by registered medical practitioners—not withstanding anything contained in the Indian Penal Code (45 of 1860), a Registered Medical Practitioner shall not be guilty of any offence under that code or under any other law for the time being in force, if any pregnancy is terminated by him in accordance with the provisions of this Act.

**Result:** Committee opinion after careful examination and study of sonography reports, it is confirmed that the fetus suffers from serious neurological abnormality in the form of open neural tube defect in the lower lumbar region with posterior fossa crowding and frontal bone scalloping, findings are so Chiari malformation type 2. The condition of the fetus fulfils the criteria of "substantial risk of serious physical handicap with very high morbidity and occasional mortality." The woman has been explained about the outcome in the language she understands. The pregnant woman has voluntarily expressed her desire to terminate the pregnancy and is well informed about the nature of the condition of fetus and its outcome. She is anguished with the condition of the fetus *in utero*. Hence, it is advisable to terminate the pregnancy. Then 26 weeks and is beyond 20 weeks cut off of the Medical Termination of Pregnancy Act. Hence, she has approached Honourable Court for termination of pregnancy and if the Court permits the pregnancy can be terminated as desired by the pregnant woman with due risk in any tertiary centre as desired by the pregnant woman. The honourable court is hereby requested to instruct the parents to take the responsibility of the child if born alive.

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**Vishal Suresh Bagul** MPharm is Assistant Professor, Department of Pharmacognosy, HR Patel Institute of Pharmaceutical Education and Research, Shirpur, Dhule, Maharashtra. He has completed his bachelor's and master's degree in Pharmacognosy in 2015 and 2017 respectively from RC Patel Institute of Pharmaceutical Education and Research, Shirpur. Recently, he received the Young Scientist Award from the Society of Pharmacognosy and Phytochemistry, New Delhi.



**Sanjaykumar B Bari** MPharm PhD is Principal and Professor, Department of Pharmaceutical Chemistry, HR Patel Institute of Pharmaceutical Education and Research, Shirpur, Dhule, Maharashtra, with more than 26 years of teaching, research, and administrative experience. Dr Bari has received a National Merit Scholarship from XIth to BPharm, Junior Research Fellowship (Gate-94) and PhD (AICTE-QIP Fellowship), VLife Sciences best publication award 2012, Dr PD Sethi Annual Award 2011—a certificate of merit for a research paper, International Achievers Award 2015 by Utkarsh & Manavseva Vikas Foundation at National Achiever's Summit, Aurangabad, Best Principal Award 2019 by KBC North Maharashtra University, Jalgaon and APTI-IPER's Principal Year Award 2021.



**Rajeshwari Satish Patil** MPharm is Assistant Professor, Department of Pharmacognosy, RC Patel Institute of Pharmaceutical Education and Research, Shirpur, Dhule, Maharashtra. She completed her bachelor's degree in pharmacy in 2017 and master's degree in pharmacognosy in 2019 from RC Patel Institute of Pharmaceutical Education and Research, Shirpur, Maharashtra.



**Deepak Manohar Patil** MPharm is Assistant Professor, Department of Quality Assurance, HR Patel Institute of Pharmaceutical Education and Research, Shirpur, Dhule, Maharashtra. He completed his bachelor's from RC Patel Institute of Pharmaceutical Education and Research, Shirpur, Dhule, Maharashtra in 2015 and a master's degree in quality assurance from AISSMS College of Pharmacy, Pune in 2017.


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