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B. Pharm
5th Semester

Read to Lead

Pharmaceutical Jurisprudence

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Dr. Rajat Kumar Kar
Dr T. Purushoth Prabhu
Dr. Kunal N. Patel

PHARMACEUTICAL JURISPRUDENCE

B.Pharm, Semester-V

According to the syllabus based on **'Pharmacy Council of India'**

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"I dedicate this book

to

my beloved father, ***Late Sri Durgaram Kar***

&

my loving mother, ***Smt. Anita Kar****"*

-Dr. Rajat Kumar Kar

"Dedicated

to

Almighty God*, my* ***Parents***

&

Family Member*"*

- Dr. T. Purushoth Prabhu

"Dedicated

to

God*,* ***Teachers***

&

Family Members*"*

-Dr. Kunal N. Patel

Preface

It is with great pleas ure that we introduce the book " **Pharmaceutical Jurisprudence**". The book allows for the lucid understanding of different fundamentals of physical chemistry . This book is a genuine effort to clarify the basics of Pharmaceutical Jurisprudence in an effortless and interesting manner and as per the syllabus prescribed for the B.Pharm Sem ester V students by Pharmacy Council of India.

All efforts have been made to keep the text error -free and to present the subject in a student friendly and easy to understand. However, any suggestions and constructive comments would be highly appreciated and incorporat ed in the future edition.

Learning Outcomes Related to Knowledge and Cognitive Skills:

At the end of the course student will be able to:

1) Understand various fundamentals of the Drugs and Cosmetics Act.
2) Know about the details of various Schedules under the Drugs and Cosmetics Act.
3) Understand the fundamentals of the Pharmacy Act, Medicinal and Toilet Preparations Act, Drugs and Magic Remedies Act, Prevention of Cruelty to Animals Act, etc.
4) Know about the Pharmaceutical Legislations, Code of Pharmaceutical Ethics, RTI Act, and IPR.

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Acknowledgement

First of all, I express my sincere gratitude to **Almighty**, for giving me enough strength for accomplishment of the book.

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-Dr. Rajat Kumar Kar

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I take th is opportunity to thank **Thakur Publication Pvt. Ltd ,** especially **Ms. Tuhina Banerjee** (Copy Editor) & **Ms. Sana** (Sr. Marketing Coordinator), for considering me author of this book.

- Dr. T. Purushotha Prabhu

Writing a book is harder than I thought and more rewarding than I could have ever imagined. None of this would have been possible without the strength given by **God**.

To write a book of this magnitude, it needs lot of patience, skill and expertise over the subject, which I have gained because of the opportunity given to me by **Dr. M. M. Patel**, Director, Shree Swaminarayan Sanskar Pharmacy College, Zundal, Gandhinagar, Gujarat and Ex Vice-Chancellor, HNGU, Patan, Gujarat. I am heartily thankful for his valuable comments, suggestions and meticulous attention in bringing out this book.

I would like to express my deep sense and profound gratitude to **Param Pujya Shastri Swami Shri Purushottam Charandasji**, Managing Trustee, Shree Swaminarayan Sanskar Deep Trust, Zundal for providing me constant encouragement during completion of this book.

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I gratefully acknowledge my **Staff Colleagues**, **Friends** and **Students**, who provided excellent and selfless support to complete this work successfully.

I would like to thank my **Parents**, **Wife** and **Daughters**, who supported me in spite of all the time which took me away from them. It was a long and difficult journey for them.

Last but not the least, I would like to thank **Thakur Publication Pvt. Ltd.,** for giving me this opportunity to publish this book.

-Dr. Kunal N. Patel

Syllabus

BP405TT: PHARMACEUTICAL JURISPRUDENCE

Sr. No.	Topics	% Weightage
1.	**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.	**10**
2.	**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 & 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, Drugs Inspector.	**10**
3.	• **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 & Proprietary Preparations. Offences and Penalties. • **Narcotic Drugs and Psychotropic Substances Act-1985 and Rules:** Objectives, Definitions, Authorities and Officers, Constitution and Functions of narcotic & Psychotropic Consultative Committee, National Fund for Controlling the Drug Abuse, Prohibition, Control and Regulation, opium poppy cultivation and production of poppy straw, m anufacture, sale and export of opium, Offences and Penalties.	**10**
4.	• **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, R ecords, 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 EssentialMedicines (NLEM	**8**
5.	• **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).	**7**

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Chapter-7: Prevention of Cruelty to Animals Act

Chapter-8: National Pharmaceutical Pricing Authority

Chapter-9: Pharmaceutical Legislations

Chapter-10: Code of Pharmaceutical Ethics

Chapter-11: Medical Termination of Pregnancy Act

Chapter-12: Right to Information Act

Chapter-13: Intellectual Property Rights

CHAPTER 1

Drugs and Cosmetics Act -I

1.1. DRUGS AND COSMETICS ACT, 1940 AND ITS RULES

1.1.1. Introduction

The main aim of The Drugs and Cosmetics Act, 1940 and Rules 1945 is to maintain the import, manu facture, distribution, and sale of drug s and cosmetics. Continuous use of cosmetics in luxury items prove to be harmful as they may contain harmful ingredients. Therefore, there is a need to control the cosmetics.

This Act verifies that the drugs and cosmetics should be manufactured, distributed, and sold only by qualified persons having a license for this purpose.

The Central and State Drugs Control authorities are also recognised to control these actions.

To this Act and Rules, timely amendments are made. The major amendment was made in **1982**, in which Schedules E, I, and L were eliminated, Schedules G and H were revised and expanded, and Schedule X was added.

Previously there were Schedule C and C $_1$ drugs, and drugs other than those specified in these schedules. At the present time, there are:

1) Drugs not specified in Schedule C, C_1, and X,
2) Schedule C and C_1 drugs, excluding Schedule X drugs, and
3) Schedule X drugs.

Schedules M and Y were established in 1988. In relation to Jammu and Kashmir, the chapter related to import of drugs and cosmeti cs should take effect from the date after the commencement of the Drugs and Cosmetics (Amendment) Act, 1972, the Central Government may appoint in this behalf by notifying the Official Gazette.

The main concern of this Act is to verify the standards and q uality of drugs manufactured in India and to regulate their manufacture, sale, and distri bution. Excise duties and imposition of narcotic drugs are not the part of this Act.

This Act aims to maintain high standards of medical treatment by avoiding sub - standard in drugs when the required concomitant of medical or surgical treatment is allowed to be diluted.

1.1.2. Definitions

1) **Drug** includes:
   i) All medicines for internal or external use of human beings or animals and all substances intended to be used for or in t he 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;

   ii) Such substances (other than food) intended to affect the structure or any function of the human body or intended to be used for the destruction of vermin or insects which cause disease in human beings or animals, as may be specified from time to time by the Central Government by notification in the Official Gazette;

   iii) All substances intended for use as components of a drug including empty gelatine capsules; and

   iv) Such devices intended for internal or external use in the diagnosis, treatment, mitigation or prevention of disease or disorder in human beings or ani mals, as may be specified from time to time by the Central Government by notification in the Official Gazette, after consultation with the Drugs Technical Advisory Board (DTAB).

2) **Patent or proprietary medicine** refers to a remedy whose formula is owned exclusively by the manufacturer and which is marketed usually under a name registered as a trademark:
   i) In relation to Ayurvedic, Siddha, Unani, or Tibb systems of medicine all formulations containing only such ingredients mentioned in the formulae described in the authoritative books of Ayurvedic, Sidha, Unani or Tibb systems of medicine specified in the First Schedule, but does not include a medicine which is administered by parenteral route and also a formulation included in the authoritative books as specifi ed in the First Schedule;
   ii) In relation to any other systems of medicine, 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 In dian Pharmacopoeia for the time being or any other Pharmacopoeia authorized in this behalf by the Central Government after consultation with the DTAB.

3) **Misbranded drug** is deemed to be misbranded:
   i) If it is so coloured, coated, powdered or polished that damag e is concealed or if it is made to appear of better or greater therapeutic value than it really is; or
   ii) If it is not labelled in the prescribed manner; or
   iii) If its label or container or anything accompanying the drugs bears any statement, design or device whi ch makes any false claim for the drug or which is false or misleading in any particular.

Misbranding should, as well, be such as cannot be detected by a lay purchaser with the ordinary diligence. A phonetic similarity in two trademarks like 'Cocogem' and 'Kotogem' is not sufficient. There should be reasonable probability of deception.

4) **Adulterated drug** is deemed to be adulterated:
   i) If it consists, in whole or in part, of any filthy, putrid or decomposed substance; or
   ii) If it has been prepared, packed or stored under insanitary conditions whereby it may have been rendered injurious to health; or
   iii) If its container is composed, in whole or in part, of any poisonous or deleterious substance which may render the contents injurious to health; or
   iv) If it bears or contains for purposes of colouring only, a colour other than one which is prescribed; or
   v) If it contains any harmful or toxic substance which may render it injurious to health; or
   vi) If any substance has been mixed therewith so as to reduce its quality or strength.

5) **Spurious drug** is deemed to be spurious:
   i) If it is imported (manufactured in relation to manufacture, sale and distribution of drugs) under a name which belongs to another drug; or
   ii) If it is an imitation of or is a substitute for, another drug or resembles another drug in a manner likely to deceive or bears upon it or upon its label or container the name of another drug unless it is plainly and conspicuously marked so as to reveal its true charac ter and its lack of identity with such other drugs; or
   iii) If the lab el or container bears the name of an individual or com pany purporting to be the manufacturer of the drug, which individual or company is fictitious or does not exist; or
   iv) If it has been substituted wholly or in part by another drug or substance; or
   v) If it purports to be the product of a manufacturer of whom it is not truly a product.

Where cartons containing drugs were sold as received from company and the accused was ignorant about the spurious contents, he is fully protected by clause (3) of Section 19 of the Act.

6) **Misbranded cosmetics** is deemed to be misbranded:
   i) If it contains a colour which is not prescribed; or
   ii) If it is not labelled in the prescribed manner; or
   iii) If the label or container or anything accompanying the cosmetic bears any statement which is false or misleading in any particular.

7) **Spurious cosmetic** is deemed to be spurious:
   i) If it is imported under a name which belongs to another cosmetic; or
   ii) If it is an imitation of, or is a substitute for, or resembles another cosmetic in a manner likely to dec eive or bears upon it or upon its label

or container the name of another cosmetic, unless it is plainly and conspicuously marked so as to reveal its true character and its lack of identity with such other cosmetic; or

iii) If the label or container bears the name of an individual or a company purporting to be the manufacturer of the cosmetic, which individual or company is fictitious or does not exist; or

iv) If it purports to be the product of a manufacturer of whom it is not truly a product.

1.1.3. Objectives

Following are the objectives of this Act:

1) For preventing substandard in drugs, probably for treatment and preserving high medical standards.
2) For controlling the import, manufacture, distribution, and sale of drugs and cosmetics by licensing.
3) For ensuring that manufacture, distribution, and sale of drugs and cosmetics is done by qualified persons only.
4) For controlling the manufacture and sale of Ayurvedic, Siddha, and Unani drugs.
5) For establishing Drugs Technical Advisory Board (DTAB) and Drugs Consultative Committees (DCC) for Allopathic and Allied drugs and Cosmetics.

1.1.4. Legal Definitions of Schedules To The Act

Drugs and Cosmetics Rules have 18 parts, and each part deals with a subject. The schedules to the Act are:

1) **First Schedule:** This includes the names of books under Ayurvedic, Siddha, Unani, and Tibb systems.
2) **Second Schedule :** This includes the standard to be complied by drugs imported and manufactured for sale, sold, stocked, exhibited for sale, or distributed.

The following appendices are also included:

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.

1.1.5. Legal Definitions of Schedules To Rules

Following are the schedules to the rules:

A – Proforma for application for the licenses, issue and renewal of licenses, for sending memoranda under the Act.

B – Rates of fee for test or analysis by the Central Drugs Laboratory or the Government Analyst.

C – List of biological and special products whose import, sale, distribution, and manufacture are governed by special provisions.

C1 – List of other special products whose import, sale, distribution, and manufacture are governed by special provisions.

D – List of drugs exempted from the provisions of import of drugs.

E1 – List of poisonous substances under the Ayurvedic (including Siddha) and Unani systems of medicine.

F (i) – Space, equipment, and supplies required for a blood bank.

(ii) – Minimum requirement for grant of license to procure blood components from whole human blood.

F1 Part I – Provisions applicable to the production of bacterial and viral vaccines.

Part II – Provisions applicable to the production of all sera from living animals.

Part III – Provisions applicable to the manufacture and standardisation of diagnostic agents (bacterial origin).

F2 – Standards for surgical dressings.

F3 – Standards for sterilised umbilical tapes.

FF – Standards for ophthalmic preparations.

G – List of substances to be used only under medical supervision and which are to be labelled accordingly.

H – List of prescription drugs.

J – Diseases or ailments which a drug may not prevent or cure.

K – Drugs exempted from certain provisions of the manufacture of drugs.

M – Good Manufacturing Practices (GMP) requirements of factory premises, plants, and equipment.

M1 – Requirements of factory premises, etc., for manufacture of ho meopathic preparations.

M2 – Requirements of factory premises for the manufacture of cosmetics.

M3 – Requirements of factory premises for the manufacture of medical devices.

N – List of minimum equipment for efficient running of a pharmacy.

O – Standards for disinfectant fluids.

P – Life periods of drugs.

P1 – Pack sizes of drugs.

Q – Part I – List of dyes, colours and pigments permitted in cosmetics and soaps.

Part II – List of colours permitted in soaps.

R – Standards for condoms made of rubber latex intended for single use and other mechanical contraceptives.

R1 – Standards for medical devices.

S – Standards for cosmetics.

T – Requirements of factory premises and hygienic conditions for Ayurvedic (including Siddha) and Unani drugs.

U – Particulars to be shown in manufacturing, raw material, and analytical records of drugs.

U1 – Particulars to be shown in manufacturing, raw material, and analytical records of cosmetics.

V – Standards for patent or proprietary medicines.

W – List of drugs to be marketed under generic names only.

X – List of drugs whose import, manufacture, sale, labelling, and packaging are governed by special provisions.

Y – Requirements and guidelines on clinical trials for import and manufacture of new drugs.

1.1.6. Import of Drugs

The Drugs and Cosmetics Act and Rules also regulate the import of drugs and cosmetics. In India, the drugs and cosmetics (whose import is not prohibited) are imported under a licensed authority. Import of certain drugs or cosmetics did not require any license in case they are of standard quality and fulfil the necessities associated to import.

The dependent will be responsible if a purchaser asking for a 'mercury ointment' is delivered an ointment having mercury in less concentration than prescribed by the Pharmacopoeia. The provisions of the Act and the Rules prescribing penalty for infringement of standard quality of Gudakhu cannot be enforced against the petitioner till the standard quality is prescribed.

The opinion of Government Analyst that sub -standard quality bandages were supplied to the hospital could not be held well. Since, the State had failed to produce any notification which makes the ISI (Indian Standard Institute) specifications applicable to the Act, the proceedings against the person who is responsible for supplying bandages not complying with the standards laid down by ISI had to be suppressed in such situations.

The accused cannot be prosecuted for any sub -standard found in the drug when examined by the Government Analyst, if the accused had discharged the obligation and proved that while in his possession the drug remained in the same state in which he acquired it.

A dealer should fulfil the requirements of Section 19(3) of the Act in case he acquired a drug from a licensed dealer under a warranty, and also if the Public Analyst finds the drug to be of non-standard quality.

1.1.6.1. Classes of Drugs and Cosmetics Prohibited from Import

The Central Government after notifying the Official Gazette appoints a date from which no person can import:

1) Any drug or cosmetic of non-standard quality,
2) Any misbranded or spurious or adulterated drug,

3) Any misbranded or spurious cosmetic,
4) Any drug or cosmetic which requires a license for import,
5) Any patent or proprietary medicine, till the true for mula or list of active ingredients contained in it, along with the quantities are displayed on the label or the container,
6) Any drug which by means of any statement, design or device accompanying it or by an y other means, purports or claims to cure or mitigate any such disease or ailment, or to have any such other effect, as may be prescribed ,
7) Any cosmetic containing an ingredient which may be unsafe or harmful for use,
8) Drugs which claim to prevent or cure an y of the diseases or ailments specified in Schedule J,
9) Drugs whose manufacture, sale and distribution are prohibited in the country of origin, except when required for the purpose of examination, test or analysis,
10) Drugs not labelled and packed in the prescribed manner,
11) Biological and other special products specified in Schedule C and C1 after their expiry date or those not complying with the standards of strength, quality and purity,
12) Any new drug except with express permission of the licensing authority, and
13) Any drug or cosmetic whose import is prohibited.

These provisions are not applicable to the import of drugs required in small quantities for examination, test or analysis.

1.1.6.2. Import under License or Permit

The licensing authority grants a license for the import of the following classes of drugs:

1) Drugs specified in Schedule C and C1 excluding those specified in Schedule X,
2) Drugs specified in Schedule X,
3) Small quantities of drugs imported for examination, test, or analysis,
4) Drugs for personal use prescribed by a Registered Medical Practitioner, and
5) Any new drug.

An application in the prescribed form should be made to the concerned author ity for the grant of import license. A license if not suspended or cancelled earlier, remains valid from its grant year up to 31st December of the same year.

If a granted import license of any individual is cancelled, he/she can appeal to the High Court against the order of the Drugs Controller of India.

A separate license is required from each manufac turer, in respect of drugs. A manufacturer living in a foreign country and have his factories located at different places require a separate import license for manufacturing drugs at each premise. A drug (or class of drugs) manufactured by the same manufacturer requires a sin gle application for the grant of import license. The Licensing Authority should be informed about any change made in the constitution of a licensed firm.

1.1.6.3. Conditions of Import License

An import license is subjected to the following conditions:

1) The manufacturer at all times should observe the duty given by him or on his behalf in Form 9.
2) The licensee should allow any authorised Inspector to enter the premises having stocked imported substances for inspection, and also withdraw samples for testing the substances.
3) The licensee should provide the Licensing Authority with adequate sample (either from all batches or from a particular batch as demanded by the Licensing Authority) for examination along with full protocol of the tests which have been applied.
4) The licensee should not sell or offer for sale any batch in respect of which a sample or protocols are furnished as above (3) till a certificate is issued by or on behalf of the Licensing Authority.
5) The licensee should recall a batch of a drug from the market i f the Licensing Authority informs that the drug fails to comply with the prescribed standard of strength, quality, and purity.
6) The licensee should maintain a record of all sales of imported substances, along with particulars of the substance and of persons to whom the substances have been sold and other particulars as demanded by the Licensing Authority.
7) The licensee should allow any authorised Inspector to inspect such records.
8) The licensee should also comply with other requirements specified by the Licensing Authority and for which he/she has got a notice of not less than 4 months.

1.1.6.4. Import of Drugs for Examination, Test, or Analysis

Import of drugs (otherwise prohibited) required in small quantities for examination, test or analysis, should be carried out under the following conditions:

1) Drugs can be imported only under a license in Form 11,
2) The substances imported should be used for examination, test or analysis in the specified place or in any other place authorised by the Licensing Authority,
3) An authorised Inspector must be allowed by the licensee to enter and inspect the premises, and to investigate the manner in which the substances are being used and to take samples from there (if required),
4) A record of the substances imported under the license, along w ith their quantities, importation date and manufacturer's name, must be maintained by the licensee and presented to the Licensing Authority, and
5) The licensee must also comply with the other requirements specified by the Licensing Authority who has given no t less than one month's notice to the licensee.

1.1.6.5. Import of Drugs for Personal Use

Drugs whose import is prohibited can be imported in small quantities under the following **conditions**:

1) The drug should be a part of the passenger's luggage and should be intend ed for the personal use of passenger.
2) The drug should be declared to the Customs Collector, if directed.
3) The quantity of a single drug to be imported should not be more than hundred average doses.

However in some cases, the Licensing Authority can approve the import of such drugs in larger quantity.

The import of drug which is not a part of the passenger's luggage but is intended for personal use may be allowed if an application is made to the Licensing Authority in Form 12A, and also if he is satisfied that:

1) The drug has been prescribed by a registered medical practitioner,
2) The drug is for personal use and is in reasonable quantity, and
3) A permit for the drug is granted in Form 12B.

If at the time of import, an individual intended to bring a drug for hi s/her personal use as a property that would be sufficient compliance of the provision under Rule 36(1).

If the individual imports for using it personally but after bringing it changes his/her mind either on advice given by a doctor or for any other reaso n that was no longer for him/her to use the drug.

The Act or the Rules framed there under do not prohibit such individual from disposing of the drug brought by him/her in any manner he/she likes. Therefore, it must be held that the petitioners have not c ommitted the offence under Section 18(b) of the Act as they have not breached the provisions of the Act or Rules framed there under by importing the bottle.

1.1.6.6. Import of New Drugs

A drug whose composition is not recognised as safe for use and includes any drug which has not been used to any large extent and for any appreciable length of time, after investigation study is considered as a **new drug**.

Without the written permission of the Licensing Authority, no new drug can be imported. While applying for such permission, all documents and other evidence related to the standards of quality, purity, strength, etc., should be supplied to the Licensing Authority.

1.1.6.7. Procedure for Import of Drugs

A drug cannot be imported if it is not packed and labelled as per the p rescribed rules. An invoice or other statement with the manufacturer's name and address, and the names and quantities of drugs should accompany all the drug consignments to be imported.

Drugs for which a license is not required should be imported after getting a declaration signed by the manufacturer on importer's behalf that the drugs comply with the provisions of the Act and Rules. This declaration should be supplied to the Customs Collector.

If the Customs Collector wants to check that whether the drugs comply with the provisions of the Act and the Rules or not, or if he has been requested by any officer appointed by the Central Government, the Customs Collector should take drug samples from the consignment.

These collected samples are supplied to the Director of the laboratory appointed by the Central Government. Till the analysis report is received, the Customs Collector may detain the drug consignment.

The Customs Collector may make over the consignment if the importer gives a statement in writing that he will not dispose of the drugs without Customs Collector's permission and will return the consignment to him within 10 days of receiving the notice.

The Customs Collector may order the importer to export the consignment back to the manufacturer in abroad within two months, if it is mentioned in the analysis report that a drug in the consignment is of non-standard quality or breaches any provisions of Chapter III of the Act or the Rules and this breach is fixed by the importer.

The distressed importer may present samples of the consignment to the Customs Collector who forwards the samples to the Licensing Authority. Decision of the Licensing Authority should be final. If the importer fixes the breach, Customs Collector allows the importer to import the drug on his written stating not to dispose of the drug without the permission of the officer authorised by the Central Government for this purpose.

1.1.6.8. Exempted Drugs

Table 1.1 shows the drugs exempted from the provisions regulating the import of drugs:

Table 1.1: Exempted Drugs

Class of Drugs	Extent and Conditions of Exemption
Substances not intended for medicinal use.	They can be imported without any restriction, provided imported in bulk and the importer certifies that they are imported for non-medicinal uses. If imported otherwise than in bulk, each container shall bear a label indicating that the substance is not intended for medicinal use.
Substances included in Schedule C1 required for manufacturing purposes but not intended for medicinal use.	Exempted from all provisions regulating import except that the importer should be holding license for manufacture of Schedule C and C1 drugs.

Substances used both as drugs as well as articles of food, **e.g.,** condensed or powdered milk whether pure, skimme d or malted, fortified with vitamins and minerals; Farex, oats, lactose and other similar cereal preparations whether fortified with vitamins or otherwise excepting those for parenteral use.	Exempted from all provisions regulating import.
Virol, bovril, c hicken essence, and all other similar pre-digested foods.	Exempted from all provisions regulating import
Ginger, pepper, cumin, cinnamon, and all other similar spices and condiments other than those of official quality.	Exempted from all provisions regula ting import

Table 1.2 shows the list of places through which the drugs are imported in India:

Table 1.2: Places through which Drugs may be Imported into India

1)	Firozpur cantonment and Amritsar Railway Station.	In respect of drugs imported by rail across the frontier with Pakistan.
2)	Ranaghat, Bongaon and Mohiassan Railway stations.	In respect of drugs imported by rail across the frontier with Bangladesh.
3)	Madras, Calcutta, Mumbai and Cochin.	In respect of drugs imported into India by sea.
4)	Madras, Calcutta, Mumbai, Delhi and Ahmedabad.	In respect of drugs imported by air into India.

Consignments which are transported to foreign countries from India are also ex - empted from the provisions regulating the import of drugs. But, if such consignments are i mported under license granted by destination countries, the importer must produce the license at the time of import.

1.1.6.9. Offences and Penalties

The offences and penalties related to the import of drugs under this Act are given in **table 1.3**:

Table 1.3: Offences Relating to Import of Drugs

Offences	Penalties	
	First Conviction	**Subsequent Conviction**
1) Import of adulterated or spurious drugs or spurious cosmetic or any cosmetics containing an ingredient which may make it harmful.	Imprisonment up to 3 years and fin e up to ₹ 5,000.	Imprisonment for up to 5 years or fine up to ₹ 10,000 or both.
2) Import of drugs or cosmetics other than those referred above the import of which is forbidden.	Imprisonment up to 6 months or fine up to ₹ 500 or both.	Imprisonment up to 1 year or fine up to ₹1000 or both.
3) Import of any drugs or cosmetics in contravent ion of any notification issued u nder Section 10A.	Imprisonment up to 3 years or fine up to ₹ 5,000 or both.	Imprisonment for up to 5 years or fine up to ₹ 10,000 or both

1.1.7. Manufacture of Drugs

The manufacture of drug under this Act include the processes of making, altering, ornamenting, finishing, packing, labelling, breaking up, or adopting drugs for their sale or distribution (except compounding or dispensing or packing of drug) .

Manufacture of drugs is a regulated process. Following are the subject related to drugs that can be manufactured under license:

1) Infrastructural facilities,
2) Technical manpower,
3) Analytical laboratory,
4) Records, and
5) Inspection and sampling of drugs.

1.1.7.1. Prohibition of Manufacture and Sale of Certain Drugs

The following drugs should not be manufactured for sale or distribution, or sold or stocked or offered for sale or distribut ion by a person himself or by any other person on his behalf, from the date notified by the State Government:

1) Any drug which is of non -standard quality or is misbranded, adulter ated or spurious,
2) Any cosmetic which is of non-standard quality or is misbranded or spurious,
3) Any patent or proprietary medicine whose formula is not disclosed on the label or container,
4) Any drug which claims to prevent, cure or mitigate any disease specified in Schedule J,
5) Any cosmetic containing any ingredient which makes it unsafe or harmful for use,
6) Any drug or cosmetic in contravention of this Act or Rules there under, and
7) Any drug or cosmetic which has been imported or manufactured in contravention of the provisions of this Act or Rules or in contravention of the conditions of a licence.

Quantity of medicine kept for the treatment of the suspect or his family members cannot be considered as an offence under the Act.

Manufacture for sale or for distribution of any drugs or class of drugs of non - standard quality can be allowed by the Central Government.

Every person, not being manufacturer of a drug or cosmetic or his agent for the distribution thereof, shall, if so required, disclose to the inspector the name, address and other particulars of the person from whom he required t he drug or cosmetic.

A drug or cosmetic should not be considered as misbranded, adulterated, spurious, or of sub-standard quality, if:

1) Any harmless ingredient required for its manufacture or preparation as an article of commerce in a state fit for carriag e or consumption and not to increase the bulk or weight of the drug or cosmetic or to conceal its inferior quality or other defects has been added, or

2) Any extraneous substance has been unavoidably inter -mixed during manufacture, preparation or transportat ion. However, this does not apply in relation to any sale or distribution of the drug or cosmetic occurring after the vendor or distributor becomes aware of such inter-mixture.

For the sake of public, the Central Government may prohibit the manufacture and sale, etc., of such drugs and cosmetics the use of which is risky to human beings or animals or if any drug does not have the claimed therapeutic value or if it contains any ingredient in quantity not therapeutically justified.

The Central Government h as recently prohibited (for the sake of public) the manufacture, sale or distribution of fixed dose combination of Metoclopramide with other drugs, except combination of Metoclopramide with Aspirin/ Paracetamol which is not therapeutically justified, with effect from 1st September, 2002.

In order to justify an action taken under this provision, the Government has to establish its satisfaction to firstly, that the use of any drug or cosmetic is likely to involve any risk to human beings or animals or that t he drug does not have the therapeutic value claimed or purported to be claimed for it and, that in the public interest, it is expedient to ban or prohibit the manufacture, sale or distribution of such drug.

The Central Government found necessary to prohibit the manufacture and sale of steroids after being satisfied that if such drugs are used for a long term in fixed dose for asthma treatment it would be harmful to human beings. It was further held that this prohibition does not impose unreasonable restriction so as to violate the provisions of Article 19(I) (g) of the Constitution.

Each and every druggist or pharmacologist involved in the business of either manufacturing or deciding in the matter need not be consulted before a ban on manufacture of certain drugs was put. The conclusion was reached by the Drugs Control Board which formed the basis of the Govern ment. Notification imposing ban on manufacture of certain drugs should be sufficient to fulfil the requirement of natural justice.

1.1.7.2. Kinds of License and Conditions for Grant of License

Following are the types of licenses under which the drugs can be manufactured:

1) Loan license,
2) Repacking license,
3) License for manufacture of Schedule C and C1 drugs,
4) License for manufacture of Schedule X drugs, and
5) License for manufacture of drugs other than those specified in Schedules C and C1 and X.

These licenses for the manufacture of drugs are issued by the Licensing Authorities appointed for their respective territories by the State Governments. The authorities issue the licenses within 3 months of the application.

An issued license is valid for one set of premises only. When the drugs are manufactured at more than one place, a separate license is needed. If there are any changes in the constitution of a licensed f irm, the licensee should inform the Licensing Authority.

Licenses of such firms are considered current for 3 months maximum period from the date of change until a fresh license has been obtained.

1.1.7.3. Loan License

This type of license is issued to a person who manufactures drugs at the premises of another person or party licensed to manufacture drugs under the Act, since he does not have his own premises and facilities for manufacturing drugs. Drugs other than those specified in Schedule X can be manufactured under the grant of loan licenses.

The holders of loan licenses must satisfy the conditions related to licenses issued under the Act, except that they may not have their own facilities for the manufacture and testing of drugs.

Applications for grant of loan licenses should be supported by documents consent of the licensee whose facilities are to be availed of, for the manufacture. The Licensing Authority before granting the loan license should satisfy himself that the person, whose facilities the applicant wishes to avail of, possesses the necessary staff, space and equipment for manufacture of drugs. The loan license will be suspended or cancelled, if the license of a person whose manufacturing facilities were being availed of by the licensee is suspended or cancelled.

The licensee is required to test each batch of raw material and finished goods and maintains records of the tests for at least 5 years from the date of manufacture (2 years in the case of drugs with an expiry date).

1.1.7.4. Repacking License

This type of license is required for ‘repacking’ the drugs other than those specified in Schedules C and C1. Repacking license can be obtained by writing an application to the Licensing Authority. Persons with re packing license should consider the following **conditions**:

1) For repacking operations sufficient space and equipment should be provided and should be carried out under hygienic conditions under the supervision of a person, approved by the Licensing Authority as a ‘Competent Person’. Persons who have passed the intermediate examination with chemistry (as principal subject) or have passed the matriculation examination or hold Diploma in Pharmacy or are registered pharmacists under the Pharmacy Act 1948 or have not less than 4 years’ experience in manufacture, dispensing or repacking of drugs are eligible to be approved as a ‘Competent Person’.
2) The licensee should have sufficient arrangements for analysis and testing of each batch of raw materials and repacked dru gs or should get them analysed and tested by an approved institution. He should also maintain records of such tests for 3 years from the date of manufac ture and in case of drugs with expiry date at least for 3 months from such date.

3) The licensee should m ake suitable arrangements for storage of drugs and should allow an authorised Inspector to inspect the premises and take samples. The factory premises should meet the requirements specified in Schedule M.
4) The licensee should maintain proper records for re packing of drugs and should allow an inspector to check the same.
5) The license should be kept on the licensed premises and should be produced before an authorized Inspector on demand.
6) Any change in the staff named in the license should be immediately informed to the Licensing Authority.
7) The drugs repacked should bear the number of the license preceded by the words 'Rpg. Lic (Repackaging License). No.' on their label.
8) The licensee should comply with the provisions of the Act and the Rules and other requirements, a notice for which has been given for not less than 4 months by the Licensing Authority.

Any new drug can be manufactured after seeking permission from the Licensing Authority. The manufacturers should submit the application for seeking permission to manufacture drugs, along with the documents proving the quality, purity, and strength of the drug. Preparations containing cyclamates cannot be manufactured in India.

Regular or loan licensed manufacturers should not manu facture drugs more than the capacity approved by the Licensing Authority. If the manufacturer wishes to produce a drug more than his capacity, by working each day for more than one shift of 8 hours, he should seek permission from the Licensing Authority. Manufacturer should send returns of quantities of drugs manufactured, with dates and quantities sold or distributed. This rule is applicable to repacking licenses, as well as where the licensee should not repack more than the calculated capacity.

An Inspection Book should be maintained b y all the persons with a license to manufacture drugs. The Inspectors may record their impressions and defects noticed by them in the Inspection Book. All the manufacturers are bound to provide such information to any authority on demand.

1.1.7.5. Licence to Manuf acture of Biological and other Special Products Specified in Schedules C and C1

Schedule C and C1 drugs are manufactured under a licence obtained from the Licensing Authority after paying the prescribed fee.

A licenced person can manufacture Schedule C and C1 drugs under the following **conditions**:

1) The licensee should provide adequate space, plant, and equipment for manufacture of drugs and the licenced premise should comply with the requirements of Good Manufacturing Practices spec ified in Schedule M (Schedule M3 for devices). Separate laboratories and utensils should be provided for culture and manipulation of spore bearing pathogenic micro - organisms which should not be used for other purpose;

2) The licensee should provide adequate arrangements for testing the strength and quality of drugs in the licenced premises and the testing unit should be separate from the manufacturing unit with an independent head, who should possess a degree in Medicine or Science or Pharmaceutical Chemistry and should have experience in testing of drugs considered adequate by the Licensing Authority. In case, the tests require sophisticated instruments or biological techniques the same may be permitted by the Licensing Authority to be carried out at an approved institution.
3) The drugs should be manufactured under the direction and supervision of technical staff, one of whom should be either:
   a) Graduate in pharmacy or pharmaceutical chemistry with an experience of at least 18 months in the manufacture of drugs (6 months training is allowed during graduation) to which this licence applies, or
   b) A graduate in medicine with an experience of at least 3 years in the manufacture and pharmacological testing of drugs to which the licence applies, or
   c) Graduate in science with chemistry or microbiology as the principal subject or graduate in chemical engineering with an experience of at least 3 years' in the manufacture and testing of the drugs to which the licence applies, or
   d) Hold any foreign qualifications which are comparable to those prescribed under (a), (b), and (c). Further, any person who was approved by the Licensing Authority as an expert responsible for the manufacture of drugs immediately before June 29, 1957 shall also be deemed to be technical staff.
4) Schedule C and C1 drugs used for animal treatment should be manufactured by or under the supervision of graduates in veterinary science or general science or medicine or pharmacy with an experience of at least 3 years in the manufacture and testing of veterinary biological products. The devices specified in Schedule C should be manufactured under the supervision of a graduate in pharmacy or science with physics or chemistry or microbiology as one of the subjects or should possess a degree/diploma in mechanical, chemical, or plastic engineering.
5) The licensee should have adequate facilities for storing the drugs manufactured by him in order to preserve their properties.
6) The licensee should maintain detailed records of the manufacture and testing of each batch of drugs. The records for those drugs which have date of expiry should be preserved for a period of 2 years from the date of their expiry and for other drugs for a period of 5 years from the date of their manufacture.
7) The licensee should allow an authorised inspector to inspect the premises, processes of manufacture, testing of drugs, records required to be maintained under the Act and the Rules, and to take samples of any drug manufactured by him.
8) The licensee should inform the Licensing Authority about any changes in the expert staff and also about any material changes in the plant or premise used for the manufacture.

9) The licensee should provide the Licensing Authority with samples of drugs either from each batch or from batches demanded by the Licens ing Authority. Along with the samp les, full details of the test applied by him should also be provided. The licensee should not sell or offer for sale any batch from which a sample has been supplied to the Licensing Authority, until a certificate authorising the sale has been issued by the Licensing Authority.

The following **provisions** related to biological and other special products must be complied with:

1) All Schedule C drugs should be issued in sterilised glass containers, sealed in such a manner that bacteria access is prevented. The Lic ensing Authority should approve the containers other than those of glass used for the packaging of Schedule C drugs. Substances issued in liquid form in multiple dose containers (except Penicillin suspension in oil and wax) should contain sufficient amount of an antiseptic to prevent microbial growth which may infect the preparation during withdrawal of doses. The containers should also comply with other requirements specified in Schedule F.
2) The drugs should comply with the standards of strength, quality a nd purity specified in Schedule F. Samples should be taken from each finished batch to check whether or not it complies with the prescribed standards.
3) The following classes of substances should be tested for the absence of aerobic and anaerobic micro-organisms:
   i) Sera and solutions of serum proteins intended for injection,
   ii) Bacterial vaccines,
   iii) Other vaccines for parenteral use,
   iv) Vaccines, antigens and mixture of toxins and antigens with serum intended for immunisation or diagnosis by inoculation,
   v) Solutions and suspensions of insulin,
   vi) Dry preparations of insulin intended for parenteral use,
   vii) Preparations of posterior lobe of pituitary intended for parenteral use,
   viii) All other preparations meant for parenteral use except those sterilised by heat after having been sealed in final containers, and
   ix) Preparations from cultures of pathogenic organisms for oral use, which are required to be sterile.
4) The sterility tests should be carried out as follows:
   If only two media are used for test, the sample quantity should not be less than 2ml or 100mg and if three separate media are used, not less than 3ml or 150mg quantity is required.

   The following rules should be followed in taking samples from batches:

Table 1.4: Rules for Taking Samples for Testing Sterility

Batches	Amount/Quantity of Samples
From batches of 10 litres or more	Not less than 10ml.
From batches of less than 10 litres	0.1% of the total volume of batch sub - ject to a maximum of 1ml.

From batches contained in separate bulk containers	Samples to be taken from each batch container according to above rules.
From filled containers	Not less than 1% containers from a batch if the total number is not more than 1000 or at least 10 containers if the number is more than 1000.

The **records of sterility tests** should be maintained with the following headings:

i) Serial no.,
ii) Name of the product, its batch number, and batch size,
iii) Whether in bulk or in final container,
iv) Number of samples used for the test,
v) Name of the antiseptic, if any, and its concentration,
vi) Volume of inoculum and of the culture media, and
vii) Date of inoculation.

5) Serum from each batch should be tested for the absence of abnormal toxicity by injecting a normal mouse with 0.5ml dose subcutaneously and a normal guinea pig with 5ml dose subcutaneously or intra -peritoneally. The serum would be deemed to be free from abnormal toxicity, if it fails to produce death or serious symptoms in the animals within seven days.
6) Solutions for parenteral administration in doses of 10ml or more at a time should be tested for the absence of pyrogen.
7) Applications to manufacture any additional categories of drugs should be accompanied by a fee of ₹15.00 for each item subject to a maximum of ₹300.00.
8) The licensee should comply with the provisions of the Act and the Rules and other requirements for which a notice has been given to him not less than 4 months by the Licensing Authority.
9) The licence and renewal certificate (if any), should be kept at the licenced premises and produced before an inspector if demanded.

1.1.7.6. Licence to Manufacture of Drugs Specified in Schedule X

The conditions that should be satisfied for the manufacture of a drug specified in Schedule X are:

1) Accounts of all the transactions associated to manufacture should be maintained in a serially bound and paged register as given below:
   i) The details of the drugs utilised in the manufacture should include:
      a) The drug name,
      b) Opening and closing balance on the day of manufacture specifying the used quantity, and
      c) Signature of the person in-charge.
   ii) The details of production should include:
      a) The drug name and batch number,
      b) The manufacture date,
      c) Quantity of raw material used,
      d) Anticipated and actual yields along with wastage, and
      e) Quantity of manufactured goods transferred.

iii) The details of manufactured drugs should include:
   a) The manufacture date,
   b) The drug name and batch number,
   c) Opening balance, quantity manufactured, quantity sold, and closing balance,
   d) Purchaser's name and address, and
   e) Signature of the person in-charge.

2) Drugs should be preserved in bulk. They should be kept in a separate place in the care of a responsible person, if required for manufacture outside the storage place.

3) The licensee in every 3 months should submit a declaration to the Licensing Authority giving particulars of the state of the drug manufactured, their supply, and sale to other manufacturers, wholesale dealers, retailers, etc.

4) Schedule X drug should not be supplied by the way of physician's samples.

1.1.7.7. Licence to Manufacture of Drugs other than those Specified in Schedules C and C1 and Schedule X

For manufacturing dr ugs other than the biological and other special products specified in Sched ules C and C1 and in Schedule X, a licence is obtained from the Licensing Authority on application and payment of the prescribed fee.

The following **conditions** should be satisfied for the grant of a licence to manufacture the above categories of drugs:

1) The premises, where the drugs are manufactured should conform to the requirements of Good Manufacturing Pract ices specified in Schedule M (M3 for devices) and adequate space, plant a nd equipment should be provided for the manufacture of drugs.

2) The drugs should be manufactured under the direction and supervision of technical staff, one of whom should be a whole time employee and either:
   i) A graduate in pharmacy or pharmace utical chemistry from a recognis ed university with an experience of at least 18 months in the manufacture of drugs after graduation, (6 months of training may, however, be taken during graduation) or,
   ii) A graduate in science (with chemistry as principal subject) or medici ne or chemical engineering or chemical technology with an experience of at least 3 years in the manufacture of drugs or,
   iii) Hold any foreign qualifications whose quality and content of training are comparable to the qualifications stated under (i) and (ii). For manufacture of veterinary science experience of at least 3 years is essential.

For the manufacture of disinfectant fluids, insecticides, non -chemical contraceptives, surgical dressings, plaster of Paris, liquid paraffin and medicinal gases, the Centra l Government may permit employment of persons holding **qualifications and experience** other than those discussed above:

1) Adequate facilities should be provided for testing the quality, strength and purity of the manufactured drugs at the licenced premises and where testing

unit is provided for on the licenced premises, it should be separate from the manufacturing unit with an independent head, who should possess a degree in medicine or science or pharmaceutical chemistry and experience in testing of drugs cons idered adequate by Licensing Authority. Tests requiring sophisticated equipment or biological techniques may be carried out at an approved institution with the previous permission of the Licensing Authority.

2) The licensee should have adequate arrangements f or the storage of drugs manufactured by him.
3) The licensee should allow an Inspector to inspect the licenced premises, all the records maintained and to take samples of the manufactured products. He should also produce the licence or renewal certificate, ke pt at the licenced premises, to the Inspector on demand.
4) Any change in the expert staff employed for manufacture or testing of drugs and change in materials in plant or premises, should be reported to the Licensing Authority.
5) If the licensee wishes to man ufacture any additional categories of drugs, he should pay a fee of ₹10.00 for each category and get the necessary endorse - ment on the licence to that effect from the Licensing Authority.
6) The licensee should keep records of the accounts of raw materi als, production, manufactured drugs and analysis of drugs for a period of 5 years from the date of manufacture or analysis.
7) The licensee should comply with the other requirements of which a notice has been given to him at least 4 months before by the Licensing Authority.
8) The licensee should provide the Licensing Authority the drug samples for examination and full protocols of the tests applied (if required). The licensee should not sell or offer for sale any drug from batches whose samples or protocols of the te st have been submitted to the Licensing Authority until a certificate authorising their sale is issued. If the Licensing Authority advises the licensee that drugs do not comply with the prescribed standards, he should withdraw the remaining batch from sale and recall all the issues made. The licensee should maintain reference samples from each batch in quantities at least twice of that needed for complete analysis. The samples should be kept at least for 3 months after the expiry date and where there is no such date at least for 3 years from the date of manufacture.
9) The licensee should maintain an Inspection Book in which the inspectors may record their impressions and defects noticed.

1.1.7.8. Manufacture of Drugs for Test, Examination, and Analysis

The drugs req uired for examination, test, or analysis should be manufactured under a licence obtained from the Licensing Authority on application. The Head of the Institution or Director of the firm or company which desires to manufacture drugs should sign the application for the grant of licence.

The drugs manufactured for the above purpose should be kept in well -labelled containers indicating the purpose for the manufacture of such drug. If these drugs

are supplied to any other person they should be labelled with th e manufacturer's name and address and with the scientific name of the substance or with other description which will enable the identification of the substance. Only when a 'No Objection' certificate is issued by the Licensing Authority (appointed by the Central Government for the import of drugs), a licence to manufacture a drug, not considered to be safe for use should be granted.

A person licenced **to manufacture** this class of drugs should satisfy the following **conditions**:

1) The drugs should be used for the purpose for which they are manufactured,
2) Licensee should maintain a record of the names and quantities of drugs manufactured and the names of persons to whom they have been supplied.
3) The licensee should allow an authorised inspector to inspect the licen ced premises and satisfy himself that only examination, analysis or test work is being done.
4) The licensee should comply with other requirements for which a notice has been given to him one month before by the Licensing Authority.

The drugs manufactured fo r the purposes of examination, test, or analysis are exempted from the provisions of the Section 1 of the Act.

1.1.7.9. Manufacture of New Drugs

The application for manufacturing a new drug including their fixed dose combinations should be supplemented along with the data mentioned in Schedule Y.

1.1.7.10. Offences and Penalties

Stocks of drugs for which an offence is committed are removed, and the drugs for which the Court is satisfied on receiving an application from an Inspector that they are of sub-standard value or misbranded are removed.

Two **conditions** are observed for all the licences of manufacturing:

1) Conditions to be fulfilled before a licence is approved (conditions precedent), and
2) Conditions to be fulfilled after a licence is approved (conditions subsequent).

The actions associated to offences in manufacture of drugs are presented in courts (not lower to that of a Metropolitan Magistrate or a First Class Judicial Magistrate) by Drug Inspectors only.

The offences and penalties associated to the manufacture of drugs under this Act are given in **table 1.5**:

Table 1.5: Offences and Penalties Related to the Manufacture of Drugs

Offences	Penalties
Manufacture of adulterated or spurious drug that may cause death or serious body hurt as per Section 320 IPC.	Imprisonment for 5 years and fine of not less than ₹ 10,000.

Manufacture of drugs without license or adulterated drug that may not cause death or serious body hurt.	Imprisonment for 1 -3 years and fine of not less than ₹ 5,000.
Manufacture of drug in contraventi on of any other provision.	Imprisonment for 1-2 years and fine.
Failure to keep records or disclose the required information.	Imprisonment for up to 1 year and/or fine of up to ₹ 1000.
False warranty by manufacturer to a purchaser.	Imprisonment or fine u p to ₹ 500 or both.
Use of Government Analysts report for advertising.	Fine up to ₹ 500.

1.2. SUMMARY

The details given in the chapter can be summarised as follows:

1) The main aim of The Drugs and Cosmetics Act, 1940 and Rules 1945 is to maintain the import, manu facture, distribution, and sale of drugs and cosmetics.

2) Drugs and Cosmetics Rules have 18 parts, and each part deals with a subject.

3) The Drugs and Cosmetics Act and Rules also regulate the impor t of drugs and cosmetics.

4) An application in the prescribed form should be made to the concerned authority for the grant of import license.

5) Without the written permission of the Licensing Authority, no new drug can be imported.

6) A drug cannot be imported if it is not packed and labelled as per the prescribed rules.

7) Loan License is issued to a person who manufactures drugs at the premises of another person or party licensed to manufacture drugs under the Act, since he does not have his own premises and facilities for manufacturing drugs.

8) Repacking License is required for ‘repacking’ the drugs other than those specified in Schedules C and C1.

9) Schedule C and C1 drugs are manufactured under a licence obtained from the Licensing Authority after paying the prescribed fee.

10) The application for manufacturing a new drug including their fixed dose combinations should be supplemented along with the data mentioned in Schedule Y.

1.3. EXERCISE

1.3.1. True or False

1) Drugs and Cosmetics Rules have 20 parts, and each part deals with a subject.
2) The Drugs and Cosmetics Act and Rules also regulate the import of drugs and cosmetics.
3) Repacking License is required for 'repacking' the drugs other than those specified in Schedules C and C1.
4) Schedule C and C1 drugs are manufactured under a licence obtained from the Licensing Authority after paying the prescribed fee.
5) Schedule F2 deals with the Standards for sterilised umbilical tapes.

1.3.2. Fill in the Blanks

6) First Schedule includes the names of books under_____.
7) List of prescription drugs come under the schedule_____.
8) Without the written permission of the _____, no new drug can be imported.
9) Schedule P deals with the_____.
10) The Drugs and Cosmetics Act and Rules also regulate the import of _____.

Answers:

1) False 2) True 3) True 4) True 5) False
6) Ayurvedic, Siddha, Unani, and Tibb systems 7) Schedule H
8) Licensing Authority 9) Life periods of drugs
10) Drugs and cosmetics

1.3.3. Very Short Answer Type Questions

1) What are the main objectives of Drugs and Cosmetics Act, 1940?
2) Define the term misbranded and adulterated drug.
3) Which schedule deals with the Good Manufacturing Practices (GMP) requirements of factory premises, plants, and equipment?
4) What are the first and second schedule of Drugs and Cosmetics Act, 1940?
5) Explain the term new drug.

1.3.4. Short Answer Type Questions

1) Write about the procedure of import of drug.
2) What are the conditions of import licence?
3) Discuss about the loan and repacking licence.
4) Write the offences and penalties related to the Manufacture of Drugs.

1.3.5. Long Answer Type Questions

1) Write the legal definitions of schedules to the Drugs and Cosmetics Act, 1940.
2) Discuss about the manufacture of drugs for test, examination and analysis.
3) Write about the offences and penalties related to the manufacture of drugs.

CHAPTER 2

Drugs and Cosmetics Act and Rules-II

2.1. DETAILED STUDY OF SCHEDULES

2.1.1. Introduction

Previously there were Schedule C and C $_1$ drugs, and drugs other than those specified in these schedules. At the present time, there are:

1) Drugs not specified in Schedule C, C_1, and X,
2) Schedule C and C_1 drugs, excluding Schedule X drugs, and
3) Schedule X drugs.

Schedules M and Y were established in 1988. In relation to Jammu and Kashmir, the chapter related to import of drugs and cosmetics should take effect from the date after the commencement of the Drugs and Cosmetics (Amendment) Act, 1972, the Central Government may appoint in this behalf by notifying the Official Gazette

2.1.2. Schedule G

Medicines listed as schedule G carry a caution on the label. The caution states that "It is dangerous to take this preparation except under medical supervision". The caution is clearly printed and surround ed by a line no other words within. It is required to make proper bill of sale of Schedule G drugs. Records of purchase and sale of these medicines should be regulated for 2 years.

Aminopterin, L -Asparaginase, Bleomycin, Busulphan, Chlorambucil, Chlorthiazide, Glibenclamide, Hydantion, Hydroxyurea, Insulin, Metformin, etc. are the **examples** of some drugs under schedule G.

2.1.3. Schedule H

This schedule contains the **prescription drugs**, i.e., drugs that should be sold by retail only when a prescription is formed by a RMP. The time and date mentioned on the prescription should be noted. The drug label should have the texts "Rx" and Schedule H drug written on it. The label should also bea r **warning** that "To be sold by retail on the prescription of a registered medical practitioner only".

Drugs under Schedule H if comes under Narcotic Drugs and Psychotropic Substances Act, 1985 are labelled with the symbol "NRx" and Schedule H drug warning.

Schedule H is a list of **536 drugs**. Some **examples** are Abxicimab, Acylovir, Diclofenac, Baclofen, Carbidopa, Terazosin, Verapamil hydrochloride, Tretinoin, Repaglinide, etc.

Schedule H_1

This schedule was i ntroduced under the Drugs and Cosmetics (4 th Amendment) Rules 2013, by MOHFW on 30August, 2013 vide GSR 588(E) to control the sale of antibiotics. It has a separate regulation to check unauthorised sale of antibiotics, hence monitors the use and abuse of these antibiotics. The drugs under Schedule H are labelled with symbol "Rx" in red noticeably displayed on the left corner of the label with the next words in box with red border. Some **examples** are Alprazolam, Gemifloxacin, Isoniazid, Cefixime, Levofloxacin, Cefpodoxime, Clofazimine, Zolpidem, etc.

Warning

1) It is dangerous to take this preparation except in accordance with the medical advice.
2) It is not sold by retail without the prescription of a RMP.

2.1.4. Schedule M

This schedule deals with **Good Manufacturing Practices and Requirements of Pilot Equipment for Allopathic Drugs**:

1) **Location and Surrounding:** The factory should be located in a place not adjacent to an open sewage, drain, public lavatory , or a factory producing offensive odour or fumes or huge a mount of soot, dust or , smoke. The factory should be situated in a sanitary place, distant from dirty surrounds.

2) **Buildings:** The buildings used for the factory should be made at licence production under hygienic situations, and should meet the conditions given in the Factories Act, 1948. The part of the building used for manufacture should not be used as a sleeping place and no sleeping place should be present in its vicinity. The walls of the rooms in which manufacturing process es are done should be 6 feet high from the floor. The walls should be smooth, wate r-proof, and easily cleanable. The floor should be smooth, even, washable, and should not allow dust accumulation. There should be no cracks or gaps in the walls or floor.

3) **Water Supply:** The water used in manufacturing process should be pure and drinkable. It should be free from pathogenic microorganisms.

4) **Waste Disposal:** Waste water and other residues from the laboratory may be harmful to the workers or the public health , thus should be disposed off after appropriate treatment to reduce them inoffensive.

5) **Health, Clothing , and Sanitary Requirements of the Staff:** All workers should be free from transmissible disease s. Their clothing should be clean and should have white or coloured uniform appropriate to the nature of work and the climate.

6) **Medical Services:** The manufacturer should provide the following facilities:
   i) Suitable facilities for first aid.
   ii) Medical inspection of the workers the time of employment, followed by periodic check-up at least once a year.
   iii) Services for vaccination and inoculation against enter ic or other epidemic group of diseases.

iv) Precautions for safeguarding the head of the workers, and alos suitable measures to avoid industrial accidents or diseases.

7) **Working Benches:** These are used by the workers for carrying out filling, labelling, packi ng operations, etc. Arrangements, separated from the manufacturing operations, for the washing, cleaning and drying containers with suitable equipment for the purpose are provided. Sterilising facilities should also be provided wherever required.

Requirements of Plant and Equipment

1) The following equipment is required for **manufacturing ointments**, **emulsions** or **lotions**, and **suspensions**:
   i) Mixing tanks,
   ii) Kettle, steam, gas or electrically heated,
   iii) A suitable power driven mixer,
   iv) Storage tanks or pots,
   v) A colloid mill or a suitable emulsifier,
   vi) A triple roller mill or an ointment mill,
   vii) Liquid filling equipment, and
   viii) Jar or tube filling equipment.

   An area of 30 square metres is required for the basic installations.

2) The following equipment is required for **manufacturing syrups**, **elixirs**, and **solutions**:
   i) Mixing and storage tanks,
   ii) Portable mixer,
   iii) Filter press or other suitable filtering equipment, such a s metafilter or sparkler filter,
   iv) Vacuum or gravity filter, and
   v) Water still or deioniser.

   An area of 30 square metres is required for the basic installations.

3) Equipment for **manufacturing pills** and **compressed tablets** including **hypodermic tablets** are divided into the following sections:
   i) **Granulation Section:**
      a) Disintegrator,
      b) Powder mixer,
      c) Mass mixer,
      d) Granulator, and
      e) Ovens, thermostatically controlled.
   ii) **Tableting Section:**
      a) Tablet machine, single punch or rotary,
      b) Pill machine,
      c) Punch and dies storage cabinet, and
      d) Tablet counter.
   iii) **Coating Section:**
      a) Jacketed kettle, steam, gas or electrically heated for preparing solution,
      b) Coating pan,

c) Polishing pan, and
d) Heater and exhaust system.

4) The following equipment is required for **manufacturing powders**:
i) Disintegrator,
ii) Mixer,
iii) Sifter,
iv) Stainless steel vessels and scoops of suitable material, and
v) Filling equipment.

An area of 30 square metres is required to allow for the basic operation.

5) The following equipment is required for **filling of hard gelatin capsules**:
i) Mixing and blending equipment,
ii) Capsule filling units, and
iii) Capsule counters.

An area of 20 square meters is required for the basic installations for capsules filling. The room shall be air conditioned and also dehumidified.

6) The following equipment is required for **manufacturing surgical dressings**:
i) Rolling machine,
ii) Trimming machine,
iii) Cutting equipment,
iv) Folding and pressing machine for gauze,
v) Mixing tanks for processing medicated dressings,
vi) Hot air drying ovens, and
vii) Steam steriliser or dry heat sterilizer.

An area of 30 square metres is required for the basic installations.

7) The following equipment is required for **manufacturing** other preparations for external use **under aseptic conditions**:
i) Hot air oven electrically heated with thermostatic control,
ii) Kettle, gas or electrically heated with suitable mixing arrangement,
iii) Colloid mill or ointment mill,
iv) Tube filling equipment,
v) Mixing and storage tanks of stainless steel or of other suitable materials,
vi) Sintered glass funnel, seitz filter or filter candle,
vii) Liquid filling equipment, and
viii) Autoclaves.

An area of 25 square meters is required for the basic installations. The manufacture and filling should be carried out in an air -conditioned room which should also be dehumidified if antibiotic-containing preparations are being manufactured.

8) The following equipment is required for **manufacturing pessaries** and **suppositories**:
i) Mixing and pouring equipment, and
ii) Moulding equipment.

An area of 20 square metres is required for the basic installations.

9) The following equipment is required for **manufacturing inhalers** and **vitrallae**:
   i) Mixing equipment,
   ii) Graduated delivery equipment for measurement of the medicament, and
   iii) Sealing equipment.

   An area of 20 square metres is required for the basic installations.

10) The following equipment is required for **repacking installations** of drugs and pharmaceutical chemicals:
   i) Sifter,
   ii) Stainless steel scoops and vessels,
   iii) Weighing and measuring equipment, and
   iv) Filling equipment.

   An area of 30 square metres is required for basic packing operations.

11) The **manufacturing process of parenteral preparations** is divided as follows:
   i) Preparation of containers including cutting, washing, drying and sterilisation of ampoules or vials prior to filling,
   ii) Preparation of solution including preparation and filtration of solution,
   iii) Sterilisation, and
   iv) Testing.

   The following equipment is recommended:
   i) **Manufacturing Area**
      a) Storage equipment for ampoules and vials,
      b) Ampoule washing and drying equipment,
      c) Dust proof storage cabinets,
      d) Water still,
      e) Mixing and prepar ation tanks or other containers made of either glass or such material as will not react with the liquids,
      f) Filtering equipments such as filter press or sintered glass funnel,
      g) Autoclave, and
      h) Hot air steriliser.

   ii) **Filling and Sealing Room**
      a) Benches for filling and sealing,
      b) Filling and sealing unit.

   iii) **Aseptic Filling and Sealing Rooms**
      a) Bacteriological filters such as seitz filter, candles or sintered glass filters,
      b) Filling and sealing unit.

   iv) **General Room**
      a) Inspection table,
      b) Leak testing equipment, and
      c) Storage equipment including cold storage and refrigerators, if necessary.

2.1.5. Schedule N

This schedule includes the **List of Minimum Equipment for the Efficient Running of a Pharmacy**. These requirements are:

1) **Entrance:** The front of a pharmacy should have an inscription "Pharmacy".

2) **Premises:** The pharmacy premises should be separated from rooms for private purposes. The premises should be well -built, dry, properly lit, ventilated, and of suf ficient dimensions to allow the goods in stock (mainly medicaments and poisons) to be kept in a clearly visible locker. The areas of the section used as dispensing department should not be less than 6 m^2 for a pharmacist working there and additional $2m^2$ for each additional pharmacist. The premises should have a minimum height of $2.5m^2$.

   The pharmacy floor should be smooth and washable. The walls should be plastered or tiled or oil painted so that the surface is smooth, durable , washable, and has no holes, cracks, and gaps. Water of good quality should be supplied to the pharmacy in sufficient amount. The dispensing department should be separated through a barrier to inhibit the entrance of public.

3) **Furniture and Apparatus:** The furniture and apparatus of a pharm acy should be designed as per their uses and should correspond to the size and need of the establishment.

   Drugs, chemicals, and medicaments should be kept in a room in special containers to inhibit the deterioration of contents within or those in the vicinity. Droppers, glasses , and other containers used for storing the medicaments should be of proper size and tightly closed to inhibit the entry of dust. Each container should have a label of proper size, readable, and having names of medicaments as given in the Pharmacopoeias.

   A pharmacy should have a dispensing bench, which should be covered with a washable and impermeable material (such as stainless steel, laminated plastic, etc.) from the top.

   A pharmacy should have a cupboard with lock and key for storing poisons. This cupboard should be marked with the word "POISON" in red letters on a white background. Containers of all concentrated solutions should have a different label marked with the words 'To be diluted'.

   Any container taken from the poison cupb oard should be replaced immediately after use and the cupboard should be locked properly. The keys should be in the personal custody of the responsible person.

   A pharmacy should have the following apparatus and books required for making official preparations and prescriptions:

   Apparatus

   i) Balance, dispensing, sensitivity 30mg,
   ii) Balance, counter, capacity 3 kgm, sensitivity 1g,
   iii) Beakers, lipped, assorted sizes,
   iv) Bottles, prescription, ungraduated assorted sizes,
   v) Corks assorted sizes and tapers,

vi) Cork extractor,
vii) Evaporating dishes, porcelain,
viii) Filter paper,
ix) Funnels, glass,
x) Litmus paper, blue and red,
xi) Measure glasses, cylindrical 10ml, 25ml, 100ml, and 500ml,
xii) Mortars and pestles, glass,
xiii) Mortars and pestles, wedgewood,
xiv)Ointment pots with bakelite or suitable caps,
xv) Ointment slab, porcelain,
xvi)Pipettes, graduated 2ml, 5ml, and 10ml,
xvii) Ring, stand (retort) iron, complete with rings,
xviii) Rubber stamps and pad,
xix)Scissors,
xx) Spatulas, rubber or vulcanite,
xxi)Spatulas, stainless steel,
xxii) Spirit lamp,
xxiii) Glass stirring rods,
xxiv) Thermometer, 0°to 200°C,
xxv) Tripod stand,
xxvi) Watch glasses,
xxvii)Water bath,
xxviii) Water distillation still in case eye drops and eye lotions are prepared
xxix) Weights, Metric, 1mg. to 100g, and
xxx) Wire Gauze:
   a) Pill finisher, boxwood,
   b) Pill machine,
   c) Pill Boxes.

Books

i) The Indian Pharmacopoeia (current edition),
ii) National formulary of India (current edition),
iii) The Drugs and Cosmetics Act, 1940,
iv) The Drugs and Cosmetics Rules, 1945,
v) The Pharmacy Act, 1948, and
vi) The Narcotic Drugs and Psychotropic Substances Act.

4) **General Provisions:** A ph armacy should be under the continuous supervision of a registered pharmacist whose name should be displayed noticeably in the premises. The pharmacist should always put on clean overalls. The premises and fittings of the pharmacy should be in good order and clean. All records and registers should be regulated in agreement with the laws in force.

2.1.6. Schedule P

This schedule deals with the **Life Period of Drug**s and the storage conditions of drugs. The period should be in months between date of manufacture and d ate of expiry. The schedule comprises of antibiotics, vitamins, insulin preparation, normal human plasma, sera toxins, toxoids, other toxins, anti-toxins, etc.

Drugs	Life Period (Months)	Storage
Adramycin	30	In a cool place
Ampicillin	36	In a cool place
Ampicillin Sodium	36	In a cool place
Ampicillin trihydrate	30	In a cool place

Schedule P_1

This schedule specifies the **Pack Size of Drugs**. It provides the names of drugs, along with the dosage form and the pack size. No other pack size than the on e listed under this schedule should be marked.

Drugs	Dosage Forms	Pack Sizes
Aspirin (Low Dose)	Tablets	14 tabs
Cholecalciferol	Granules	1gm sachet
Famotidine	Tablets	14 tabs
Glyceryl Trinitrate	Capsules	25 cap

2.1.7. Schedule T

This schedule deal s with **Good Manufacturing Practices for Ayurvedic, Siddha, and Unani Medicines**.

1) **Factory Premises:** The manufacturing plant should have adequate space for:
   i) Receiving and storing raw material,
   ii) Manufacturing process areas,
   iii) Quality control section,
   iv) Finished goods store,
   v) Office, and
   vi) Rejected goods/drugs store.

2) **Location and Surroundings:** For the manufacturing of Ayurveda, Siddha , and Unani medicines, the factory building should be situated and constructed to avoid contamination from open sewerage, drain, public l avatory for any factory forming loathsome odour or fumes or extreme soot, dust and smoke.

3) **Buildings:** The factory buildings should facilitate drug production under hygienic conditions free from cobwebs and insects/rodents. The buildings should have proper facility of light and ventilation. The floor and the walls should not be damp or moist. The buildings used for manufacturing, processing, packaging , and labelling should be in conformity with the provisions of the Factory Act.

4) **Water Supply:** Pure and potabl e water should be used in manufacturing. Sufficient provisions of water should be available for washing the premises.

5) **Disposable of Waste:** The waste water and the residues f rom the manufacturing section and laboratories should be disposed off properly as i t may be harmful to the workers and public health.

6) **Container's Cleaning:** The factory areas where containers like glass bottles, vials and jars are used should have enough arrangements separated from the

manufacturing operations for washing, cleaning and dr ying of such containers.

7) **Stores:** These areas should have appropriate ventilation and should be free from dampness. The stores should have ample of space for storing different types of material s, like raw material s, packaging material s, and finished products.

8) **Raw Materials:** For manufacturing the raw materials should be stored in the raw materials store. Every container for raw material storage should be appropriately labelled specifying the name of the raw material, its source of supply, and also the status like UNDER TEST or APPROVED or REJECTED.

9) **Packaging Materials:** Bottles, jars, capsules etc. should be suitably stored. All containers and closure s should be sufficiently cleaned and dried before packing the products.

10) **Finished Goods Stores:** After proper pack aging, the finished goods transferred from the production area should be stored in the finished goods stores in quarantine area. After the accuracy of finished goods quality (its packaging and labelling) is checked by the quality control laboratory, they should be moved to 'Approved Finished Goods Stock' area.

11) **Working Space:** Manufacturing area should have enough space (manufacture and quality control) for proper arrangement of equipment and materials used in any operations to ease the safe working , to reduce or remove the risk of mix -up between different drugs, raw materials , and to inhibit the chances of cross contamination of one drug with another drug manufactured, stored, or handled in the same sites.

12) **Health Clothing, Sanitation, and Hygiene of Workers:** The workers should not have any contagious diseases. The ir clothing should have proper and clean uniform appropriate to the nature of work and climate. The uniform should have cloth or synthetic co vering for hands, feet , and head . Facilities for personal cleanliness like clean towels, soap and scrubbing brushes should be available. Separate provision should be made for lavatories to be used by men and women, and these lavatories should be situated at places away from the proces sing rooms. Facilities for ch anging clothes and to keep personal belongings should also be provided to the workers.

13) **Medical Services:** The manufacturer should provide services for first aid, medical examination of the workers at the time of employment, and periodical check-up (once a y ear) by a physician to make sure the workers have no infections. Records for such details should be maintained.

14) **Machinery and Equipments:** Manufacturing should be done using appropriate equipment (either manually operated or semi -automatic or fully automatic) based on the operation size and the nature of manufactured product. These equipments should be correctly installed and kept clean.

15) **Batch Manufacturing Records:** The licensee should maintain batch manufacturing record of each batch of Ayurvedic, Sidd ha an d Unani drugs

manufactured. These records give an account of the list of raw materials and their quantities obtained from the store, tests conducted during the different phases of manufacture such as taste, colour, physical features and chemical tests.

16) **Distribution Records:** Records of sale and distribution of each batch of Ayurveda, Siddha and Unani drugs should be maintained for the quick recall of the batch, whenever required.

17) **Record of Market Complaints:** A register to record all the reports of market complaints related to the products sold in the market should be maintained. The manufacturer should submit the record of such complaints to the licensing authority once in every six months.

18) **Quality Control:** Every licensee should provide a quality control section in his premises or by Government approved testing laboratory. The test s in this section should be conducted as per the Ayurveda, Siddha and Unani Pharmacopoeial standard.

2.1.8. Schedule U

This schedule deals with **Particulars to be shown in Manufacturing Records**:

1) **Substances Other than Parenteral Preparations in General**
   - i) Serial number,
   - ii) Name of the product,
   - iii) Reference of Master Formula Records,
   - iv) Lot/Batch size,
   - v) Lot/Batch number,
   - vi) Date of beginning and completing the manufacture and assigned date of expiry,
   - vii) Name of all ingredients and their quantities,
   - viii) Control numbers of raw materials used in the formulation,
   - ix) Date, time, and duration of mixing,
   - x) Details of environmental controls like room temperature, relative humidity,
   - xi) Date of granulation, wherever applicable,
   - xii) Theoretical weight and actual weight of granules/powder blend,
   - xiii) Records of in-processes controls:
     - a) Uniform 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.
   - xiv) Date of compression of tablets or date of filling of capsules,

xv) Date of sealing, coating, or polishing of capsules and tablets.,
xvi) Reference to analytical report number indicating the result of analysis,
xvii) Separate records of the disposal of rejected batches and of the batches withdrawn from the market,
xviii) Theoretical yield an d actual production yield and packing particulars indicating the size and quantity of finished packings,
xix) Specimen of label , carton with batch coding information like batch number, manufacture and expiry date, retail price and inserts used in the finished packings,
xx) Date and signature of the skilled technical staff,
xxi) Counter-signature of the head of the testing units or other approved person-in-charge of testing who has verified the batch records and released the batch for sale and distribution,
xxii) The release date and quantity released of finished packings for sale and distribution,
xxiii) The quantity of finished packings transferred to warehouse, and
xxiv) Records should be maintained for hypodermic tablets and ophthalmic preparations manufa ctured under aseptic conditions t o indicate the precautions taken during the ir manufacturing to confirm that aseptic conditions were maintained.

2) **Parenteral Preparations:** (i) to (x) points are same as that of **Substances Other than Parenteral Preparations in General**:
   i) pH of the solution,
   ii) Date and method of filtration,
   iii) Sterility test, reference on bulk batch wherever applicable,
   iv) Record of check on volume filled,
   v) Date of filling,
   vi) 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, and
      d) Toxicity test, wherever applicable.
   vii) Records of checking of instruments and apparatus of sterilisation,
   viii) Records of cleaning and sterilisation of containers and closures,
   ix) Records of heat sterilisation of parenteral preparations comprising of the time, temperature, and pressure used. These records should be marked to relate to the sterilisation of the batch,
   x) Number and size of containers filled and quantity rejected,
   xi) Reference to analytical report numbers stating whether or not of standard quality,
   xii) Records should be maintained to indicate the precautions taken during the manufacturing to confirm that aseptic conditions were maintained,
   xiii) Points (xvii) to (xxi) are of **Substances Other than Parenteral Preparations in General**, and
   xiv) Records of reprocessing and particulars of reprocessing.

Records of Raw Materials

Records related to each raw material should be maintained properly to indicate the receipt date, invoice number, name and address of the manufacturer/supplier, batch number, quantity received, pack size, manufacture and expiry date, date of analysis (if any), release/rejection by quality control, analytical report number (if any), quality issued, date of issue , and details of the name and batch numbers of products, and proper disposal of the stocks.

Particulars to be shown in the Analytical Records

1) **Tablets and Capsules:**
   i) Analytical report number,
   ii) Name of the sample,
   iii) Date of receipt of sample,
   iv) Batch/Lot number,
   v) 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, and
      g) Results of assay.
   vi) Signature of the analyst, and
   vii) Opinion and signature of the approved analyst.

2) **Parenteral Preparations:** (i) to (iv) points are same as that of **Tablets and Capsules**:
   i) Number of containers filled,
   ii) Number of containers received,
   iii) Protocols of tests applied,
      a) Clarity,
      b) pH wherever applicable,
      c) Identification,
      d) Volume in container,
      e) Sterility:
         - Bulk sample wherever applicable,
         - Container sample.
      f) Pyrogen test, wherever applicable,
      g) Toxicity test, wherever applicable,
      h) Any other tests, and
      i) Results of Assay.
   iv) Points (vi) and (vii) are of **Tablets and Capsules**.

3) **For Other Drugs :** (i) to (iv) points are same as that of **Tablets and Capsules**:
   i) Protocol of tests applied:
      a) Description,
      b) Identification,

c) Any other tests, and
d) Results of assay.

ii) Points (vi) and (vii) are of **Tablets and Capsules**.

4) **Raw Materials**
i) Serial number,
ii) Name of the materials,
iii) Name of the manufacturer/supplier,
iv) Quantity received,
v) Invoice/Challan number and date, and
vi) Protocols of tests applied.

5) **Container Packing Materials, etc. :** (i) to (vi) points are same as that of **Raw Materials**:
i) Remarks,
ii) Signature of the examiner.

2.1.9. Schedule V

This schedule deals with **Standards for Patent or Proprietary Me dicines**. Subject to the provisions of these rules, patent or proprietary medicines should fulfil the following standards:

1) Patent or proprietary medicines should fulfil the following needs:
i) **Tablets:** Medicines should fulfil the needs for tablets as given in the I.P. The nature of coating and the permitted colours should be added on the label. Nature of tablets (uncoated, sugar coated, or film coated) should be given on the label.

ii) **Capsules:** Medicines should fulfil the requirements for capsules as given in the I.P. The capsules should be free from distortion , discolouration , and other physical defects such as leakage of powder from joints, pinholes or cracks.

iii) **Liquid Oral Dosage Forms:** On shaking, e mulsions 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 90-110% of the labelled contents.

iv) **Injections:** Medicines should fulfil the needs for injections as given in the I.P.

v) **Ointments:** Medicines should fulfil the needs for ointments as given in the I.P.

2) The content of active ingredients, other than vitamins, enzymes , and antibiotics, should be between 90 -110% of the labelle d content. In dry formulations of antibiotics, the limit should be 90 -130% of the labelled contents. In liquid antibiotic s, the limit should be 90 -140% of the labelled contents.

3) All patent or proprietary medicines having aspirin should undergo free salicylic acid test, the limit of which should be 0.75%.

4) 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 60kg human.
5) In injectable patent or proprietary medicines , the test for freedom from toxicity should be conducted as given in the I.P.

2.1.10. Schedule X

This schedule deals with the **List of Narcotic Drugs and Psychotropic Substances**. Amobarbital, ampheta mine, barbital, cyclobarbital, dexamphetamine, ethchlorvynol glutethimide, meprobamate, methaqualone, methylphenobarbital, pentobarbital, phencyclidine, phenmetrazine, phenobarbital, secobarbital are the **examples** of drugs comes under schedule X.

Any stereoisometric form of the substance specified in this Schedule, any salt of the substance and preparation containing such substances are also covered by this Schedule. Preparations containing the above substances are also covered by this Schedule.

2.1.11. Schedule Y

This schedule deals with the **Requirements and Guidelines for Permission to Import and/or Manufacture of New Drugs for Sale or to Undertake Clinical Trials**.

1) **Application for Permission:** Application for approval to import or manufacture new drugs for sale or to undertake clinical trials should be made in Form 44 along with the following data:
   i) Chemical and pharmaceutical information,
   ii) Animal pharmacology data:
      a) Certain pharmacological actions and therapeutic potential for humans should be defined as per the ani mal models and species used,
      b) General pharmacological actions, and
      c) Pharmacokinetic data of the test substance.
   iii) Animal toxicology data,
   Human clinical pharmacology data:
      a) Clinical trials for new drug substances discovered in India are carried out from Phase I and related data should be submitted.
      b) The data needed will be based on the purpose of the new drug application. The number of study subjects and sites to be involved in the clinical trial will be based on the study nature and objective.
      c) Application for p ermission to start a phase of clinical trial should also have the investigator„s brochure, proposed protocol, case record form, study subject„s informed consent document(s), investigator„s undertaking, and ethics committee clearance.
      d) The study report shou ld be certified by the p rincipal investigator, otherwise by each investigator involved in the study.

v) Regulatory status in other countries having information on limits enforced, on the use of drug s in other countries (such as dosage limits, exclusion of s pecific age groups, warning related to adverse drug reactions, etc.).

vi) The prescribing information should be submitted as part of the new dru g application for marketing. This information (package insert) should include generic nam e, composition, dosage form , indications, dose, administration method, use in special populations (like pregnant women, lactating women, paediatric s, geriatric s, etc.), contraindications, warnings, precautions, drug interactions, side effects, overdose, pharmacodynamic and pharmacok inetic properties, incompatibilities, shelf-life, packaging information, storage and handling instructions.

vii) As a part of new drug application for marketing, the testing protocol for quality control testing with complete impurity profile and release specifications for the product should be submitted.

2) **Clinical Trial:**

i) **Human Pharmacology (Phase I):** The aim of this phase is to estimate the safety and tolerability with the initial administration of an investigational new drug to human(s). Drugs with potential toxicity (such as cytotoxic drugs) are mainly studied. Phase I trials should be conducted by i nvestigators skilled in clinical pharmacology who carefully observe and monitor the subjects. Following are the **objectives** of studies conducted in phase I trials:

a) **Maximum Tolerated Dose:** It is done to regulate the tolerability of the dose range that may be required in future for clinical studies and to control the nature of expected adverse reactions.

b) **Pharmacokinetics:** It is done to characterise a drug's absorptio n, distribution, metabolism, and excretion.

c) **Pharmacodynamics:** The pharmacodynamic data acquired from the subjects can lead the dosage and dose regimen to be used in later studies if there are suitable validated sign of ac tivity and potential efficacy.

d) **Early Measurement of Drug Activity:** Preliminary studies of activity or potential therapeutic benefits are conducted in later phases; however it is suitable when drug activity can be easily measured with a small duration of drug exposure in patients at this initial stage.

ii) **Therapeutic Exploratory Trials (Phase II):** The main objective of phase II trials is to assess the efficiency of a drug for a specific indication/s in patients with the situations under study. Another objective is to determine the common short -term side -effects and risks related to the drug.

iii) **Therapeutic Confirmatory Trials (Phase III):** The main objective of phase III trials is to demonstrate the therapeutic benefits, to confirm the

results of Phase II that a drug is safe and effective for a parti cular indication and recipient population. These studies should provide a suitable basis for marketing approval.

iv) **Post Marketing Trials (Phase IV):** These studies are done after the approval of drug and related to the approved indication(s). These trials go beyond the previous demonstration of the drug„s safety, efficacy, and dose. These trials cannot be considered necessary at the time of new drug approval, however can be needed by the Licensing Authority for optimising the drug's use. Phase IV trials compr ise additional drug-drug interaction(s), dose response or safety studies , and trials intended to support use under the approved indication(s), such as mortality/morbidity studies, epidemiological studies, etc.

2.1.12. Schedule F - Part XII B

This schedule deals with the **Requirements for the Functioning and Operation of a Blood Bank and/or for Preparation of Blood Components**.

1) **General Requirements:**
   i) **Location and Surroundings:** The blood bank should be at a place away from open sewage, drain, public lavatory, or unhygienic surroundings.
   ii) **Buildings:** The building s used for operation of a blood bank and/or preparation of blood components should be build such that all the operations and manufacturing are done under hygienic conditions. Also, the entry of insects, rodents , a nd flies should be avoided. The building should be adequately lighted, ventilated , and screened. The walls and floors of premises where collection of blood or preparation of blood components or blood products is done should be smooth, washable, and cleanable.
   iii) **Health, Clothing and Sanitation of Staff:** The employees should not have contagious or infectious diseases. They should wear clean overalls, head-gears, foot-wears, and gloves. The premises should have clean and convenient hand washing and toilet services.

2) **Accommodation for a Blood Bank:** A blood bank should be of 100m^2 area to carry out the operations, and an extra 50 m^2 area for preparation of blood components. It should have room for:
   i) Registration and medical examination with enough furniture and services for registration and selection of donors,
   ii) Blood collection (air-conditioned),
   iii) Blood component preparation (air-conditioned to maintain temperature between 20-25°C),
   iv) Laboratory for blood group serology (air-conditioned),
   v) Laboratory for blood transmissib le diseases like hepatitis, syphilis, malaria, and HIV-antibodies (air-conditioned),
   vi) Sterilisation-cum-washing,
   vii) Refreshment-cum-rest room (air-conditioned), and
   viii) Store-cum-records.

3) **Personnel:** Each blood bank should have the following groups of full time competent technical staff:
   i) Medical officer with required qualifications,
   ii) Blood bank technician(s) with:
      a) Degree in Medical Laboratory Technology (M.L.T) from a Central or State Government recognised university/institution and 6 months' experience in the testing of blood and/or its components, or
      b) Diploma in Medical Laboratory Technology (M.L.T) from a Central or State Government recognised university/institution and a year's experience in the testing of blood and/or its components.
   iii) Registered nurse(s), and
   iv) Technical supervisor with:
      a) Degree in Medical Laboratory Technology (M.L.T) and 6 months' experience in the preparation of blood components, or
      b) Diploma in Medical Laboratory Technology (M.L.T) and a year's experience in the preparation of blood components.

4) **Maintenance:** The premises should be clean and properly managed for accurate cleaning and operation maintenance. The following facilities should be included:
   i) Privacy and thorough examination of individuals should be done for determining whether or not they are suitable donors,
   ii) Collection of blood from donors with negligible risk of contamination of exposure to actions and equipment unconnected to blood collection,
   iii) Storage of blood or blood components pending completion of tests.
   iv) Provision for quarantine and storage of blood and blood components pending repetition of the tests that initially gave questionable serological results.
   v) Provision for quarantine, storage, handling, and disposal of products and reagents not suitable for use.
   vi) Storage of finished products prior to distribution.
   vii) Proper collection, processing, compatibility testing, storage, and distribution of blood and blood components to prevent contamination.
   viii) Proper conduction of all plasmapheresis, plateletpheresis and leucapheresis procedures.
   ix) Proper conduction of all packaging, labelling, and finishing operations.
   x) Provisions for disposal of blood and/or blood components not suitable for use, distribution, or sale. Also provisions for trash and items used during the collection, processing and compatibility testing of blood and/or blood components are available.

5) **Equipment:** Collection, processing, testing, storage, and sale/distribution of blood require clean equipments, which should be observed, standardised, and calibrated regularly.

General Equipments and Instruments

i) **For Blood Collection Room:**
   a) Donor beds, chairs and tables of appropriate size should be suitably and comfortably cushioned.
   b) Beside table.

c) Sphygmomanometer and stethoscope.
d) Recovery beds for donors.
e) Refrigerators, for storing separately tested and untested blood, maintaining temperature between 2 -6°C with digital dial thermometer, recording thermograph and alarm device, with provision for continuous supply.
f) Weighing devices for donor and blood containers.

ii) **For Haemoglobin Determination:**
a) Copper sulphate solution,
b) Sterile lancet and impregnated alcohol swabs,
c) Capillary tube (1.3 × 1.4 × 96mm for Pasteur pipettes),
d) Rubber bulbs for capillary tubings, and
e) Sahli's haemogolobinometer/Colorimetric method.

iii) **For Temperature and Pulse Determination:**
a) Clinical thermometers,
b) Watch (fitted with a second-hand) and a stop-watch.

iv) **For Blood Containers:**
a) Only disposable PVC blood bags shall be used (closed system) as per specifications of IP/USP/BP.
b) Anti-coagulant solution, which should be sterile, pyrogen -free, and of such composition that will ensure satisfactory safety and efficacy of the whole blood and/or for all the separate blood components.
c) Citrate Phosphate Dextrose Adenine solution (CPDA) or Citrate Phosphate Dextrose Adenin-1 (CPDA-1) solution should be required for 100ml of blood.

v) **Emergency Equipments/Items**
a) Oxygen cylinder with mask, gauge and pressure regulator,
b) 5 per cent Glucose or Normal Saline,
c) Disposable sterile syringes and needles of various sizes,
d) Disposable sterile I.V. infusion sets,
e) Ampoules of adrenaline, noradrenaline, mephentin, betamethasone, dexamethasone, and metoclopramide injections, and
f) Aspirin.

vi) **Accessories**
a) Such as blankets, emesis basins, haemostats, set clamps, sponge forceps, gauze, dressing jars, solution jars, waste cans,
b) Medium cotton balls, 1.25cm adhesive tapes,
c) Denatured spirit, tincture iodine, green soap or liquid soap,
d) Paper napkins or towels,
e) Autoclave with temperature and pressure indicator,
f) Incinerator, and
g) Stand-by generator.

vii) **Laboratory Equipment**
a) Refrigerators, for storing diagnostic kits and regents, maintaining a temperature between 4 -6°C (±2°C) with digital dial thermometer having provision for continuous power supply,

b) Compound microscope with low and high power objectives,
c) Centrifuge table model,
d) Water bath between 37-56°C,
e) Rh viewing box in case of slide technique,
f) Incubator with thermostatic control,
g) Mechanical shakers for serological tests for syphilis,
h) Hand-lens for observing tests conducted in tubes,
i) Serological graduated pipettes of various sizes,
j) Pipettes (Pasteur),
k) Glass slides,
l) Test tubes of various sizes/micrometre plants (U or V type),
m) Precipitating tubes 6mm × 50mm of different sizes and glass beakers of different sizes,
n) Test tubes racks of different specifications,
o) Interval times electric or spring wound,
p) Equipment and materials for cleaning glass wares adequately,
q) Insulated containers for transporting blood, between 2 -10°C temperatures, to wards and hospitals,
r) Wash bottles,
s) Filter papers,
t) Dielectric tube sealer,
u) Plain and EDTA vials,
v) Chemical balance (wherever necessary), and
w) ELISA reader with printer, washer and micropipettes.

6) **Supplies and Reagents:** All the supplies and reagents utilised in the collection, processing, c ompatibility testing, storage , and distribution of blood and blood components should be stored in a safe and hygienic area at a proper temperature:
   i) The supplies coming in contact with blood and blood components to be used for transfusion should be sterile, pyrogen -free, and should not interact with the product in a way to produce an adverse effe ct on the safety, purity, potency, or effectiveness of the product.
   ii) The supplies and reagents not having an expiry date should be stored in a way that the oldest one is used first.
   iii) The supplies and reagents should be used in a way consistent with instructions given by the manufacturer.
   iv) The final containers and closures for blood and blood components not to be used for transfusion should be clean and free of surface solids and other contaminants.
   v) The blood collecting containers and satellite containers (if any) should be visually examined for damage or contamination prior to use and also after filling. The examination should include inspection for breakage of seals and abnormal discoloration. In case of any defect, the container should not be use d. If the def ect is detected after filling , the container should be discarded.

vi) Representative samples of each lot of the following reagents and/or solutions should be tested periodically by methods given in the Standard Operating Procedures Manual for determining their performing ability.

Special Reagents

i) Standard blood grouping sera anti-A, anti-B and anti-D with known controls. Rh typing sera shall be in double quantity and each of different brands or if from the same supplier each supply shall be of different lot numbers.
ii) Reagents for serological tests for syphilis and positive sera for controls.
iii) Anti-human globulin serum (Coomb's serum).
iv) Bovine albumin 22% enzyme reagents for incomplete antibodies.
v) ELISA or RPHA test kits for hepatitis and HIV I and II.
vi) Detergent and other agents for cleaning laboratory glass wares.

7) **Criteria for Blood Donation:**

i) No one should donate blood and no blood bank should draw blood from a person more than once in three months. The donor should be in good health, mentally alert , physically f it, and should not be jail prisoners, having multiple sex partners , and drug -addicts. The donors should comply with the following requirements:
   a) The donor should be in the age group of 18-65 years,
   b) The weight of the donor should not be less than 45kg,
   c) Temperature and pulse of the donor should be normal,
   d) The systolic and diastolic blood pressure of the donor should be normal without medication,
   e) Haemoglobin should not be less than 12.5gm,
   f) The donor should not have any acute respiratory diseases,
   g) The donor shou ld not have any skin dis eases at the site of phlebotomy,
   h) The donor should not have any disease that could be transmitted via blood transfusion, and
   i) The arms and forearms of the donor should not have any punctures or scars indicative of professional blood d onors or addiction of self - injected narcotics.

ii) **Additional Qualifications of Donor:** No one should donate blood and no blood bank should take blood from a donor under the conditions given in column (1) and before the expiry of the deferment period given in column (2) of the **table 2.1**:

Table 2.1: Deferment of Blood Donation

Conditions	Deferment Period
Abortions	6 months
History of blood transfusion	6 months
Surgery	12 months
Typhoid	12 months after recovery
History of malaria and duly treated	2 months (endemic) and 3 years (non-endemic area)

Tattoo	6 months
Breast feeding	12 months after delivery
Immunisation (Cholera, Typhoid, Diphtheria, Tetanus, Plague, Gammaglobulin)	15 days
Rabies vaccination	1 year after vaccination
History of Hepatitis in family or close contact	12 months
Immunoglobulin	12 months

iii) No one should donate blood and no blood bank should take blood from an individual suffering from cancer, heart disease, abnormal bleeding tendencies, unexplained weight loss , diabetes-controlled on insulin , hepatitis, chronic nephritis, signs and symptoms of AIDS, liver diseases, tuberculosis, polycythemia, asthma, epilepsy, leprosy, schizophrenia, and endocrine disorders.

8) **Testing of Whole Blood:**

i) The licensee should confirm that the whole blood collected, treated, and supplied obeys the standards given in the I.P. and other tests published by the Government.

ii) The licensee should get blood samples tested (prior to use) for freedom from HIV 1 and HIV II antibodies either from the Central Government laboratories or from his own laboratory. The results of such tests should be mentioned on the container label.

iii) The blood units should also be tested to be free from Hepatitis B surface antigen and Hepatitis C Virus antibody and malarial parasite. The results of such tests should be mentioned on the container label.

9) **Records:** The licensee should maintain records including the following particulars:

i) **Blood Donor Record:** It shows serial number, date of bleeding, name, address, signature, age, weight, haemoglobin, blood group, blood pressure, and medical examination of the donor, bag number, and details of the patient for whom blood was donated in case of replacement donation, donation category (voluntary/ replacement), deferral records, and signature of the medical officer in-charge.

ii) **Master Records for Blood and its Components:** It shows the bag serial number, date of collection, date of expiry, and quantity in ml.

iii) **Issue Register:** It shows serial number, date and time of issue bag serial number, ABO/RH Group, tot al quantity in ml, name and address of the recipient, group of recipient, unit/institution, details of cross-matching report, and indication for transfusion.

iv) **Records of Components Supplied :** It shows the quantity supplied, compatibility report, details of recipient, and signature of issuing person.

v) Records of ACD/CPD/CPD -A/SAGM bags show the details of manufacturer, batch number, date of supply, and results of testing.

vi) **Register for Diagnostic Kits and Reagents Used:** It shows name of the kits/reagents, details of batch number, date of expiry, and date of use.

vii) Blood bank should issue the cross -matching report of the blood to the patient together of the blood unit.

viii) Transfusion adverse reaction records.

ix) Records of purchase, use and stock in hand of disposabl e n eedles, syringes, blood bags should be maintained.

10) **Labels:** The labels on bag s containing blood and/or blood components should bear the following particulars:

i) The product name in a prominent place and in bold letters on the bag.

ii) Name and address of the blood bank.

iii) Licence and serial number.

iv) The date on which blood was drawn and the date of expiry.

v) A coloured label should be place d on the blood-containing bags. The colour scheme in the table below for the said labels should be u sed for various blood groups:

Blood Groups	Colour of the Label
O	Blue
A	Yellow
B	Pink
AB	White

vi) The test results for h epatitis B surface antigen and hepatitis C virus antibody, syphilis, freedom from HIV I and II a ntibodies, and malarial parasite.

vii) The Rh Group.

viii) Total volume of bl ood, preparation of blood, and nature and percentage of anticoagulant.

ix) The whole human blood and/or components should be kept at 2 -6°C temperature.

x) Disposable transfusion sets with filter should be used in administration equipment.

xi) Proper compatible cross -matched blood without atypical antibody in recipient should be used.

xii) The bag contents should not be used in case of any sign of deterioration, such as haemolysis, clotting, or discoloration.

xiii) The proper donor classification such as Voluntary Donor or Replacement Donor in no less prominence than the proper name.

2.1.13. DMR (OA)

The Drugs and Magic Remedies (Objectionable Advertisements) Act, 1954 is passed for regulating the advertisements of some drugs, and the advertisements of remedies having qualities of magic.

The objective of this Act is to maintain ethical standards when manufacturers advertise any drugs. Under the guidelines of this Act, advertisements offending

the decency or morality can be banned. Also, those claiming magical powers for certain drugs, **e.g.,** enhancement of potency, cure for incurable diseases, etc. should be banned. Magical remedies include the use of talismans or charms such as “mantras”, “kavachas”, etc.

2.1.14. Sale of Drugs

Sale is the process of passage of drugs from the manufactur ers to the consumers. The different kinds of licenses issuable for wholesale and retail of drugs are in **figure 2.1**:

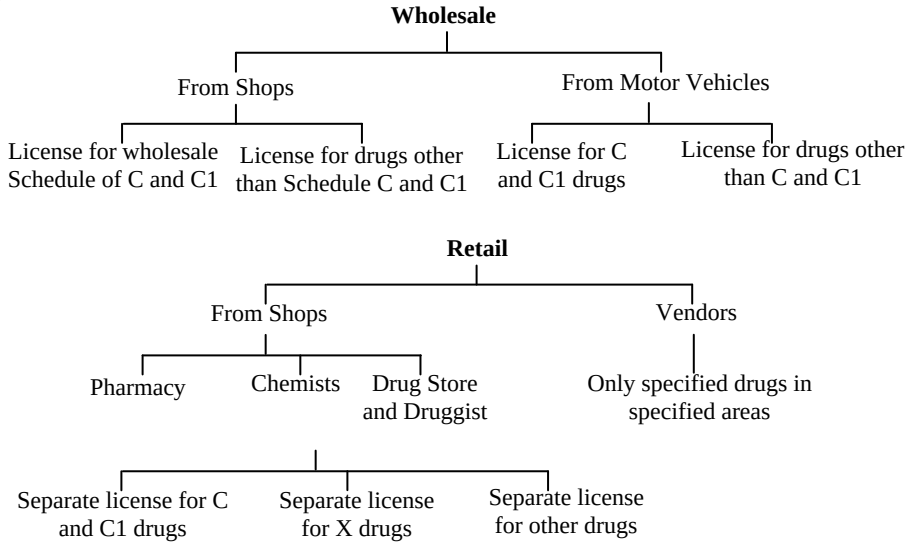


Figure 2.1: Licenses for Wholesale and Retail Sale of Drugs

The process of **passing drugs from manufactur ers to consumers** is termed as **sale**. In India, selling of drugs was an open trade til l 1940; hence, anyone can sell, compound, or dispense drugs without any restriction. But, after the implementation of the Drugs and Cosmetics Act 1940, selling of drugs became a restricted practice, and only the licenced individuals (by the Licensing Authorities of the States) can involve in wholesale, retail, compounding, or dispensing of drugs.

Licences are required for the wholesale or distribution from a motor vehicle or retail sale of drugs, and a separate licence is needed for each premise where drugs are sold.

2.1.14.1. Wholesale of Drugs

A wholesaler with a valid trade licence can approach the drug manufacturer for supplying medicine for selling to the retailers. Following are the **conditions** of granting the licences for wholesale of drugs:

1) Adequate infrastructural facilities,
2) Records,
3) Sale only to licenced retailers, and
4) Inspection.

Wholesale from Fixed Premises

Wholesale of drugs can be done from fixed premises or by motor vehicles. Separate licences are needed for wholesale of drugs under Schedules C and C_1 and other than those in Schedules C and C_1.

Wholesale of Schedule C and C_1 Drugs

Licences for wholesale of Schedules C and C_1 drugs can be granted on the following **conditions**:

1) The licensee must have adequate pr emises not be less than 10 square meters in area, equipped with adequate facilities for storage of drugs in order to preserve their potency.
2) No drug, to which this licence is applicable, should be sold unless precautions have been taken for its preservation when it was possessed by the licensee.
3) The drugs should be sold to persons with licence to retail them. However, this condition is not applicable to the sale of drugs to hospitals, medical, educational or research institutions or manufacturers of hydroge nated vegetable oils, beverages, confectionery and other non -medical products where such drugs are used for processing products or to an officer or authority purchasing on behalf of the Government. Along with the supplies of drugs, a cash or credit memo wi th the supply date, name, address and the licence number of the licensee to whom sold, names, quantities and the batch numbers of drugs and names of the manufacturers should also be accompanied.
4) If the licensee desires to sell any other categories of drugs (not specified in his license), he should seek permission from the Licensing Authority.
5) Records of all purchases and sales of Schedule C drugs by wholesale dealings should be maintained under the following headings:
   i) The dates of purchases and sales,
   ii) Names and addresses of the firms from whom purchased and of the firms to whom sold,
   iii) Names and quantities of the drugs and their batch numbers, and
   iv) Names of the manufacturers of drugs.
6) The records should be preserved from the date of sale to a period of at least three years.
7) Licence should be displayed in the premises so that it is open to the public.

Wholesale of Drugs other than those Specified in Schedules C and C_1

Licences for wholesale of drugs other than those specified in Schedules C and C_1 can be granted on the following conditions:

1) The drugs should not be sold to any person who does not possess a licence for the retail sale or distribution of drugs. However, this condition is not applicable to the sale of drugs to hospitals, medical, educational or rese arch institutions and manufacturers of hydrogenated vegetable oils, beverages, confectionery and other non -medical products where such drugs are needed for processing of these products or to registered medical practitioners or officers authorised by the Government for the purchase of drugs.

2) The licence should be displayed in such a part of the premises from where it is open to the public.
3) All other provisions of the Act and the Rules discussed above should be observed as far as applicable.

Wholesale from Motor Vehicles
At the present time, licences are being granted for drug distribution via motor vehicles. Separate licences are needed for wholesale of drugs under Schedules C and C_1 and other than those in Schedules C and C_1. The conditions for these licenses are same as the conditions for wholesale of drugs. Drugs should be bought from a licenced manufacturer or wholesaler and distributed to individuals having valid licences for retail sale of drugs. The drugs are distributed to an officer or authority pur chasing on behalf of a Govern ment or to hospitals, educational or research institutions or to registered medical practitioner. They are also distributed to manufactur ers of beverages, confectionery, or other non - medical products which require these drugs for the manufacturing products.

The licences should be displayed on the vehicle. In case any change is made in the ownership of the vehicle or constitution of the firm that was granted licence, the Licensing Authority should be informed within a week of the change made.

2.1.14.2. Retail Sale of Drugs

Retailing of drugs is done through shops or by vendors. Certain important basics for retail selling of drugs are given below:

Retail Sale from Shops
Following are the rules for the retail sale from shops:
1) Facilities as per Schedule N
2) Purchase only from licenced wholesaler,
3) No sale of specified drugs (Schedule H and Schedule X without prescription),
4) Separate licences for Schedules C, C1 and X drugs,
5) Sale under qualified supervision,
6) Records,
7) Inspection, and
8) Sale of specified household drugs from drug stores (Condi tions (1) to (5) not applicable).

Retail sale of drugs can be done from the following shops:
1) **Chemists and Druggists Establishments:** Chemists and Druggists establishments, functioning un der the supervision of a „registered pharmacist' but do not compound drugs.

2) **Pharmacies:** Establishments, functioning under the su pervision of a 'Registered Pharmacist' and engaged in compounding of drugs.

3) **Drug Stores:** Drug Stores, which do not have a registered pharmacist and sell drugs specified as household remedies.

Chemists, Druggists and Pharmacists require **separate licences** for the sale of:
1) Schedules C and C1 drugs,
2) Schedule X drugs, and
3) Drugs other than those specified in Schedules C and C1, and Schedule X.

After the fulfilment of the following **conditions**, licences for chemist's and druggist's shops and pharmacies are granted:
1) The licensee should have premises equipped with adequate facili ties for proper drug storage and a registe red pharmacist should supervise and control the sale and distribution of drugs.
2) Requirements specified in Schedule N for a 'pharmacy' should be fulfilled.
3) A person (with a licence to sell Schedule C and C1 drugs) should seek permission from the Licensing A uthority if he wishes to sell categories of drugs not listed in his licence.
4) All registers and records maintained should be kept for a period of at least 2 years from the date of the last entry made.
5) Licensee should allow the inspection of the premises and the registers and records by an authorised Inspector to ascertain whether or not the provisions of the Act and Rules are being followed.
6) The Licensing Authority should be informed about any change in the qualified staff by the licensee within a month of such change.
7) Schedule C and C1 drugs should not be sold without taking precautions for their storage during the period when they were possessed by the licensee.

Retail Sale from Vendors
Sometimes drugs are sold by vendors who do not have a fixed place of b usiness but have been granted a licence by the Licensing Authority to conduct business in a particular area. Persons who distribute drugs in sparsely populated areas with no other agencies for drug distribution or to travelling agents of firms dealing in drugs are issued licences to sell drugs. The licences to sell drugs are issued only for drugs other than those specified in Schedules C and C_1.

2.1.14.3. Restricted Licences

For the restricted sale of drugs other than those specified in Schedule C, C_1 and X and those specified in Schedule C and C $_1$ but not in Schedule X, licences are issued in Form 20A and 21A, respectively.

Restricted licences can be given to:
1) Dealers or persons for drugs whose sale does not need to be supervised by a qualified person.
2) Itinerant vendors in exceptional cases, for *bona fide* travelling agents of firms dealing in drugs, or
3) To a vendor who purchases drugs from a licenced dealer for distributing drugs in sparsely populated areas with no other agencies dealing wi th drug distribution.
4) To a travelling agent of a firm for drug distribution to medical practitioners or dealers, for supply of biological and other special products specified in Schedule C.

Travelling agents of licenced manufacturers and agents of importers of drugs can distribute the free medicine samples to any member of medical profession, hospitals, dispensaries, and medical or research institutions without any licence.

Conditions for Restricted Licence

1) The licensee should have premises well-equipped with drug storage facilities; but this condition is not valid for the vendors.
2) The licence should be displayed in the premises in such a place that it is easily visible to the public; while the vendors should keep the licence with them so they can present it on demand to an authorised Inspector or any other officer (appointed by the State Government).
3) The licensee should fulfil the provisions of the Drugs and Cosmetics Act and Rules.
4) The drugs should be bought only from a licenced dealer or manufacturer.
5) The licensee can deal in those drugs that can be sold without the supervision of a 'qualified person'.
6) In case the licensee is a vendor and has no fixed place of business, he should purchase the drugs from dealers as given in his licence.
7) Drugs should be sold in their original container.

The Licensing Authority should consider the occupation, trade, or business of the applicant and also the number of licences granted in a area in the last three years, before granting the restricted licence.

2.1.14.4. Procedure for the Sale, Purchase, and Storage of Drugs

In different kinds of establishments for the sale of a drug, following important procedures should be followed:

1) **Dispensing and Compounding of Drugs:** Drugs compounded at the premises against the prescription of a Medical Practitioner should be compounded either by a Registered Pharmacist or under his supervision. All supplies of drugs on a prescription should be recorded in a register maintained with the following headings:
   i) Serial No. of the entry,
   ii) Date of supply,
   iii) Prescriber's name and address,
   iv) Patient's name or name and address of the owner of animal, if drug is for veterinary use,
   v) Names and quantities of the drugs,
   vi) Manufacturer's name, batch number and expiry date of Schedule C and H drugs,
   vii) Signature of the Registered Pharmacist under whose supervision the medicine was made up and supplied,
   viii) Drug supplied on a prescription should comply with its description in the prescription, manufacturer, etc.
   ix) The details of the drugs which are not compounded but supplied in or from original containers should be entered in a cash or credit memo book, serially numbered and properly maintained for this purpose. If the

Licensing Authority feels that the entries of carbon copies of the cash/credit memo book are not understandable he shou ld maintain records in a register.

2) **Sale of Schedule X and Schedule H Drugs :** Substances specified in Schedules H and X should be retailed only on a Registered Medical Practitioner's prescription. Dispensing of drugs prescribed in such prescription should not be done more than once. However, it may be repeated if it is specified in the prescription that it may be dispensed more than once at specified intervals. The dispenser should note the prescriber's name, address and the date of dispensing above signature, at the time of dispensing.

No substitution should be made in dispensing prescriptions with Schedule H and X drugs. The prescriptions should be in duplicate and retained for 2 years, in case of Schedule X drugs. Separate bound and paged registers with separate sheets allotted for each drug should be maintained for supply.

At the time of supply the following particulars should be entered:

i) Date of supply and opening and closing stocks of drug on that day and relevant bill numbers,
ii) Drug's name, manufacturer's name and batch no.,
iii) Purchaser's name and address,
iv) Date of prescription and RMP's name and address, and
v) Signature of Registered Pharmacist under whose supervi sion the supply is made.

3) **Supply/Sale of Schedule C Drugs:** At the time of supply, the supply of Schedule C drugs should be recorded in a register or cash or credit memo book maintained for this purpose. The recording should be done with the following headings:

i) Serial no. of the entry,
ii) Date of supply,
iii) Purchaser's name and address,
iv) Name and quantity of the drugs supplied,
v) Manufacturer's name,
vi) Batch No. as recorded on its label,
vii) The expiry date as indicated on the label, and
viii) Signature of the registered pharmacist under whose supervi sion the sale was affected.

Schedule C drugs, with an expiry date ma rked on the label, should not be sold after the expiry of such date. Schedule C and F drugs sold or supplied by wholesale dealings or on the prescriptions of medical practitioners are exempted from the provisions of the above rules.

4) **Supply/Sale of Other Drugs:** Following particulars should be included in the cash/credit memo in case of the supply of all the drugs other than those specified above:

i) Name, address and licence number,
ii) Name and quantity of drug supplied, and
iii) Serial number of cash/credit memo.

5) **Records of Purchases of Drugs:** Records with the following headings should be maintained for all the drugs purchased, whether for selling by retail or wholesale:
   i) Purchase date,
   ii) Name and address of the licensee from whom drugs are purchased and no. of relevant licence held by him,
   iii) Drug's name, quantity, and batch number, and
   iv) Manufacturer's name.

   Purchase bills, including cash/credit memos should be kept as records.

6) **Storage of Schedule X Drugs and Drugs with Expiry Dates:** Schedule X drugs should be stored under lock and key, either in a drawer or a cupboard, for storing in the establishment in a part situated separately from the remainder of the premises with no access to the customers. Other drugs with an expiry date should be stored in a separate cupboard.

7) **Storage of Veterinary Medicines:** Drugs for veterinary use should be stored in a separate drawer or cupboard in a part of the premises where the entry of customers is prohibited.

8) **Drug Stores:** Licences for drug stores are granted on the following conditions
   i) The licensee can only deal with drugs which are sold without the Registered Pharmacist's supervision.
   ii) If the licensee is a vendor with no fixed place of business, he should buy drugs only from dealers specified in his licence.
   iii) Licensee must take adequate precautions for preserving the properties of the drugs in his possession and drugs which have not been stored under prescribed conditions should not be sold.
   iv) The licence should be displayed in a part of the premises open to the public. If the licensee is a vendor with no fixed place of business, he should produce the licence on demand.
   v) Drugs should be sold in their original container.

The Licensing Authority should consider the number of licences granted in a locality during the last one year and the occupation, trade or business of the applicant, before granting the restricted licence.

2.1.14.5. Classes of Drugs whose Sale is Prohibited

The drugs or classes of drugs whose sale is prohibited are:

1) Misbranded, spurious, adulterated, and non-standard quality drugs.
2) Patent and proprietary drugs with undisclosed formulae.
3) Drugs claiming by any statement, design, or device to cure any diseases specified in Schedule J.
4) Drugs manufactured or imported in violation of the provisions of the Act and the Rules.
5) Expired drugs; however, such drugs can be stocked in packages labelled "Not for sale" pending their withdrawal by manufacturers or disposal.
6) Drugs to be consumed by E.S.I.S., Central Government Health Scheme, Government Medical Depot, Armed Forces Medical Stores, or other Government institutions.

7) Drugs to be distributed as a free sample to the members of the medical profession and bearing the words "Physician's Sample. Not to be sold" on the container.
8) Drugs not to be sold.

It is a defence to prove that the person who s old the drug in violation of the Rules:
1) Acquired the same from a duly licenced manufacturer or dealer and the drug remained in the same state as when he obtained it and also it was stored adequately.
2) And he was not conscious and could not have with reasona ble diligence determined that the drug was in violation of the law.

A person who needs to take benefit of the defence warranty given above should send a copy of the warranty to the prosecuting inspector within 7 days of the service of summons on him with the notice of his intention to take benefit of it.

2.1.14.6. Offences and Penalties

The offence and penalties regarding the sale of drugs under this Act are enlisted in **table 2.2**:

Table 2.2: Offences and Penalties with Respect to Sale of Drugs

Offences	Penalties
1) Sale, stocking, exhibition, or offer for sale of drugs which may cause death or serious hurt as per Section 320 of IPC.	Imprisonment from 5 years to life and fine of not less than ₹ 10,000.
2) Sale, stocking, exhibition, or offer for sale of spurious drugs.	Imprisonment of 1-3 years and fine of up to 5,000 rupees on first conviction; and imprisonment for 2 -6 years and fine of ₹ 10,000 on subsequent convictions.
3) Sale, stocking, exhibition, or offer for sale of spurious drugs.	Imprisonment for 3 -5 years (les s for adequate reasons) on first conviction; and imprisonment for 2 -6 years and fine of ₹10,000 on subsequent offences.
4) Sale, stocking, exhibition, or offer for sale in contra vention of any other provision.	Imprisonment from 1 to 2 years and fine (less on adequate reasons) for subsequent offence 2 to 4 years and/or ₹ 5,000 fine.
5) Failure to keep records or disclose required information.	Imprisonment for 1 year and/or fine of up to ₹ 1,000.
6) False warranty to purchaser	Imprisonment for 1 year and fine of up to ₹ 5,000 on first conviction; and imprisonment for up to 2 years or fine or both on subsequent conviction.
7) Use of reports of government analysts or central drug laboratory for advertising.	Fine of up to ₹ 500 on first conviction; and imprisonment for up to 10 years or fine or both on subsequent convictions.

2.1.15. Labelling and Packing of Drugs

The legal requirements for labelling of drugs are given as follows:

1) Identity of drug and its manufacturer is done by its official name, trade name, manufacturer's name and address and licence number and batch number. Official names are used for Schedule W drugs.
2) Potence, standard, grade, dose, etc. are expressed in millilitres, grains, units, etc.
3) Net contents are expressed as volume or weight or number.
4) Manufacturing and expiry dates should be given for schedule P and C drugs only.
5) Precautions for handling, storage, sale/usage, should be given properly.
6) Special requirements for certain drugs such as physicians' samples, veterinary drugs, drugs having certain materials like spirit, colour, etc.
7) There should be certain provisions for dispensed drugs or drugs for export.

The only aim of pharmaceutical packaging is to confirm the safety of pharmaceutical preparations so they do not get contaminated. Packaging also prevents microbial growth, thus the product remains stable during the intended shelf-life. Packing is an important tool in pharmaceutical industries for product delivery and compliance associated with regulatory authorities.

2.1.15.1. General Labelling Requirements

The labelling requirements related to the name and use of drug, caution, etc. are enlisted in **table 2.3**:

Table 2.3: Special Labelling Requirements for the Medicines of Different Schedules

Class and Nature of Medicines in which Contained	Particulars which should Appear on Label
Schedule C_1 Schedule C_1 drugs and their preparations including combinations with other drugs	1) The manufacture date. 2) The expiry date. 3) Import license number (if applicable).
Schedule F and F_1	The prescribed name
Schedule G Medicines made up ready for internal use in the treatment of human ailments.	The words "Caution. It is dangerous to take this preparation except under medical supervision", should be clearly printed and surrounded by a line within which there should be no other words.
Schedule H Medicines for internal use of human beings.	1) Symbol should be clearly displayed on the left top corner of the label. 2) "Schedule H Drug – Warning: To be sold by retail on the prescription of a Registered Medical Practitioner only".
Schedule H Falling under Dangerous Drugs Act, 1930.	1) Symbol N should be clearly displayed on the left top corner of the label. 2) "Schedule H Drug – Warning: To be sold by retail on the prescription of a Registered Medical Practitioner only".
Schedule X Medicine for internal use of human beings.	1) Symbol N should be clearly in red on left top corner of the label. 2) "Schedule X Drugs – Warning: To be sold by retail on the prescription of a Registered Medical Practitioner only."

Schedule X Bulk form	Symbol X given conspicuously in red.
Schedule P Any drug	1) The manufacture date. 2) The expiry date.
Schedule C In original form	1) Proper name of the substance along with the name of any patent or proprietary. 2) License No. under which manufactured or imported. 3) Batch No. or Lot. No. 4) Statement of potency in units. 5) Name and address of the manufacturer of final product. 6) The manufacture date. 7) If a test for maximum toxicity is prescribed, a statement that the drug has passed the test. 8) The expiry date. 9) Nature and percentage of added antiseptic. 10) Precautions for preserving the drug properties.
Schedule G Any Drug	1) Proper name. 2) Manufacturing or import license No. 3) Batch No. 4) Potency in units. 5) The expiry date.
Schedule W Single ingredient	Proper name (no trade name).
Preparations containing New Drug as Single Ingredient	Generic name only.
Patent and Proprietary	1) Quantities of the active ingredients. 2) Manufacturer's name and address.
Patent and Proprietary containing Vitamins for Prophylactic or Therapeutic use	1) "For Prophylactic use" or 2) "For Therapeutic use"
Non-Surgical Ligature and Suture	The words, "Non -sterile surgical ligature (suture) – not to be used for operations upon the human body unless effectively sterilised," should be clearly printed with indelible red ink.
Pharmacopoeial and Other Drugs	1) Name or synonym as specified in the Pharmacopoeia followed by the letters – 'I.P.', 'B.P.', 'B.P.C', 'U.S.P.', 'N.F.', etc., as the case may be or description of the substance (proper name being not less visible than trade name, if any). 2) Net amo unt of the drug in terms of weight or measure in metric system or units of activity or in case of tablets, capsules, etc., the quantity in each. 3) Amounts of active ingredients (content per single dose in oral preparations and in terms of volume in case of p arenteral preparations). For preparations of antibiotics, hormones, and other drugs for parenteral use whose dosage is expressed in units or by weight: total units or quantity in each container or number of units or weight per g or ml (not necessary in cas e of pharmacopoeial preparations). 4) Manufacturer's name and address. 5) Manufacturing License No. and Batch No.

Alcoholic Preparations Any drug containing more than 3% v/v alcohol.	Statement of the quantity of alcohol as average % of absolute alcohol by volume.
Preparations for External Application Embrocation, liniment, lotion, ointment, antiseptic cream, liquid antiseptic, or other liquid medicine.	'For External Use Only'
Ophthalmic Ointments	1) Special storage instructions. 2) **Warning:** If irritation persists or increases discontinue the use and consult the physician.
Medicines for Animals Medicines for the treatment of animals.	1) The words, „Not for human use. For animal treatment only.' 2) Symbol depicting the head of a domestic animal.
Medicines Containing Methylated Spirit Medicines for the treatment of human ailments and containing industrial methylated spirit.	'For External Use Only'.
Disinfectants	1) Product name and manufacturer's name and address. 2) Grade, type, and R.W. coefficient of the product. 3) Manufacture and expiry date. 4) Quantity in the container. 5) Indications and mode of use.
Mechanical Contraceptives	1) Particulars specified in Schedule R. 2) Manufacture and expiry date. 3) Storage conditions.
Oral Contraceptives	Manufacture date.
Coloured Medicaments	Common name and % of colour.
Replaced Containers Drugs supplied in containers other than those marketed by the manufacturer.	Drug name and quantity, and the seller's name and address.
Drug Samples Drugs for free distribution to the medical profession.	The words, 'Physician's Sample', 'Not to be sold'.

2.1.15.2. Specimen Labels for Drugs And Cosmetics

Details mentioned on the container's label should be properly visible on the innermost container having the drug is present and also on every following covering in which the container is packed.

Any transparent covering or wrapper, or any other covering used for packing during transportation are not labelled with these details.

The particulars should be either printed on the attached label, or are painted or permanently marked on the container (excluding the drug name which should not be so clear on only glass container except the ampoules).

Red coloured letters are used for writing the drug name and followed by its trade name (if present). The trade name should not be written in red, and should be of the same size as proper name, except for veterinary, ear and eye drops, and sterile products.

The containers of Schedules H and G drugs should be labelled in red letters against white background before being manufactured in dosage forms.

Following are some **examples** of sample labels of the rules given above:

1) For 10ml vial of insulin 80units/c.c.
(Schedule C and Schedule G drug.)

10c.c.

Insulin
80 units/c.c.

Caution: It is dangerous to take this preparation except under medical supervision

Mfg. License No. 345 Batch No. 345
Date of Manufacture 1-1-98

NANDY and SEN Ltd.
20, Bow Bazar, Calcutta

2) For hair lotion containing 2% w/v Mercuric chloride

RINSO HAIR LOTION

Contains 2% w/v
Mercuric Chloride

For External Use Only

Delhi Cooperative Chemists
32, The Fountain, Delhi

3) For 100 tablets of Phenobarbitone (Schedule X drug)

100 × 50mg.
Tablets of Phenobarbitone

Schedule X drug.
Warning: To be sold by retailers on the prescription of a Registered Medical Practitioner only.

JOHN & JOHN Ltd.
Chemists
75, Park Street, Calcutta

4) For 10ml of Anti-pneumococcus Serum Type 1

10ml

Pneumocure
(Anti-pneumococus Serum, Type 1)
Natural Serum

Containing 0.5% Phenol

License No. 345 Batch No. 863
Date of manufacture 28-6-97 Date of expiry 28-6-99

Mehta & Co.
Pharmaceutical Chemists
24th Road, Chembur, Bombay

2.1.15.3. List of Permitted Colours

Following are the colours that can be added to the medicines. The common names and the percentage of colour added should be mentioned on the label of container. The medicines to which these colours are added shall not be deemed to be misbranded only due to the fact of adding of colours within:

1) **Natural Colours:** Annatto, carotene, cochineal, curcumin, chlorophyll, red oxide of iron, yellow and black oxide of iron, and titanium dioxide.

2) **Artificial Colours:** Caramel.

3) **Coal Tar Colours**

Table 2.4: Colours and their Chemical Names

Common Names of Colours	Colour Index Number	Chemical Names
Green		
Quinizarine Green SS	61565	1, 4-Bis (*p*-tolyamino) anthraquinone.
Alizarin Cyanine Green F	61570	Disodium salt of 1,4 -bis (*o*-sulfo-*p*-tulouino) anthraquinone
Fast Green FCF	42053	Disodium salt of 4 -{[4-(N-ethyl-p Sulfobenzylamino) -phenyl-]-(4-hydroxy2- sulfoniumphenyl)-methylene} [1 -(N-ethyl-N-p-sulfobenzyl]Δ 2, 5-cyclohexadienimine].
Green S	44090	
Yellow		
Tartrazine	19140	Trisodium salt of 3 -carboxy-5- hydroxy-lp-sulfophenyl-4-p- Sulfophenyl azopyrazole.
Sunset Yellow FCF	15985	Disodium salt of 1 -p-sulfophenyl azo -2- naphthol-6-sulfonic acid.
Quinoline Yellow WS	47005	Disodium salt of disulfonic acid of 2(2 - quinolyl)-1, 3 -indandione.
Red		
Amaranth	16185	Trisodium salt of 1(4 -sulfo-Inaphthylazo) 2 -naptho 1 -3, 6-disulfonic acid.
Erythrosine	45430	Disodium salt of 9 -o-carboxyphenyl 6 -hydroxy 2,4 -5,7-tetriodo-3-isoxanthone.

Eosin YS or Eosin G	45380	Disodium salt of 2,4,5,7 -tetrabromo-9-p-carboxyphenyl-6-hydroxy 3-isoxanthone.
Toney Red or Sudan III	26100	1-p-phenylazophenylazo-2-naphtho.
Ponceau 4 R	16255	Trisodium salt of 1 -(4-sulpho-1-1- Napthylazo)- 2 napthol-6 : 8-disulphonic acid.
Carmoisine	147720	Disodium salt of 2 -(4-sulpho-1-napthylazo)-1 napthol -4 sulphonic acid.
Fast Red E	16005	Disodium 2 -hydroxy-1-(4-sulpho-1-naphthylazo) naphthalene -6-sulfonate acid.
Blue		
Indigo Carmine	73015	Disodium salt of indigotin
Brilliant Blue FCF	42090	Disodium salt of 4 -[{4-(N-ethyl-psulfobenzylamino)-phenyl }-](2- sulfonium phenyl)-methylene)-1-(N- ethyl-N-psulfobenzyl)- Δ 2, 5-cyclohexadienimine.
Violet		
Alizurol Purple	60725	Disodium salt of 1 phenylazo -2-naphtho1-6,8-disulphonic acid.
Brown:		
Resorcin Brown	20170	Monosodium salt of 4 -*p*-sulfophenylazo-2(2,4-xylylazo1)-3-resorcinol.
Black		
Naphthol Blue	20470	Disodium salt of 8 -amino-7,5-nitrophenylazo-2-naphthol-3,6-disulfonic acid

2.1.15.4. Offences And Penalties

The offences which can be committed while packaging and labell ing of medicinal products are:

1) Selling or supplying a product not in a container,
2) Issuing a false or misleading label with the medicinal product,
3) Packing a product in a container that does not fulfil the requirements of the regulations,
4) Selling, supplying, or possessing for sale a product that is not of the colour or not marked requirements of the regulations, and
5) Selling products from an automatic machine not marked as per the requirements of the regulations.

2.1.16. Administration of the Act and Rules

The Drugs and Cosmetics Act forms the agencies given in **table 2.5**, along with their functions:

Table 2.5: Agencies and their Functions

Agencies	Functions
1) **Advisory**	
i) Drugs Technical Advisory Board (DTAB)	Advises Central and State Governments on technical matters arising out of the operation of the Act.
ii) Drugs Consultative Committee	Advises governments and DTAB on issues related to uniform operation of the Act throughout country.
2) **Analytical**	
i) Central Drugs Laboratory	Analyses and submits report on samples of drugs o r cosmetics sent by custom collectors or courts.

ii) State Drug Control Laboratory	Analyses and submits report on samples of drugs or cosmetics sent by the drug inspec tor; analyses samples of private agencies on prescribed payment.
3) **Executive**	
i) Licensing Authority	In-charge of drugs control; issues licenses and implementation of Act.
ii) Drug Inspectors	Inspects the licensed establishments and assists the licensing authorities in implementation of the Act.
iii) Customs Collectors	Aids in the implementation of the Act to a certain extent with respect to imported drugs or cosmetics.

2.1.16.1. Drugs Technical Advisory Board (DTAB)

DTAB has the following members:

1) ***Ex-Officio*** **Members**
   i) Director-General of Health Services, who is also the Chairman,
   ii) Drugs Controller of India,
   iii) Director, Central Drugs Laboratory, Kolkata,
   iv) Director, Central Research Institute, Kasauli,
   v) Director, Indian Veterinary Research Institute, Izzatnagar,
   vi) President, Pharmacy Council of India,
   vii) President, Medical Council of India, and
   viii) Director, Central Drugs Research Institute, Lucknow.

2) **Nominated Members**
   i) One person from pharmaceutical industry nominated by the Central Government,
   ii) Two government analysts, appointed under the Act, nomi nated by the Central Government, and
   iii) Two persons from amongst the persons who are in -charge of the drug control agencies in the States, nominated by the Central Government.

3) **Elected Members**
   i) A teacher in pharmacy, pharmaceutical chemistry, or pharmacognosy on the staff of a university or affiliated college elected by the Executive Committee of Pharmacy Council of India,
   ii) A teacher in medicine or therapeutics on the staff of a university or affiliated college elected by the Executive Committee of the Medical Council of India,
   iii) One person elected by the Council of the Indian Pharma ceutical Association,
   iv) One person elected by the Council of the Indian Medical Association, and
   v) One pharmacologist elected by the Governing Body of the Indian Council of Medical Research.

Functions

1) It advises the Central and the State Governments on technical matters of the administration of this Act.
2) It makes modifications and amendments in the Act by consulting the Board.
3) It carries out the other functions assigned by the Act.

2.1.16.2. Central Drugs Laboratory

The Central Drugs Laboratory is established in Calcutta under the control of a Director.

Functions

1) It analyses or tests the drug or cosmetic samples sent by the customs collectors or courts
2) It carries out the analytical Q.C. of the imported samples.
3) It collects, stores, and distributes internal standards.
4) It prepares reference standards and also maintains them.
5) It maintains microbial cultures.
6) It performs any other duties entrusted by the Central Government.
7) It acts as an appellate authority in matter of disputes.
8) It provides training of drug analysis.
9) It advises the central drugs control administration in respect of quality and toxicity.
10) It works out analytical specification of monographs for IP and Homeopathic Pharmacopoeia.

Central Drugs Laboratory at Calcutta does not carry out the biological and microbiological tests and analysis. Thus, the samples of sera, vaccines, toxins, antigens, antitoxins, sterilised surgical ligature and suture, bacteriophage, and solutions of serum proteins for injection are sent to the Director of the Central Research Institute, Kasauli; while the samples of antisera, vaccines, toxoids, and diagnostic antigens for veterinary use are sent to the Director of Indian Veterinary Institute, Izzatnagar. These institutes carry out the functions of the Director of Central Drugs Laboratory with these classes of drugs.

All the drug or cosmetic samples sent to the Central Drugs Laboratory for analysis by courts should be sent in registered and sealed covers, along with a memorandum to the Director. A memorandum copy and a specimen impression of the seal (used to seal the packet) should also be sent separately via post. The Director or other officer approved by him should record the condition of the seals, on receipt of the packet.

2.1.16.3. Drugs Consultative Committee

This agency comprises of two representatives nominated by the Central Government and one nominee of each of the State Governments. This body has the power to regulate its own procedure.

Functions

1) It advises the Central Government, the State Governments, and the Drugs Technical Advisory Board on any other matter tending to secure uniformity throughout India in the administration of this Act.
2) The Drugs Consultative Committee meets when required has power to regulate its own procedure.

2.1.16.4. Government Drug Analysts

Government analyst analyses in labs the drug and cosmetics test samples sent by the drug inspectors.

Qualifications of Government Analysts

The Government Analyst should have no financial interest in import, manufacture, or sale of drugs and cosmetics, and should have the following qualities:

1) He/She should be a graduate in medicine, science, pharmacy, or pharmaceutical chemi stry with minimum experience of 5 years; or he /she should be a postgraduate in the above areas with minimum experience of 3 years under the control of:
   i) A government analyst under the Act, or
   ii) Head of an approved institute or testing laboratory.
2) He/She should have Associateship Diploma of the Institution of Chemists (India) after passing the examination with „Analysis of drugs and pharmaceuticals' as a subject with minimum experience of 3 years in drug analysis in a laboratory under the control of any authority given under (i).

Duties of Government Analysts

1) They analyse and test the drug and cosmetic samples sent by the drug inspectors or other persons. Then , they prepare reports of test or analysis according to the Rules.
2) They involve in any research work an d provide the Government with timely results of analytical and research work with a view to publication at the pleasure of the Government.

Procedure of Analysis done by the Government Analyst

The Government Analyst on receiving the sample package from an Inspector should compare the seals on the packet with the specimen impression received separately. He should also note the condition of the seals on the package. On completing the test or analysis, he prepares a report and sent it to the Inspector in triplicate along with full protocols of the tests or analysis.

A Government Analyst should submit the report in Form I of the result of test or analysis along with full protocols of the test applied. If the full protocols of tests are not supplied, the report of the Government Analyst is not considered a conclusive sign or as any evidence of the fact stated within.

When various tests carried out by the analyst to test the drug purity are exemplified in the report, the report is considered as a certain evidence of the specified results.

If the two reports of Government Analyst provide different conflicting opinions, in which the first report declared the drug sample of standard quality whereas the second report declared the sample for active ingredients of low standard quality.

The suspect did not accept the second report. The Magistrate has jurisdiction to send the sample for test and analysis to the Central Drugs Laboratory.

Even if the public analyst was not physically present when the analysis was being performed, and if there was any doubt regarding the authenticity of the analysis, the public analyst would not have released the report.

If the manufacturer is not the supplier of the drug to the person from whom a sample is procured by the Drug Inspector , the manufacturer is neither provided with a copy of the analyst's report nor with a sample portion.

The report of Government Analyst is a definite evidence of the facts laid down by the Section 25(3) of the Act. The report of the Government Analyst is a definite evidence of the facts given without any proof of the same. Examination of the Government Analyst to prove his opinion is not required.

2.1.16.5. Licensing Authorities

The Central Government appoints the Licensing Authorities to issue licenses for drug import. The State Government appoints them for their respective territories to issue licenses for the drug manufacture and sale and for cosmetic manufacture.

It is the choice of Licensing Authorities to either issue or refuse licenses to the applicants, depending on whether or not they satisfy the prescribed rules. If the licensees fail to follow any condition of licenses, the Licensing Authorities can cancel or suspend their licenses after providing them an opportunity of givi ng explanation. However, the decision of Licensing Authorities can be challenged in the courts of law as given before.

These authorities are designated differently in different states, mainly they are given the designation of 'Drug Controller' whereas in certain states they are called as 'Director, Drug Control Administration' and in some places they are called as „Officer-in-charge, Drug Control'

2.1.16.6. Controlling Authorities

Drugs inspectors chosen under this Act are under the control of a controlling authority. The qualification of a controlling authority has been prescribed under the new "Rule 50 A" by the Drugs and Cosmetics (Ninth Amendment) Rules, 1989.

Qualification

No person is qualified to be a controlling authority under the Act, until unless:

1) He//She is a graduate in Pharmacy/Pharmaceutical Chemistry/Medicine with specialisation in Cli nical Pharmacology/Microbiology from a recognised university, and
2) He//She has experience in drug manufacturing and testing or enforcement of the provisions of the Act for five years.

Provided that the requirement as to the academic qualification shall not apply to Inspectors appointed under this Act and who are in position on the date of commencement of the Drugs and Cosmetics (Ninth Amendment Rules, 1989).

2.1.16.7. Drug Inspectors

Under the Act, the Central Government or the State Governments are required to appoint a suitable number of drug inspectors for their respective areas. The Inspectors may be appointed either to inspect the premises licensed for the sale of

drugs or to inspect the establishments licensed for the manufacture of drugs and cosmetics. No person having any financial interest in the import, manufacture or sale of drugs and cosmetics can be appointed as a drug inspector under the Act.

All drug inspectors are public servants within the meaning of Section 21 of Indian Penal Code. Inspectors are required to keep all information acquired by them, in the course of their duty, confidential and not disclo se it except for official business or when required to do so before a court of law. Inspectors held guilty of any vexatious searches, seizures, etc., are liable to fine up to ₹1,000.

Qualifications for the Appointment of Inspectors

Degree in pharmacy or p harmaceutical sciences or degree in medicine with specialisation in clinical pharmacology or micro biology from a recognised university or associate diploma of the Institution of Chemist (India) obtained by passing the examination with analysis of drugs and pharmaceuticals as one of the subjects, or provided that, for the purpose of inspection of shops in any area, any officer of the medical or public health department may be appointed as *ex-officio* inspector, if he is either a graduate in medicine or scien ce or a registered medical practitioner.

For the purpose of inspection of the manufacture of Schedule C drugs, persons who have not less than 18 months experience in the manufacture or testing of Schedule C drugs in a laboratory approved for this purpose by the licensing authority or 3 years' experience of inspection of establishments for manufacture of Schedule C drugs. For inspection of the manufacturing establishments for veterinary biological products, the inspectors should be graduates in veterinary science or medicine or science or pharmacy and should have at least 3 years' experience in manufacture and testing of such products.

Duties of Inspectors

The duties of drugs inspectors are classified as follows:

1) **Inspection of Premises Licensed for the Sa le of Drugs:** Given below are the duties of a drug inspector subjected to the instructions of the controlling authority:
   i) He/She should inspect all the premises licensed for the sale of drugs in his area atleast twice a year in order to confirm whether or no t the conditions of the license are being followed.
   ii) He/She should obtain and send drug samples for analysis. The samples can also be obtained from dealers or from persons who are con veying, delivering, or preparing to deliver any drug to a purchaser.
   iii) He/She should investigate any written complaints made to him, and to make such inspections and enquiries that are necessary to detect the sale of drugs in contravention of the Act and the Rules.
   iv) He/She along with his assist ants should enter and search (at all reasonable times) all places, vessels, vehicles, or persons where or by whom an offence under the Act is believed to be committed.

v) He/She should order any person in possession of illegal drugs to not to dispose of such drugs for a period of not more than 20 days, or if the defect is such that it cannot be improved by the possessor, to seize the stock of the drugs.

vi) He/She should institute legal proceedings if the Act and the Rules have been breached.

vii) He/She should detain packages of imported drugs which are prohibited to be imported, only if he has been authorised by the State Government to do so.

viii) He/She should exercise such other powers to give effect to the provisions of the Act and Rules.

ix) He/She should maintain records of all inspections and also of the actions taken, including taking the samples and seizing stocks, and submitting copies of such records to the licensing authority.

2) **Inspection of the Premises Licensed for the Manufacture of Drugs and Cosmetics:** Given below are the duties of a drug inspector subjected to the instructions of the controlling authority:

i) He/She should inspect, not less than twice a year, all premises licensed for the manufacture of drugs (in the case of establishments licensed for the manufacture of Schedule C and C_1 drugs to ins pect the plant, the process of manufacture, the means employed for standardising and testing of drugs), the methods and places of storage, details of location, construction and administration of the establishment and enquire into the technical qualifications of the staff employed, in order to satisfy himself that the provisions of the Act and the Rules are being observed.

ii) He/She should obtain samples of drugs manufactured in the premises and send them for test or analysis.

iii) He/She should check all records an d registers need to be maintained under the Rules in order to satisfy himself that the provisions are being observed.

iv) He/She should send detailed report of each inspection to the controlling authorities indicating how far the provisions of the Act and the Rules are being observed.

Powers

1) He/She may i nspect any premises where drugs or cosmetics are being manufactured or sold.
2) He/She may take samples of drugs or cosmetics being manufactured or sold.
3) He/She may enter and search any premises in which an offence is believed to be committed.
4) He/She may examine and seize any records, registers, and documents.
5) He/She may search any person, who he has reason to believe has secreted about any drug or cosmetic in respect of which an offence is being committed.
6) He/She may stop and search any vehicle, vessel or other conveyance used for carrying any drug or cosmaticin respect of which an offence being committed.
7) He/She may exercise such other power as may be necessary.

Procedure of Inspection

Following procedure involves inspecting a drug:

1) **For Taking Samples of Drugs and their Dispatches to the Government Analysts:** If any Inspector takes drug samples, he should intimate the purpose in writing to the person from whom he takes them, tender a fair price in cash or kind and also gets a receipt for the same. If the price is not accepted, he should tender a receipt for the drug quantity taken by him in the prescribed form. The sample should be divided into four parts in front of the person, from whom the samples have been o btained unless he deliberately absents himself, and each part should be sealed and marked with the same, and the person is permitted to add his mark or seal to these parts if required.

   The samples obtained from the premises licenced for the manufacture of drugs should be divided into three parts. If the drug is in small volume containers or it can deteriorate on exposure, the Inspector should take 3 to 4 such containers, and mark and seal them in the normal manner.

   One portion of the sample should be sent to the government analyst. The second part is kept to be presented before the court if the proceedings are instituted in respect of this sample. The third part should be sent to the warrantor. The fourth part lastly should be returned to the person from whom the sample was taken.

   The sample part sent to the government analyst should be either sent by registered post or should be personally delivered in a sealed packet. On receiving the analysis or test report from the government analyst, the Inspector decides whether or not any for the further action is required.

2) **For Entry and Search of Places, Persons, Vehicles, Vessels, etc.:** If an inspector suspects that certain drugs (which are in contravention of the Act) are stocked in any place, he can enter that pl ace either alone or with assistants at any time to search for the drugs, or any vessels or persons. The Inspectors can even stop and search any vehicle he suspects to be carrying any drug in contravention of the Act.

3) **For Seizure of Stocks:** Any stocks, reco rds, registers, documents, material objects, etc., if assumed to be evidences of the commission of an offence under the Act, are seized by the Inspector, and he should immediately inform a Magistrate and take his orders for the custody of seized materials. Records should be returned to the owner within 20 days after making copies, extracts, etc.

2.2. SUMMARY

The details given in the chapter can be summarised as follows:

1) Schedules M and Y were established in 1988.
2) Medicines listed as schedule G carry a caution on the label. The caution states that “It is dangerous to take this preparation except under medical supervision”.

3) Schedule M deals with **Good Manufacturing Practices and Requirements of Pilot Equipment for Allopathic Drugs.**

4) Schedule N includes the **List of Minimum Equipment for the Efficient Running of a Pharmacy.**

5) Schedule P deals with the **Life Period of Drug**s and the storage conditions of drugs.

6) Schedule T deals with **Good Manufacturing Practices for Ayurvedic, Siddha, and Unani Medicines**.

7) Schedule U de als with **Particulars to be shown in Manufacturing Records.**

8) Schedule V deals with **Standards for Patent or Proprietary Medicines.**

9) Sale is the process of passage of drugs from the manufactur ers to the consumers.

10) A wholesaler with a valid trade licence can ap proach the drug manufacturer for supplying medicine for selling to the retailers.

11) Retailing of drugs is done through shops or by vendors.

12) The Central Drugs Laboratory is established in Calcutta under the control of a Director.

13) Government analyst analyses in labs the drug and cosmetics test samples sent by the drug inspectors.

14) The Central Government appoints the Licensing Authorities to issue licenses for drug import.

15) Drugs inspectors chosen under this Act are under the control of a controlling authority.

16) Under the Act, the Central Government or the State Governments are required to appoint a suitable number of drug inspectors for their respective areas.

2.3. EXERCISE

2.3.1. True or False

1) Schedule V deals with Particulars to be shown in Manufacturing Records.

2) Schedule X deals with the List of Narcotic Drugs and Psychotropic Substances.

3) Drugs Consultative Committee comprises of four representatives nominated.

4) The Central Drugs Laboratory is established in Calcutta under the control of a Director.

5) Sale is the process of passage of drugs from the manufacturers to the consumers.

2.3.2. Fill in the Blanks

6) Schedules M and Y were established in_____.
7) Schedule _____includes the List of Minimum Equipment for the Efficient Running of a Pharmacy.
8) _____ is the process of passage of drugs from the manufacturers to the consumers.
9) Retailing of drugs is done through _____.
10) Schedule P deals with the_____ and the _____.

Answers:

1) False 2) True 3) False 4) True 5) True
6) 1988 7) N 8) Sale 9) Shops or by vendors
10) Life Period, storage conditions of drugs

2.3.3. Very Short Answer Type Questions

1) Write about the schedule M and T.
2) Define the DMR.
3) Which schedule deals with the life period and conditions of drugs?
4) Explain the schedule G.
5) What are the controlling authorities?

2.3.4. Short Answer Type Questions

1) Write about the whole sale and retail sale of drugs.
2) Mention the classes of drugs whose sale is prohibited.
3) Give the list of permitted colours.
4) Discuss about the drugs technical advisory board (DTAB).

2.3.5. Long Answer Type Questions

1) Write a note on drug inspector.
2) Discuss about the labelling and packing of drugs.
3) Give the procedure for sale, purchase and storage of drugs.

CHAPTER 3

Pharmacy Act, 1948

3.1. PHARMACY ACT - 1948

3.1.1. Introduction

Pharmacy profession was accepted quite late in India. Until the fifth decade of 20th century, no laws for controlling the operations and exercises related to drugs in India were in existence. In the earlier times, pharmacy profession was represented merely by the compounders. In health profession, compounder was recognised as a lowest rank worker who does not require any recognised education. If an individual can read a prescription and do some dispensing work, he/she can become a compounder.

This situation was changed by the commencement of the Pharmacy Act. It was passed with the objective:

1) To formalise the education and training of profession of pharmaceutical sciences, and
2) To control the operations and practices related to pharmacy.

The Pharmacy Act was implemented everywhere in India, but not in Jammu and Kashmir. The Act was amended in 1959, 1976, and 1982.

3.1.2. Definitions

1) **Central r egister** is a r egister of pharmacists maintained by the Central Council.
2) **Medical practitioner** is:
   i) A person who holds a qualification granted by an authority specified or notified under Section 3 of Indian Medical Degrees Act 1916, or specified in the schedules of the Indian Medical Council Act 1956, or,
   ii) A person registered or eligible for registration in a medical register of a state meant for the registration of a person practicing modern scientific system of medicine, or
   iii) A person registered in a medical register of a state who although not falling within sub -clause (i) or (ii) is decl ared by a general or special order made by State Government in this behalf as a person practising the modern scientific system of medicine for the purpose of this Act, or
   iv) A person who is engaged in the practice of veterinary medicine and who possesses qualification approved by State Government.
3) **Registered pharmacist** is a person whose name for the time being is entered in the register of pharmacists of the state, in which he is for the time being residing or carrying on his profession or business of pharmacy.

4) **Displaced person** is:
   i) A person who on account of the setting up of the Dominions of India and Pakistan or on account of the civil disturbances or the fear of such disturbances in area now forming part of Pakistan has on or after the first day of March 1947, left or been displaced from his place of residence in such area and who has since then been residing in India.
   ii) Any person who on account of civil disturbances or the fear of such disturbances in any area now forming part of Bangladesh, has after the 14th day of April 1957 but before the 25 th day of March 1971, left or has been displaced from his place of residence in such area and who has since then been residing in India.

5) **Repatriate** is any person of Indian origin who on account of civil disturbances in any area now forming part of Burma, Sri Lanka or Uganda, or any other country has after the 14 th day of April 1957, left or has been displaced from his place of residence in such area and who has since then been residing in India.

6) **University Grants Commission** means the University Grants Commission established under section 4 of the University Grants Commission Act, 1956.

7) **Indian university** means a university within the meaning of Section 3 of the University Grants Commission Act, 1956 and includes such other institutions, being institutions established by or under a Central Act, as the Central Government may, by notification in the 'Official Gazette' specify in this behalf.

3.1.3. Objectives

The Pharmacy Act was passed with the following objectives:

1) The prime need of this act was to limit the practice of pharmacy profession only to those who are qualified and trained, and also to establish an organisation which can monitor their work.

2) In order to fulfil this need, the individuals who wanted to practice pharmacy or opted pharmacy as their career had to join a session of education and practical training. These individuals on completion of education and training were suitable for practicing pharmacy in the new age.

The above mentioned objectives were fulfilled by the establishment of the central council, i.e., the **Pharmacy Council of India**. A pharmacy council for state was also established in each state to register and monitor the pharmacists and other practices, regarding the profession in their respective states.

3.1.4. Pharmacy Council of India

After the enactment of the Pharmacy Act in 1949, Central Government established the first Pharmacy Council of India, which needs to be reconstituted after every 5 years

3.1.4.1. Constitution

The present constitution of the Pharmacy Council of India is given in table 3.1:

Table 3.1: Constitution of Pharmacy Council of India

Members	Eligibility
Six Teachers	Elected by the University Grant Com mission from among the staff of Univers ities/Colleges conducting Pharmacy Degree/Diploma programmes. Out of 6 teachers at least one should be from the specialities of Pharmacy Pharmacology, Pharmaceu tical Chemistry, and Pharmacognosy.
One nominee of each State Pharmacy Council	Should be a Registered Pharmacist.
One nominee of each State Government	Should be a Registered Pharmacist.
Six nominees of Government of India	At least 4 of them should hold a Degree/Diploma in Pharmacy and be engaged in the practice of Pharmacy/Pharma ceutical Chemistry.
One nominee of the Medical Council of India	Should be elected by the members of the Council.
One representative of the University Grants Commission	No specific background provided for.
One representative of the All India Council of Technical Education	No specific background provided for.
Director of Central Drugs Laboratory established under the Drugs and Cosmetics Act	Ex-officio.
Director General of Health Services of the Government of India who is in charge of all health matters across nation	Ex-officio.
Drug Controller of India having administrative control over matters related to drugs	Ex-officio.

President and Vice-President

The PCI, being a corporate body, has a perpetual succession, a common seal and the power to acquire and hold movable or immovable property.

The members of the Council amongst themselves elect the President and the Vice-President of the Central Council for a period of 5 years and not beyond the expiry of their tenure as the Central Council member. However, they are e ligible for re-election. In case the President or Vice -President's tenure as member of the Central Council expires before the expiry of the 5 years, he should hold office as the President or Vice -President for the full term for which he is elected (if he i s re-elected or re-nominated as a member of the Central Council).

Elections are conducted as prescribed, and in case of any dispute the same can be referred to the central government whose decision is the final. A nominated or elected member holds office for 5 years from the date of his nomination or election or until his successor is nominated or elected (whichever is earlier). A nominated or elected member can also resign his membership by writing to the President. In case a nominated or elected member r emains absent from 3

consecutive meetings of the Central Council without sufficient reason to satisfy the Central Council, he is considered to have vacated his seat.

The members nominated by the University Grants Commission or Medical Council of India or State Pharmacy Councils should terminate their membership with the Central Council, if they are no longer members of the teaching staff in a university or college or of the Medical Council of India or are not registered pharmacist in the states. This vaca ncy in the Central Council should be filled by fresh nomination or election, and the nominated or elected person should hold the office for the remaining term.

The members of Central Council are eligible for re-nomination or re-election.

The Central Council should:
1) Appoint a Registrar who should act as the Secretary to the Council and also as its Treasurer (if needed), and
2) Appoint other officers and servants so that the Council carry out its statutory functions.

The Central Council may also take neces sary security from the Registrar or any other officers or servant for performing his duties. The Council with the prior sanction of the central government is authorised to fix:
1) The remuneration and allowances to be paid to the President, Vice-President, and other members of the Council, and
2) The pay and allowances and other conditions of service of officers and servants of that Council.

The Central Council constitutes an executive committee of the President (Chairman of the Committee) and Vice -President (*ex-officio*), and 5 other members elected by the Central Council from amongst its members.

A member of the Central Council should hold office till the expiry of his term as the Council member; however he is eligible for re -election. The Executive Committee is also authorised to constitute other committees from amongst its members for 5 years.

3.1.4.2. Functions

The Pharmacy Council of India performs the following functions:
1) **Design of the Educational Pattern:** The major f unction of PCI is to frame the educational structure for future pharmacists and updating it timely as per the new requirements. The education standards framed for the pharmacists by the Council are known as the **Education Regulations**. Some of the essential education standards are:
   i) Minimum qualification for getting admission in a pharmacy course,
   ii) The training period and the course to be followed during the education session,
   iii) The type and duration of practical training after the regular course is complete (tra ining period should not be less than 500 hours and should be within 3 months from a recognised institution, hospital, pharmacy or dispensary, or a licensed chemist and druggist shop),

iv) The subjects to be studied and the standards for qualifying examinations,
v) The facilities and equipment that the institutions running such courses should provide,
vi) The conditions to be fulfilled by the institutions provided practical training,
vii) The conditions to be fulfilled by the authorities conducting approved examinations,
viii) The minimum education standard required to qualify as a pharmacist,
ix) Education regulations prescribing conditions to be fulfilled by the institutions seeking PCI approval for providing pharmacy education,
x) Ensuring that the entire country is following the ed ucation standards set by the PCI,
xi) Timely inspecting the pharmacy institutions seeking approval under the Pharmacy Act to verify that the prescribed norms are available,
xii) Giving approval to the course of study and examination for pharmacists by approving th e academic training institutions imparting pharmacy education,
xiii) Withdrawing approval if the approved course of study or an examination does not adapt the educational standards set by the PCI,
xiv) Giving approval to the qualifications granted outside the territo ries to which the Pharmacy Act extends, i.e., approving foreign qualification, and
xv) Maintaining the Central Register of Pharmacists.

The education regulations are framed after getting approval from the Government of India, circulating the draft to each Sta te Governments, and taking into consideration if there are any comments. The Executive Committee of the Council should monitor from time to time the effectiveness of the regulations. This committee can also recommend the PCI in case any amendments are requ ired. The PCI has to follow the procedure for initial drafting; thus whenever any amendment has to be made in the education regulation, the draft should be circulated to the State Governments and approval from the Central Government should be gained.

By c onsulting with the respective State Pharmacy Councils, the State Governments should promulgate the Education Regulations in the States after the formation of the State councils. If no action is taken by any State Government on this behalf, the Act provides that automatically on the expiry of three years from the date of the constitution of the State Council, the Education Regulations should take effect in that State.

2) **Approval of Institutions/Withdrawal of Approvals:** Any insti tution or authority which runs a study course or conducts an examination for the pharmacists has to apply to the PCI for the approval of the course or the examination. In this case, the PCI appoint officers to inspect the institution and confirm that whether the facilities prescribed for imparting training or holding examinations are being conformed or not with the Education Regulations.

The allotted officers, in order to judge the standards may attend any examination, without interfering with its conduct. These officers then report to the Council about the sufficiency or insufficiency of the facilities available in the institution and also on the conduct and standards of the examinations held.

The Council grants approval to the inspected institution, if satisfied with the received report that the course or the examination standards are in conformity with the Education Regulations. On receiving approval the course or the examination become qualified for registration as a pharmacist under the Act. A resolution passed at a meeting of the Council should declare the approval and also it should be published in the Official Gazette.

The PCI may notify any institution or authority about its intention to withdraw the approval if any approved course of study or examination no longer conforms to the Education Regulations. The institution, after receiving the notice regarding the withdrawal of approval, takes necessary steps within three months of the notice. After considering these modifications made by the institution or authority, the Council decides whether to withdraw the approval or to continue, if the concerned authority or institution fulfils the specified conditions.

3) **Recognition of Foreign Qualifications:** Any qualification, granted by an authority outside India affording guarantee of requisite skill and knowledge to be a sufficient qualification for registration as a pharmacist under the Act should be recognised by the Council. The Council may further specify that such qualification shall be deemed to be sufficient, only when granted before or after a particular date subject to such additional conditions as may be specified by the Council. Only Indian citizens, possessing such qualifications should be eligible for registration. Citizens of other countries, holding qualifications granted there, shall be registrable in this country when an Indian national, holding the same qualification, is by law, allowed to enter and practice the profession of pharmacy in that country.

4) **Maintenance of Central Register of Pharmacists:** The Pharmacy Council of India should maintain a register in which names of all the registered pharmacists of different States should be contained, as per the provisions of the Pharmacy (Amendment) Act 1976. The Registrar, as per the directions of the Pharmacy Council of India, should maintain this register, revise it timely and also publish it in the Gazette of India. As per the Indian Evidence Act 1872, this register would be a public document.

5) **Registration of Pharmacists :** For controlling the entry of persons in the profession of pharmacy, registration of the pharmacists is required as per the Pharmacy Act. Therefore, only those persons who are qualified, trained and experienced related to compounding, dispensing, handling, storage, etc., of the drugs are allowed to practice pharmacy.

3.1.5. Education Regulations

With the approval of central government, the Pharmacy Council of India makes Education Regulations, in which they mention the minimum qualification needed for registration of pharmacists. The Education Regulations, 1991 **advises**:

1) The type and periods of theoretical study and practical training (should not be less than 500 hours and 3 months, provided that not less than 250 hours are utilised in dispensing prescription medicines in any recognised hospital/dispensary or Pharmacy/Chemist and Druggist or licensed drug manufacturing unit), and

2) The equipment and facilities to be provided for the students.

Education Regulations 1991 cancelled the Education Regulations 1981.

The Central Government approves the Education Regulations. If any amendments are to be made to these regulations, they are first circulated to the State Governments for their opinion. If they give any opinions within 3 months, they are considered by the Central Council before recommending to the Central Government.

3.1.5.1. Applications of Education Regulations to States

Education Regulations become effective in a State when the State Government passes a notification in the Official Gazette, only after consul ting with the State Council (after it is constituted). The Education Regulations take effect in the State for 3 years from the constitution date of the State Council.

The Central Council should provide the Central Government with the copies of its proceedings and that of the Executive Committee and also an annual report of its activities. The Central Council has made the following **regulations** for:

1) Management of the property,
2) Conduction of elections,
3) The functions of Executive Committee,
4) The procedure for s ummoning and calling meetings, conducting business, and the number of members required to constitute the quorum,
5) The powers and duties of the President and Vice-President,
6) The qualifications, terms of office, and powers and duties of the registrar, secretary, inspectors, and other office bearers and servants of the Central Council, including the amount and nature of security to be furnished by the registrar or any other officer or servant,
7) The manner in which the Central Register is to be maintained and published, and
8) The c onstitution and functions of the committees other than the Executive Committee, the procedure for summoning and holding meetings and the number of members necessary to constitute the quorum.

The Central and various State Pharmacy Councils provides the course which the 'would be' pharmacists should undertake, the nature and period of practical training they should undergo, and the examinations they should pass to become eligible for registration; and only after getting registered as a pharm acist one can practice this noble profession.

3.1.5.2. Approval of Study Courses and Examinations

In India, any institute or authority running pharmacy course can send an application to the Central Council for getting approval of the courses and examination.

On receiving the application, the Central Council allots its inspectors for visiting the institute and confirming whether or not the minimum facilities for running a pharmacy course or conducting the examinations as per the Education Regulations are available.

The inspectors are also obligatory to appear in any examination for evaluating the standards of the institute without interfering in the examination process. After

this, the inspectors submit their report and recommendations, and then the Central Council decides whether or not the institute should be given approval. This approval of course is necessary for the students to get registered as pharmacists under the Act.

Pharmacy education is also a technical education as per the All India Council for Technical Education (AICTE) Act. Thus, the AICTE sends its expert committees to evaluate whether or not the facilities to start a new course of pharmacy, along with the existing ones are available.

As a result, there is a dual control on pharmacy education and it is necessary for the two Councils to sign a Memorandum of Understanding (MoU) among them to avoid confusion.

Under Section 12 (Sub-Section 1), the Central Council approves the course only after getting satisfied with the inspection and getting convinced that the course of study is complying with the regulations. For this purpose, the Central Council made this enquiry from the Board that the necessary approval under Sub-Section (1) of Section 12 was granted.

If the Board feels that the institute (which has applied for approval) is not in conformity with the affiliation rules and the provisions of Education Regulations, it sends report to the Pharmacy Council of India and asks it to remove its approval for the following year. As long as the petitioner institute has been given approval under Sub-Section (1) of Section 12, the students will be allowed to be examined by the Board, having been approved by the Pharmacy Council of India under Sub-Section (2) of Section 12.

3.1.5.3. Withdrawal of Approval

The following **actions** the Central Council takes for withdrawing an approval of the course:

1) When the Central Council receives report from the Executive Committee stating that an approved course or an examination are not complying with the rules of Education Regulations, the Central Council sends a notice to the concerned authority for withdrawal of approval. Within 3 months from the receipt of notice, the authority should forward to the Central Council through the State Government such representation in the matter, as it may request to make.
2) After considering the representation received from the concerned authority and any observations made by the State Government, the Council declares that the course of study or the examination should be granted approval only when completed or passed before a specified date.

In **1937**, the pharmacy education to obtain a degree began with a 3-year course of Bachelor of Pharmacy (B. Pharm) at Banaras Hindu University in India. Pharmaceutical chemistry, analytical chemistry, and pharmacy were included in the syllabus to make the graduates work efficiently in quality control and standardisation of drugs for pharmaceutical companies; however this was not sufficient enough to make them eligible for practicing pharmacy. There were 3 institutions of pharmacy degree course before 1947. The Punjab University started a pharmacy department in 1944 and L.M. College of Ahmedabad started in 1947.

India at independence (in 1947) inherited the pharmacy profession system from the British rulers as it was unorganised and had no legal restriction on the pharmacy practice. The concept of pharmacy practice was not realised till independence. The Pharmacy Act was passed in 1948, which provided the nation's first minimum standard of educational qualification for practicing pharmacy to regulate the pharmacy practice, education, and profession. At the present time, for practicing pharmacy as a pharmacist, the minimum desired qualification is a diploma degree. Pharmacy council of India implemented the provisions of the Pharmacy Act. Under this Act, individual states are required for establishing state pharmacy councils for controlling and registering pharmacists in their individual states.

3.1.5.4. Approval of Other Qualifications

The Central Council may approve a qualification granted by an authority outside India to be an approved qualification for qualifying for registration under this Act if a sufficient guarantee of the requisite skill and knowledge is afforded. The Council also declare that if such qualification at any time should be deemed additional, to be approved only when granted before or after a specified date, only if the state or country in which the qualification is granted allows the citizens of India to enter and practice the profession of pharmacy. Thus, foreign qualifications are approved on a reciprocal basis.

In the following way, any authority who wishes to conduct any course can apply for obtaining approval:

1) Any authority in a State which is conducting a study course for pharmacist can apply to the Central Council for gaining approval. If the Central Council after inspection is satisfied that the course is complying with the Education Regulations, it grants approval to the course for the purpose of admission to an approved examination for pharmacists.
2) Any authority in a State conducting an examination in pharmacy can apply to the Central Council for gaining approval. If the Central Council after inspection is satisfied that the examination is complying with the Education Regulations, it grants approval to the examination for the purpose of qualifying for registration as a pharmacist, under this Act.
3) Every authority in the State conducting an approved course or an examination should provide timely information to the Central Council regarding the courses, training, and examination, their duration, and the requisites for such courses and examination.

Approval of courses and examinations, withdrawal of approval, and approval of foreign qualifications are declared in the meeting of the Central Council by making a resolution, which becomes effective as they are published in the Official Gazette.

3.1.5.5. The Central Register of Pharmacists

As per the provisions of the Pharmacy (Amendment) Act, 1976, the Central Council should maintain a central register and the State Council should maintain a state register having all the details of the registered pharmacists. Each State

Council should supply five copies of its register to the Central Council every year after 1st April. The Registrars of each State Council should timely inform the Central Council about the new additions or amendments in the state register. Thus, central register is a collation of all the state registers.

It is the duty of the Registrar of Central Council to maintain the central register as prescribed by the Council. The Registrar should also timely revise the Central Register and publish the same in the Gazette of India. The Central Register is deemed to be a public document within the meaning of the Indian Evidence Act, 1872.

3.1.6. State and Joint State Pharmacy Council

According to the Pharmacy Act, a State Pharmacy Council is constituted under each State Government. This Council maintains a register for the pharmacist of the state, as well as monitor their activities regarding the profession.

3.1.6.1. Constitution

The constitution of State Pharmacy Council is given in the **table 3.2**:

Table 3.2: Constitution of the State Pharmacy Council

Members	Elected/Nominated
Six registered pharmacists in the state.	To be elected by all the Registered Pharmacists. Election to be conducted by the State Pharmacy Council.
Five nominees of the State Government.	At least 3 should have Degree/Diploma in Pharmacy/Pharmaceutical Chemistry.
One representative of the State Medical Council.	To be elected by the State Medical Council.
One Government Analyst appointed under the Drugs and Cosmetics Act.	To be nominated by the State Government.
Chief of the Drug Control Department of the State.	Ex-officio.
Chief Administrator of the State Medical Services.	Ex-officio.

President and Vice-President

The State Pharmacy Council has continuous progress and involvement of corporate bodies with power to gain and hold the position and property. Each State Pharmacy Council has a President and a Vice-president. The Vice-president is elected by the members of the Council themselves for five years from the first constitution of the council.

The President is nominated by the State Government and if he is not already a member, then he becomes a member of the Council in addition after being elected as President. All the members of the Council, either nominated or elected, hold the office for 5 years. However, they may resign their membership by writing to the President.

If a member remains absent during three consecutive meeting of the council without giving any sufficient reason of absence then that person will be deemed to vacate his position in the Council.

The members who were either elected by the Pharmacy Council or by the Medical Council of the State shall cease to be members of the State Councils, in case, they cease to be either Registered Pharmacists or members of the Medical Council. In the Council, any casual vacancy can be filled by fresh election or nomination depending on the situation. However, all the members of the Council are eligible for the re-election and re-nomination.

An Executive Committee is constituted as per the requirement of the Council, which includes the President, the Vice President and other members as may be needed. A Registrar (also act as its Secretary) and other officers as well as staff appointed by the State Council to cater the functions of the council. The Registrar is appointed by the State Government for the first four years from the constitution of the council. Salary and other wages paid to the officers and other members of the Council is decided and fixed by the Council itself.

The State Pharmacy Council and Executive Committee should provide copies of their records and proceedings, along with abstract of the account to the State Government and to the Pharmacy Council of India. The State Government has power to publish any reports or proceedings if they found.

In each year before the end of June the State Council required to pay some fees to the Pharmacy Council of India. The amount of the fee is equivalent to one-fourth of the fees, realised by them during the period of 12 months ending on the 31st day of March in the given year.

Constitution of Joint State Pharmacy Council

Under the Joint State Pharmacy Council, two or more states enter into an agreement. According to the agreement, State Pharmacy Council of one State serves the needs of other state/states. The members (one having a degree or diploma in pharmacy or pharmaceutical chemistry or a member of the profession) of the Joint State Pharmacy Council are nominated by each of the State Governments.

During signing the agreement and constituting the Joint State Pharmacy Council, the participating states decide that which Government will perform various functions of the State Government under the Act and fulfil the needs of other state/states. The amount of the expenditure is shared by the participating states. At the same time, other important and required provisions are made for giving effect to the agreement.

Table 3.3: Constitution of the Joint State Pharmacy Council

Members	Number of Members
Registered Pharmacists	3 to 5 from each State instead of 6 in the Single State Council
Government Nominees	2 to 4 from each State instead of 5
Medical Council Nominees	1 from each State
Chief Administrative Medical Officer, Government Analyst and Officer-in-charge, Drug Control	Ex-officio from each State

3.1.6.2. Functions

The functions of the State Pharmacy Council are:

1) **Maintenance of Registers:** The State Governments prepared the very First Register of Pharmacists by a Tribunal. Names in the First Register can be entered on the basis of the qualifications which were slightly different and who had passed the State approved examinations of compounders/dispensers or had any degree and experience of dispensing drugs for 3 years or experience in dispensing the prescriptions of doctor for 5 years. This process was continued for about 3 years but when it did not end, in 1976 an amendment was made in the Act that the First Registers will be handed over to the State Councils by the State Governments.

   After the first register was prepared the State Councils were constituted and from thereafter the registers we re handed over to them. Maintenance of the register was the responsibility of The State Councils.

2) **Entry of Names from the Register:** When a date is given, the Registrar of the State Pharmacy Council receives all the registration applications. On receiving these applications, if the Regis trar is satisfied that the applicant is qualified as per the requirement and is eligible for registration, he may enter his or her name in the Register. Persons who got their names removed from the registers of other States should not be registered without the approval of the State Council. If the Registrar rejects any application for registration, the applicant (within three months of the rejection) may appeal to the State Council, the decision of which should be final.

   The Registrar issues a registration certificate to the person whose name has been entered in the Register. Annual payment of the prescribed fee to the State Council by the appointed date retains the names of the persons in the Register. If the person does not pay the renewal fee till the given date, the Registrar should remove his/her name from the Register. However, the name which has been once removed from the Register can be restored if the person fulfils the prescribed conditions. The Registrar issues a rec eipt after the renewal fee is paid and such receipts are confirmations of renewed registration.

   If after the first registration, a registered pharmacist procures any further professional qualifications, it could be mentioned in the Register against his name, on paying the prescribed fees.

3) **Removal of Names from the Register:** A registered pharmacist may get his/her name removed from the Register in the following cases:
   i) If his/her name has been entered in the Register due to error, misrepresentation or suppression of facts, or
   ii) If he/she has been imprisoned for an offence in any professional respect, due to which the Executive Committee renders him/her unfit to be on the Register of Pharmacists, or
   iii) If a person, employed to work under him in connection with any business of pharmacy, has been convicted of an offence or held guilty of an infamous conduct, such that if he was a registered pharmacist himself,

his name would have been removed from the Register. Action against the pharmacist can be taken only if it is proved that:

a) The objectionable conduct was instigated or connived at by the pharmacist himself, or
b) The registered pharmacist, during the period of 12 months preceding the offence, has been guilty of a similar offence or conduct, or
c) Any person, employed by the pharmacist for purposes of business of pharmacy, has been guilty of similar offence during the preceding 12 months and the pharmacist had the knowledge of the offence, or
d) The offence or conduct had continued over a long period and the pharmacist had or should have had the knowledge of the continuing offence, or
e) The act is an offence under the Drugs and Cosmetics Act, 1940 and the pharmacist did not use his intelligence to see that the provisions of this Act were being observed at his place of business by persons under his control.

After the Executive Committee of the State Pharmacy Council has made enquiries and given a chance to the concerned person to explain his/her conduct, it can pass order for their names to be removed. However, the removal of names from the Register may either be permanent or momentary (i.e., for specified time period).

When the Executive Committee passes an order for the removal of a name from the Register, it should be confirmed by the State Pharmacy Council. The name is removed after three months from the date of passing the order. Therefore, for the next three months the pharmacist (who is guilty) continues to be a registered pharmacist. But when the period of three months gets over he should be ceased to be a registered pharmacist. This grace period of three months is given so that the person could find another means of support.

Any pharmacist, if feels distressed after getting the order of removal of his/her name, has the right to appeal (within 80 days) to the State Government whose decision shall be final. After a person's name is removed from the Register, he/she should surrender his/her registration certificate to the Registrar of the Pharmacy Council.

Also, the State Pharmacy Council may give a restoration order of a person's name into the Register for sufficient reasons. But if the concerned person has already made an appeal to the State Government against the removal and the appeal has been rejected, the name cannot be restored, unless confirmed by the State Government.

4) **Printing of Registers:** On 1st April, after the commencement of the Pharmacy (Amendment) Act, 1959, the Registers were published by the Registrars of the State Pharmacy Councils. From then onwards on 1st April of every year, Registers were publishedwith all the amendments or modifications.

All Registers, prior to printing should be brought up to date three months before ordinary elections to the State Pharmacy Council. On payment of the

prescribed fee, the copies of the printed registers and all the supplements should be supplied to the persons applying for them. These Registers and supplements are the evidences that persons with their names in it are registered pharmacists.

5) **Inspection by the State Council:** A number of inspectors (with required qualifications) are appointed by the State Pharmacy Councils for inspecting premises where drugs are dispensed or compounded. These inspectors also investigate the complaints of contravention of the act and to institute prosecutions as per the direction of the Executive Committees of the State Councils.

Inspectors appointed by the State Council should have the required qualifications so that they are eligible for:

i) Inspecting premises where drugs are dispensed or compounded,
ii) Enquiring whether a person engaged in compounding or dispensing of drugs is a registered pharmacist,
iii) Investigating any complaint made in writing regarding the contravention of the Act,
iv) Instituting prosecution when ordered by the Executive Committee of the State Council to do so, and
v) Exercising other powers as necessary for certain purposes of this Act or any rules made thereunder.

As per the Indian Penal Code (Section 21), every inspector is a public servant. A person obstructing an inspector to exercise his powers would be punished with imprisonment up to six months or with fine up to ₹1000 or both. The State Council, similar to the Central Council, constitutes an Executive Committee and should also submit the required information to the State Government which may be published in the desired manner.

3.1.7. Registration of Pharmacists

For controlling the entry of persons in the profession of pharmacy, registration of the pharmacists is required as per the Pharmacy Act. Therefore, only those persons who are qualified, trained and experienced related to compounding, dispensing, handling, storage, etc., of the drugs are allowed to practice pharmacy.

After the Education Regulations have become effective in the State, a person can be registered as a pharmacist if he/she complies with the following conditions:

1) He/She should attained the age of 18 years,
2) He/She should resides or carries on the business or profession of pharmacy in the State,
3) He/She should pass an approved examination or possesses a qualification granted by an authority outside India and approved by the Central Council, or
4) He/She should be a registered pharmacist in another State.

The registers maintained by the State Councils and the Central Council should have the names of the registered pharmacists. As soon as the registration of pharmacists has taken effect in any State, the first registers in each State are prepared by the State Governments. Thereafter, as the State Councils are constituted, they are responsible for maintaining the first registers.

The following **particulars** are included in the register:
1) Full name and the residential address of the registered pharmacist,
2) Date of his first admission to the register,
3) His qualifications for registration,
4) His professional address and the name of the employer (if he is an employee), and
5) Other particulars (that may be prescribed).

Maintenance of register is required for entering the names and qualification details of the pharmacist. The registers are of the following **two types**:

1) **First Register:** After notifying in the Official Gazette, the State Government constitutes a Registration Tribunal for preparing the first register. The members constituting this Tribunal are three persons and a Registrar, appointed as the secretary. For registration the pharmacists have to submit the concerned ap plication along with the prescribed fee to the Registration Tribunal before the final date appointed by the State Government. The Tribunal after receiving all the applications within the final date examines them properly. If the applicant is found to be el igible for registration, his/her name is entered in the register.

   The manner in which the first register is to be published is prescribed by the State Government. If a pharmacist is not satisfied with the decision of Tribunal, he/she may appeal to the co ncerned authority appointed by the State Government. This appeal should be made within 60 days from the date of publication. The register is amended according to the decision taken by such authority and then a registration certificate is issued by the Regi strar to each and every applicant with their name entered in the register. After the constitution of the State Council, the register is handed over to it.

   Qualification for Entry on First Register: An individual becomes eligible to get his name entered in the first register at 18 years of age on paying the prescribed fee. The name of individual can also be entered if he/she lives or carries the business or profession of pharmacy in the State and if:
   i) Holds a degree or diploma in pharmacy or pharmaceutical c hemistry or a chemist and druggist diploma of an Indian university or a State Government, as the case may be or a prescribed qualification granted by an authority outside India, or
   ii) Holds a degree of an Indian university other than a degree or diploma in pharmacy or pharmaceutical chemistry and has an experience of compounding drugs in a hospital or dispensary or other place in which drugs are regularly dispensed on prescriptions of medical practition ers, for a not less than three years, or
   iii) Has passed an ex amination which is recognised as passable by the State Government for compounders or dispensers, or
   iv) Has an experience of compounding drugs in a hospital or dispensary or other place in which drugs are regularly dispensed on prescriptions of medical practit ioners, for not less than five years prior to the date notified by the State Government for receipt of applications for entry of names on the first register to the Registration Tribunal.

2) **Subsequent Register:** After the date appointed by the State Govern ment for receiving registration applications by the Registration Tribunal and before the Education Regulation have taken effect in the State, an individual who is 18 years and is living or carrying the business or profession of pharmacy in the State can have his/her name entered in the subsequent register on paying the prescribed fee and fulfilling the following conditions:
   i) Satisfies the prescribed conditions as approved by the Central Council or where no qualification has been prescribed, the conditions enti tling a person to have his name entered on the first register and has passed a matriculation or an equivalent examination, or
   ii) Is a registered pharmacist in another State, or
   iii) Possesses a qualification granted by a foreign authority, but approved by the Cent ral Council and has passed a matriculation or equiva lent examination.

3.1.8. Offences and Penalties

The serious offences and their penalties are discussed under:

1) **Falsely claiming to be a Registered Pharmacist:** A person falsely claiming to be a registered pharma cist or using with his name such words or letters (‘Pharmacist’, ‘Chemist’, ‘Druggist’, ‘Dispenser’, ‘Dis pensing Chemist’ or any of their combinations with any other words) that signifies his name to be entered in the Register, is punishable with a fine u p to ₹500, on the first conviction. But if a person has filed an application for registration at the time of making claims regarding registration in the State is not considered to be guilty of the offence.

   The person who claims to be a registered pharmacis t should prove that his name is on the Register of another State. The State Government or the officers authorised by them or the Executive Committee of any State Pharmacy Council will take complaints if any offence comes to their knowledge.

2) **Dispensing by U n-Registered Persons:** If a person is not a registered pharmacist, he is not eligible for compounding, mixing or dis pensing drugs on the prescriptions of Medical Practitioners after the date notified by the State Government. But this clause is brought unde r operation after 8 years from the commencement of the Amend ment Act of 1976, if no such date is notified by the State Government.

   Medical Practitioners dispense medicines to their own patients and may also dispense to patients of other medical practiti oners (only after seeking the State Government’s permission). The later part of the rule can hardly lead to a rise in the standard of the profession of pharmacy in the country. As the practice continues at present, most of the General Medical Practitioners do not provide their patients with prescriptions but have allotted compounders for dispensing the drugs. This practice is corrupt but continues in view of the rule mentioned above.

   A person is punished with imprisonment up to six months or a fine up to ₹1,000 or with both if breaches this rule. The State Government or an officer

authorised by it or the Executive Committee of any State Pharmacy Council take complaints if any such offence comes to their knowledge.

3) **Failure to Surrender Certificate of Registra tion:** A person is punishable with a fine up to ₹50, if his/her name has been removed from the State Register and has not surrendered his registration certificate to the Registrar without sufficient reason.

4) **Commissions of Enquiry:** The Central Government ma y appoint a Commission of Enquiry, consisting of 3 persons (2 nominated by the Government, one of whom should be a High Court Judge and one nominated by the Council), if it appears that the Central Council of Pharmacy is not functioning properly.

   The Central Government then acts as per the recommendations given by the Commission and also orders the Central Council to remove the defects. The Government may pass orders to give effect to the recommendations of the Commission, if still the Council fails to implement the recommendations.

   Similarly, whenever the State Governments realise that the Pharmacy Councils of the States are not functioning properly, they may also appoint Commissions of Enquiry to give recommendations for removing the defects and pass orde rs to give effect to the recommendations made by the Commissions.

3.2. SUMMARY

The details given in the chapter can be summarised as follows:

1) Pharmacy profession was accepted quite late in India.
2) **Registered pharmacist** is a person whose name for the time being is entered in the register of pharmacists of the state, in which he is for the time being residing or carrying on his profession or business of pharmacy.
3) **Central register** is a register of pharmacists maintained by the Central Council.
4) After the enactment of the Pharmacy Act in 1949, Central Government established the first Pharmacy Council of India.
5) In **1937**, the pharmacy education to obtain a degree began with a 3 -year course of Bachelor of Pharmacy (B. Pharm) at Banaras Hindu University in India.
6) For con trolling the entry of persons in the profession of pharmacy, registration of the pharmacists is required as per the Pharmacy Act.
7) The registers main tained by the State Councils and the Central Council should have the names of the registered pharmacists.
8) The PCI, being a corporate body, has a perpetual succession, a common seal and the power to acquire and hold movable or immovable property.

3.3. EXERCISE

3.3.1. True or False

1) The registers maintained by the State Councils and the Central Council should have the names of the registered pharmacists.
2) Central Government established the first Pharmacy Council of India before the enactment of the Pharmacy Act in 1949.
3) Education Regulations 1991 cancelled the Education Regulations 1981.
4) The Pharmacy Act was implemented everywhere in India.
5) As per the Indian Penal Code (Section 21), every inspector is a public servant.

3.3.2. Fill in the Blanks

6) The Pharmacy Act was implemented everywhere in India, but not in _____.
7) Central register is a register of pharmacists maintained by the_____.
8) After the enactment of the _____, Central Government established the first Pharmacy Council of India.
9) The education standards framed for the pharmacists by the Council are known as the _____.
10) The State Governments prepared the very First Register of Pharmacists by a _____.

Answers:

1) True	2) False	3) True	4) False	5) True
6) Jammu and Kashmir		7) Central Council		
8) Pharmacy Act in 1949		9) Education Regulations		10) Tribunal

3.3.3. Very Short Answer Type Questions

1) What is central register?
2) Who is known as the registered pharmacist?
3) Write the objective s Pharmacy Act-1948.
4) Explain any two functions of pharmacy council of India.

3.3.4. Short Answer Type Questions

1) Write the constitution of pharmacy council of India.
2) Explain the functions of state and joint state pharmacy council of India.
3) Write a short note on education regulations by PCI.
4) Mention the offences and penalties given in Pharmacy Act in 1949.

3.3.5. Long Answer Type Questions

1) Give a note on pharmacy council of India.
2) Explain the constitutions and functions of state and joi nt state pharmacy council of India.

CHAPTER 4

Medicinal and Toilet Preparations Act, 1955

4.1. MEDICINAL AND TOILET PREPARATION ACT-1955

4.1.1. Introduction

The Medicinal and Toilet Preparations Act was passed in **1955** in regard to collection of tax and excise duties on medicinal and toilet preparations having alcohol, narcotic drugs, or narcotics, and the corresponding rules to the Act were passed in **1956**. This Act was enforced since **1st April**, **1957** to all over India.

4.1.2. Definitions

The definitions and important terms of The Medicinal and Toilet Preparations Act, 1955 are as follows:

1) **Alcohol** is ethyl alcohol of any concentration and purity having the chemical composition C_2H_5OH.
2) **Excise Officer** is an officer of the Excise Department of any State and includes any person empowered by the collecting Government to exercise all or any of the powers of an excise officer under this Act.
3) **Medicinal Preparation** includes all drugs which are remedy or prescription prepared for internal or external use of human being or animals; and all substances intended to be used for or in the treatment, reduction, or prevention of disease in human beings or animals.
4) **Narcotic Drug** or **Narcotic** is a substance which is coca leaf or coca derivative or opium or Indian hemp and shall include any other substance capable of causing or producing in human beings depend ence, tolerance, and withdrawal syndromes and which the Central Government may by notification in the Official Gazette, declare to be narcotic drug or narcotic.
5) **Toilet Preparation** is a preparation which is meant to be used in the toilet or in perfuming apparel of any description or any substance intended to cleanse, improve or alter the complexion, hair, skin or teeth and includes deodorants and perfumes.
6) **Bonded Manufactory** is the site recognised and licensed for the manufacture and storage of medicinal and toilet preparatio ns containing alcohol, opium, Indian hemp or other narcotic drugs on which duty has not been paid.
7) **Non-Bonded Manufactory** is the site approved and licensed for the manufacture and storage of the medicinal and toilet preparations containing alcohol, opium, Indian hemp and other narcotic drug or narcotics on which duty has been paid.

4.1.3. Objectives

The Medicinal and Toilet Preparations Act deals with the regulatory problems resulting from the use of alcohol in many medicinal and toilet preparation s. It significantly assisted in limiting the large scale inter-state smuggling of alcoholic medicinal and toilet preparations that was previously in existence due to different rates of excise duties in various states. This Act made uniform rates of duty applicable in all over the country.

The **objectives** of Medicinal and Toilet Preparation (Excise Duties) Act, 1955 are given below:

1) It provides the collections of tax and duties of excise on medicinal and toilet preparations having alcohol, narcotic drugs, or narcotics.
2) It provides uniformity in the rules and rates of excise duties leviable on these preparations in all over the country.

4.1.4. Licensing

Manufacture of alcoholic preparations and narcotics or narcotic drugs can be done only by an authoris ed license e to whom the license is issued only if he already has the license for manufacturing drugs under the Drugs and Cosmetics Act and Rules. An application for the license or for its renewal is made to the Licensing Authority, who is either:

1) The Excise Commissioner in case of a bonded manufactory or warehouse, or
2) An officer authorised by the State Government.

The application for the license should be filled up and submitted along with the prescribed fee, two months before the planned date for beginning the manufacture. The **following details** should be mentioned in the application for obtaining license to manufacture dutiable goods in or outside bond:

1) The applicant's name, address, and the location where the manufactory is or is to be built.
   i) In case the application is for a firm, the name and address of each partner of the firm, and
   ii) In case the application is for a company, the registered name and address of the company and of its directors, managers, and managing agents.
2) The amount of the capital planned to be invested in the project.
3) The expected date of starting the manufactory along with the statement whether the bonded laboratory will need excise officer to provide a whole time or part-time services, and whether the quarters for excise staff will be in the manufactory or its nearby area.
4) The number and full description of containers, stills , other permanent apparatus, and the machines required to set up.
5) The maximum quantity of alcohol and alcohol content in the finished preparations and the maximum quantities by weight of op ium, Indian hemp or other narcotic drugs or narcotics and their content in finished and unfinished preparations.
6) The plans for the progress of manufactory and of the quarters of the excise officer along with proper records.

7) The amount in either cash or Go vernment Promissory notes the applicant prepared to abide by the conditions on which the license can be obtained.
8) The type of license and its number issued to the applicant under the Drugs and Cosmetics Act.
9) A list of the preparations that the applicant means to manufac ture and/or those he had manufactured in the previous year along with the percentage or amount of alcohol in alcoholic preparation s or opium, India hemp or other narcotic drugs in terms of weight in proportions having those substances, stating the Pharmacopoeia under which these preparations are/were planned to be manufactured.

On receiving the application, the **Licensing Authority can inquiry** about:
1) The qualifications and earlier experience of the personnel in manufacturing,
2) The equipment of the bonded and non-bonded laboratory,
3) The applicant's financial status, and
4) The suitability of the building where the manufacturing unit has to be built.

4.1.5. Manufacture In Bond and Outside Bond

Manufacturing of alcoholic preparation can be done either **in bond** or **outside bond** according to the following differences:

Manufacture of Alcoholic Preparations

In Bond

1) Licence.
2) Construction of bonded lab as per law - necessary compartments (raw spirit store manufacturing room, store room for finished goods, and excise staff office).
3) Excise duty payable on removal of goods from bonded lab.
4) Bonded lab to function under excise staff.
5) Suitable for large scale manufacture.

Outside Bond

1) Licence.
2) Construction of non -bonded lab as per law-necessary compartments (raw spirit store manufacturing room, finished goods store).
3) Excise duty payable at the time of spirit purchase.
4) No excise staff.
5) Suitable for small scale manufacture.

4.1.5.1. Manufacture In Bond (Bonded Laboratory)

Only one entrance and one door to every compartmen t should be provided in the bonded factory. The doors should be protected by excise ticket locks, when the officer-in-charge is not available.**Provisions** required for the bonded laboratory are:
1) If the manufactory is not situated near the distillery or spir it warehouse, one plain spirit store should be arranged.
2) A large room should be present to manufacture medicinal preparations and separate arrangements should be there for manufacturing toilet preparations.
3) Separate rooms should be present to stock up the manufactured medicinal and toilet preparations.
4) In the bonded premises, a room with basic furniture should be present to accommodate the officer-in-charge.
5) Each window should be fitted with flexible iron rods (of thickness not less than 3/4 inches) placed 4 inches apart, embodied up to a depth of 2 inches in

brick work, and internally covered with strong wire netting or a mesh of diameter or length not greater than 1 inch.
6) In the manufactory, outside each room a board carrying the name of the room and a serial number (if any), painted in oil colour should be placed.
7) Each pipe coming from the sinks or wash basins in the manufactory area should be attached to a common drainage system to dispose of all the waste.
8) In the licensed premises, all gas and electrical connections should supply gas or electricity effectively, and every regulators or switches can be locked safely after the working hours.

Licence for Bonded Laboratory

To manufac ture alcoholic preparations and narcotics (or narcotic drugs), an authorised licence is needed, which is issued only if the individual already has the licence to manufacture drugs as per Drugs and Cosmetics Act and Rules. To obtain the licence or in order to renew it, an application is forwarded to the Licensing Authority, who may be:

1) The Excise Commissioner, when the license has to be obtained for a bonded manufactory or warehouse, or
2) An officer appointed by the State Government, when the license has to be obtained for non-bonded manufactory or warehouse.

The licence application contains a prescribed form which the individual should fill properly and submit along with the mentioned fee before 2 months to the proposed date from the commencement of manufacturing.

Following **particulars** are included in the **application** submitted to o btain licence for manufacture of dutiable goods in bond:

1) Applicant's name and address, along with the place and site where the manufactory is established or to be constructed. Application for a firm should include:
   i) The name and address of each partner associated with the firm, and
   ii) In case of a company, its registered name and address, and also the names and addresses of the directors, managers, and managing agents.
2) The amount of the capital to be invested in the project.
3) The expected date of starting the ma nufactory and the statement to inform if the bonded laboratory requires the whole time or part -time service of an Excise Officer, and whether staff quarters will be provided within the manufactory or the surrounding area.
4) The applicant should mention the n umber and full description of containers, stills, and other permanent apparatus and machines to be employed. The maximum amount of alcohol and alcoholic content in the final preparations should also be specified. The maximum amount of opium, Indian hemp, o r other narcotic drugs or narcotics and their contents present in finished and unfinished preparations should be described as per weight.
5) The future plans for developing manufactory, building, and the staff quarters for Excise Officer together with appropriate records should be presented.
6) The amount in cash or Government Promissory Notes prepared by the applicant for the due performance of the conditions on the basis of which the license has to be issued.

7) Every type of license (with its number) that the ap plicant holds under the Drugs and Cosmetics Act.
8) All preparations that will be manufac tured and/or those which have been manufactured in the previous year should be enlisted. It should also mention the percentage or amount of alcohol in alcoholic preparat ion or opium, India hemp, or other narcotic drugs as weight in proportions of the substances containing them. The Pharmacopoeia as per which the preparations were or are to be manufactured should also be stated.

Fees

The application for licence should be accompanied with following fees:

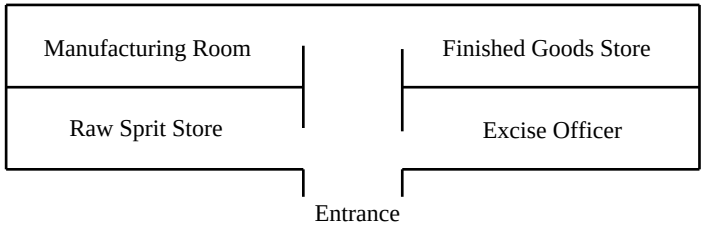
1) When consumption of alcohol is less than 4,000 L.P. litres per annum …₹100.00
2) When consumption is 4,000 L.P. litres or more …₹200.00
3) Manufacture for sale of Ayurvedic or Unani medicines containing self-generated alcohol or containing alcohol produced by distillation …₹25.00

After attaining the application, the **Licensing Authority may present query** for:

1) The qualifications and previous experience of the personnel involved in the manufacturing operations,
2) The equipment present in the bonded and non-bonded laboratory,
3) Applicant's financial position sustainability, and
4) The building where manufacturing is to be carried out.

Design and Construction of Bonded Laboratory

A bonded laboratory has the compartments as shown below:



The laboratory should own a single entrance and a single door for each compartment. The laboratory can be opened only when the Excise Officer -in-charge is present, and when the officer is unavailable, each door should be secured with excise ticket locks. In the bonded premises, the windows should carry non-malleable iron rods (of thickness 1.9cm or more) set at 10cm apart, embodied in brick work to a minimum 5cm depth, and internally covered with strong wire netting or expanded metal of a mesh with diameter or length not greater than 2.5cm.

Each room in the laboratory should bear a board at its entrance mentioning serial number and purpose. The sinks pipes of the laboratory should be linked to the drainage system of the premises. Arrangement of the gas and electric connections should allow ease in cutting-off its supply at the end of the working day. Alcohol and other narcotic drugs received under bond should be stored in permanent vessels.

All vessels carrying alcohol and other liquid preparations should bear a serial number and a statement depicting its full capacity. At 2.5cm and at 2.5mm, the contents of each vessel should be denoted in tabular form. Excise ticket secured locks are compulsory for vessels having preparations whose duty is pending to be paid.

Manufacture of Alcoholic Preparations in Bonded Laboratory

The steps to manufacture alcoholic preparations in bonded laboratory are:

1) **Procurement of Rectified Spirit:** Obtaining rectified spirit to produce medicinal and toilet preparations require attested indent by the officer-in-charge from any distillery or spirit warehouse. As soon as the distillery or spirit warehouse officer receives the duplicate copy of the indent, he should issue the spirit in properly sealed containers. The same should be informed to the officer-in-charge.

2) **Verification of the Rectified Spirit Received:** At the bonded laboratory, the received consignments of spirit under bond needs to be checked for volume, strength, and the amount entered in the maintained register. The spirit should be stored in the respective store after verification.

3) **Issue of the Spirit from the Spirit Store:** The calculated quantity of alcohol can be obtained upon the licensee's request to the officer-in-charge. Manufacturer should keep the other ingredients of the preparation ready, and should immediately add alcohol in the presence of the officer-in-charge. Each percolator or other vessel (proposed for alcohol) at every use should be attached with a label indicating:
   i) Preparation name and batch number,
   ii) Description and quantity of alcohol incorporated, and
   iii) Date on which the preparation was taken out and also its quantity.

   The manufactured preparation should be transferred to the finished goods store, to get it carefully measured. It should be stored in separate vessels provided for the purpose and then mentioned in the record maintained.

   All the entries of the batches of finished preparations should be attested in the stock register maintained. This should be done by the officer-in-charge. The samples should be supplied free of cost (required for the analytical purpose) by the licensee. In addition, he should also bear all the packaging and shipment cost of the samples. The samples can also be sent to the chemical examiner for analysis.

4) **Storage of Finished Products:** The finished medicinal and toilet preparations should be stored in jars or bottles with capacity of 80 fluid ounce volume. The ready-to-use preparations should be filled in bottles or containers with 2 fluid ounce volume. Permission could be obtained from the Excise Commissioner for filling up of small capacity bottles or containers. All the containers of finished products should bear a label signifying the name, batch number, alcoholic strength, and manufacturer's name.

   A record of the shortage in bulk content related to finished products should be maintained by the officer-in-charge. Information for shortage of contents should be passed to the Excise Commissioner quarterly. The Excise Commissioner assures himself that the shortage of the content occurred due

to natural or unavoidable reasons implying that the alcoholic preparation has not been consumed. Then, the duty payable is passed by the Excise Commissioner; or else these losses are considered to pay levy of duty at penal rate, twice the prescribed rates.

5) **Issue of Alcoholic Preparations from the Bonded Laboratory:** An application in the prescribed form is sent to the Excise Officer after paying for it, a manufacturer can acquire alco holic preparations from a bonded laboratory. The Excis e Officer verifies whether the entries and the payment made by the manufacturer allows the required quantities to be removed. These preparations should be delivered to bonded warehouse or institutions or should be exported with no payment of duty.

6) **Deficiencies in Finished Store:** A record is prepared and maintained by the officer-in-charge in store for shortages of finished medicinal or toilet preparations. This report should be forwarded to the Excise Commissioner quarterly. If the Excise Commissioner consi ders the reasons for the shortage to be inappropriate, all the losses become part of levy of duty at penal rates, not more than double the rates prescribed.

7) **Disposal of Sub -Standard Preparations:** If the quality of the finished medicinal or toilet preparati ons have depleted, the manufacturer should destroy it after obtaining permission from the Excise Commis sioner. The Excise Commissioner in this case should allow the manufacturer to re - process the preparation (of sub -standard quality). When the reason for the decline of preparation or its improper manufacture gets justified as an uncontrollable event by the licensee in eyes of the Excise Commissioner, the duty imposed on alcoholic content present in the destroyed preparation should be submitted by the Excise Commissioner.

8) **Disposal of Recovered Alcohol:** While manufacturing a medicinal or toilet preparation, the alcohol recovered or distilled separately from the mark of such preparation, should be employed in the following manufacture of the same preparation.

9) **Remission of Duty in Case of Loss due to Accident:** The alcohol lost either accidentally in a bonded manufactory (else by theft) or due to any reason uncontrollable by the licensee is liable to submit the duty with the consent of the Excise Commissioner.

4.1.5.2. Manufacture Outside Bond (Non-Bonded Laboratory)

The production of medicinal and toilet preparations can be carried out without bond by the manufacturer after availing the respective license. An application for the licence in the prescribed form is sent to the officers appointed by the State Government for this purpose. The licence specifications are same for the manufacturing of medicinal preparations outside bond and in bond. Non -bonded manufactory requires separate premises where only medicinal and toilet preparations will be manufactured.

Licence

The licence required for manufacturing medicinal and toilet preparations without bond can be obtained by giving an a pplication to officers appointed by the State

Governments. The application form and other conditions of the licence for manufacturing medicinal preparations outside bond are the same as those for manufacturing under bond. The following fee structure should be followed for obtaining a licence for non-bonded manufactory:

a) Consumption of alcohol is 125 L.P. litres or less per annum. …₹10.00
b) Consumption of alcohol per annum is more than 125 but less than 500 L.P. litres …₹25.00
c) For manufacturing Ayurvedic Unani preparations containing either self-generated alcohol or distilled alcohol. …₹25.00

Non-bonded manufactory should be separate from the other working area, and should be used only for manufacturing spirituous medicinal and toilet preparations.

Design and Construction of Non-Bonded Laboratory

In a non-bonded laboratory, the production and sale should be done on days approved by the Excise Commissioner and from sunrise to sunset. The manufactory should have a spirit store, a laboratory, and a finished goods store. The manufactory should possess only one entrance. Each laboratory, spirit store, and finished product store should have a single door.

The windows should be protected by iron bars, etc. (as in bonded laboratories). Every pipe from sinks and wash basins should discharge the wastes into the main drainage system. Provision to cut off electric and gas connections at the end of each working day should be present. Collection and stocking of rectified spirit and finished preparations should be done in proper containers and vessels.

Manufacture in Non-Bonded Laboratory

The steps followed for manufacture in non-bonded laboratory are as follows:

1) **Obtaining the Spirit:** Two copies of an application (one to the distiller or the warehouse keeper and the other to the Excise officer-in-charge of the warehouse or the distillery) should be sent for getting spirit, either from a distillery or a spirit warehouse.

   First of all the manufacturer should pay the excise duty on the quantity of spirit required to be purchased and the 'Chalan' of the payment along with the application should be submitted prior to sending the duplicate copy of the application to the distillery officer-in-charge. The Treasury Officer should send an invoice to the distillery Excise officer-in-charge. After knowing that the correct amount of duty has been paid for the spirit, the Excise officer in-charge of the distillery should issue the spirit along with a permit. The manufacturer on receiving the spirit should make entry in the maintained register. Thereafter, the spirit should be transferred to the spirit store.

2) **Manufacture:** The preparations utilising the duty paid spirit should be manufactured at the authorised premises. After manufacturing the preparations, each one should be assigned a batch number.

3) **Storage:** After manufacturing, the finished preparations should be shifted from the laboratory to the finished goods store. Arrangement of these preparations should be such that they allow easy access from the stock register. Bulk preparations stored should be measured using storage vessels

of around 28.350 ml capacities. The quantities taken at each interval should be mentioned in the stock card to verify whenever required.

4) **Sampling:** Samples of 10-15% of the total number of batches manufactured each month should be withdrawn by the Excise Officer (authorised to the non-bonded laboratory) for analysis. The samples can be obtained by the officer himself, without giving early notice to the manufacturer, but should withdraw sample in front of the manufacturer or an agent authorised by him. Every sample should be taken in duplicate and bottle labels should be signed. The officer's seal should be affixed on the cork of each bottle from which sample has been withdrawn. The manufacturer may put its own signs and seals on the sample bottles at its own will. No compensation should be provided to the manufacturer for the samples.
5) **Returns:** The manufacturer should keep track on the business transactions in the manufactory. The accounts maintained should be sent to the authorised officer on the 5th of every month. The manufacturer should maintain a list of names including Manager, Assistant Manager, and other employees of the non-bonded laboratory. No one other than those having their names in the list should be allowed to enter the laboratory. Any change made in the staff by the manufacturer should be notified to The Excise Commissioner and other concerned officers.
6) **Inspection:** The inspection of the non-bonded laboratory (at least once in a month) should be done by the Excise Commissioner and other Excise Officers authorised in that area. An authorised person appointed by the State Government could be an officer of Prohibition, Land Revenue, or Medical and Public Health Departments having the right to inspect the non-bonded laboratory.

4.1.6. Export of Alcoholic Preparations

In India, the alcoholic preparations are exported duty free. An application in triplicate is submitted by the exporter. This application holds a declaration for the goods to be exported by land, sea, air, or by post parcel to the officer-in-charge or the other concerned officer.

Each consignment requires a separate application. At the export area, the original application is handed over to the Customs Officer or the Border Examiner or the Post Master by the officer-in-charge or the concerned officer. The consignor receives the duplicate copy, and the third copy is kept for office records.

Export under Bond

The goods should be packed in cases or packages for export from a bonded manufactory or warehouse and the **following details** should be marked in ink or oil colour:

1) Progressive number starting from 1 for each year,
2) Name of the owner and its special mark (if any), and
3) Quantity of dutiable goods and their alcoholic content (in L.P. gallons).

The officer-in-charge or the concerned officer verifies the application details including:

1) Consignee's name and address,
2) Goods details,

3) Quantity of packed goods,
4) Alcoholic content present in the goods in L.P. gallons as stated by the manufacturer, and
5) Package gross weight.

Each package is sealed with an official seal by the concerned officer prohibiting the opening of the package without breaking the seal.

Export of Duty Paid Goods

In order to export duty paid goods, the owner of the non-bonded manufactory or a warehouse dealer needs to provide a notice of 48 hours to the concerned officer to supervise the goods packed to be exported. The concerned officer, withdraw samples of the goods from entire consignment need for analysis performed by the Chemical Examiner. The warehouse dealer should mention the alcoholic content of the goods packed (as reported by the Chemical Examiner) in the duplicate copy of the application. Exporter need to submit this copy to the Excise Commissioner, demanding for the refund of excise duty. The details stated in the application are scrutinized by the officer-in-charge and enters the following **data** on each package:

1) Name and address of the consignee,
2) Details of the goods,
3) Total quantity of the goods packed and their alcoholic content in L.P. gallons, and
4) Gross weight of the package.

To make the goods temper proof, officer-in-charge should seal each package with the official seal. These packages are exported just like the bonded goods.

Export by Parcel Post

After sealing the goods to be exported by post, the exporter needs to present the duplicate copy of application along with relevant packets or packages to the Post Master at the booking office. The Post Master of the final post office of disposal should mention on the duplicate application that the goods are properly exported out of India. The duplicate application must also carry that the goods have been returned to the exporter through post master at the booking post office. The original application and the export certificate is returned to the officer-in-charge or the concerned officer.

Inter-State Transport of Alcoholic Goods

The inter-state transportation of medicinal and toilet preparations containing alcohol, opium, Indian hemp, or other narcotic drugs is possible once the payment of duty is made.

The Excise Commissioner access into a bond with security (to remove goods from time to time) permits to shift goods from one warehouse to another. The application with this regard is also made in triplicate (along with other details requested by the Excise Commissioner), by the consignor to the removal warehouse officer-in-charge, at least 24 hours before to the removal. The officer receiving application must verify the goods and once the removal certificate on all the application copies are carried out, the duplicate copy has to be given to the officer-in-charge of the warehouse and the triplicate copy is retained by the consignor to dispatch the goods to the consignee.

The officer-in-charge also issues the consignor a transport permit. The consignee arranges together each product arriving at the warehouse, the triplicate copy of application along with the transport permit and puts before the warehouse officer-in-charge. The goods need to be observed and the re-warehousing certificate on the duplicate or triplicate copy of application has to be issued.

The warehouse officer-in-charge of removal keeps the duplicate copy and the triplicate copy is handed over to the consignor. Within 90 days of issue of transport permit, the consignee has to submit the triplicate (with properly validated certificates) copy to the warehouse officer-in-charge of removal.

Failure to Pay Duty

The authorised officer has power to either continue the bond implemented by the owner or restrain some goods, for which the payment has to be done by the owner. If the payment is not made within 10 days from the date of detention, the goods held back are sold through public auction or by any possible way ordered by the Excise Commissioner.

4.1.7. Procedures

Many procedures are included in the medicinal and toilet preparations:

1) **Inspection:** The premises licensed to manufacture or store dutiable goods can be inspected any time. This could be done with or without early notice from the officer authorised by the Excise Commissioner. The building, plant, machinery, etc., are inspected and the records and registers are verified in order to assure the accuracy of returns submitted under these Rules. Any person found bringing hindrance in respect to duties of the officer through giving false or misleading information is punishable under the Rules.

2) **Entry, Search and Seizures:** Excise Officers (superior to sub-inspector) may stop and search any vessel, vehicles, car, etc. or any land, building, enclosed space, vessel, conveyance, etc., at any time. This is done in case of suspicion that manufacturing and storing of dutiable goods is carried against the provisions of the Act and Rules. If the officers are hindered in the performance of their duties, they are allowed to break open any door and also remove other obstacles from their way. The goods with no payment of duty or which seems to be in contravention of the Act could be seized or detained by the officer's order. Following are seized removed or detained when required: containers, packages or coverings holding the goods; animals, vehicles, vessels or other transportation facility used for such goods or articles; and any equipment and machinery employed to manufacture such goods.

3) **Detention and Disposal of Persons and Articles:** Excise officers authorised in this behalf by the State Governments can stop and detain an individual who is carrying goods which require a permit for their transport. The permit is required from individuals in possession of dutiable goods. The authorised officers can examine the goods to make sure whether or not they are in conformity with the permit. The Excise officers (not below the rank of sub-inspectors) can even arrest an individual who are liable to be punished under the act, who refuse to give his name and address, or who gives a false name and address.

The articles seized by officers should be quickly disposed-off according to the provisions of law. In case an animal is seized, the owner should provide for its day to day keep; and if he fails to do so, the animal is sold by public auction. The seized articles which were later released should be collected by their owners within a month of the order of release and any due penalties or charges should be paid. If the owner fails to do so, the articles are disposed-off by public auction and any due penalties or other charges are incurred from the proceeds of the sale.

The arrested individual without any delay should be taken to the nearest excise officer, who is authorised to produce the individual before a magistrate. If there is no excise officer nearby, the individual is taken to the officer-in-charge of the nearest police station. The officer then either admit the arrested person to bail before a magistrate or hand him over to judicial custody, within 24 hours of his arrest (excluding the time required for travelling from the place of arrest to the court). However, if the excise officer to whom the arrested person was forwarded is not satisfied due to insufficient evidence or ground of suspicion against the accused, he may release the individual on executing a bond, as per which the individual has to appear before a magistrate whenever required. The excise officer when releasing a person should prepare a full report of the case and submit it to his superior officer.

4) **Summons by Excise Officers:** Excise officers (not below the rank of sub-inspectors) can call for any individual to give evidence or product documents, by serving on him a written notice to this effect. If the summoned individual cannot be found, a copy of the summons may be affixed in the house in which he was living or carrying on with his business. No notice should be deemed to be void on account of an error in the name or designation of the individual referred, unless such error has misled the intended intimation.

5) **Prosecutions:** Only an excise officer (not below the rank of a sub-inspector) can introduce a prosecution.
   i) **Confiscations:** On confiscating an article under the act or the rules, the article should vest in the collecting government and may be disposed-off as directed. A court, trying an offence under the act, may order penalty of any goods, by means of which an offence has been committed to the collecting government. Goods contained together with forfeitable goods, may also be ordered to be forfeited.
   ii) **Attachment of Properties:** The Excise Commissioner can detain any machinery, plants, goods, etc. In lieu of duty that may be due to the government and such direction should have effect not withstanding any change in the ownership of the trade or business.
   iii) **Appeals:** An appeal can be made to the Excise Commissioner against the decision of an excise officer; while an appeal against the decision of the Excise Commissioner should be made to the State Government. Appeals should be filed within 3 months of the date of decision. The decision of the authorities, to whom appeals are directed, should be final.

   An appeal should be accompanied by a copy of the decision or the order by which the appellant is distressed. The Central Government can

reverse or modify any decision of the Excise Commissioner or of the State Government for which appeals have been made.

iv) **Excise Commissioner's Power of Confiscation/Penalties:** Where an individual is liable to penalty or an article is liable to seizure under these rules, the Excise Commissioner can charge the penalty and confiscation. The State government may confer the power of adjudgement of penalty and confiscation on an excise officer and prescribe the limits within which such power can be exercised. The Excise Commission er or any other authorised excise officer can accept from an individual, a sum of money not exceeding ₹2000 for possessing any property which can be seized or for breaking any provision of the act or the rules.

4.1.8. Manufacture of Ayurvedic, Homeopathic, Patent and Proprietary Preparations.

'Asavas' and 'Aristas' are the major Ayurvedic formulation types that have self-generated alcohol. Recently, the Pharmacopoeias used in many states are known as standard Ayurvedic Pharmacopoeias. Ayurvedic preparations having self-generated alcohol in content not more than 2% proof spirit are considered to be non-alcoholic; and thus , are released from the payment of the excise duty. Preparations having more than 2% alcohol, however not capable of consumption as ordinary alcoholic beverage are also excused from excise duty. Preparations that can be consumed as alcoholic beverages have to pay duty of Re 1 per L.P. litre.

The popular r egistered Ayurvedic p ractitioners can manufacture and dispense alcoholic preparations free of duty, only if they obtained the license and use such preparations solely for their patients. These practitioners should permit the excise officer to take samples to confirm that the preparations have only self-generated alcohol. Also they should keep an account of all the preparations manufactured and dispensed on a regular basis, along with the names and addresses of the patients. Ayurvedic preparations made through distillation or to which alcohol has been added at any stage of manufacture are preparati ons that can be used as alcoholic beverages; therefore, they are liable to duty of ₹30 per L.P. litre.

Homeopathic Preparations

American, British and General Pharmacopoeias are considered standard for homeopathic preparations. The Homoeopathic preparations having alcohol are used as ordinary alcoholic beverages, and thus are liable to pay duty prescribed for such preparations.

Patent and Proprietary Preparations

Allopathic preparations are prepared according to the modern medicine system, and are classified as:

1) Official preparations prepared according to the formulae in the current editions of B.P., B.P.C., I.P., U.S.P., N.F (U.S.), any other pharmacopoeia recognised under the Drugs and Cosmetics Act, 1940 by the Government of India, and Veterinary Codex recognised by the Government of India.
2) Non-official allopathic preparations (proprietary preparations) prepared according to the allopathic system of medicine and obeying the formula on the label.

Medicinal and toilet preparations that can be used as alcoholic beverages are considered as **restricted preparations** . The other standard preparations and proprietary preparations that can not be used as alcoholic beverages are considered as **unrestricted preparations**.

The misused unrestricted preparations are considered as restricted approaches by the Central Government either on the demand of the State Government or on its own and on the advice of the Standing Committee, comprising the Drugs Controller of India, Chief Chemist of Central Revenues Laboratory, one pharmacologist nominated by the Central Government, and the Adviser on indigenous system of medicine, Ministry of Health, Family Planning and Urban Development.

A new proprietary preparation is a restricted preparation if not declared to the contrary by the C entral Government on the advice of the Standing Committee. Anyone who wishes to manufacture a proprietary preparation should submit to the State Government two samples of the preparation along with its formula. Then, the State Government should forward samples to the Central Government that after taking advice of the Standing Committee will declare whether the sample is to be considered as a restricted or an unrestricted preparation.

The Committee should advise the Central Government on the matters of technical aspects of administration of the Act and Rules and in specific whether:

1) A preparation is to be considered as a genuine medicinal or toilet preparation for the purposes of the Act, and if so
2) Whether it should be considered as a restricted or unrestricted preparation.

4.1.9. Offences and Penalties

The offences and related penalties to The Medicinal and Toilet Preparations Act are enlisted in **table 4.1**:

Table 4.1: Offences and Penalties of Medicinal and Toilet Preparations Act

Offences	Penalties
1) Non-compliance with conditions of licence and failure to pay duty, or	Imprisonment for up to 6 months or fine of up to ₹200 or both.
2) Failure to supply information asked or supplying false information.	Same as above
3) Attempting or committing or helping commission of any offence.	Same as above
4) Involvement in offences by owners or occupiers of land.	Imprisonment for up to 6 months or fine of up to ₹500 or both.
5) Aggravating s earch, seizure, etc. by Excise Officer.	Fine of up to ₹ 2000 for every offence.
6) Failure of Excise Officer on duty.	Imprisonment for up to 3 months or fine of up to 3 months' pay or both.
7) Improper keeping of stocks or accounts.	Fine of up to ₹100.
8) Making false entries or tearing pages from stock book.	Fine of up to ₹ 2000 and goods liable to confiscation.

9) Sale of dutiable goods otherwise than in prescribed containers bearing the labels.	Fine of up to ₹1000 and goods liable to confiscation.
10) Failure to f urnish proof of export within specified period.	Fine of up to ₹2000.
Offences with Respect to Warehousing	
1) Opening any locks or door of warehouse without prior consent, or	Fine of up to ₹2000 and goods liable to confiscation.
2) Making any alteration in wa rehouse without prior consent, or	Same as above
3) Warehousing or removing goods in contravention of the rules, or	Same as above
4) Privately removing or concealing any goods either before or after being warehoused.	Same as above
5) Obstructing the officers and giving false information.	Fine of up to ₹ 500.
6) Wilfully and maliciously giving false information and causing arrest.	Imprisonment for up to 2 years or fine of up to ₹2000 or both.
7) Disclosure of information by Excise Officers.	Fine of up to ₹1000.
8) Breach of any rule where no penalty is provided.	Fine of up to ₹1000 and goods liable to confiscation.

4.2. SUMMARY

The details given in the chapter can be summarised as follows:

1) The Medicinal and Toilet Preparations Act was passed in **1955.**
2) The Medicinal and Toil et Preparations Act deals with the regulatory problems resulting from the use of alcohol in many medicinal and toilet preparations.
3) **Alcohol** is ethyl alcohol of any concentration and purity having the chemical composition C_2H_5OH.
4) Manufacturing of alcoholic preparation can be done either **in bond** or **outside bond.**
5) The production of medicinal and toilet preparations can be carried out without bond by the manufacturer after availing the respective license.
6) The other standard preparations and proprietary preparati ons that cannot be used as alcoholic beverages are considered as **unrestricted preparations**.
7) Medicinal and toilet preparations that can be used as alcoholic beverages are considered as **restricted preparations**.
8) 'Asavas' and 'Aristas' are the major Ayurvedic formulation types that have self-generated alcohol.

4.3. EXERCISE

4.3.1. True or False

1) Alcohol is methyl alcohol of any concentration.
2) American, British and General Pharmacopoeias are considered standard for homeopathic preparations.
3) Medicinal and toilet preparatio ns that can be used as alcoholic beverages are considered as unrestricted preparations.
4) The Medicinal and Toilet Preparations Act was passed in 1965.
5) Toilet Preparation is a preparation which is meant to be used in the toilet or in perfuming apparel.

4.3.2. Fill in the Blanks

6) The Medicinal and Toilet Preparations Act was passed in_____ .
7) Alcohol is ethyl alcohol of any concentration and purity having the chemical composition_____.
8) Manufacturing of alcoholic preparation can be done either_____ or _____ .
9) Medicinal and toilet preparations that can be used as alcoholic beverages are considered as _____.
10) _____ are the major Ayurvedic formulation types that have self-generated alcohol.

Answers:

1) False 2) True 3) False 4) False 5) True
6) 1955 7) C_2H_5OH 8) In bond, outside bond
9) Restricted preparations 10) 'Asavas' and 'Aristas'

4.3.3. Very Short Answer Type Questions

1) Write the objectives of medicinal and toilet preparations act-1955.
2) Define the narcotic drugs.
3) What is bonded manufactory and non-bonded manufactory?
4) What are medicinal preparations?

4.3.4. Short Answer Type Questions

1) Differentiate between inbound and outside bound manufacturing.
2) Write a short note on ayurvedic and homeopathic preparations.
3) Explain the offences and penalties of medicinal and toilet preparations act-1955.
4) What are patent and proprietary preparations?

4.3.5. Long Answer Type Questions

1) Write a note on inbound and outside bound manufacturing.
2) Explain the export of alcoholic preparations.

CHAPTER 5

Narcotic Drugs and Psychotropic Substances Act and Rules

5.1. NARCOTIC DRUGS AND PSYCHOTROPIC SUBSTANCES ACT-1985 AND RULES

5.1.1. Introduction

Since the history of civilization, the drugs obtained from plants have much more value than the other naturally obtained drugs. Drugs like coca, hemp, and opium are valuable and also known to mankind, but these drugs are addictive and the user undergoes degenerating effect. In 1857, Opium Act was introduced with the main objective of protecting the public by maintaining good health and removing disagreeable changes in the behaviour of the user, resulting mainly from random intake of drug.

Various drugs, **e.g.,** LSD, heroin, brown sugar, smack, etc. are included in the list of addictive drugs.

To be at the same level, as the varying time and the devastating exploitation of these harmful drugs, a new legislation was needed. This resulted in the introduction of the 'Narcotic Drugs and Psychotropic Substances Act and Rules, 1985

5.1.2. Objectives

The main **objectives** of this Act were:

1) To either combine or modify the laws associated to narcotics and psychotropic to make strict provisions for them, and also controlling their operations.
2) These provisions are also used to confiscate the property, either obtained or used in exploitation of narcotic drugs and psychotropic substances.
3) The provisions of the International Convention of Narcotic Drugs and Psychotropic Substances and matters related to them are also put into effect by the Narcotic Drugs and Psychotropic Substances Act and Rules, 1985.

The Supreme Court stated about the objective of this Act that, the activities of the underworld, trafficking narcotics and psychotropics into this country stealthily, and illicit marketing of such drugs have resulted in addiction of these drugs in large number of people (especially, in adolescents and students of both sexes). This threat has spread widely in the past few years. So, the progress of these

substances needs to be removed, as they results in deadly effects and slow impact on the society. This can be done by the provisions of this Act made by the Parliament mentioning, minimum but obligatory, fine and imprisonment.

On **14 November 1985** , this Act came into force, covering all the regions of India. This Act is applicable for:

1) All Indian citizens living outside India, and
2) All registered Indians, either on ships or airplanes.

The Opium Act, 1857, the Opium Act, 1878 and the Dangerous Drugs Act, 1930 have been abolished by the Narcotic Drugs and Psychotropic Substances Act and Rules. The Central Opium Rules, 1934, the Dangerous Drugs Rules, 1957 and the Central Manufactured Drugs Rules, 1962 have been abolished by the rules of this Act. The provisions made under this Act shall be included in the provisions made under the Drugs and Cosmetics Act 1940 and Rules.

5.1.3. Definitions

The definitions and important terms of the Narcotic Drugs and Psychotropic Substances Act, 1985 and Rules, are as follows:

1) **Addict** is a person addicted to any narcotic or psychotropic substance.
2) **Board** is the Central Board of Excise and Customs constituted under the Central Board of Revenues Act, 1963.
3) **Cannabis** means:
   i) Charas, a resin separated from cannabis plant (either in crude or purified form). This also comprises of concentrated preparations and resin called 'hashish oil or liquid hashish',
   ii) Ganja comprises of the flowering and fruiting tops of the cannabis plant. It does not include the seeds and leaves (not contained in the flowering tops), and
   iii) Mixture (with or without a neutral material) of any of the above mentioned forms of cannabis plant, or any drink prepared from them.
4) **Cannabis Plant** is a plant of the genus Cannabis.
5) **Coca Derivative** means:
   i) Extract of coca leaf (crude cocaine) used directly or indirectly for manufacturing cocain,
   ii) Ecgonine and its derivatives from which cocaine can be obtained,
   iii) Cocaine which is the methyl ester of benzyl -ecgonine, along with its salts, and
   iv) Preparations containing >0.1% cocaine.
6) **Coca Leaf** means:
   i) The coca plant leaf except the one from which ecgonine, cocaine and any other ecgonine alkaloids have been removed, and
   ii) Any mixture (with or without neutral material) containing ≤ 0.1% cocaine.
7) **Coca Plant** is the plant of any species of the genus Erythroxylon.

8) **Controlled Substances** is a 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 or psychotropic substances or to the provisions of any International Convention, by notification in the Official Gazette, declare to be a controlled substance.

9) **Manufacture**with respect to narcotic drugs or psychotropic substances, includes:
   i) All processes (except production) used for obtaining drugs or substances;
   ii) Purification of these drugs or substances,
   iii) Alteration of such drugs or substances, and
   iv) Making preparations (otherwise than in a pharmacy on pre scription), with or without containing such drugs or substances.

   An illegal manufacture of the smuggled goods means the ir illegal possession and the suspect should not be convicted for both the offences (i.e., manufacture, as well as possession).

10) **Manufactured Drugs** means:
   i) All coca derivatives, medicinal cannabis, opium derivatives and poppy straw concentrate, and
   ii) 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 manufac tured drug, but does not include any narcotic substance or preparation declared not to be manufactured drug.

   Morphine is the derivative of opium and is covered by the definition of manufactured drug.

11) **Medicinal Cannabis** is medicinal hemp, means any extract or tincture of cannabis (hemp).

12) **Narcotic Drug** is coca leaf, cannabis (hemp), opium, and poppy straw and includes all manufactured drugs.

13) **Opium** means:
   i) The viscous juice obtained from opium poppy, and
   ii) Any mixture (with or without any neutral material) of th e coagulated juice of opium poppy, without including any preparations that contain ≤ 0.2% of morphine.

   Opium does not mean any preparation containing not more than 0.2% morphine; instead, the coagulated juice of poppy is the crude opium. Mixture of water with capsules of poppy, or with the juice of capsules of poppy, or its mixture with neutral materials, is known as the ‘opium water’.

14) **Opium Derivative** means:
   i) Opium which has gone through the necessary processes to make it medicinally useful (either in powd er form, or granulated, or mixed with neutral materials), is known as ‘medicinal opium,’ as per the requirements of Indian or any other Pharmacopoeia notified in this behalf by the Central Government,

ii) Any opium product achieved by chain of operations, int ended to convert opium into an extract suitable for smoking and the dross, or other residue remaining after opium is smoked. This is known as the 'prepared opium',
iii) Phenanthrene alkaloids, namely morphine, codeine, thebaine, and their salts,
iv) Diacetylmorphine (an alkaloid also known as diamorphine or heroin) and its salts, and
v) All preparations containing >0.2% of morphine or contain ing any diacetylmorphine.

Morphine, being an alkaloid of opium, is a preparation of opium and, as such, it is opium.

15) **Opium Poppy** means:
i) The plant of *Papaver somniferum* Linn species, and
ii) The plants of any other Papaver species from which opium or other phenanthrene alkaloid can be obtained and which should be declared to be the opium poppy by the Central Government, after notify ing the Official Gazette.

16) **Poppy Straw** is all the harvested parts of the opium poppy (except the seeds), present either in their original form, or cut, or crushed, or powdered, and whether or not juice has been extracted from them.

17) **Poppy Straw Concentrate** is the material resulting when poppy straw has undergone a process of concentrating the alkaloids.

18) **Preparation** with respect to a narcotic drug or psychotropic substance is one or more of such drugs or substances present in dosage forms or any solution or mixture, in any physical state.

19) **Production** is the separation of opium, poppy straw, cocoa leaves or cannabis from the plants from which they are obtained.

20) **Psychotropic Substances** is a substance (natural or synthetic), or a natural material, or a salt, or pr eparation of such substance or material, included in the list of psychotropic substances mentioned in the Schedule.

21) **Illicit Traffic**, with respect to narcotic drugs and psychotropic substances, it means:
i) Cultivation of any coca plant or gathering any portion of coca plant,
ii) Cultivation of opium poppy or any cannabis plant,
iii) Involvement in the production, manufacture, possession, sale, pur chase, transportation, warehousing, concealment, use or consumption, import inter-State, export into India, export from I ndia or trans -shipment, of narcotic drugs or psychotropic substances,
iv) Dealing in any activities in narcotic drugs or psychotropic sub stances other than those provided in sub-clauses (i) to (ii), or
v) Handling or allowing any premises for carrying out the ac tivities mentioned in sub-clauses (i) to (iii), other than those permitted under the Narcotic Drugs and Psychotropic Substances Act, 1985, or any rules or order made, or any condition of any licence or authorisation issued thereunder.

5.1.4. Authorities and Officers

The officers under this Act are as follows:

1) Measures by central government for preventing abuse of and illicit traffic in narcotic drugs, etc.,
2) Officers of central government,
3) Constitution and functions of narcotic and psychotropic consultative committee,
4) National fund for controlling the drug abuse, and
5) Officers of state government.

5.1.4.1. Measures by Central Government for Preventing Abuse of and Illicit Traffic in Narcotic Drugs, etc.

To prevent, as well as to conflict against the use of narcotic and psyc hotropic substances and the illegal traffic, the Central Government can take measures in the following matters:

1) Task management by various officers, State Government and other authorities under this Act or any other law which are involved in the enforcement of the provisions of this Act,
2) Requirements as per the International Conventions,
3) Helping the concerned authorities in foreign countries and international organisations, enabling coordination and universal action for preventing and suppressing illicit traffic in narcotic drugs and psychotropic substances,
4) Identification, treatment, education, after care, rehabilitation, and social re - integration of addicts, and
5) Other matters, regarded as suitable by the Central Government for the purpose of this Act and preventing the use of narcotic drugs and psychotropic substances and illegal traffic.

An authority or hierarchy of authorities, for exercising or dealing with the above mentioned matters in a specific order, has been constituted by the Central Government. T he powers and the functions are managed by an authority or authorities as per the supervision and control of the Central Government.

5.1.4.2. Officers of Central Government

Apart from the above authorities, a Narcotics Commissioner and such other officers should also be appointed by the Central Government to carry out the functions of this Act. The duty of such persons is to exercise all powers and perform all functions associated with the supervision of opium poppy cultivation and produc tion. Also the Narcotics Commissioner should perform other functions, assigned to him by the Central Government.

These officers should work under the guidance and supervision of the Central Government, or also of the Board or any other authority or officer (if stated by the Gove rnment). The Narcotics Commissioner has the right to empower any officer subordinate under him, who can exercise all or any of his powers under the Rules.

5.1.4.3. Constitution and Functions of Narcotic and Psyc hotropic Consultative Committee

The Central Govern ment may constitute this Committee (by giving a notice in the Official Gazette), to provide advises to the Central Government on matters involving the administration of this Act (as directed by the Government from time to time). The Central Government appoin ts the members of this Committee, consisting of a Chairman and few other members. The number of members in this Committee should not be more than twenty.

The Committee should meet when ever needed by the Central Government and should have the power to regulate its own way of working. The Committee can even constitute one or more sub -committees to carry out its functions more effectively and can appoint a non-official person (not a member of the Committee) to any sub-committee, either normally or after considering a specific matter.

The rules made by the Central Government guide the following:

1) The term of the office,
2) The method of recruitment in the office,
3) The allowances to be paid to the Chairman and other members of the Committee, and
4) The conditions and restrictions, according to which the Committee appoints a non-member as a member of its sub-committee.

5.1.4.4. National Fund for Controlling the Drug Abuse

The National Fund for control of drugs abuse is constituted by the Central Gov - ernment (only after notify ing the Official Gazette). This fund should meet the expenses suffered, while preventing the illegal trafficking or use of narcotic drugs or psychotropic substances. A Governing Body, for advising the Government regarding the fund applications, is constitu ted by the Central Gov - ernment. This Governing Body comprises of a Chairman (not below the rank of an Additional Secretary to the Central Government) and six such other members as appointed by the Central Government. The Governing Body should have the power to regulate its own procedure. After the end of each financial year, the Central Government should submit a report in the Official Gazette (as soon as possible), giving the details of all the activities funded during the financial year, along with a statement of accounts.

5.1.4.5. Officers of State Government

Officers are ap pointed by the State Government, with designations appropriate for the purpose of this Act. These officers act under the control and directions of the State Government, or any other authority or officer (if directed by that Government).

Other Amendments: The amendments made are as follows:

1) Court may require bonds for abstinence, up to 3 years, from same offence,
2) Name, address, offences, etc., should be published at convicts cost, in newspapers,

3) Enhanced punishments for second or subsequent offences which may be double or so,
4) Persons imprisoned in foreign countries for same offences should be liable to enhanced punishment,
5) Attempts or abetments carry same punishments,
6) Some minor offences which can be tried, and
7) Mental state may be taken as defence.

5.1.5. Prohibition, Control and Regulation

Prohibition of Certain Operations

No person should cultivate coca plant; collect any portion of it; cultivate opium or any cannabis plant; produce, manufacture, possess, sell, purchase, transport, warehouse, use, consume, import and export inter -state, or tranship any narcotic drug or psychotropic substances (for any purpose other than medical or scientific) in the manner and in the amount not in accordance with the terms and conditions of a licence, permit, or authorisation.

The prohibition against the cultivation of cannabis, production of ganja , or production, possession, use, consumption, purchase, sale, transport, warehousing, inter-state import and export fo r any purpose other than medical and scientific should be put from the date given by the Central Government:

Prohibition of Certain Activities Relating to Property Derived from Offence

1) Convert or transfer any property derived from an offence committed under this Act or any other corresponding law of any other country or from involvement in such offence for hiding the illicit origin of the property or to help any person in the commission of an offence or to avoid the legal penalties, or
2) Conceal the true na ture, source, location, and disposition of any property derived from an offence committed under this Act or any other corresponding law of any other country, or
3) Knowledgeably obtain, possess, or use any property derived from an offence committed under th is Act or any other corresponding law of any other country.

Power of Central Government to Permit, Control and Regulate

The Central Government may:

1) Permit and regulate:
   i) The cultivation and collection of a portion of coca plant, or the production, possess ion, sale, purchase, transport, inter -state import and export, use, or consumption of coca leaves,
   ii) The cultivation of opium poppy,
   iii) The production and manufacture of opiu m and production of poppy straw,
   iv) The sale of opium and opium derivatives from the Cent ral 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) or their preparation from materials which the maker is legally allowed to possess, and

vi) The manufacture, possession, transport, inter -state import and export, sale, purchase, consumption, or use of psychotropic substances.

2) Prescribe any other requisite for effective control of the Central Government over the above mentioned matters.

Power to Control and Regulate Controlled Substances

If the Central Government has opinion that using any controlled substances in the production or manufacture of narcotic drug or psychotropic substance, it is required to do so in the public interest, it can provide for regulating or prohibiting the production, manufacture, supply , and distribution, and trade and commerce within.

Without bias to the generalis ation of the power discussed above and order made thereunder can regulate with licences or permits the production, manufacture, possession, transport, inter-state import and export, sale, purchase, consumption, use, storage, distribution, disposal, or attainment of any controlled substance.

Power of State Government to Permit, Control and Regulate

The State Government may:

1) Permit and regulate:
   i) The possession, transport, inter -state import and export, warehousing, sale, purchase, consumption, and use of poppy straw,
   ii) The possession, transport, inter -state import and export, sale, purchas e, consumption and use of opium,
   iii) The cultivation of cannabis plant, production, manufacture, possession, transport, inter-state import and export, sale, purchase, consumption , or use of cannabis (excluding charas),
   iv) The manufacture of medicinal opium or preparation s containing manufactured drug from materials which the maker possesses legally,
   v) The possession, transport, purchase, sale, inter -state import and export, use, or consumption of manufactured drugs (other than prepared opium) and their preparations, and coca leaf, and
   vi) The manufacture and possession of prepared opium using opium legally possessed by an addict registered with the State Government on medical advice for his personal consumption.
2) Prescribe any other requisite for effective control of the State Government over the above mentioned matters.

Narcotic Drugs and Psychotropic Substances are Not Liable to Distress or Attachment

Narcotic drugs, psychotropic substances, coca plant, opium poppy, or cannabis are not liable to be distressed or attachment by any person for recovering any money under any order of any court or authority.

Restrictions over External Dealings in Narcotic Drugs and Psychotropic Substances

No person should involve in any trade where a narcotic drug or psychotropic substance has been obtained from outside India or has been supplied to any person outside India unless authorised by the Central Government and obey the conditions imposed by the Government.

Special Provisions Relating to Coca Plant and Leaves for Use in the Preparation of Flavouring Agent

The Central Government may permit (on behalf of the Government) in the amount necessary the cultivation and collection of coca plant or the production, possession, sale, purchase, transport, inter-state import and export, or import in India of coca leaves to be used for the preparation of flavouring agent not containing alkaloid.

Special Provision Relating to Cannabis

The Government by a general or special order may permit the cultivation of cannabis plant for industrial use, for obtaining its fibre or seed , or for horticultural purposes.

5.1.6. Opium Po ppy Cultivation and Production o f Poppy Straw

The cultivation of opium poppy required for the production of opium or poppy straw is done on behalf of the Central Government in M.P., U.P., and Rajasthan. The cultivation should be done as per the conditions of the license issued by the District Opium Officer. This licence is granted on filing an application in Form II along with fee of ₹5 and the license is issued in Form I.

The **application** should contain the following **information**:

1) Crop year,
2) Cultivator's name, father's name, and address,
3) Khasra number of the plot of land over which poppy is to be cultivated,
4) Whether the plot is in the applicant's name (as per the revenue records) and if not, then in whose name,
5) Whether the plot has facilities of irrigation and other such facilities are available,
6) Required area for opium poppy cultivation,
7) Whether the applicant has cultivated poppy in the past and the latest year in which it was cultivated,
8) Details about the pr escription of the applicant (if any) from the poppy cultivation, etc., and
9) Cultivator's signature and attestation by the Lambardar.

The **licence** is subjected to the following **conditions**:

1) The licensee should not transfer his licence and cultivate poppy for production of opium or poppy straw only over the area of plot(s) specified in the licence,

2) The land for poppy cultivation should be free from litigation,
3) The daily collections of opium obtained from the crop should be taken to the Lambardar by the license e for weighing and his signa ture/thumb impression should be affixed against each entry made by the Lambardar as a sign of the correctness of the entries. The licensee should also submit initial weighments (carried out by the staff of Narcotic Department i n the village), which is the entire quantity of opium collected by him,
4) All the opium collected by the licensee should be delivered at the place fixed for weighment. The licensee should accept the price fixed by the Central Government for the opium collected by him,
5) After the licensee delivers the opium for weighment, under the supervision of the District Opium Of ficer or any other officer authorised by the Narcotics Commissioner, the opium is weighed,
6) The licensee will be accused if he does not submit his entire produce of opium to the Government, or if he retains, misuses or illegally disposes off a portion of his collection,
7) The licensee should extract maximum opium,
8) At the appropriate time the final payment for opium (delivered by the licensee) should b e made and accordingly the final adjust ment of account is also made, and
9) The licensee should abide by the provisions of the Narcotic Drugs and Psychotropic Substances Act and Rules and orders issued by the authorities. If the licensee is found to be ineli gible for the grant of a licence due to any reason, the licence may be cancelled or suspended at any time.

Given below are the **provisions** for cultivation, weighing, adulteration, price, supervision, and licence cancellation of opium production:

1) **Cultivation:** For the cultivation of opium poppy, the area used has to be mentioned in the licence. The District Opium officer should appoint a Lambardar (one of the cultivator of opium poppy) for villages where poppy is cu ltivated. The Lambardar should perform his duties, and should follow the terms and conditions laid by the Narcotics Commissioner.

   The complete opium poppy cultivation is inspected by an appointed officer in the presence of the cultivator and the Lambardar. The Narcotics Commissioner further validates the measurements obtained by the officer.

2) **Weighing:** The daily cultivation of opium poppy should be brought to the Lambardar by the cultivator for weighing. The record maintained by the Lambardar should have th e required entries made on the daily basis. These entries are attested by both the cultivator and the Lambardar. An authorised officer should weigh the amount of opium poppy collected and make entries in the Lambardar's register.

   This officer can even as k question on the differences obtained (if any) in the quantities of opium submitted by the cultivator (as per the entries in the Lambardar register) and the amount weighed by him. Then this collected opium should be submitted by cultivator at a place spec ified either by the District Opium Officer or by any other authorised officer.

The District Opium Officer on receiving the opium from the cultivator should sent it to the Government Opium Factory after proper weighing, examining, and classifying. All the se process should be done appropriately either in the presence of the cultivator or a person appointed by him, and the Lambardar. In case the cultivator feels that opium collected by him has not been classified in a proper manner, he should ask the District Opium Officer to send the properly sealed opium separately to the Government Opium Factory; and this act should be carried out in the presence of the cultivator and the Lambardar.

3) **Adulteration:** If it is suspected that the opium delivered by the cultivato r is adulterated, it should be sealed in the presence of the cultivator and the Lambardar and send to the Government Opium Factory. The seal is opened in the presence of the cultivator and a sample is withdrawn for evaluation. If the opium is found to be contaminated, the General Manager should seize the entire opium and take the required steps.

4) **Price:** The Central Government at frequent intervals fixes the opium price to be paid to the cultivator; while the District Opium Officer based on this price calculates the total price which is to be paid to the cultivator, and pay 90% of it. This price should be adjustable against the final price to be paid to the cultivator. The price to be paid to the cultivator for the non -contaminated opium should be reduced to the rates specified by the Central Government if after examination in the Government Opium Factory the opium is found to be contaminated. It is the duty of the District Opium Officer to adjust the accounts of the cultivator for a particular crop year, when the next licence for subsequent year is to be issued. If any amount is due to be paid to the cultivator, it should be calculated and paid.

5) **Supervision:** The opium forwarded by the District Opium Officer to the Government Opium Factory should be re ceived, weighed, examined, and classified as prescribed, under the supervision of General Manager.

6) **Cancellation of Licence:** The licence can be cancelled by an officer superior to the District Opium Officer anytime if the provisions under this Act are not properly followed; however an opportunity of explanation is given to the licensee. In case if the licensee wants to withdraw his license, his standing crop (if any) should be destroyed as specified by the Narcotics Comissioner, under the supervision of an authorised officer.

5.1.7. Manufacture of Opium

The manufacture of crude cocaine, ecgonine and its salts and diacetyl morphine and its salts is banned. However, the drugs from opium can be manufactured by the Government Opium Factory or by chemical staff working under the Central Board of Excise and Customs, or any person authorised by the Narcotics Commissioner. A special licence is granted for medical and scientific purposes.

Some substances and preparations, in January 1993, have been declared to be as manufactured drugs. They are:
Acetyl-alpha-methylfantanyl, Alpha -methylfantanyl, Alphamethyl -thiofentanyl, Beta-hydroxyfentanyl, Beta -hydroxy-3-methylfantanyl, Dimepheptanol,

Hydroxypethidine, Levorphanol, 3 -Methylfentanyl, 3 -Methylthiofentanyl, Morphine methobro mide and other pentavalent nitrogen morphine derivatives including in particular the Morphine -N-oxide deriva tives one of which is Codeine-N-Oxide, MPPP, Nicomorphine, Oxymorphine, Para -flurofentanyl, PEPAP, and Thiofentanyl.

5.1.7.1. Manufacture of Naturally Manufactured Drugs

The manufacture of cocaine and its salts is forbidden, however, cocaine HCl can be manufactured from the seized cocaine by the chemical staff working under the Central Board of Excise and Customs.

Only the Government Opium Factories are all owed to manufacture morphine, codeine, dionine, thebaine, dihydro -codeinone, acetyldihydrocodeine, acetyldihydrocodeinone, dihydromorphine, dihydromorphinone, dihydro -hydroxycodeinone, pholcodine and their salts, else it is banned. Medicinal hemp should be manufactured (under a licence granted by the State Government) after the payment and as per the conditions suggested by State Government.

5.1.7.2. Manufacture of Synthetically Manufactured Drugs

The manufacture of manufactured drugs is not banned, if done under a licence granted by the Narcotics Commissioner or such other officer assigned by the Central Government. For the manufacture of manufactured drugs, an application for the grant of a licence should be made in the form, directed by the Narcotics Commissioner and the **applicant** should fulfil the following **conditions**:

1) The manufacturing licence, granted under the Drugs and Cosmetics Act and Rules, should be presented by the applicant to the State Government, for the possession, distribution and sale of the drugs;
2) For the due observance of the conditions of licence, the applicant should deposit the security money and satis fy the issuing authority that he is prepared and financially stable to properly carry out the business, as mentioned in the application;
3) The lic ensee should manufacture drugs only from those materials which he possesses legally;
4) The quantity of the drug, licensee should manufacture, will be decided by the Issuing Authority, after considering the following:
   i) Quantity of drug (to be manufactured in t he licensee's manufactory) assigned by the State Government,
   ii) Quantity of drug to be supplied to other organisations within or outside the country, and
   iii) Quantity required for reasonable inventory.

   Only if the total drug quantity, manufactured in one year does not surpass the expected requirements of this coun try for the relevant year, furnished to the International Narcotics Control Board, the Issuing Authority decides the quantity.
5) All essential security arrangements (as indicated by the Issuing Authority) are safeguarded by the licensee;

6) A 15 days' notice in writing should be given to the Issuing Authority by the licensee from the date of beginning of manufacture and atleast one month's notice before ending the manufacture of the same; and
7) When the licensee ends the manufacturing operations, the Issuing Authority should be immediately informed about this by the licensee. He should also mention the date on which he intends to restart the manufacturing operations, only if the Issuing Authority do not prohibit all further manufacture (in case the termination period of manufacture surpasses 30 days).

The possession or selling or distribution of drugs should be done by the licensee, as per the Rules prescribed by the State Government under the Act. Accounts of all the transactions (including the account of materials used for the manufacture of the drug, the quantities manufactured, sold or disposed off) should be maintained by the licensee, in a specified manner by the Narcotics Commissioner.

An officer assigned by the Issuing Authority should inspect the drugs, materials used for their manufacture, accounts, and records of transactions related to the drugs. The licensee (for the use of the officer) should maintain a serially numbered Inspection Book. Without making prior judgments about the action taken under the provisions of the Act, the Issuing Authority may suspend or cancel a licence:

1) If the licence is transferred or hired to any other place without the approval of the Issuing Authority; or
2) If the licensee fails to satisfy any condition of the licence; or
3) If the licensee has committed any offence under the Act or any other law related to the narcotic drugs and is imprisoned for the time being.

After a licence has been granted to manufacture drugs, following conditions should be considered:

1) The licence is not transferable,
2) The licence and any certificate to be renewed should be kept on the approved places and presented to the officer, assigned for this purpose by the Licensing Authority,
3) The process of manufacture, or the manufactured drug or the materials used for manufacture should be carried out or kept only at his place of business,
4) Drugs should be manufactured by the licensee as per the standards and specifications mentioned under the Drugs and Cosmetics Act, 1940,
5) If the licensee wants his licence to be renewed, he should fill up a form (meant for the same purpose), and apply to the Licensing Authority, 30 days before his licence expires, and
6) The Licensing Authority should be informed (in writing) about any change in the constitution of the firm operating under the licence, by the licensee. If a change occurs in the constitution of the firm, the existing license should remain valid for maximum three months, either from the date on which the change has taken place or the normal expiry of the licence (whichever is earlier). In the meantime, a fresh licence has been issued by the Licensing Authority in the name of the firm involving the changed constitution.

5.1.8. Sale and Export of Opium

The Government Opium Fa ctory (at Ghazipur) should only sell opium to State Governments or manufacturing chemists. The price of opium, to be paid to the cultivators, should be adjusted from time to time by the Central Government, in a manner they believe to be appropriate. The pr ice should be fixed per kilogram of opium of a standard texture.

The Government Opium Factory (at Ghazipur) should deliver opium to the manufacturing chemists only if they have been granted permission, as per the orders of the State Government. The manuf acturing chemists exist or have his place of business within the jurisdiction of the State Government. The permit should be issued in quadruplicate (i.e., four copies). The Issuing Authority retains the fourth copy with them, while the remaining three are forwarded to the Government Opium Factory, Ghazipur. The duplicate copy should be retained for record by the factory, the original copy (with the consignment of opium) should be send, and the triplicate copy (after approving the quantity supplied and the date of dispatch) should be returned to the Issuing Authority.

Opium can be exported only on behalf of the Central Government, otherwise it is prohibited.

Without an export authorisation issued by the Issuing Authority, narcotic drugs or psychotropic subs tances (specified in Schedule II) should not be exported out of India.

When applying for an export authorisation, the exporter should submit:
1) The original or a valid copy of the excise permit (issued by the State Government), along with the application, when the export authorisation is related to narcotic drugs, and
2) The import certificate in original (issued by the government of the import ing country), verifying the official permission of the concerned Government.

Declaration Form: The **original and duplicate copies** of the declaration in Form VI are filed by the exporter with the Narcotics Commissioner. Then, he transfers the **duplicate copy** of the declaration to the concerning authority of the importing country, requesting him to return the duplicate copy after declaring in it that the actual quantity of the psychotropic substances have been properly imported. After this process is complete, psychotropic substances specified in Schedule III can be exported out of India. Along with the consignment of the sa id substance by the exporter, the **triplicate copy** of the declaration should be sent to the importing country and the **quadruplicate copy** should be retained by the exporter.

The **five copies** of the **export authorisation** prepared by the Issuing Authority are as follows:
1) The **original copy**, along with the consignment should be delivered to the consignor,
2) The **duplicate copy**, indicated with date of export and the quantity exported, should be forwarded to the Collector of Customs of the port who will return it to the Issuing Authority,

3) The **triplicate copy** should be dispatched to the Government of the importing country,
4) The **quadruplicate copy** should be forwarded to the Excise Authority of the State in which the exporter has his place of business, and
5) The **quintuplicate copy** should remain with the Issuing Authority.

Supplementary number of copies of export authorisation may be needed when the consignment of narcotic drugs or psychotropic substances is to be transported to one or more countries. In such cases, extra number of copies are created and sent to the concerned country.

Narcotic drugs or psychotropic substances specified in Schedule IV should not be exported. However, specified quanti ties of such narcotic drugs or psychotropic substances or their preparati ons can be exported under the authorisation of the Narcotics Commissioner on the basis of the special import license issued by the competent authority of the importing country. The consignment should be shipped, along with a copy of the special import lice nce, properly validated by the Narcotics Commissioner.

5.1.9. Offences and Penalties

The punishments for offences related to narcotic drugs and psychotropic substances have been enhanced by this Act. The offences and penalties are given in the **table 5.1** on the basis of punishments:

Table 5.1: Offences and Penalties of Narcotic and Psychotropic Substances

Offences	Penalties
1) i) Contraventions of provisions in the Act or Rules there under in respect of poppy straw, opium poppy, coca plant and coca leaves, prepare d opium, manufactured drugs and psychotropic substances.	Rigorous imprisonment for 10-20 years
ii) Illegal import or export or external dealings in narcotic drugs or psychotropic substances.	Fine between ₹1 to 2 lacs or more.
iii) Allowing use of premise s, vehicles, etc., for commission of an offence under the Act.	
iv) Embezzlement of opium by licensed cultivators.	
v) Contravention in respect of cannabis plant and cannabis other than ganja.	
2) Contravention in respect of cannabis plant and cannabis related to ganja.	Rigorous imprisonment for up to 5 years and fine of up to ₹50,000.
3) i) Failure to keep accounts or submit returns as required by law or keeping of false accounts or making of false statements.	Rigorous imprisonment for up to 5 years or fine or both.
ii) Failure to produce licences, permits, authorisations, etc., on demand by authorised persons.	Rigorous imprisonment for up to 3 years or fine or both
iii) Wilful and deliberate indulgence in breach of any provision of the Act or conditions of licence, etc., for which no penalty is otherwise imposed by the Act.	

4) Illegal possession for personal consumption or consumption of cocaine, morphine, diacetyl-morphine or any other narcotic drug or psychotropic substance specified in this behalf.	Rigorous imprisonment for up to 1 year or fine or both.
5) i) Illegal possession for personal consumption or consumption of substances other than those mentioned under point 4. ii) Offences for which no punishment is separately provided.	Rigorous imprisonment for up to 6 months or fine.
6) Abetment/attempt of above	Same punishment as for the main offence.

5.2. SUMMARY

The details given in the chapter can be summarised as follows:

1) **Addict** is a person addicted to any narcotic or psychotropic substance.

2) **Board** is the Cent ral Board of Excise and Customs constituted under the Central Board of Revenues Act, 1963.

3) **Coca Plant** is the plant of any species of the genus Erythroxylon.

4) **Medicinal Cannabis** is medicinal hemp, means any extract or tincture of cannabis (hemp).

5) **Narcotic Drug** is coca leaf, cannabis (hemp), opium, and poppy straw and includes all manufactured drugs.

6) The National Fund for control of drugs abuse is constituted by the Central Government (only after notifying the Official Gazette).

7) Officers are ap pointed by th e State Government, with designations appropriate for the purpose of this Act.

8) No person should involve in any trade where a narcotic drug or psychotropic substance has been obtained from outside India or has been supplied to any person outside India.

9) The cultivation of opium poppy required for the production of opium or poppy straw is done on behalf of the Central Government in M.P., U.P., and Rajasthan.

10) The manufacture of crude cocaine, ecgonine and its salts and diacetyl morphine and its salts is banned.

11) The Government Opium Factory (at Ghazipur) should only sell opium to State Governments or manufacturing chemists.

5.3. EXERCISE

5.3.1. True or False

1) The four copies of the export authorisation prepared by the Issuing Authority.
2) Addict is a person addicted to any narcotic or psychotropic substance.
3) Private Opium Factories are also allowed to manufacture morphine, codeine, dionine, thebaine.
4) Coca Plant is the plant of any species of the genus Erythroxylon.
5) Medicinal Cannabis is medicinal hemp, means any extract or tincture of cannabis (hemp).

5.3.2. Fill in the Blanks

6) _____ is a person addicted to any narcotic or psychotropic substance.
7) Coca Plant is the plant of any species of the genus _____.
8) The Government Opium Factory is located at_____.
9) _____ is coca leaf, canna bis (hemp), opium, and poppy straw and includes all manufactured drugs.
10) _____ is the separation of opium, poppy straw, cocoa leaves or cannabis from the plants from which they are obtained.

Answers:

1)	False	2)	True	3)	False	4)	True	5)	True
6)	Addict	7)	Erythroxylon	8)	Ghazipur	9)	Narcotic Drug	10)	Production

5.3.3. Very Short Answer Type Questions

1) Write the objectives of narcotic drugs and psychotropic substances act-1985.
2) What are controlled substances?
3) Define the narcotic drugs.
4) Write the officers that come under the narcotic drugs an d psychotropic substances act-1985.

5.3.4. Short Answer Type Questions

1) Write a short note on manufacture of opium.
2) Explain the sale and export of opium in detail.
3) What are the offences and penalties of narcotic drugs and psychotropic substances act-1985?
4) Explain the constitution and functions of Narcotic and Psychotropic Consultative Committee.

5.3.5. Long Answer Type Questions

1) Discuss the power of central government to permit, control and regulate the narcotic substances.
2) Discuss the opium poppy cultivation and production of poppy straw.

CHAPTER 6

Drugs and Magic Remedies Act and Rules

6.1. SAILENT FEATURES OF DRUGS AND MAGIC REMEDIES ACT AND ITS RULES

6.1.1. Introduction

It is seen in India that some persons are selling magic remedies such as kavachas, mantras, talismans, etc., and claiming them as universal treatment for any disease, etc . Likewise, advertisements in magazines, newspapers, and on premises of some doctors, hakims, or vaids are also found claiming to cure diseases not cured by any other drug or treatment. These tricks are mainly applied on the innocent people, and they end u p wasting their time and money, also damaging their health, and sometimes premature death.

The Drugs and Magic Remedies Act, 1954 is passed for regulating the advertisements of some drugs, and the advertisements of remedies having qualities of magic.

6.1.2. Objectives

The objective of this Act is to maintain ethical standards when manufacturers advertise any drugs. Under the guidelines of this Act, a dvertisements offending the decency or morality can be banned. Also, those claim ing magical powers for certain dru gs, **e.g.,** enhancement of potency, cure for incurable diseases, etc. should be banned. Magical remedies include the use of talismans or charms such as “mantras”, “kavachas”, etc.

6.1.3. Definitions

The definitions and important terms of The Drugs and Magic Remedi es Act, 1954 are as follows:

1) **Advertisements** are all notices, circulars, labels, wrappers, or other documents and all announcements, made orally or by means of producing or transmitting light, sound or smoke.
2) **Drugs** are substances used for the diag nosis, cure, mitigation, prevention, or treatment of diseases in human beings or an imals, or for the alteration of any structure or functions of the body of human beings or animals.
   According to this Act, the definition of drugs is different from the definition of drugs in the Drugs and Cosmetics Act, in several characteristics. For example, the insect repellents, insecticides which kill insects causing diseases in human beings, etc., are believed to be drugs in the Drugs and Cosmetics Act, but not under this Act.

3) **Magic remedies** are talismans, mantras, kavachas, and other similar substances or charms of any kind, possessing miraculous powers and prevent or cure diseases, or affect or alter any body functions of the human beings or animals.

6.1.4. Prohibition of Certain Advertisements

Following are the classes of advertisements prohibited under this Act:

1) Advertisement of drugs:
   i) For miscarriage or for preventing conception in women,
   ii) For removing menstrual disorders in women,
   iii) For improving the capacity of sexual pleasure in humans, and
   iv) For diagnosing, preventing, or curing appendicitis, arte riosclerosis, blindness, blood poisoning, cancer, cataract, deafness, diabetes, brain disorders, uterus disorders, disorders of menstrual flow, disorders of nervous system and prostatic gland, dropsy, epilepsy, female diseases (in general), fevers (in general), fits, form and structure of female bust, gall stones, kidney and bladder stones, gangrene, glaucoma, goitre, heart diseases, high or low blood pressure, hydrocele, hysteria, infan tile paralysis, insanity, leprosy, and leucoderma.
2) Advertisements providing false impression about any drug or making false claims for it, or if the advertisements are false and misleading, and
3) Advertisement of magic remedies, claiming to be efficient in a ny conditions produced by the person, who wants to carry on the profession of administering magic remedies.

6.1.5. Classes of Exempted Advertisements

The classes of advertisements given in **table 6.1** have been removed from the provisions of this Act:

Table 6.1: Advertisements Not Prohibited Under Special Conditions

Advertisements	Conditions
1) Leaflets or literature accompanying packing of drugs Or Advertisement of drugs in medical, pharmaceutical, scientific, and technical journals.	1) The advertisement containi ng information needed for the guidance of RMPs in the following matters: i) Therapeutic use of the drug, ii) Its administration and dosage, iii) Its side effects, and iv) The precautions to be taken in treatment with the drug. 2) It is the advertiser's duty to prove that any claim made in the advertisement about the drug should not be false, overstated, or misleading.
2) Price lists or Therapeutic indexes published by the drug manufacturers, importers, or distributors duly licensed under the Drugs and Cosmetics Act, 1940 and the Rules	1) The advert isement containing information needed for the guidance of RMPs in the following matters: i) Therapeutic use of the drug, ii) Its administration and dosage,

Or Medical Literature distributed by medical representatives appointed by the drug manufacturers, importers, or distributors duly licensed under the Drugs and Cosmetics Act, 1940 and the Rules thereunder.	iii) Its side effects, and iv) The precautions to be taken in treatment with the drug. 2) It is the advertiser's du ty to prove that any claim made in the advertisement about the drug should not be false, overstated, or misleading. 3) This literature should be distributed only to RMPs, hospitals, dispensaries, medical and research institutions, chemists, druggists, and pharmacies licensed under the provisions of the Drugs and Cosmetics Act and Rules.

6.1.6. Powers of Entry, Search, and Seizure

According to the provisions of this Act, any Gazetted Officer authorised by the State Government has the following powers:

1) According to the provisions of this Act, any Gazetted Officer appointed by the State Government, possessing the powers of entry, search, etc., within the local limits of the area, may:
   i) Enter and search any place at any time, along with his assistants, where he believe s that a crime under this Act has been or is being committed,
   ii) Seize any advertisement which he believes to be breaking the provisions of this Act. Also, he has the power of seizing any document or article containing any such advertisement, if the advertise ment cannot be separated from such document because of being imprinted, without altering its integrity, utility, or saleable value, and
   iii) Examine any record, register, document, or any other material found in a place mentioned in (i) and seize the same, if h e believes that it may provide evidence of a punishable offence, under this Act.
2) The provisions of the Code of Criminal Procedure should be applied to any search or seizure under this Act, made under the authority of a warrant issued under section 98 of the said Code, and
3) If a Gazetted Officer seizes anything, he should immediately inform the Magistrate.

6.1.7. Exemptions

These prohibitions put on advertisements however should not cover:

1) Sign boards or notices put by the RMPs on their premises, claiming to cure certain diseases or disorders, whose advertisements are forbidden.
2) Books or articles published from bonafide scientific or social standpoint containing matter related to certain diseases or ailments, whose advertisements are forbidden.
3) Advertisements of d rug sent to RMPs in the prescribed and private manner by post on the top of which following words are written " **For the use of Registered Medical Practitioners**".

4) Advertisements of drugs published by the Government or by any other person who has taken perm ission from the Government. To take permission from the Government, the person should apply to the officers authorised by the Central or State Governments, stating the registered name and trademark of the drug and reasons for justifying the approval.
5) Advertisements, labels, or instructions permitted under the Drugs and Cosmetics Act or Rules.

In case the Central Government feels that the advertisement of some drug (which are banned under the Act), should reach the public, it can allow the advertisement only after informing the Official Gazette.

6.1.8. Offences and Penalties

If a person breaks or disobeys the provisions of the Act and Rules, by involving in the advertisement of prohibited drugs, he/she will be punished with imprisonment for 6 months or a fine, o r both on first conviction, and imprisonment for 1 year or a fine, or both on successive convictions.

If a company disobeys or breaks the provisions of the Act, every single person who was in -charge of the company when the offence was committed, are held responsible. They are considered to be guilty of the offence, till the time they can prove that the offence was committed in the absence of their awareness and they had tried to prevent the offence from being committed. Any strict action should not be take n against a person for disobeying the provisions of the Act, who do anything in good faith, for any breach of the Act.

Any officer appointed by State Government can enter and search any place at any time, along with his assistants, where he believes that a crime under this Act has been or is being committed. He can also seize and detain any documents, articles or things, containing prohibited advertisement under the Act. The Courts, trying such offences, can order for surrendering to the Government, the a rticles, documents, etc., containing prohibited advertisements. These officers are considered to be public servants under the Section 21 of the IPC (Indian Penal Code). When an article is seized, orders for the custody of seized article should be taken from the Magistrate.

6.2. SUMMARY

The details given in the chapter can be summarised as follows:

1) It is seen in India that some persons are selling magic remedies such as kavachas, mantras, talismans, etc., and claiming them as universal treatment for any disease, etc.
2) The objective of this Act is to maintain ethical standards when manufacturers advertise any drugs.
3) **Advertisements** are all notices, circulars, labels, wrappers, or other documents and all announcements, made orally or by means of producing or transmitting light, sound or smoke.

4) If a company disobeys or breaks the provisions of the Act, every single person who was in-charge of the company when the offence was committed, are held responsible.

5) Any officer appointed by State Government can enter and search any place at any time, along with his assistants, where he believes that a crime under this Act has been or is being committed.

6.3. EXERCISE

6.3.1. True or False

1) The Drugs and Magic Remedies Act is passed in 1950.
2) If a Gazetted Officer seizes anything, he should immediately inform the Magistrate.
3) Advertisement of drugs for preventing conception in women is legal in India.
4) If a person breaks the provisions of the Act and Rules, he/she will be punished with imprisonment for 6 months or a fine.

6.3.2. Fill in the Blanks

5) The Drugs and Magic Remedies Act is passed in _____.
6) _____ are talismans, mantras, kavachas, and other similar substances or charms of any kind, possessing miraculous powers and prevent or cure diseases.
7) The Drugs and Magic Remedies Act, 1954 is passed for regulating the _____ _____.
8) Any officer appointed by _____ can enter and search any place at any time, along with his assistants.

Answers:

1) False 2) True 3) False 4) True 5) 1954
6) Magic remedies 7) Advertisements of some drugs 8) State Government

6.3.3. Very Short Answer Type Questions

1) Write the objectives of drugs and magic remedies act.
2) Define the term magic remedies.
3) What are advertisements?
4) Give the definition of drugs.

6.3.4. Short Answer Type Questions

1) Write the classes of advertisements prohibited under drugs and magic remedies act.
2) What are the offences and penalties of drugs and magic remedies act?
3) Write the powers of gazetted Officer authorised by the State Government.

6.3.5. Long Answer Type Questions

1) Discuss the salient features of drugs and magic remedies act and its rules.
2) Write the classes of exempted advertisements under this act.

CHAPTER 7

Prevention of Cruelty to Animals Act

7.1. PREVENTION OF CRUELTY TO ANIMALS ACT-1960

7.1.1. Introduction

Nearly, all developing countries have laws to save animals from cr uelty, i.e., unnecessary pain and sufferings. It can also be said that these laws have been made to prevent humans from behavi ng cruelly towards the animals. In India, certain rules for this purpose were applied to various parts; h owever, most of them remained ineffective.

For assessing the efficiency of the existing legislation on the subject and for combining several laws into a single Act, the Indian Government appointed a Committee, which introduced the 'Prevention of Cruelty to Animals Act'.

This Act was passed to prevent the animals from needless pain and suffering s and is effective to all parts of the country.

7.1.2. Objectives

Following are objectives of Prevention of Cruelty to Animals Act-1960:

1) It prevents the infliction of unnecessary pain or suffering on animals and also to prevent cruelty to animals.
2) The term **animals** comprises of any living creature but not the human being.
3) The term **cruelty** has not been defined under this Act; however it means the infliction of unnecessary pain or suffering.

7.1.3. Definitions

The definitions and important terms of Prevention of Cruelty to Animals Act, 1960 are as follows:

1) **Animal** is any living creature other than a human being.
2) **Board** is the Animal Welfare Board established under Section 4 of the Act.
3) **Breeder** is a person owing an institution, which breeds ani mals for transferring to the authorised institution for performing experiments.
4) **Committee** is constituted under Section 15 of the Act for control and supervision on animals.
5) **Establishment** is any individual, company, firm, corporation, institution, other than schools up to higher secondary level, performing experiments on animals.

6) **Experiment** is any programme/project involving experiments on animal/ animals for the purpose of advancement by new discovery of physiological knowledge which will be useful for saving or prolonging life or alleviating suffering or for combating any disease whether on human beings or animals.

7) **Institutional Animals Ethics Committee** is a body including a group of persons registered by the Committee for control and supervision on animals, performed in an establishment which is constituted and operated according to the procedures stated by the Committee for this purpose.

8) **Contract research** is commenced by an individual, company, firm, corporation or institution on behalf of a foreign individual, company, corporation or institution for any consideration.

9) **Collaborative research** is started between two or more research institutions on an equal footing which does not involve any financial or monetary considerations and is undertaken only for the purpose of advancement of scientific research and human welfare.

7.1.4. Institutional Animal Ethics Committee (IAEC)

IAEC is a Committee with a group of individuals registered by the Committee for the Control and Supervision of Experiments on Animals (CPCSEA). The expert Consultant of CPCSEA is at Chennai and its Member Secretary f or Animal Welfare is at New Delhi under the Ministry of Environment and Forests.

The 8 members in **IAEC constitution in National Institute of Biologicals (NIB)** include:

1) The chairperson,
2) Two scientists from two different Biological disciplines,
3) A scientist from the outside Institute,
4) A non-scientist socially aware member,
5) A CPCSEA nominee,
6) A scientist in-charge of animal facility of establishment concerned,
7) A veterinarian in case of animal, and
8) Co-opted in-house scientist (either a microbiologist or pathologist).

7.1.5. CPCSEA Guidelines for Breeding and Stocking of Animals

Only the registered establishments can carry out the business of breeding or trading animals for performing experiments on them. The breeder or the establishment carrying on this business should apply for registration within 60 days from the date of starting the Breeding of and Experiments on Animals (Control and Supervision) Rules, 1998 (CPCSEA). In case the Committee denies giving registration, the breeder should stop animal breeding. The breeder or the establishment should apply for registration (in the prescribed format), either to the Member-Secretary or any other person appointed by the Committee on this behalf.

The breeder or the establishment should stock the animal s as specified. Animal houses should be located in a quiet atmosphere with no traffic. The buildings should

be neat, hygienic, and the animals should be protected from drought and extreme conditions of weather. Small animals should be kept in cages and large animals should be given shelter under stables for their comfort and to avoid overcrowding. The animals should also be looked after during off-hours and on holidays.

The cages or the stables for the animals should follow the standards given by the Indian Standards Institution (ISI). The attendants of the animals should be well-trained and experienced in their work. The Committee or IAEC should lay down some conditions to make sure that the animals do not suffer from needless pain or problems either before, during, or after the experiments have been performed on them. These conditions become effective when the Committee plans to approve the conduction of experiments. The Committee can also ask for information or reports after the experiments from the establishments, IAEC, and individuals performing experiments on animals.

7.1.6. Performance of Experiments

As per the rules of this Act, no illegal experiments or experiments on animals for discovering physiological knowledge or knowledge valuable in saving or lengthening life or decreasing suffering or fighting any disease (in human beings, animals, or plants) should be performed.

7.1.6.1. Committee for Control and Supervision of Experiments on Animals

When the Central Government after being advised by the Board holds view that it is required to regulate or supervise the experiments on animals, the Official Gazette should constitute a Committee comprising of sufficient number of officials as well as non-officials. The Chairman of the Committee should be appointed by the Central Government.

This Committee should have the power to regulate its own procedure in order to perform its duties effectively. The funds of the Committee should contain grants (often made to it by the Government) and contributions, donations, subscriptions, bequests, gifts, etc. (made to it by any other person).

7.1.6.2. Sub-Committee

The Committee can even constitute several sub-committees (comprising of the Committee members) to effectively exercise its power, perform duties, or to investigate, report and counsel the Committee related to any matter.

7.1.6.3. Staff of the Committee

The Committee (controlled by the Central Government) can appoint officers and other employees in sufficient number to effectively exercise its powers and perform its duties. The compensation and other terms and conditions of service of these officers and employees can be determined by the Committee.

7.1.6.4. Duties of the Committee and Power of the Committee to Make Rules Relating to Experiments on Animals

It should be the duty of the Committee to take steps so that the animals can be prevented from getting exposed to unnecessary pain or suffering during or after

the experiments. This s hould be done by informing the Gazette of India and subject to the condition of earlier publication. Then, the Gazette m akes rules appropriate for the animals undergoing experiments. In particular and without any bias to the generalisation of the earlier power, these rules:

1) Provide for the registration of individuals or institutions conducting experiments on animals, and
2) Allow the submission of reports and other information by the individuals and institutions performing experiments on animals to the Committee.

In particular and without any prejudice to the generalisation of the earlier power, rules made by the Committee should secure the following objects:

1) When experiments are performed in any institutio n, the responsibility is placed on its in-charge; and when experiments are performed by individuals outside an institution, the individuals are held responsible for the experiments.
2) The experiments are performed carefully and kindly under the effect of anaesthesia so that the animals do not sense the pain.
3) The animals injured during the experiments and those who would suffer severely during their recovery are killed when they are still under the effect of anaesthesia.
4) The experiments on animals in medical schools, hospitals, colleges, etc. should be avoided if sufficient books, models, films, etc. teaching devices are available.
5) Performing experiments on large animals should be avoided if sufficient results can be attained by conducting experiments on small laboratory animals (such as guinea-pigs, rabbits, frogs, and rats).
6) The experiments should not be performed merely to gain manual skill.
7) The animals on which experiments are to be performed should be carefully looked after before and even after the experiments.
8) Records should be maintained with respect to the experiments performed on animals.

Although the Committee makes rules under this section, the Central Government should still give frequent orders to achieve the goals of Committee.

The rules made by the Committee should be followed by the in-charge of institutions where experiments are conducted and also by the individuals who conduct experiments outside institutions.

7.1.6.5. Power of Entry and Inspection

The Committee can appoint any officer or an individual to inspect any institution or place performing experiments on animals to assure that whether or not the rules made by it are being followed. A report of such inspection sho uld be maintained by the concerned officer and he/she can perform following functions:

1) He/She can at any time enter any institution or place where experiments are performed on animals for inspection, and
2) He/She can also ask for the records maintained by th e one performing experiments on animals.

7.1.6.6. Power to Prohibit Experiments on Animals

The inspection report made by an officer (appointed by the Committee) is thoroughly checked by the Committee. If the Committee remains dissatisfied and feels that the rules made by it are not being followed, it can refuse to give permission to the person or institution to further conduct experiments (after warning the person or institution).

This ban is either for a li mited time period or permanent; however, the person or the institution can conduct experiments on certain situations imposed by the Committee.

7.1.7. Transfer and Acquisition of Animals f or Experiment

Transferring an animal by selling or by a breeder to any unregistered establishment is not legal under this Act . Likew ise, any establishment after purchasing animal should not sell them to an y other unregistered breeder or establishment. But, the animals on which experiments are conducted in a production/breed improvement programmes are given out for domestic use by the breeder or the institution.

The guidelines put forward by the Committee for controlling and suspending experiments on animals should be obeyed by the breeder or the establishment. Importing an animal which is already available in the country by a breeder o r establishment is also not legalised.

7.1.8. Records

A record (in the prescribed format) of the animals under the control and custody of every establishment or IAEC should be maintained and presented to the Committee whenever asked for. The number or species of animal's possessed by the laboratories should be in formed (in the prescribed format) to the Secretary or any other officer appointed by the Committee on this behalf.

7.1.9. Power to Suspend or Revoke Registration

When the rules put forward by the Committee ar e not obeyed by any establishment, breeder, or IAEC , it may cancel their regi stration after giving a warning either for a definite time period or permanently. The Committ ee can permit the establishment, breeder, or IAEC to continue to work according to certain conditions enforced by the Committee.

The Committee can cancel the re gistration of any establishment or breeder not acting in accordance with the provisions. The Committee can make some guidelines for caring and protecting animals which are under the custody of any establishment or breeder, whose registration is being cancelled. These guidelines should be immediately considered by the establishment or breeder so that they are not prohibited from performing experiments on animals, or from obtaining or transferring animals.

7.1.10. Offences and Penalties

An individual is held responsible of an offence under this Act, if he/she:

1) Exhibits or trains any animal not registered under this amendment,
2) Exhibits or trains any animal with respect to which he/she is not registered,
3) Exhibits or trains any animal on which experiments should not be conducted,
4) Does not allow any individual or police officer to enter and inspect the place where experiments are conducted,
5) Hides any animal to avoid inspection,
6) Despite of being registered under this Act, fails to produce the certificate with no genuine reason, or
7) Applies to get registered under this Act when not entitled to be so registered.

If found to be guilty of any of these offences, an individual is punished with a fine of ₹500 or is imprisoned for 3 months or both.

On contravening any condition enforced by the Committee, an individual is punished with a fine up to ₹200. If the contravention of rules takes place in any institution, the in -charge of it should is held respon sible for the offence and punished.

7.2. SUMMARY

The details given in the chapter can be summarised as follows:

1) Nearly, all developing countries have laws to save animals from cruelty, i.e., unnecessary pain and sufferings.
2) **Animal** is any living creature other than a human being.
3) **Board** is the Animal Welfare Board established under Section 4 of the Act.
4) IAEC is a Committee with a group of individuals registered by the Committee for the Control and Supervision of Experiments on Animals (CPCSEA).
5) Only the regist ered establishments can carry out the business of breeding or trading animals for performing experiments on them.
6) The breeder or the establishment should stock the animals as specified
7) As per the rules of this Act, no illegal experiments or experiments on animals for discovering physiological knowledge.
8) The Chairman of the Committee should be appointed by the Central Government.
9) Transferring an animal by selling or by a breeder to any unregistered establishment is not legal under this Act.
10) When the rules put forward by the Committee are not obeyed by any establishment, breeder, or IAEC.
11) On contravening any condition enforced by the Committee, an individual is punished with a fine up to ₹200.

7.3. EXERCISE

7.3.1. True or False

1) The term animals comprises of any living creature but not the human being.
2) Transferring an animal by selling or by a breeder to any unregistered establis hment is legal under this Act.
3) As per the rules of this Act, no illegal experiments or experiments on animals for discovering physiological kno wledge.
4) Only the registered establishments can carry out the business of breeding or trading animals for performing experiments on them.
5) Ten members are present in IAEC constitution in National Institute of Biologicals (NIB).

7.3.2. Fill in the Blanks

6) _____ is any living creature other than a human being.
7) _____ is a Committee with a group of individuals registered by the Committee for the Control and Supervision of Experiments on Animals
8) Board is the Animal Welfare Board established under _____ of the Act.
9) CPCSEA is stands for _____.
10) The expert Consultant of CPCSEA is at _____ and its Member Secretary for Animal Welfare is at _____ .

Answers

1) True 2) False 3) True 4) True 5) False
6) Animal 7) IAEC 8) Section 4
9) Control and Supervision of Experiments on Animals 10) Chennai, New Delhi

7.3.3. Very Short Answer Type Questions

1) Write the objectives of prevention of cruelty to animal act-1960.
2) What is Institutional Animals Ethics Committee?
3) Write the composition of IAEC constitution in National Institute of Biologicals.
4) Write about the institutional animal ethics committee (IAEC).

7.3.4. Short Answer Type Questions

1) Explain the CPCSEA guidelines for breeding and stocking animals.
2) Give a short note on transfer and acquisition of animals for experiment.
3) What are the conditions of offences and pe nalties under prevention of cruelty to animal act-1960?
4) Write about the Institutional Animal Ethics Committee (IAEC)

7.3.5. Long Answer Type Questions

1) Write a note on performance of experiments.
2) Explain the prevention of cruelty to animal act-1960 with their objectives.

CHAPTER 8

National Pharmaceutical Pricing Authority

8.1. NATIONAL PHARMACEUTICAL PRICING AUTHORITY

8.1.1. Introduction

National Pharmaceutical Pricing Authority (NPPA) was established in **1997**. It is an independent body regulated by the Department of Pharmaceuticals, Ministry of Chemicals and Fertilisers. It aims to fix and revise the prices and formulations of controlled bulk drugs, and enforce prices and availability of medicines under DPCO, 2013. It also regulates the prices of decontrolled drugs to keep them at reasonable levels. The regulator implements and applies the provisions of DPCO. It also recovers the amounts overpriced by the manufacturers for controlled drugs from the consumers.

8.1.2. Drug Price Control Order (DPCO)-2013

The latest Drug Price Control Order (DPCO-2013) was issued on **15th May, 2013** by the Ministry of Chemicals and Fertilisers based on the basis of National Pharmaceutical Pricing Policy, 2012 (NPPP). The NPPP was issued on 7th December, 2012 with the main purpose to control the price of the medicines listed under National List of Essential Medicines -2011 (NLEM-2011), issued by the ministry of Health and Family welfare.

Under the latest DPCO 2013, the prices of 348 drugs listed in the National List of Essential Medicines-2011 covering around 628 formulations have been brought in the section of price control by the latest DPCO-2013.

The authority which controls and monitors the drug prices is **National Pharmaceutical Pricing Authority** (NPPA). It has all the delegate powers of Government of pricing according to the Essential Commodities Act.

Under DPCO-2013 the powers to review are vested by the Government; because of this reason the Department of Pharmaceuticals is the authority which comes into the picture when the pharmaceutical companies file the review petitions on any of the issue on price fixation done by NPPA. The policy related matters are also being reviewed by the Department of Pharmaceuticals.

8.1.3. Objectives

Following are the main objectives of DPCO 2013:

1) To ensure the availability of all the essential drugs at a reasonable price.
2) To confirm that the quality of drugs does not decline with price fixation.
3) To promote the rational use of prescribed drugs in a cost-effective manner.

8.1.4. Definitions

In this order, unless the context otherwise requires:

1) **Act** is the Essential Commodity Act, 1950 (10 of 1955).
2) **Active pharmaceutical ingredients or bulk drug** is a pharmaceutical, chemical, biological or plant product including its salts, esters, isomers, analogues and derivatives, conforming to standards specifie d in the Drugs and Cosmetics Act, 1940 (23 of 1940) and which is used as such or as an ingredient in any formulation.
3) **Brand** is a name, term, design, symbol, trademark or any other feature that identifies one seller's drug as distinct from those of other sellers.
4) **Ceiling price** is a price fixed by the Government for Scheduled formulations in accordance with the provisions of this order.
5) **Dealer** is a person carrying on the business of purchase or sale of drugs, whether as a wholesaler or retailer and includes his agent.
6) **Distributor** is a person engaged in the work of distribution of drugs an includes an agent or a stockist for stocking drugs for sale to a dealer.
7) **Existing manufacture** means manufacture existing on the date of publication of this order in the Official Gazette.
8) **Form** is a form specified in the Second Schedule.
9) **Formulation** is a medicine processed out of or containing one or more drugs with or without use of any pharmaceutical aids, for internal or external use or in diagnosis, treatment, mitigation or prevention of disease and, but shall not include:
   i) Any medicine included in any bona fide ayurvedic (including Siddha) or Unani (Tibb) systems of medicines,
   ii) Any medicine included in the homeopathic system of medicine, and
   iii) Any substance to which the previous of the Drugs and Cosmetics Act, 1940 (23 of 1940) do not apply.
10) **Generic version of a medicine** is a formulation sold in pharmacopoeial name or the name of the active pharmaceutical ingredient contained in the formulation, without any brand name.
11) **Government** is the Central Government.
12) **Import** with its grammatical variations and cognate expressions means bringing a drug into from a place outside India for its sale.
13) **Local taxes** is any tax or levy (except excise or import duty included in retail price) paid or pa yable to Government or the State Government or any local body under any law for the time being in force by the manufacturer or his agent or dealer.
14) **Manufacturer** for the purpose of this order is anyone who manufactures, imports and markets drugs for distribution or sale in the country.
15) **Market share** is the ratio of domestic sales value (on the basis of moving annual turnover) of a brand or a generic version of a medicine and the sum of total domestic sales value of all the brands and generic versions of that medicine sold in the domestic market having same strength and dosage form.

16) **Margin to retailer** for the purposes of this order is a percentage of price to retailer.

17) **Market based data** means the data of sales related to a drug collected or obtained by the government as deemed fit, from time to time.

18) **Maximum retail price** is the ceiling price or the retail price plus taxes and duties as applicable, at which the drug shall be sold to the ultimate consumer and where such price is mentioned on the pack;

19) **Moving annual turnover** in a particular month is cumulative sales value for twelve months in domestic market, where the sales value of that month is added and the corresponding sales of the same month in the previous year are subtracted.

20) **National List of Essential Med icines**, 2011 published by the Ministry of Health and Family Welfare is updated or revised from time and included in the first schedule of this order by the Government through a notification in the Official Gazette.

21) **New drug** for the purposes of this order i s a formulation launched by an existing manufacturer of a drug of specified dosages and strength as listed in the National List of Essential Medicines by combining the drug with another drug either listed or not listed in the National List of Essential Medicines or a formulation launched by changing the strength or dosage or both of the same drug of specified dosages and strength as listed in the National List of Essential Medicines.

22) **Non-scheduled formulation** is a formulation, the dosage and strengths of which are not specified in the First Schedule.

23) **Pharmacoeconomics** is a scientific discipline that compares the therapeutic value of one pharmaceutical drug or drug therapy to another.

24) **Price list** is a price list referred to in paragraphs 24 and 25 and includes a supplementary price list.

25) **Price to retailer** is the price of a drug at which it is sold to a retailer which includes duties and does not include local taxes.

26) **Retail price** is the price fixed by the Government for a new drug under paragraph 5.

27) **Retailer** is a dealer carrying on the retail business of sale of drugs to customers.

28) **Scheduled formulation** is a formulation, included in the First Schedule whether referred to by generic versions or brand name.

29) **Schedule** is a schedule appended to this order.

30) **Wholesaler** is a dealer or his agent or a stockist engaged in the sale of drugs to a retailer, hospital, dispensary, medical, educational or research institution or any other agency.

31) **Wholesale price index** is an annual wholesale price index of all commodities as announ ced by the Department of Industrial Policy and Promotion, Government of India, from time to time.

8.1.5. Sale Prices of Bulk Drugs

The Government notifies the Official Gazette and on periodic intervals fixes a maximum sale price at which the bulk drug should be sold. This is done to control the equitable distribution, increase the supplies of a bulk drug given in the First Schedule , and make it available at a reasonable price from different manufacturers.

At the time of enquiry, apart from the information needed to be provided by the manufacturers under this Order, the y should also furnish any extra information that may be needed by the Government . The manufacturers should allow the inspection of their manufacturing area by the Government for verification of the manufacturing procedures, facilities, and records.

While fixing the maximum sale price of a bulk drug, the Government should consider a post-tax return of 14% on net worth or a return of 22% on capital employed or in respect of a new plant an internal rate of return of 12% depending on the long-term marginal costing based on the choice for any of the certain rates of return exercised by a bulk drug manufacturer.

The Government should consider a post-tax return of 18% on net worth or a return of 26% on capital employed, in case the production is from basic stage.

If the option with respect to the rate of return has been once exercised by a manufacturer, it should be final and no alteration in rates should be made without the Government approval.

No person should sell a bulk drug at a price more than the maximum sale price plus local taxes.

Until the price of a bulk drug is fixed by the Gove rnment, the price of bulk drugs should be that price which prevailed before the beginning of this Order. The manufacturer of those bulk drugs should also not sell the drug at a price more than the price prevailing before the beginning of this Order.

Any manufacturer commences the production of a bulk drug given in the First Schedule after the commencement of this Order . The manufacturer within 15 days of the commencement of production of such bulk drug should furnish the particulars to the Government in Form I. Any additional information as needed by the Government should also be provided. The Government on receiving the information and after making the necessary inquiry fixes the maximum sale price of the bulk drug by notifying the Official Gazette.

If a manufacturer wants to revise the maximum sale price of a bulk drug, he should make an application to the Government i n Form 1. The Government on receiving the application should make enquiry and within 4 months from the date of receiving the full information, either fixes a revised price for the bulk drug or cancels the request of revision if not satisfied with the furnished records.

8.1.6. Price of Formulations

The following formula should be used to calculate the retail price of a formulation:

$$RP = (MC + CC + PM. + PC) \times (1 + \frac{MAPE}{100}) + ED$$

Where,

RP = Retail price.

MC = Material cost including the cost of drugs and other pharmaceutical aids used including overages, if any, plus process loss specified as a norm from time to time by notification in the Official Gazette.

CC = Conversion cost worked out in accordance with the established procedures of costing and fixed as a norm every year by notification in the Official Gazette.

PM = Cost of the packing material used in the packing of the formulation, including process loss, and fixed as a norm every year by notification in the Official Gazette.

PC = Packing charges worked out in accordance with the established procedures of costing and fixed as a norm every year by notification in the official Gazette.

MAPE = (Maximum Allowable Post-manufacturing Expenses) = All costs incurred by a manufacturer from the stage of ex-factory cost to retailing and includes trade margin and margin for the manufacturer. It shall not exceed 100% for indigenously manufactured Scheduled formulations.

ED = Excise duty.

8.1.6.1. Retail Price of Scheduled Formulations

The Government can timely fix the retail price of any scheduled formulation in accordance with the formula discussed above.

The Government fixes or revises the price of a bulk drug under the provisions of this Order and a manufacturer uses the bulk drug in his scheduled formulations. He should make an application to the Government in Form-III for revision of the price of all the formulations within 30 days of such fixation or revision. The Government on receiving the application if feels satisfied fixes or revises the formulation price. The retail price of a formulation after getting fixed by the Government should not be increased by the manufacturer without the Government's approval.

If a manufacturer wants to revise the retail price of a formulation, he should make an application to the Government in Form III or Form IV. On receiving the application, the Government should make necessary enquiry and within 2 months from the date of receiving the complete information either fixes a revised price for such formulation or cancels the application if dissatisfied with the records furnished. Until the price of a bulk drug is fixed by the Government, the price of bulk drugs should be that price which prevailed before the beginning of this Order. The manufacturer of those bulk drugs should also not sell the drug at a price more than the price prevailing before the beginning of this Order.

No manufacturer or importer should market a new pack or a new formulation or a new dosage form of his existing Scheduled formulation without the prior approval of its price from the Government. Also no person should sell or dispose any imported scheduled formulation without the prior approval of its price from the Government.

8.1.6.2. Ceiling Price of Scheduled Formulations

The calculation of ceiling price of a scheduled formulation of a specific strength and dosage can be calculated as given below:

Step 1: The average price to the retailer of the scheduled formulation [P(s)] is calculated as follows:

Average Price to Retailer [P(s)] = (Sum of prices to retailer of all the brands and generic versions of the medicine having markets share more than or equal to 1% of the total market turnover on the basis of moving annual turnover of that medicine)/(Total number of such brands and generic versions of the medicine having market share more than or equal to 1% of total market turnover on the basis of moving annual turnover for that medicine)

Step 2: The ceiling price of the scheduled formulation [P(c)] can be calculated as:

$$P(c) = P(s) \cdot (1 + M/100)$$

Where,

P(s) = Average price to retailer for the same strength and dosage of the medicine as calculated in step 1 above.

M = % Margin to retailer and its value = 16

The formula given above is notified by the government, and is used to calculate the ceiling price of scheduled imported formulations.

8.1.7. National List of Essential Medicines (NLEM)

Essential medicines fulfil the healthcare requirements of the population. They are selected with respect to the public health significance, evidence on efficacy and safety, and comparative cost effectiveness. They are obtainable all the time in the context of functioning health systems in sufficient amounts and at affordable price. The WHO developed a directory of such medicines in **1977** and named it **WHO Model List of Essential Medicines**. This list is updated in every 2 years, and in March 2011 its current version was updated.

India maintains its own EDL just like other countries and it is reviewed in every few years by a national committee. Total 348 medicines (excluding repetitions for different indications) are in the National List of Essential Medicines (NLEM) 2011. However, the presence of a list does not assure that Indians have access to the essential medicines. In June 2012, the General Secretary of the All India Drugs Control Officers' Confederation said that 50-65% of the country's population cannot access the vital medicines (as estimated by the WHO), even if the country's drug production had exceeded ₹1 lac crore (i.e., 1 billion rupees). Due to this pricing deregulation which started in the 1990s, increasing number of people are falling below the poverty line because of increasing costs of care they faced.

The Government appointed **Hathi Committee** in **1975**. This committee had recommended the development of an EDL and took actions to ensure their production. Thus, the country could commence a gradual shift from expensive branded drugs to cheaper generics. The committee also recommended the implementation of price controls to make life -saving drugs and essential drugs affordable, and that the public sector play a leading role in drug production. The committee also suggested the removal of irrational drugs. The Essential Commodities Act empowered the central government to monitor and enforce price ceilings on drugs by issuing the DPCOs. But the number of drugs brought by the committee has reduced with the passage of time.

Presently, the government controls the prices of 74 bulk drugs and their formulations through the NPPA. The government assured to regulate the prices of all medicines under NLEM in the Pharmaceutical Policy 2012, however remained unsuccessful. In September 2012, a group of ministers headed by the Minister for Agriculture approved a radical proposal to bring all the 348 drugs of the NLEM under price control, ineffect extending the price controls from generics to patented, branded products. These drugs have annual sales of about ₹29,000 crore, accounting for up to 60% of the domestic market. When passed, this can restore the level of drugs under price controls to levels not seen since the late 1970s.

8.2. SUMMARY

1) The details given in the chapter can be summarised as follows:
2) National Pharmaceutical Pricing Authority (NPPA) was established in **1997**.
3) The latest Drug Price Control Order (DPCO-2013) was issued on **15th May, 2013** by the Ministry of Chemicals and Fertilisers.
4) Under the latest DPCO 2013, the prices of 348 drugs listed in the National List of Essential Medicines-2011 covering around 628 formulations.
5) The authority which controls and monitors the drug prices is **National Pharmaceutical Pricing Authority** (NPPA).
6) **Brand** is a name, term, design, symbol, trademark or any other feature that identifies one seller's drug as distinct from those of other sellers.
7) **Non-scheduled formulation** is a formulation, the dosage and strengths of which are not specified in the First Schedule.
8) **Pharmacoeconomics** is a scientific discipline that compares the therapeutic value of one pharmaceutical drug or drug therapy to another.
9) **Retailer** is a dealer carrying on the retail business of sale of drugs to customers.
10) The Government notifies the Official Gazette and on periodic intervals fixes a maximum sale price at which the bulk drug should be sold.
11) The Government can timely fix the retail price of any scheduled f ormulation in accordance with the formula.
12) Essential medicines fulfil the healthcare requirements of the population
13) The Government appointed **Hathi Committee** in **1975**.

8.3. EXERCISE

8.3.1. True or False

1) The authority which controls and monitors the drug prices is NPPA.
2) The latest Drug Price Control Order (DPCO-2013) was issued on 15th May, 2017.
3) The Government appointed Hathi Committee in 1975.
4) Price list is the price fixed by the Government for a new drug under paragraph 5.
5) Retailer is a dealer carrying on the retail business of sale of drugs to customers.

8.3.2. Fill in the Blanks

6) The latest Drug Price Control Order (DPCO-2013) was issued on 15 th May, 2013 by the _____.
7) National Pharmaceutical Pricing Authority (NPPA) was established in_____.
8) The authority which controls and monitors the drug prices is _____.
9) _____ is a name, term, design, symbol, trademark or any other feature that identifies one seller's drug as distinct from those of other sellers.
10) Presently, the government controls the prices of _____ and their formulations by the NPPA.

Answers:

1) True 2) False 3) True 4) False 5) True
6) Ministry of Chemicals and Fertilisers 7) 1997 8) NPPA
9) Brand 10) 74 Bulk drugs

8.3.3. Very Short Answer Type Questions

1) What is drug price control order (DPCO)-2013?
2) Give the main objectives of DPCO 2013.
3) Define the Non-scheduled and Scheduled formulation.
4) Write the formula used to calculate the retail price of a formulation.

8.3.4. Short Answer Type Questions

1) Write about the sales prices of bulk drugs.
2) Give a short note on national list of essential medicines.
3) Explain about the DPCO-2013.

8.3.5. Long Answer Type Question

1) Discuss about the price of formulations in detail.

CHAPTER 9

Pharmaceutical Legislations

9.1. PHARMACEUTICAL LEGISLATIONS

9.1.1. Introduction

A society's social and economic aspect can be secured through Pharmaceutical Legislations, denoting mixed type legislation.

Pharmaceutical legislation ensures the drug quality, its testing and evaluation criteria, and efficacy for its intended use by the patient. Overall these legislations function as a backbone of our healthcare system.

9.1.2. Origin

Towards the closing of 19 th century, manufacturing of modern drug began in India. Bengal Chemical and Pharmaceutical Works (Calcutta) was established by **Acharya P.C. Ray** in **1901**. A small factory at Parel (Bombay) was initiated by **Prof. T.K. Gajjar** in **1903**. Later, Alembic Chemical Works (Baroda) was laid down by **Prof. T. K. Gajjar Rajmitra** , and **B.D. Amin** in **1907**. All these became the foundation stone.

India imported crude drugs costing around ₹73 lacs in 1908 -09. In the same period, India also exported finished drugs of about ₹15.5 lacs. This era had no legislation available in India for governing the import or expor t of drugs. At that time anything could be manufactured as drug. During the First World War due to 'Swadeshi' movement, the Indian Pharmaceutical Industry advanced and restarted the import of drugs. Back then the manufacturing plants of sera, vaccines, and surgical dressings were established. Still, the legislation required for controlling or ensuring the quality of imported drugs was absent. Foreign fraudulent manufacturers took this as an advantage and saturated Indian markets with adulterated and spuriou s drugs. An **example** of such a condition is the **Great quinine fraud** which occurred under the British rule in India.

Then the need for an organisation to control such misconducts arose. The press media, along with Pharmaceutical Journal of England was in fa vour of it. In **1926**, The Medical Research Workers Conference passed a resolution to ask the Central Government for an organisation and a laboratory that would check for the standardisation of drugs issued through the medical stores.

From **1920-1930**, many r eports were published in Indian press regarding the marketing of harmful substitutes and adulterants instead of genuine drugs and also the toxic effects of drugs. A report submitted by the Indian Medical Gazette stated that there was no control over the ma nufacturing, sale, and distribution of

drugs in India. Many lost their lives on consuming the spurious drugs. Eye drops were replaced with croton oil. Chalk powder was used to adulterate drug formulations. Many cases of toxicity were reported due to overdo se of mercury compounds. Since there were no effective Acts and Rules related to drugs and pharmaceuticals in the country, all the fraudulent manufacturers were in a competition to manufacture sub-standard, spurious, and adulterated formulations.

When a l arge number of people started dying due to spurious and adulterated drugs, the public started protests in the country and even outside as the British rulers in India provided poor medical facilities. As a result, the British Government was forced to take action for drug legislations.

During the Presidential address at Indian Science Congress in **1927**, Lahore appealed for necessary steps to eradicate spurious drugs. The Council of States on **March 9**, **1927** put forward a resolution to the Governor General to ma ke quick control over the craze for medicinal drugs by Legislation including standardisation and sale of drugs. **Sir Haroon Zaffer** stated that the drugs of defective strength and impure quality have taken over the market. The deceitful traders are making sa le of potent drugs including sera and vaccines, without evaluating their quality and efficacy. Therefore, the **Council of State in British India**, headed by the **Viceroy** passed a resolution to put a check on the malpractices in drug dispensation and medication.

In **1928** on **May 3**, a letter was written to the Indian Government by the Secretary of the Indian Merchant of Bombay. The letter contained about stocking of inferior quality drugs by the Indian druggists for sale. Manufacturers bearing machineries and lab oratory of poor standards were producing low quality drugs to have profit on sale. These malpractices were damaging the health sectors along with pharmaceutical industry.

In **1928** on **4th September**, **Lt. Col. H.A.J. Gidney** asked for immediate control on adul terated drugs in India through the implementation of 'Food and Drugs Act' and 'Pharmacy and Poisons Act'. The present day Drugs and Cosmetics Act and the Pharmacy Act are established due to the opinion by medical practitioners, research scientists, leaders , and merchant chambers regarding the safety and efficacy of drugs.

On **11th August**, **1930**, **Drugs Enquiry Committee (DEC)** was constituted under the **Chairmanship of Col. R. N. Chopra**. This was a historic development which marked the beginning of new era of d rug legislation in India. Before this committee was established, there was no such legislation to control the import, manufacture, sale, and distribution of drugs. Neither was any Act laid mentioning the desired qualification of a pharmacist nor a systemat ic procedure was adopted for registration as pharmacists.

9.1.3. Scope and Objectives

In **1940**, the Drug Bill was put forward in the Legislative Assembly. It was passed by considering the report of Selection Committee. After seven years (in **1947**), the

Drug Bill was enforced as the **Drug Act**, **1940**. The Drug Act has been amended several times by then, and presently it withholds all the provisions related to Drugs and Cosmetics, Ayurvedic, Unani, and Homeopathic medicines. Today's Drug and Cosmetics Act is an enhanced form of Drug Act, 1940. The Act regulates the import, manufacture, distribution, and sale of drugs and cosmetics.**The Drug and Cosmetics Rules**, **1945** framed by the Central Government is a set of rules for the manufacture, distribution, and sale of drugs and cosmetics in India. These act and rules are amended at suitable intervals of time.

Drugs Enquiry Committee and Health Survey and Development Committee gave recommendations, which laid the foundation for the Pharmacy Act, 1948. Government of India introduced the **Pharmacy Bill** in **1945** in order to regulate the profession and practice of pharmacy. This Bill was later passed as **Pharmacy Act**, **1948** (Act No. VIII of 1948).

It became necessary after independence to control the advertisements of drugs which were in overstated and deceptive form. Many manufacturers were making overstated claims for their medicines and exploiting the weaknesses of human, particularly in the advertisements of STDs, menstrual disorders, loss of vigour, stamina, etc. The magic remedies were advertised for the treatment of Bhanamati, epilepsy, diabetes and many other ailments. The magic remedies were given in the form of Kavachas, Taits, Talisman, Sacred Bones, Sacred Bhasmas, Mantras, etc. Through this poor and illiterate people were abused. **The Drugs and Magic Remedies (Objectionable Advertisements) Act** was approved by the Parliament in **1994** for the regulation of these offensive trends.

The important solvent of pharmaceutical industry is alcohol, used as a vehicle, preservative, and therapeutic agent in the manufacturing and formulation of drugs. Manufacturing, sale, and distribution of alcohol were regulated by province and states at the time of independence; and the rates charged by provinces/states in the form of excise duties were different for different areas. Alcohol was also exploited and was the drug of abuse. The **Medicinal and Toilet preparations (Excise Duties) Act** was passed by the Parliament in **1955** for controlling the production, sale, and distribution of alcohol and for maintaining regularity in the excise duties.

The **Drugs Price Control Order**, **1970** was passed for regulating the prices of drugs. The main aim of this act was to fix the rate of every drug and their formulations categorised into essential and non-essential groups. This was done for maintaining uniform retail rates for certain drug categories and for controlling the drug prices of life saving drugs.

In **1985**, the **Narcotic Drugs and Psychotropic Substances Act** and Rules was passed with the removal of the Dangerous Drugs Act, 1930 and Opium Act, 1878. The Act aims at consolidating and amending the law for Narcotic Drugs and set strict provision to control and regulate operations and other matters related to Narcotic Drugs and Psychotropic Substances. This act contains the **Ordinance**, **1988** that prevents the illegal transfer of Narcotic Drugs and Psychotropic Substances.

Few more enactments which are directly or indirectly linked to manufacture, distribution, and sale of Drugs and Pharmaceuticals in India are:

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 Diseases Act, 1897, and
9) Shops and Establishments Act of respective states.

9.1.4. Study of Drugs Enquiry Committee

In 1927, a resolution was made acco rding to which Drugs Enquiry Committee (DEC) was setup by the Indian Government; this committee is also known as **Chopra Committee. Dr. B. Mukherjee** , the Assistant Secretary of this committee later became the Director of Central Drugs Labora tory and subsequently of the Central Drug Research Institute.

Functions of DEC were to:

1) Identify the quality and quantity of impure drugs imported, manufactured, or sold in British India as per the British Pharmacopoeia,
2) Report the recommendations for the above by diffe rent approved medicinal preparations and indigenous drugs preparations, and
3) Enquire the legislations that allow only qualified persons to access the pharmacy profession.

A report was submitted in **1931** by the Drug Enquiry Committee making the following recommendations:

1) A drug industry should be established in India.
2) A Central Legislation should be implemented either combined or individually as the Drugs and Pharmacy Act.
3) An advisory board should be appointed by the Central Government to look after the obj ectives of the Act and to give timely advice about the necessary amendments in the Act to the Government.
4) All Indian states should have modern test laboratories and quality control laboratories to test and manage the quality of drugs and its products manufactured in pharmaceutical industries along with the drugs imported.
5) Crude drugs individually or compounded into medicines in traditional treatment system should be included under the Legislation.
6) Manufacturing should be gradually reduced in Medical Stores Departments.
7) Guideline should be framed for pharmacy course. Training courses in pharmacy should be setup. Minimum qualification for registration as a pharmacist should be imposed.

8) Patent and proprietary medicines of undisclosed formula (manufactured in India or imported) should be registered. Cinchona cultivation in India should be initiated.
9) Compilation of Indian Pharmacopoeia is required.

In **1932**, at Banaras Hindu University (BHU), the first pharmacy department of Pharmaceutics was initiated. In **1935**, at Uttar Pradesh, Indian Pharmaceutical Association was created. In **1940**, they arranged All India Pharmaceutical Conference. The Indian Journal of Pharmacy which is now known as the Indian Journal of Pharmaceutical Science was publishing scientific reviews and findings. Thus, in India pharmacy profession raised and got more attention. This brought awareness to a great extent.

Drugs Act, 1940

A Bill in **1940** was brought up by the Indian Government, and was submitted to a committee of highly qualified and dignified personnel. The Bill emphasised on import, manufacture, distribution, and sale of drugs in Indian Territory. The committee passed the bill on **5th April**, **1940** and on **10th April**, **1940** received Governor General's approval. Then the bill became **Drugs Act**, **1940** (Act No. XXIII of 1940).

9.1.5. Health Survey and Development Committee

Government of India, on **October 1943** framed the Health Survey and Development Committee under the **chairmanship** of **Sir Joseph Bhore**. The committee focused on making a thorough survey on infrastructure of health organisations (formed during British India) and giving necessary recommendations for development.

The important **recommendations** that the Health Survey and Development Committee made are:

1) Establishment of Central Drug Laboratory (CDL),
2) Strict implementation and enforcement of the Drug Act, 1940 throughout the country,
3) Establishment of All India Pharmaceutical Council and Provincial Pharmaceutical Council organisations to appoint representatives of pharmaceutical trade, pharmacy education, and other pharmaceutical operations.
4) Issuance of guidelines for pharmacist registration in India,
5) Provision for revised study courses for licenced pharmacists, graduate pharmacists, and pharmaceutical technologists, as per their role in the profession,
6) Framing of a committee to examine the country's requirements regarding drugs and other medical fundamentals,
7) Measures for maintaining discipline in the profession and practice of pharmacy,

8) Appointing qualified pharmacists and engaging them in all the areas of pharmacy profession to implement the Pharmaceutical Legislation strictly, and
9) Elevating the professional standards, thereby protecting the profession from unskilled persons.

9.1.6. Hathi Committee

Jaisukhlal Hathi Committee was appointed by the government of India to monitor the various factors of the drug industry in India in order to promote the growth of drug industry.

Following are the terms of reference of the committee:

1) It enquires about the development of the industry and the status it has attained.
2) It recommends measures to ensure that the public sector achieves a leadership role in the manufacture of basic drugs, formulations , and in research and development.
3) It recommends measures to support the growth of the drug industry, especially that of the Indian and small scale industrial sector.
4) It examines the arrangements for the flow of new technology into the industry and makes necessary commendations.
5) It recommends measures for effective quality control of the drugs and for helping the small scale units.
6) It examines the steps taken to decrease the prices for the consumer and to recommend more such measures to rationalise the prices of basic drugs and formulations.
7) It recommends measures to provide the general public (especially in the rural areas) with essential drugs and common household remedies.
8) It recommends institutional and other arrangements to confirm equitable distribution of basic drugs and raw materials, especially in the small scale industrial sector.

The summary of the recommendations of the Hathi Committee report is as stated below:

1) Around 20% of the total sales of drugs and pharmaceuticals are carried out by small firms and/or by multinational units over the world. Similar pattern was developed by the Hathi committee.
2) The success of larger units in the modern pharmaceutical industry depends on their ability to develop new products based on research and to create and sustain a demand for their product. This is achieved by the effective selling techniques and by product adaptation to assist in effective marketing.
3) Some evidence suggests that the growth of pharmaceutical industry in last 15 years has been impressive in terms of product composition and the pricing policies of the industry.
4) The committee recommends to continuously reviewing the packing methods and the packing materials used to develop an appropriate packing standard.

5) It also recommends that more attention should be given to standardisation and economy of packing materials reliable with the protection of the consumer's interest.
6) The committee recommends providing information related to production, stocks, costs, sales, profitability, etc., on a regular basis to allow the government to act in an efficient and rapid way.
7) It also recommends developing an effective and continuing monitoring system for the industry in order to attain the essential objectives.
8) The committee puts forward an alternative that the ceiling of profit may lay between 10 -12.5% post -tax on net worth, i.e., paid up capital as other standard. The committee identified 13 drugs (for generic usage) that should be free from price regulation.
9) The committee considers the question of the return rate on investment needed for bulk drug production and recommends that a ret urn of post -tax between 12-14% on paid up capital plus reserves can be accepted as the base for price fixation.

9.1.7. Mudaliar Committee

Mudaliar Committee was appointed by the Government of India in **1961** to analyse the progress made in medical relief and public health after the submission of t he Bhore Committee's report. This committee also frames guidelines and proposals for inclusion in the subsequent Five Year Plans.

According to this committee, a system of graded charges should be established for all hospital services; however this is not applicable for genuinely poor patients. It al so suggested that the Employees State Insurance Scheme and the Central Government Health Scheme should be extended to cover more sectors of the population.

Mudaliar Committee recommended to strictly adhere to the references of the Bhore Committee related to the implementation of the programme of primary health centres. It recommended that the taluk hospital s should take over the routine medical, surgical, obstetrical and gynaecological requirements of the area, whereas the district hospitals should provide medical care and specialist services in medicine (including chest and heart diseases), surgery, obstetrics , gynaecology, ENT, ophthalmology, paediatrics, orthopaedics, dentistry, venereal diseases, etc. Some district hospitals should have a teaching hospital for getting expert advice and help related to the investigation, diagnosis, and treatment.

Blood bank services should be available in every district and teaching hospital. The out -patient department shoul d be separated from the in -patient department with separate entrances for each. Children's hospitals, maternity hospitals, cancer hospitals, leprosy hospitals , T.B. hospitals, etc . should be present at the state level. There should be an ophthalmic hospital (with 300-500 beds) in every state, whereas there should be a fully equipped and staffed dental clinic in every district.

The Mudaliar Committee deeply looked into the public health problems and gave recommendations to help in the development of curative and preventive health services. Like other countries, in India also hospitals and dispensaries should be present to provide relief against sickness to the patients . It can be said that hospitals are temporary homes for the patients, and h ospital authori ties and the government should together form favourable conditions for them.

Buildings, equipment , and skill play a significant role for curative services. However, caring and kind treatment and welfare facilities also have important role. Additionally, each patient demand individual attention as each have some special needs based on the social background and personality traits . Wealth and political effect should not get privileged treatment in hospitals.

9.2. SUMMARY

The details given in the chapter can be summarised as follows:

1) Towards the closing of 19th century, manufacturing of modern drug began in India.
2) Bengal Chemical and Pharmaceutical Works (Calcutta) was established by **Acharya P.C. Ray** in **1901**.
3) In **1928** on **May 3** , a letter was written to the Indi an Government by the Secretary of the Indian Merchant of Bombay.
4) In **1928** on **4th September**, **Lt. Col. H.A.J. Gidney** asked for immediate control on adulterated drugs in India.
5) On **11th August**, **1930**, **Drugs Enquiry Committee (DEC)** was constituted under the **Chairmanship of Col. R. N. Chopra.**
6) In **1940**, the Drug Bill was put forward in the Legislative Assembly.
7) Government of India introduced the **Pharmacy Bill** in **1945**.
8) The **Medicinal and Toilet preparations (Excise Duties) Act** was passed by the Parliament in **1955.**
9) The **Drugs Price Control Order** , **1970** was passed for regulating the prices of drugs.
10) In **1985**, the **Narcotic Drugs and Psychotropic Substances Act** and Rules were passed with the removal of the Dangerous Drugs Act, 1930 and Opium Act, 1878.
11) Government of India, on **October 1943** framed the Health Survey and Development Committee under the **chairmanship** of **Sir Joseph Bhore.**
12) Jaisukhlal Hathi Committee was appointed by the government of India to monitor the various factors of the drug industry in India.
13) Mudaliar Committee was appointed by the Government of India in **1961**.

9.3. EXERCISE

9.3.1. True or False

1) Mudaliar Committee was appointed by the Government of India in 1945.
2) The Drugs Price Control Order, 1970 was passed for regulating the prices of drugs.
3) The important solvent of pharmaceutical industry is alcohol, used as a vehicle.
4) In 1932, at Banaras Hindu University (BHU), the first pharmacy department of Pharmaceutics was initiated.
5) Government of India introduced the Pharmacy Bill in 1961.

9.3.2. Fill in the Blanks

6) Bengal Chemical and Pharmaceutical Works (Calcutta) was established by _____ in 1901.
7) The Drugs Price Control Order, 1970 was passed for _____.
8) The Medicinal and Toilet preparations (Excise Duties) Act was passed by the Parliament in_____.
9) On 11th August, 1930, D rugs Enquiry Committee (DEC) was constituted under the Chairmanship of_____.
10) In 1932, at_____ the first pharmacy department of Pharmaceutics was initiated.

Answers:

1) False 2) True 3) True 4) True 5) False
6) Acharya P.C. Ray 7) Regulating the prices of drugs 8) 1955
9) Col. R. N. Chopra 10) Banaras Hindu University (BHU)

9.3.3. Very Short Answer Type Questions

1) Write the scope of pharmaceutical legislations.
2) Write the approvals made by health survey and development committee.
3) What is hathi committee?
4) Explain about the drug enquiry committee.

9.3.4. Short Answer Type Questions

1) Explain the objectives of pharmaceutical legislations.
2) Write a short note on mudaliar committee.
3) Discuss the origin of pharmaceutical legislations.

9.3.5. Long Answer Type Questions

1) Write a short note on health survey and development committee.
2) Discuss about hathi and mudaliar committee in detail.

CHAPTER 10

Code of Pharmaceutical Ethics

10.1. CODE OF PHARMACEUTICAL ETHICS

10.1.1. Introduction and Definition

The **code of moral principles** or the **science of morals** is termed as **ethics**.

The pharmacy profession possesses noble ideas and pious nature. It has been a career for earning livelihood and has also got the attitude of service and sacrifice in the interests of the suffering humanity.

A pharmacist works in association with medical professionals and others (who have been given the responsibility of protecting the health of people) in handling, selling, distributing, compounding, and dispensing medical substances including poisons and potent drugs. Generally, before anything else the pharmacist has to support the needs of his consumers.

Charaka (the ancient Indian philosopher, physician, and pharmacist) stated that "**Even if your own life be in danger you should not betray or neglect the interests of your patients**". This saying should be valued by each pharmacist.

Pharmacy practice has been restricted by the Government only to those who have qualified under regulatory requirements. The Government also grants them privileges which are denied to others and in return expects that the pharmacists should understand their responsibilities and fulfil their professional duties honourably for the well-being of the society.

As per the nature of pharmaceutical practice, its demands are more than the ability of the individual to carry out as quickly or as efficiently as the needs of the public. Therefore, the pharmacist should always be ready to provide information or advice to their colleagues.

Above everything, the pharmacist should be a good citizen and should undertake and defend the laws of the State and the Nation.

10.1.2. Principles

Area of Focus	Principles
Consumer	1) **Recognising the Consumer's Health and Well-Being as the First Priority:** A pharmacist should make use of expert knowledge and provide care to the consumer compassionately and professionally. 2) **Respecting the Consumer's Autonomy and Rights, and Encouraging them to Participate in Decision-Making:** A pharmacist should respect the dignity and privacy of the consumer, including the consumer's individuality, and their right to refuse advice or treatment. He should also maintain the privacy and confidentiality of the information provided by the consumer.

Community	1) **Upholding the Reputation and Public Trust of the Profession:** A pharmacist should not abuse the trust and respect of individuals and society. 2) **Acknowledging the Professional Roles and Responsibilities to the Wider Community:** A pharmacist s hould maintain accountable control and supply of therapeutic goods and should also contribute to public health and enhance the quality use of medicines.
Pharmacy Profession	1) **Demonstrating a Commitment to the Development and Enhancing the Profession:** A phar macist should advance the profession by involving himself in activities such as training staff, engaging in teaching, acting as a preceptor, mentoring students, interns and colleagues, engaging in discussions and participating in initiatives to develop the profession, and showing professional leadership. 2) **Maintaining a Contemporary Knowledge of Pharmacy Practice and Ensuring Health and Competence to Practise:** A pharmacist should know the importance of lifelong learning and self -development and their effect on professional competence. He should also maintain personal health to support health professional colleagues. 3) **Agreeing to Practice Only Under Conditions which Uphold the Professional Independence, Judgement, and Integrity of Themselves or Others:** A pharmacist should exercise professional autonomy, objectivity, and independence and manage actual and potential situations of conflict of interest.
Business Practices	**Conducting the Pharmacy Business Ethically and Professionally:** A pharmacist should conduct the business practices in the best interest of the consumer by paying due respect to colleagues, and upholding the reputation of the profession.
Other Healthcare Professionals	**Working Collaboratively with Other Health Professionals for Optimising the Health Outcomes of Consumers:** A pharmacist should consult and work co-operatively with other healthcare professionals to achieve expected or optimal health outcomes for the consumer.

10.1.3. Pharmacist in Relation to His Job

With relation to job, the pharmacists should follow the following ethics:

1) **Scope of Pharmaceutical Services:** Premises registered under statutory requirements and opened as a pharmacy should provide complete pharmaceutical services including the supply of frequently asked medicines without delaying. It also involves the readiness to provide all time emergency services.

2) **Conduct of the Pharmacy:** The pharmacy should be in such a condition that the risk of accidental contamination in the preparation, dispensing, and supply of medicines should be avoided.

   The professional character of pharmacy is reflected by the appearance of the premises; therefore, the public should be made content with the fact that a pharmacist is practicing pharmacy in an establishment. The size, design and terms of signs, notices, descriptions, wording on business, stationery, and related indications should be restrained. Descriptions denoting pharmaceutical qualifications should be limited to those of which the use is restricted by law and should not discriminate between pharmacists.

The premises should display a notice stating that dispensing is carried out under **Employees State Insurance Scheme (ESIS)** or any such other scheme supported by Government. There should be a pharmacist in every pharmacy, solely responsible for controll ing the pharmacy's activities. In case, the owner obstructs the pharmacist in his duties, then it will be regarded as a failure on the part of owner in maintaining and observing the standards.

3) **Handling of Prescriptions:** The pharmacist on receiving the pres cription (presented to him for dispensing) should not discuss or comment over it with respect to the merits and demerits of the therapeutic efficacy of the drug prescribed. The pharmacist on receiving the prescription should not show any expression of alarm or astonishment because it may cause anxiety in patients and may also hamper their confidence in the physician. If a patient makes any query regarding the prescription, the pharmacist should answer very carefully without offending the physician and disc losing any information which was required to be kept hidden from the patient.

   The pharmacist cannot add, remove or replace any ingredient or change the prescription's content, without the prescriber's approval. But he may be allowed to do this if the chan ge is emergent or is demanded by the technique of the pharmaceutical art and does not alter the therapeutic action of the regime. If due to any alteration, incompatibility or over -dosage, an error is observed in the prescription, it should be referred back to the prescriber for correction or approval of the change suggested by the pharmacist. This task is purely for the benefit of the patient but it should be carried out in such a way that the reputation of the concerned physician does not get affected.

   In case of refilling prescriptions, the prescriber should guide the pharmacist with appropriate instructions. The pharmacist should advise the patients to use those medicines or remedies which are prescribed by the physician.

4) **Handling of Drugs:** All necessary steps should be taken to dispense a drug in a correct manner. All the ingredients with the help of scales and measures should be weighed in correct proportions and visual estimations should be avoided. The pharmacist should never fill the prescription wit h spurious, substandard and unethical preparations, and should always use standard quality drugs and medicinal preparations.

   Poisonous, abusive or addictive drugs should be dealt with full care by the pharmacist. These preparations should be supplied to an yone only if it has been prescribed to do so.

5) **Apprentice Pharmacist:** When a pharmacist is an incharge of a dispensary, drug store or hospital pharmacy where intern pharmacists are trained practically, he should provide the trainees with all the work facili ties. This is done so that the trainees after completing their training have gained sufficient technique and skill to become responsible pharmacists. The trainee is not granted a certificate if all the criteria are not fulfilled and he/she has not proved themselves worthy enough.

10.1.4. Pharmacist in Relation to His Trade

In relation to trade, the pharmacist should follow the following ethics:

1) **Price Structure:** The price being charged from the customers should include the quality and quantity of the commodity supplied, and the labour invested in their preparation so that the pharmacists are supplied with proper monetary gain. The knowledge, skill, time consumed, and responsibility of the pharmacist should also be considered while managing their earning, but the customer also should not be burdened with excessive taxes.

2) **Fair Trade Practice:** Prizes, gifts, or any kind of allurement should not be offered to patronisers or lower prices (than those charged by a fellow pharmacist) for medical commodities should not be charged intentionally in order to capture the contemporary business.

   If an order or prescription of a customer to be served by some other dispensary is mistakenly brought to any other dispensary, the latter should direct the customer to the right place with out accepting the prescription. The labels, trademarks, signs, and symbols of other contemporaries should not be copied.

3) **Purchase of Drugs:** Drugs should be purchased only from genuine and reliable sources. A pharmacist should not assist (directly or indirectly) the manufacture, possession, distribution, and sale of spurious or substandard drugs.

4) **Hawking of Drugs:** Drugs and medications should neither be hawked, nor should be sold from door to door. Pharmacies and drug stores should not follow the "**self-service**" method because it will result in distribution of therapeutic substances without an expert advice. Thus, encouraging self-medication is undesirable.

5) **Advertising and Displays:** The pharmacist should not use any display material for the sale of inappropriate medicines or medical appliances such as:
   i) Wording, design, or illustration unfavourably reflecting on other pharmacists,
   ii) Disapproving reference to other suppliers, products, remedies, or treatments,
   iii) Misleading or exaggerated claims,
   iv) The word "**cure**" for any disease or symptoms of any disease,
   v) Guarantee of therapeutic efficacy/treatment,
   vi) Appeal to fear,
   vii) Offer to refund the paid money,
   viii) Prize, competition, or similar scheme,
   ix) Reference to medical practitioner or a hospital, or use of the terms "**Doctor**" or "**Dr**." or "**Nurse**", with the name of a preparation not established, and
   x) Reference to sexual weakness, premature ageing, or loss of virility.

A pharmacy premise should not advertise any article or preparation to the public with the aid of any kind of display material mentioned above. However, it is allowed if the reason for such advertisement is genuine.

The pharmacy should not advertise or illustrate contraceptive preparations and appliances until a notice with the words " **Family Planning Requisites** " or approval by the regulatory authorities. Lustful and indecent publications of any kind should not be sold or distributed on any condition as this would be disadvantageous to the moral welfare of the nation.

10.1.5. Pharmacist in Relation to His Medical Profession

The ph armacist plays an essential role in medical profession by acting as a mediator between a medical professional and patient. However, few limitations are faced by the pharmacist in this profession:

1) **Limitation of Professional Activity:** The medical practitioners do not open drug stores for practising pharmacy because it leads to coded prescriptions and monopolistic practices. This proves to be disadvantageous for profession of pharmacy and interest of the patients. Therefore, pharmacists should not practice medical (diagnosing diseases and prescribing medicines) even if the customer asks them. However in accidental or emergency cases, a pharmacist may help the victim with first aid. A pharmacist should also not recommend a particular medical practitioner (unless he has been asked to do so).

2) **Clandestine Arrangements:** A pharmacist should not make a secret agreement or contract with any physician who would provide him commission or advantage by recommending the patients to his drug store.

3) **Libation with Public:** A p harmacist should always keep his knowledge upgraded by reading books, journals, magazines, and other periodicals regularly as he is the mediator between the medical professionals and people. Information acquired by the pharmacist during his professional activities should not be revealed to any third person (unless required by law to do so).

10.1.6. Pharmacist in Relation to His Profession

With relation to profession, the pharmacists should follow the following ethics:

1) **Professional Vigilance:** A pharmacist should be law -abiding, and should prevent doing activities offensive to the society as well as to the pharmacy profession. His duty is also to force others to comply with the pharmaceutical provisions and other laws and regulations. He should not be afraid of bringing or causing a miscreant (may be a member of his own profession) to be brought to book. It is essential for a pharmacist to help and cooperate with a fellow member in his needs, scientific, technical, or else he should be aware of the undesirable and mo ve them out of the profession. This helps maintaining the name and traditions of the pharmacy profession.

2) **Law-Abiding Citizen:** A pharmacist should be well -educated, and should possess a fair knowledge of the laws of the land. He should be aware of all the enactments related to food, drug, pharmacy, health, sanitation, and should comply with them. A pharmacist's life cannot be divided into different sections as he has to act as a whole unit.

3) **Relationship with Professional Organisations:** If a pharmacist wants to train his professional colleagues about corporate life, he himself should connect with and motivate certain organisations which favour the scientific, moral, and cultural well-being of pharma cists and are not working against the code of pharmacy ethics.
4) **Decorum and Propriety:** A pharmacist should avoid doing activities which are not in accordance with the dignity of pharmaceutical profession and can bring dishonour to the profession or to him.

10.1.7. Pharmacist's Oath

Given below is the Pharmacist's Oath which should be taken without hesitation by a young and potential pharmacist:

1) I swear by the Code of Ethics of Pharmacy Council of India in relation to the community and shall act as an integral part of healthcare team.
2) I shall uphold the laws and standards governing my profession.
3) I shall strive to perfect and enlarge my knowledge to contribute to the advancement of pharmacy and public health.
4) I shall follow the system, which I consider best for pharmaceutical care and counselling of patient.
5) I shall endeavour to discover and manufacture drugs of quality to alleviate sufferings of humanity.
6) I shall hold in confidence the knowledge gained about the patients in connection with my professional practice and never divulge unless compelled to do so by the law.
7) I shall associate with organisations having their objectives for betterment of profession of pharmacy and make contribution to carry out the work of these organisations.
8) While I continue to keep this oath inviolate, may it be granted to me to enjoy life and practice of pharmacy respected by all, at all times! Should I trespass and violate the oath, may the reverse be my lot.

10.2. SUMMARY

The details given in the chapter can be summarised as follows:

1) The **code of moral principles** or the **science of morals** is termed as **ethics**.
2) **Charaka** stated that " **Even if your own life be in danger you should not betray or neglect the interests of your patients** ".
3) The professional character of pharmacy is reflected by the appearance of the premises.
4) The pharmacist cannot add, remove or replace any ingredient or change the prescription's content, without the prescriber's approval.
5) Poisonous, abusive or addictive drugs should be dealt with full care by the pharmacist.
6) Drugs should be purchased only from genuine and reliable sources.

7) The pharmacist should not use any display material for the sale of inappropriate medicines.
8) The pharmacist plays an essential role in medical profession by acting as a mediator between a medical professional and patient.
9) A pharmaci st should not make a secret agreement or contract with any physician.
10) A pharmacist should be well -educated, and should possess a fair knowledge of the laws of the land.

10.3. EXERCISE

10.3.1. True or False

1) The code of moral principles or the science of morals is termed as ethics.
2) Pharmacies and drug stores can follow the "self-service" method.
3) ESIS is the Employees State Insurance Scheme.
4) Poisonous, abusive or addictive drugs are not dealt by the pharmacist.
5) A pharmacist should be well -educated, and should possess a f air knowledge of the laws of the land.

10.3.2. Fill in the Blanks

6) The code of moral principles or the science of morals is termed as _____.
7) _____ stated that "Even if your own life be in danger you should not betray or neglect the interests of your patients".
8) The professional character of pharmacy is reflected by the _____.
9) Drugs should be purchased only from_____.
10) The premises should display a notice stating that dispensing is carried out under_____.

Answers:

1) True 2) False 3) True 4) False 5) True
6) Ethics 7) Charaka 8) Appearance of the premises
9) Genuine and reliable sources 10) ESIS

10.3.3. Very Short Answer Type Questions

1) Define the term ethics.
2) What are the limitations faced by the pharmacist in his profession?
3) Explain the code of pharmaceutical ethics.

10.3.4. Short Answer Type Questions

1) Discuss the principles of code of pharmaceutical ethics.
2) Explain the various ethics followed by the pharmacist with relation to his profession.
3) Write a short note on pharmacist in relation to his job.

10.3.5. Long Answer Type Questions

1) Give a note on pharmacist's oath.
2) Explain the ethics of pharmacist with relation to his trade and medical profession.

CHAPTER 11

Medical Termination of Pregnancy Act

11.1. MEDICAL TERMINATION OF PREGNANCY ACT

11.1.1. Introduction

The Medical Termination of Pregnancy Act, 1971 , Rules, 1975 and Regulation, 1975 set standards for certain cases of pregnancy termination by regis tered medical practitioners and related matters. This Act extends to all the states of India, except Jammu and Kashmir.

11.1.2. Definitions

1) **Registered Medical Practitioner** is a person possessing any recognised medical qualification as defined under the Indian Medical Council Act and whose name has been entered in a State Medical Register and who has such experience or training in gynaecology and obstetrics as may be prescribed by rules made under this Act.
2) **Hospital** is a hospital established and maintained by the Central Government or the Government of the Union Territory.
3) **Guardian** is a person having the care of a minor or a lunatic.
4) **Lunatic** is a person who is mentally ill, dangerous, foolish or unpredictable: a condition called **lunacy**. It is also defined in Section 3 of the Indian Lunacy Act.
5) **Minor** – In law, the term **minor** (also **infant** or **infancy**) is used to refer to a person who is under the age of adulthood. Depending on the jurisdiction and application, this age may vary, but is usually marked at either 18, 20, or 21. Specifically, the status of minor is defined by the age of majority.

11.1.3. Termination of Pregnancies

During pregnancy, an embryo or foetus develops within the female body. Signs of pregnancy include interrup tion of menstruation, morning sickness, breast enlargement, and pro gressive enlargement of abdomen. In abortion, the pregnancy is terminated before the foetus becomes viable.

As per this act, pregnancies should be terminated only by Registered Medical Practitioners with experience or training in gynaecology and obstetrics in accordance with the following provisions:

1) If the duration of pregnancy has not exceeded 12 weeks and the medical practitioner suggests that continuance of pregnancy will risk the wom an's life or her mental or physical health, or the child will be handicapped due to

any physical or mental abnormality. The pregnancies caused if any family planning devices have not be en used or if the woman has been raped, may pose serious mental health injury.

The medical practitioners registered before the origination of the Act should possess experience of 3 years in gynaecology and obstetrics; while those registered after the commencement of the Act should comply with any of the following:

i) Have comp leted atleast 6 month's house surgery in gynaecology and obstetrics, or
ii) Possess experience of 1½ years, or
iii) Have assisted a RMP in not less than 25 pregnancy termination cases, or
iv) Hold post graduate degrees in gynaecology and obstetrics.

2) The pregnancy is terminated with an agreement written by the woman who is 18 years or more. The pregnancy is terminated with an agreement written by the woman's guardian, if her age is less than 18 years or if she is a lunatic (as defined in the Lunacy Act 1972).

3) If the duration of pregnancy has exceeded 12 weeks but not 20 weeks, it can be terminated only if two medical practitioners suggest that termination is required due to complications discussed above. If two medical practitioners suggest that pregnancy should be immedi ately terminated or else the woman's life would be at risk, pregnancy of any length can be terminated even by medical practitioners not having any expe rience or training in gynaecology and obstetrics.

4) The pregnancy termination should be done only at a Gov ernment hospital or a Government approved private hospital. The Government should give its approval to places where safe and hygienic conditions have been maintained, and an operation table along with other required accessories, drugs, etc., for abdominal/gynaecological surgery, anaesthesia, sterilisation, etc. are available.

   These approved places should be inspected by the District CMO (Chief Medical Officer) as many times he thinks is required. On each visit he should be shown the approval certificates. The CMO can demand any other information and can even seize any article, document, etc., if he feels that the place lacks adequate safety and hygienic conditions, which has led to the death or injury to a woman. The CMO can even cancel or suspend the approval certificates.

5) The prescribed forms for consent, opinion of RMP's, etc., used should be kept in a safe custody and sent in envelopes marked "Secret " to the hospital head, owner of approved place, or the CMO of the State.

6) An admission register maintained as per the prescribed pro forma should be kept safely by the hospital head or the place owner. It should not be presented for inspection to anyone except the person acting under the authority of Chief Secretary of the State, a First Class Magistrate, or a District Judge. All the entries in the register should have a serial number. The register should be destroyed after the last entry.

11.1.4. Experience or Training

As per the Act, the RMP should have atleast one or more of the following experience or training in gynaecology and obstetrics:

1) If the RMP was registered in a State Medical Register before the commencement of the Act, he should have experience in gynaecology and obstetrics for atleast 3 years.
2) If the RMP was registered in a State Medical Register on or after the commencement of the Act:
   i) He should have 6 months experience of house surgery in gynaecology and obstetrics, or
   ii) If he has not done any such house surgery, he should have work experience at any hospital for atleast a year in gynaecology and obstetrics, or
   iii) If he has assisted a RMP in the performance of twenty five cases of medical termination of pregnancy in a hospital established or maintained, or a training institute approved for this purpose, by the Government.
3) The RMP registered in a State Medical Register should hold a post-graduate degree or diploma in gynaecology and obstetrics, and should also have experience or training gained during the course of degree or diploma.

11.1.5. Approval of a Place

A RMP can terminate pregnancy only at an approved place. The applications for place approval should be addressed to the District CMO, who should verify or inspect the place (for which approval has been requested) to make sure that the following conditions are satisfied:

1) The place should have an operation table and instruments required for abdominal or gynaecological surgery.
2) The place should have anaesthetic equipment, resuscitation equipment, and sterilisation equipment.
3) The place should have drugs and parenteral fluids required during emergencies.

After considering the application and recommendations of the District CMO, the Government gives approval to the place and issues an approval certificate. This certificate should be displayed at such a place that it is easily visible to those who visit the place.

The district CMO can inspect the approved place whenever required. If he feels that the prescribed facilities and adequate safety and hygienic conditions are not maintained at a place, he should prepare and send a detailed report to the government. On receiving the report, the government gives the owner of the place a reasonable opportunity of being heard, and then either cancels the approval certificate or suspends it for a suitable period. The certificate can be renewed or a fresh certificate can be issued to the owner when he gives an application after making the necessary improvements in his place. If the certificate has been suspended, the place no longer remains an approved place and pregnancy termination cannot be performed from the date of communication of the order of such suspensions.

11.1.6. Admission Register

The hospital head or owner of the approved place should maintain a register to keep a record of the women who got admitted for terminating their pregnancies. The entries in this register should be made in a serial order year wise (**e.g.,** 5/97 indicates serial number 5 of 1997).

The admission register should be a secret document and the information about the pregnant women contained within should not be revealed to anyone. The hospital head, or the owner of approved place, or any other a uthorised person should keep the register in safe custody. The admission register should not be presented to any person for inspection apart from the one who is authorised to do so:

1) In case of a departmental or other enquiry, the Chief Secretary to the Government of a Union Territory,
2) In case of an investigation into an offence, a Magistrate of the first class within the local limits of whose jurisdiction the hospital or approved place is situated, and
3) In case of suit or other action for damages, the Distri ct Judge within the local limits of whose jurisdiction the hospital or approved place is situated.

The RMP should on the application of an employed woman (whose pregnancy has been terminated), grant a certificate for allowing her to obtain leave from her employer, provided that the employer should not disclose this information to anyone else.

Every admission register should be destroyed on the expiry of 5 years from the date of the last entry, and other papers should be destroyed on the expiry of 3 years from the date of the termination of the pregnancy.

No entry should be made in any case sheet, operation theatre register, follow - up card, or any other document or register maintained at any hospital or approved place. The names of the pregnant women and reference to them should be made in the admission register by the serial number assigned to each women.

11.1.7. Custody of Forms

The approval given by a pregnant woman for the termination of her pregnancy should be placed in an envelope along with the certified o pinion. The RMP who has terminated the pregnancy should seal this envelope and keep safely until it is sent to the hospital head or owner of the approved place or the State CMO. The envelope should be marked as “SECRET” and the serial number assigned to th e pregnant woman and the name of the RMP who has terminated the pregnancy should be noted down. Then the envelope is sent immediately to the hospital head or owner of the place where the pregnancy was terminated. On receiving the envelope, the head of the hospital or the owner of the approved place should keep it in safe custody. He should also send a weekly statement of cases of medical termination of pregnancies to the State CMO.

11.1.8. Power to Make Rules

The Central Government may make rules to carry out the provisions of this Act, to provide for the experience or training or both which a RMP should have if he/she aims to terminate any pregnancy under this Act.

The rules made by the Central Government under this Act should be laid (immediately after it is mad e) before each parliament house while it is in session for 30 days which may be comprised in one or two successive sessions, and if before the expiry of the session in which it is so laid or the session immediately following, both houses agree in making an y modification in the rule or both houses agree that the rule should not be made, the rule shall have effect only in such modified form or have no effect; and any such modification should be without bias to the validity of anything previously done under th at rule.

11.1.9. Power to Make Regulations

The State Government may make regulations for:

1) Taking of opinion, its certification by RMP, etc., and the preservation or disposal of such certificates,
2) Requiring any RMP who terminates a pregnancy, to give intimation of such termination and such other information relating to the termination as may be specified, and
3) Prohibiting the disclosure of intimations given or information furnished in pursuance of regulations to any unauthorised person.
4) Any person who deliberate ly contravenes or fails to comply with the requirements of any regulation should be punished with fine of around one thousand rupees.

11.1.10. Offences and Penalties

The offences and their respective penalties under this Act are:

Offences

1) **Offences by Companies:** If a company is found to be committing an offence, following are the provisions:
   i) If a company breaches any provision of this Act, every person who at the time of offence was in -charge of and was responsible for the conduct of the business of the company, along with the company is considered guilty of the contravention and should be proceeded against and punished accordingly.
   ii) Notwithstanding anything contained in sub section (1) wher e an offence under this Act has been committed by a company and it is proved that the offence was committed with the consent or connivance of or is attributable to any neglect on the part of any director or manager secretary or other officer of the company such director manager secretary or other officer of the company is also considered guilty of that offence and should be proceeded against and punished accordingly.

2) **Offences to be Cognizable:** Notwithstanding anything contained in the Code of Criminal Proc edure, 1898 (5 of 1898) an offence punishable under this Act should be cognizable.

Penalties

Whoever contravenes the provisions of this Act or its rules should on conviction, be punishable:

1) In case of first conviction, the person is imprisoned for 6 month s, or is charged with a fine, or with both.
2) In case of subsequent conviction, the person is imprisoned for a year, or is charged with a fine, or with both.

11.2. SUMMARY

The details given in the chapter can be summarised as follows:

1) The Medical Termination of Pregnancy Act, 1971 , Rules, 1975 and Regulation set standards for certain cases of pregnancy termination by registered medical practitioners and related matters.
2) **Registered Medical Practitioner** is a perso n possessing any recognised medical qualification as defined under the Indian Medical Council Act.
3) **Hospital** is a hospital established and maintained by the Central Government or the Government of the Union Territory.
4) A RMP can terminate pregnancy only at an approved place.
5) The hospital head or owner of the approved place should maintain a register to keep a record of the women who got admitted for terminating their pregnancies.
6) The approval given by a pregnant woman for the termination of her pregnancy should be placed in an envelope along with the certified opinion.
7) The pregnancy termination should be done only at a Government hospital or a Government approved private hospital.

11.3. EXERCISE

11.3.1. True or False

1) Guardian is a person having the care of a minor or a lunatic.
2) A RMP can terminate pregnancy only at any place.
3) Registered Medical Practitioner is a person possessing any recognised medical qualification as defined under the Indian pharmacy Council Act.
4) The approval given by a pregnant woman for the termina tion of her pregnancy should be kept in an envelope along with the certified opinion.

11.3.2. Fill in the Blanks

5) _____ is a person possessing any recognised medical qualification as defined under the Indian Medical Council Act.
6) _____ is a person who is mentally ill, dangerous, foolish or unpredictable.
7) _____ is a person having the care of a minor or a lunatic.
8) The envelope should be marked as_____.

Answers:

1) True 2) False 3) False 4) True
5) Registered Medical Practitioner 6) Lunatic 7) Guardian 8) "SECRET"

11.3.3. Very Short Answer Type Questions

1) What is medical termination of pregnancy act, 1971?
2) Who is registered medical practitioner?
3) Explain the term Lunatic.
4) Write the offences and penalties under the medical termination of pregnancy act, 1971.

11.3.4. Short Answer Type Questions

1) Explain about the termination of pregnancies.
2) Write a short note on admission register.
3) What is custody of forms and approval of place for termination of pregnancies?

11.3.5. Long Answer Type Questions

1) Write a note on medical termination of pregnancy act, 1971.
2) Discuss about the experience or training of registered medical practi tioner.

CHAPTER 12

Right to Information Act

12.1. RIGHT TO INFORMATION (RTI) ACT

12.1.1. Introduction

Freedom of speech and expression has been guaranteed by the Indian Constitution. Similarly, right to equality, life and liberty has been construed by the Supreme Court of India from the beginning. Right to freedom of speech and expression holds in its scope the freedom of propagation and interchange of ideas and distribution of information to help the citizens in understanding the working of the Government and its structures in a democracy.

The Constitution framers give significant importance to this freedom as is evident from the fact that restrictions on that right can be placed by law only on the limited grounds given in Article 19(2). The belief that access to information is a human right is reflected in the Article 19 of the Universal Declaration of Human Rights proclaimed in December 1948 – "Everyone has the right to freedom of opinion and expression; this right contains freedom to hold opinions without interference and to seek, receive and communicate information and ideas by any media regardless of frontiers".

The right of citizens access to information helps in obtaining an accountable, transparent and participating Government.

12.1.2. Salient Features

Following are the salient features of the RTI Act:

1) It confers on all citizens the right of access to the information and also makes the distribution of such information a responsibility on all public authorities.
2) It appoints a public information officer in every department for providing information to the public on request.
3) It fixes a 30-day limit for providing information; deadline is 48 hours in case the information concerns life or liberty of a person.
4) For the people below the poverty line, the information will be free , while those above the poverty line will be charged.
5) The Act imposes obligation on public agencies to reveal the information *suo motu* in order to decrease the demands.
6) Government bodies published the details of staff payments and budgets.
7) Specific types of information related to sovereignty and integrity of India, security, scientific or economic interest of the country, cabinet discussions, etc. are not disclosed.

8) A public information officer can cancel a request for information in case it includes an infringement of copyright existing i n a person other than the state.
9) The r estrictions are for the third party information. The submission of third party is considered while making a decision for the disclosure of information.
10) The Act establishes a Central Information Commission and State Information Commissions to implement its provisions. These bodies will be high-powered and independently behave as appellate authorities and conferred with the powers of a civil court.

12.1.3. Objective

Following are the objectives of RTI Act:

1) **To Set -Up the Practi cal Regime:** This Act helps the citizen s to gain all types of information with reasonable restriction stated as a general and specific exclusion under Section 8, 9, and 24 of the similar Act.

2) **For Citizens:** According to this Act, the Indian c itizens are eligible to file application for any information subject to this Act.

3) **To Promote Transparency and Accountability in the Working of Every Public Authority:** This Act helps in the elimination of any type of corruption in Public Authority by providing mandatory ob ligation to the Public Authority to confirm the distribution of information required by the Indian citizens in a definite time period with minimal fee.

4) **Constitution of a Central Information Commission and State Information Commissions:** This Act provides the proper remedy with objectivity state and formed the central commissions separately. Citizens can file Second Appeal and Complaint i n such Commissions without any fee. The status of Chief Commissioners and other Commissioners are similar as the Chief and other Election Commissioners, respectively.

5) **Matters Connected to Public Authority or Incidental Thereto:** In India, this is the first Act to provide regulatory power to the citizen s. In this, the Public Authorities are forced to distribute the information d irectly or indirectly related to them. When needed information is not related to specific Public Authority, the Authority is bound to transfer to the relevant Public Authority in place of rejection.

12.1.4. Definitions

Following are the definitions under the RTI Act:

1) **Record** is:
   i) Any document, manuscript and file,
   ii) Any microfilm, microfiche and facsimile copy of a document,
   iii) Any re -production of image or images embodied in such micr ofilm (whether enlarged or not), and
   iv) Any other material produced by a computer or any other device.

2) **State Chief Information Commissioner** is the State Chief Information Commissioner and the State Information Commissioner appointed under sub-section (3) of Section 15.

3) **State Public Information Officer** is designated under sub -section (1) and includes a State Assistant Public Information Officer designated as such under sub-section (2) of Section 5.

4) **Third Party** is a person other than the citizen making a request for information and includes a public authority.

12.1.5. Right to Information

The Act describes "right to information" as the right to access information available under the Act that is regulated by a public authority.

"Right to Information" means the right to information accessible under this Act that is regulated by any public authority and contains the right to:

1) Inspection of work, documents, records,
2) Taking notes, extracts, or certified copies of documents or records,
3) Taking certified samples of material, and
4) Obtaining information in the form of diskettes, floppies, tapes, video cassettes or in any other electronic mode or through printoutsif such information is in a computer or in any other device.

The right to information conferred on citizens by the RTI Act is enforceable against the public authorities.

12.1.6. Obligation of Public Authorities

Every public authority should:

1) Maintain its records properly catalogued and indexed to enable the right to information under this Act and ensure that the records to be computerised are within a reasonable time and subject to availability of resources, computerised and connected through a network all over the country on different systems to facilitate the access to such records.
2) Publish within 120 days from the enactment of this Act:
   i) Particulars of its organisation, functions, and duties,
   ii) Powers and duties of its officers and employees,
   iii) Procedure of decision-making, including channels of supervision and accountability,
   iv) Norms set for carrying out its functions,
   v) Rules, regulations, instructions, manuals, and records under its control or used by its employees,
   vi) A statement of the categories of documents under its control,
   vii) Particulars of any arrangement existing for consultation with or representation by the members of the public in relation to the formulation of its policy or implementation,

viii) A statement of the boards, councils, committees , and other bodies (having two or more members) for the purpose of its advice, and to make sure that the meetings of th ese boards, councils, committees , and ot her bodies and their records are open to the public,

ix) A directory of its officers and employees,

x) Monthly wage received of each officers and employees, including the system of compensation as provided in its regulations,

xi) Budget of each agency, indicating th e particulars of all the planned expenditures and reports on the previous payments,

xii) Manner of execution of subsidy programmes, including the amounts allocated and the details of beneficiaries,

xiii) Particulars of recipients of granted concessions, permits or authorisations,

xiv) Details of the information available to or held by it in an electronic form,

xv) Particulars of facilities for the citizens to obtain information, including the working hours of a library or reading room,

xvi) Names, designations and other particular s of the Public Information Officers, and

xvii) Such other information as may be prescribed, and thereafter updat e these publications every year.

3) Publish all the significant facts while formulating important policies or announcing the decisions affecting public,

4) Provide reasons for its administrative or quasi-judicial decisions to the affected persons.

Every public authority should make continuous effort to take steps to provide as much information *suo motu* to the public at regular intervals by different modes of communication such as internet, to provide the public with minimum resort to use this Act to achieve information. Every information should be distributed in such a manner that it is easily accessible to the public.

Entire materials should be distributed considering the cost effectiveness, local language, and the most effective communication mode in the local area.

The information should be easily accessible to maximum amount in electronic format with the Central Public Information Officer or State Publ ic Information Officer as the case either free or at the medium or the print cost price prescribed.

12.1.7. *Suo Motu* Disclosure

Each public authority should make available as much information *suo motu* to the public by different communi cation modes so that the public have the least requirement to use the Act for getting information. Internet is one of the most effective means of communi cations as t he information can be posted on the website.

The public authority should yearly update the information published by them as it is not enough to publish the entire information once. It is important that to update the information after any development is made . The information should be updated every time, generally in case of publication s on the internet.

12.1.8. Exemption from Disclosure of Information

This Act sets -out some information exempted from disclosure. If a request is made to a public authority for obtaining information falling under any of th e following categories, the Act exempts a public authority from the obligation of disclosure:

1) Information affect ing the sovereignty and integrity of India, the security, strategic, scientific or economic interests of the State, relation within foreign state or lead to incitement of an offence.
2) Information forbidden by any Court of law or disclosure of which may constitute contempt of Court.
3) Information the disclosure of which would breach the privilege of Parliament or State Legislature.
4) Information of trade s ecrets or intellectual property the disclosure of which would harm the competitive position of third parties.
5) Information available to a person in his fiduciary relationship.
6) Information received confidentially from a foreign Government.
7) Information th at would risk the life or physical safety of any person or identify the source of information or assistance given confid entially to a law enforcement agency.
8) Information that would obstruct the investigation process.
9) Personal i nformation the disclosure of which has no relationship to any activity or interest, or would cause unwarranted invasion of the individual's confidentiality.
10) Information the disclosure of which would breach the copyright subsisting in a person other than the State.

A public authority can reveal any of the above mentioned information in case public interest in disclosure outweighs the harm to the protected interest. A public authority can deny access to information the disclosure of which would breach the provisions of this Act . The Ac t does not limit the way in which an applicant make use of the information given by a public authority under the Act.

12.1.9. Central and State Information Commission

Central Information Commission means the Centra l Information Commission constituted under sub-section (1) of section 12 of Right to Information Act.

State Information Commission means the State Information Commission constituted under sub-section (1) of Section 15 of Right to Information Act.

12.1.9.1. Constitution of the Central and State Information Commission

The Act envisages the constitution of Central and State Information Commissions. The Central Information Commission should be headed by a Chief Information Commissioner assisted by Ce ntral Information C ommissioners appointed by the President of India.

The State Information Commission should be headed by a State Chief Information Commissioner assisted by State Information Commissioners appointed by the Governor of India.

12.1.9.2. Powers and Functions of Information Commission

It is the duty of the Central Information Commission or State Information Commission to obtain and inquire into a complaint from a person:

1) Who has not submit a request for information to a Central or State Public Information Officer, either by giving a reason that no such officer has been appointed under this Act, or because the Central or State Assistant Public Information Officer has not accepted the application for forwarding the same to the Central or State Public Information Officer or senior officer or the Central or State Information Commission,
2) Who has been denied access to any information requested under this Act,
3) Who has not been given a response to a request for information or access to information within the specified time limit under this Act,
4) Who has been required to pay fee of unreasonable amount,
5) Who believes that he or she has been given incomplete, misleading , or false information under this Act, and
6) In resp ect of any other matter related to requesting or obtaining access t o records under this Act.

The Central or State Information Commission should while inquiring into any matter have those powers conferred in a civil court whereas trying a suit under the Code of Civil Procedure, 1908, in respect of the following matters:

1) Summoning and enforcing the attendance of persons and convincing them to give oral or written evidence on oath and to produce the documents or things,
2) Requiring the discovery and inspection of documents,
3) Receiving evidence on affidavit,
4) Requesting any public record or copies from any court or office,
5) Issuing summons for examination of witnesses or documents, and
6) Any other matter as may be prescribed.

Notwithstanding anything inconsistent contained in any other Act of Parliament or State Legislature, as the case may be, the Central Information Commission or the State Information Commission, as the case may be, may, during the inquiry of any complaint under this Act, examine any record to which this Act applies which is under the control of the public authorit y, and no such record may be withheld from it on any grounds.

12.1.10. Jurisdiction of Courts[Section 23]

No court should entertain any suit, application, or other proceedings in respect of any order made under this Act and no such order should be questioned other than by way of an appeal under this Act.

Lower Courts are banded from entertaining suits or applications against any order made under this Act . But, the writ jurisdiction of the Supreme Court and High Courts of the Constitution remains unaffected.

12.2. SUMMARY

The details given in the chapter can be summarised as follows:

1) The RTI Act describes "right to information" as the right to access information available under the Act that is regulated by a public authority.
2) Every public authority should make continuous effort to take steps to provide as much information *suo motu* to the public at regular intervals by different modes of communication such as internet, to provide the public with minimum resort to use this Act to achieve information.
3) This Act sets-out some information exempted from disclosure. If a request is made to a public authority for obtaining information falling under any of the following categories, the Act exempts a public authority from the obligation of disclosure:
4) Central Information Commission means the Central Information Commission constituted under sub-section (1) of section 12 of Right to Information Act.
5) State Information Commission means the State Information Commission constituted under sub-section (1) of Section 15 of Right to Information Act.
6) The Central Information Commission should be headed by a Chief Information Commissioner assisted by Central Information Commissioners appointed by the President of India.
7) The State Information Commission should be headed by a State Chief Information Commissioner assisted by State Information Commissioners appointed by the Governor of India.

12.3. EXERCISE

12.3.1. True or False

1) Freedom of speech and expression has been guaranteed by the Indian Constitution.
2) The belief that access to information is a human r ight is reflected in the Article 20 of the Universal Declaration of Human Rights.
3) The Central Information Commission should be headed by a Chief Information Commissioner assisted by Central Information Commissioners appointed by the Governor of India.

12.3.2. Fill in the Blanks

4) _____ is a person other than the citizen making a request for information and includes a public authority.
5) The State Information Commission should be headed by a State Chief Information Commissioner assisted by State Information Commissio ners appointed by the _____ of India.
6) _____ are banded from entertaining suits or applications against any order made under this Act.

Answers:

1) True 2) False 3) False 4) Third party 5) Governor
6) Lower courts

12.3.3. Very Short Answer Type Questions

1) Write the objectives of Right to Information Act.
2) What is third party?
3) Define the Right to Information Act.
4) Write some features of right to information act.

12.3.4. Short Answer Type Questions

1) Explain about the central and state information commission.
2) What is *suo motu* disclosure?
3) Write the duties of public authorities.

12.3.5. Long Answer Type Questions

1) What is the Right to Information Act? Also mention its features and objectives.
2) Discuss the powers and functions of information commission.

CHAPTER 13

Intellectual Property Rights

13.1. INTELLECTUAL PROPERTY RIGHTS (IPRS)

13.1.1. Introduction

Intellectual property corresponds to **ideas owned by a person or a firm**, and thus subjected to legal protection under the law. The main **purpose** of intellectual property is to give encouragement to the innovators of new concepts by giving them the opportunity to make sufficient profits from their inventions and recover their manufacturing costs and efforts.

The intellectual property is considered like any other commercial property which could be possessed, used, enjoyed, or disposed of by its legal owner at his own will. Therefore, all the rights originating from the legal protection granted to the possessors, creators, owners, or legal successors of intellectual property to employ, trade, allocate, rent out, or authorise the precious possession to someone, are generally referred to as **intellectual property rights**.

Intellectual property rights include patents, trademarks, copyrights, trade secrets, licensing and franchising.

13.1.2. Legislations Regulating Intellectual Property in India

There are several **legislations** regulating and developing the concept of IPRs in India. They are as follows:

1) The Patents Act, 1970,
2) Copyrights Act, 1957,
3) The Trade Marks Act, 1958 and Trademarks Act, 1999,
4) The Geographical Indications of Goods (Registration and Protection) Act, 1999,
5) The Semiconductor Integrated Circuits Layout-Design Act, 2000, and
6) The Designs Act, 2000.

The idea of intellectual property can be dated to the era of Byzantine Empire which was known for approving monopoly. **For example,** monopoly for one year was provided to the chefs of Greece to use their exclusive recipes. A constitutional law of Council of Venice offered special rights to those who created the device or method for gearing up silk production.

Thus, the concept of intellectual property has come a long way from being unknown to earlier communities to a modern era where every new idea is patentable.

13.1.3. Forms of IPRs

The different forms of IPRs discussed below are:

1) Patents, 2) Trademarks, 3) Copyrights,
4) Trade secrets, 5) Licensing, and 6) Franchising.

13.1.4. Patents

An exclusive and absolute right granted to the owner or inventor of an invention to create, utilise, produce, and market the invention is termed as **patent**. Such rights are awarded by the country for a limited time period, presuming that the invention fulfils all the conditions specified in the law. These rights are said to be 'exclusive' because no other person can create, utilise, produce, or market the invention in the absence of proper approval of the patent holder. The right of granting a patent is territorial in nature, i.e., one need to apply for a patent in countries of their interest separately by submitting prescribed fees, completing formalities and documentation, etc. **For example**, a new electronic circuit, a drug molecule, a new surgical instrument, a new vaccine or an innovative chemical process are all patentable inventions.

For all the types of products, the **validity of patent** is **20 years** from the date on which the patent application is filed. Without the written sanction sought in a stipulated manner and bestowed by or on behalf of the Controller, no person can apply for the patent outside India. The following **two conditions are exceptions** to it:

1) If the application for patenting the same product or idea has been filed in India atleast before 6 weeks than the date of filing the same in any other country.
2) Secrecy clause of the Patent Act either does not have direction or all the directions have been made ineffective.

13.1.4.1. Conditions of Patentability

Not every product or invention is patentable. The following conditions should be fulfilled by an invention in order to be patentable:

1) **Novelty:** The element of novelty depends on the fact whether a particular invention is already in the market or not. Thus, where an invention is already a part of existing knowledge, it cannot be regarded as novel. Hence, for making an invention patentable, it must involve innovation.

2) **Non-Obvious:** Another condition for claiming patent is that the product or invention in question must be non-obvious to individuals who are expert in the field to which the invention belongs. Hence, it is vital that the invention can be patentable only if it has not been previously recognised, documented, or used in any form (nationally and internationally) prior to applying for patentability.

3) **Useful and Industrially Applicable:** Even if an invention is novel and non-obvious, it cannot be patented unless it is beneficial to the people. Thus, it is essential for the invention to be beneficial for the society. Also, it must be industrially applicable.

13.1.4.2. Applying for Patent Right

Patent rights in India are allowed on the basis of first -to-apply. Inventor himself or his representative can apply for obtaining patent rights. Both Indian, as well as foreign applicants, are treated equally. The detailed process for obtaining patent rights is given below:

1) **Filing Application:** The very first requirement for obtaining patent rights i s to file an application. Application number is provided to the applicant on the day his application is filed. An objection letter is forwarded to the applicant in case of any error in the application, within a month from the date of filing. Further, the a pplicant needs to send a reply concerning the objection letter within the stipulated time period.

2) **Publication of the Application:** After 18 months of filing, the application is published in the official gazette. This means now the patent information is in public and anyone having problem can oppose it from getting permitted following the legal procedures. The applicant can request for an examination within 36 months of filing the application.

3) **First Examination Report:** This report is issued by the examiner, and contains reviews on any opposition filed till date against the granting patent. The report may further give rise to several objections against which the applicant needs to reply within 6 months.

4) **Grant:** If the applicant successfully answers against all the objections imposed on him/her complying legally, patent right is granted. However, in case of failure to do so, the application is cancelled.

5) **Post-Grant Opposition:** Opposition against patent can be filed even after it has been passed. Such objection c an be imposed within a year of the grant of patent.

13.1.4.3. Rights of a Patentee

The patent law confers the following rights to a patentee for en forcing his/her claim under the law:

1) **Exploitation of the Patent:** The main purpose of applying for a patent is to gain an exclusive right to eco nomically exploit the invention, and to produce and sell the invention in the market. Even if the patent rights are not applied for, the inventor still owns the right to produce and sell the goods. However in that case, he/she can not restrict others from manufacturing or selling the same item.

2) **Licensing the Patent to Other:** A patentee may transfer his/her rights obtained under the patent by entering into a licensing agreement , thereby giving others the right to economically exploi t his/her invention. By its very nature, the licence can be voluntary, statutory , or exclusive. The **voluntary licence** consists of the terms and conditions established between the licensee and the patent holder by themselves. In **statutory licensing system** , the patent holder and the government play prominent roles. Further, an exclusive license confers the licensee with all the rights under the patent excluding other individuals.

3) **Assigning a Patent to Other:** Assignment of rights involves the transfer of one's rights and interests in the property in favour of another. The licensee merely enjoys personal privilege by performing a certain act. In other words, it does not involve transfer of interest in a licence.

   Transfer of rights requires assignment, which can be done through legal assignment, equitable assignment, or through mortgage. A **legal assignment** requires entering into an agreement, which further requires registration with the controller. Only after this type of assignment, the lawful assignee is allowed to get his name registered in the form of a patent holder and is allowed to exercise all the rights under the patent conferred upon him /her by the patent's proprietor. In contrast to legal assignment, **equitable assignment** does not require a greement for t ransfer of rights; i nstead, the transfer is affected through delivery of a letter.

4) **Surrendering the Patent:** The patentee may surrender his /her patent at any time by giving notice to the controller. After receiving such a notice, it is the Controller's duty to duly publish the surrender and notify all the interested parties. This publishing allows any party to object to the surrender. The Controller is then authorised to hear both the parties and revoke the patent by accepting the surrender offer.

5) **Suing for Infringement of the Patent:** Some special privileges are granted to the patentee through patent right, which e ntitles him to distribute, sell, or manufacture the patent within the country. Violation of any of these rights leads to infringement. Patent rights may be infringed in the following ways:
   i) Colourable imitation of an invention,
   ii) Unimportant variations in the invention, or
   iii) Using mechanical counterparts in the invention.

   Though the colourable copying or unimportant changes involve making a little alte ration in the original product, yet it is copying of the basic components of the innovation by the patentee. The suit of infringement may be brought forward in a District Court. Under certain circumstances, the case may be transferred to a High Court, **for example,** when the defendant gives a counter claim revocation, the case is transferred to a High Court.

13.1.4.4. Importance of Patents

The importance of patents is explained below:

1) They provide the right to the patentee to restrict others from manufacturing the product.
2) The right of exclusivity allows the patentee to market his product without competition for a considerable period of time enabling him to obtain higher prices for his invention.
3) They enable the patentee to legally sue anyone who attempts to make or se ll patentee's product without his permission.
4) They allow the patentee to generate money by selling or licensing his product to someone else, who may economically exploit the patentee's invention.

5) They provide 'a negative right' to the inventor, which prevents others from making, selling, or importing the product for a certain period of time. This gives enough time to the patentee to economically exploit his invention.
6) They encourage incremental changes in the existing product by recognising innovation; bes ides invention as such patents are more interested in 'evolution' rather than 'revolution'.
7) The rights granted under the patent law are territorial in nature. The rights of a patent holder having his invention registered in India are limited to India only.
8) They promote technological innovations by recognising and protecting new inventions and innovations.
9) They safeguard the creation and the resources spent on making the invention by awarding appropriately the creative endeavour.
10) They help in safeguarding a ll the technological innovations related to the industry, like mechanical and electronic devices and chemical compositions.

13.1.5. Trademarks

Certain products or services are recognised as those manufactured or provided by a specific individual or business enterprise by means of an exclusive sign, that sign is termed as **trademark**. A trademark can simply be a word, a number, an alphabet, or their combination. It may also include symbols, piece of drawing, certain colours, or unique shape and packaging of product. The trademark owner is authorised to use it to differentiate his/her products or services from others or to permit other people to utilise it in exchange of some fees or compensation. A trademark which becomes popular within a considerab le segment of population is called as a **renowned trademark** in context of the products or services the trademark owner deals in.

Implementation of the **Indian Trademarks Act , 1999**, is a huge breakthrough from the earlier versions, i.e., the Trademark Act, 1 940 and the Trade and Merchandise Marks Act, 1958. With the adoption of this Act, following changes occurred:

1) Enabling registration of trademarks in more than one class by filing of only one application,
2) Simplifying the registration procedure and widening the scope of permitted use,
3) Registration of certified trademarks, service marks, and collective marks,
4) Comprehensive definitions for the terminologies often used,
5) Registration and renewal period has been increased from 7 years to 10 years and
6) More intense punishments for trademark violations.

13.1.5.1. Features of Trademarks

Following are the basic features of a trademark:

1) **Uniqueness:** The uniqueness of the trademark can be either inherent or acquired. **Inherent uniqueness** refers to the dissimilar features in itself and it could not be rationally claimed by anyone else. **Acquired uniqueness** means that the trademark has attained uniqueness by continuous usage. The inherent uniqueness can be formulated by using innovative names. **For example,** imaginary names such as Nirm a for washing powder, Videocon and LG

electrical appliances, iPhone and Samsung for Smartphone are intrinsic unique terms. On the other hand, personal names or surnames like Ferrari or Tata for automobiles and Godrej for home appliances have attained uniqueness through usage.

2) **Non-Descriptive Names:** It should be a non -descriptive name. It can be a word which is different from the common words previously being used or it can be an innovative term. **For example,** a common word such as 'role' can be prefixed or suffixed to form a new word as 'Rolex' for a brand of wrist watches.

3) **Not a Geographical Name:** Trademarks should not be the name of a place. This implies that the geographical names denoted for various areas are restricted to be registered as a trademark of a brand. The reason behind this is that the trademark is meant to signify the origin of products from a specific trader. If a geographical name is used, it will lead the customers to believe that the products originated from that particular location/place /region, thereby creating confusion and act of fraudulence.

4) **Non-Deceptive:** Trademark must not be deceptive in the form of claiming features or qualities which it does not possess; **for example,** name of a juice brand "Southern oil" when it is not actually from southern region.

13.1.5.2. Types of Trademarks

Following are the basic kinds of trademarks:

1) **Non-Traditional or Non -Conventional Trademark:** This type of trademark has been recently originated. Though, it is not generally easy to get them registered, yet, they st and for the goods and services offered by some specific organisation. The basic variation in them is that they need not essentially have symbol, logo, numbers , or letters. This trademark may comprise of concrete symbols like colour, shape, hologram, moving objects, or abstract idea like fragrance, textures, sound/musical notes , or even flavours. Following can be included under this:
   i) **Colour:** Colours can be a unique characteristic to show the goods manufactured by a specific company. **For example,** Microsoft has obtained trademark for its unique colours it uses in its windows software.
   ii) **Sound:** Some symbols can be heard and are differentiated due to some unique and special sound, such as musical note. **For example,** sound of Intel Inside and Britannia.
   iii) **Shape of Go ods and/or Packaging:** Sometimes the shape of either goods or packaging has some unique characteristics. **For example,** heart shape of Britannia little hearts biscuit.
   iv) **Trade Dress:** It is associated with creating the marketing image of the product. It compris es of the non -functional components like designing, labelling (such as colour, shape , or symbol), or packaging. The idea of dress code helps to easily identify the product without reading the brand name. In this way the manufacturers can reach out to a lar ge number of people with great ease.

2) **Motion Trademark:** With the growth of online stores, there is a drastic rise in the motion trademarks. These trademarks are also called **animated trademarks**, **movement trademarks** , **moving trademarks** , or **moving image marks**. Getting them registered is not an easy task. One can observe these trademarks appearing on the top right side of the screen when a website is accessed by the visitor.

3) **Service Mark:** This mark is used in the service industry and the goods represented through the trademark are actually not traded. It is a way of safeguarding the trademarks of the service business. Thus, those trades which provide services like assemblage and maintenance of hardware, hotels and hospitality, courier, transportation, beauty, healthcare, publishing, advertising, educational, etc., are able to safeguard their identity and trademarks. The service marks are also a specific type of trademark; hence, rules for safeguarding these trademarks are same by its very nature. These marks are meant for those service sectors where the goods represented through the trademark are actually not offered. **For example,** sign of aeroplane tail for Air India airline services.

4) **Collective Mark:** The trademarks which are collectively used by a certain trade group can be jointly protected. The idea behind using a collective trademark is to highlight the special or unique feature of the good which is associated with the group that produces it. The owners of the group can be business associates, private collaborators, or public organisation. The collective mark is used for the promotion of specific products which contain some features specific to the manufacturer of a particular area.

5) **Certification Mark:** This mark denotes a certain degree of quality. The purpose behind these trademarks is quality assurance. Certification mark is a proof of the fact that the product has gone through certain quality checks and is recommended for consumption. The mark assures the customer that the manufacturer has followed all the rules and norms in the production of the good concerned to guarantee that the product is of standard quality. It is mainly used for the edible items, electrical appliances, toys, etc. It certifies that the product fulfils some specific guidelines of the quality assurance. **For example,** Agmark, ISI Mark, etc.

6) **Well-Known Mark :** Greater protection is granted to these trademarks. A trademark can become renowned if it is known by significant section of people comprising both actual and possible users, distributors and the dealers of goods/services. **For example,** marks of Audi, Mercedes-Benz, Nike, Adidas, Coca Cola, etc.

13.1.5.3. Procedure for Registration of Trademark

Stage 1: The availability of the trademark should be verified before the application is made. If a word, symbol, or design is not intended to be used in advertisement, but may be employed for a short period, even then the availability must be established. It may help in avoiding potential lawsuits and other legal issues. The applicant may also make an effort to check the resemblance of intended trademark to the existing data.

Stage 2: Once an applicant has made the decision to apply for registration, he/she need to provide necessary details to the agent or attorney for filing the application. The application ne eds to be submitted to the Trademark Registrar who may accept the application and allot a unique number. The applicant may start using the trademark once the number is granted.

Stage 3: Application is securitis ed at this stage. Any objections raised by th e Registrar are communicated to the applicant or the attorney.

Stage 4: The Registrar may grant the date for personal hearing, if requested by the applicant or the attorney.

Stage 5: The Registrar may announce the decision, based on hearing.

Stage 6: Under Section 20 of the Trademarks Act, once the application has been accepted, either absolutely or conditionally, the Registrar will pass an order for an advertisement in the Trademarks Journal. This is to enable third parties to file their objection, if a ny. The applicant is required to pay the prescribed fee and may also be required to provide printing block. The Registrar may also require the applicant to file additional information. If there is no objection, then Registration Certificate is granted and the applicant may start using the trademark.

13.1.5.4. Importance of Trademarks

The importance of trademarks is explained as follows:

1) **Recognition:** One of the basic objectives behind creating trademark is that it involves brand recognition. Trademark allows customers to easily distinguish and select a particular product from a large range of products available in the market. With the help of trademark, logos, unique colours and names, customers can easily distinguish the brand they seek.

2) **Association:** With the help of trademarks, customers relate the products with each other or with the firms that manufacture them.On successfully launching a product in the market, the company may wish to adopt the same trademark for designating the upcoming products. In this way, cus tomers can associate themselves with the new product. This also encourages brand loyalty . **For example,** after capturing market in instant noodles, Maggie has introduced several other related products like soups, magic masala, ketchup, etc.

3) **Investment:** A huge amount of money is spent on creation of the trademark, specifically in exploring a unique and distinctive one. Expenditures are also incurred in employing designers for designing the trademark and merging it with the marketing efforts. But in the long r un it proves to be an asset as it helps in creating brand image which would eventually bring sumptuous gains. Also, it is the trademark which represents a particular company.

4) **Protection:** The trademark and patent rights help the companies to safeguard their product against duplication, fraudulence, or misuse. Like in case of copyright, trademark owners are also required to identify and report any incidents of trademark infringement. Since a lot of costs are associated with the trademark, companies must make efforts to protect them.

5) **Set Company Apart from Competitors:** Businessmen should always consider having a trademark for their offerings. In today's world of cut-throat competition, it is vitally important to have a distinguished presence in the market. A unique trademark is a great way of achieving this goal. It will help the consumers to distinguish it from other products and aids companies to beat the market competition.

6) **Valuable Marketing Tool:**Trademark stands out as a valuable marketing tool. It is specifically for those who are taking the first step towards trading and are looking for creating a reputed and long lasting position in the market. It has been shown through various studies that the consumers prefer to select the products with trademark orbranded products instead of choosing the unknown one.

13.1.6. Copyrights

A right available for developing an original work related to the fields of literature, art, music, or drama is termed as **copyright**. Copyrights protect the cinematographic films such as videos and sound -tracks and their recordings on discs, tapes, perforated rolls , and other such devices. Not only the different literatures but also computer programmes and software come under the purview of literary work, which obtain protection in India under The Copyright Act.

The **term of a copyright** is **60 years** from the starting of the calendar year succeeding the year in which the work was published. This term is applicable for cinematographic films, records, works of government and international agencies, posthumous publications, photographs, anonymous publications, etc. Only for broadcasting, the term is 25 years from the starting of the calendar year subsequent to the year in which the work was broadcasted.

13.1.6.1. Types of Work Covered under Copyright

The different types of work covered under copyright are as follows:

1) **Literary Work :** This includes fictions like stories, novels, plays, poems, screenplays, scripts, non -fictions like magazine, newspaper, biographies, histories, and reference works like dictionaries , encyclopedias, software programmes, and databases. This implies that the literary work includes all the original works, regardless of their creative or literary value. It is important to note here that although the thoughts and ideas of the work need not to be original but its expression should be done in a distinctive manner by the author. Following are included in the literary works:
   i) **Adaptation:** This means converting the literary work into a dramatic performance in front of the people.
   ii) **Abridgement:** This refers to rewriting the original work in shorter form.
   iii) **Translation:** This means rewriting the work in some other language.

2) **Dramatic Work:** This includes the written narration, choreographic work, mimicry, dramatic arrangement, or enacting form pre-fixed in writing.

3) **Musical Work:** This includes music and any pictorial notation of such work. However, it does not involve any act or words which are intentionally sung,

performed, or spoken. In case any musical work includes some more harmonies, rhythm, or accompaniments, it is placed under the category of 'adapted'.

4) **Artistic Work:** This work includes drawings, paintings, photographs, architectural, and artistic craftsmanship work.

5) **Cinematographic Films:** This work refers to visual recording on any medium which helps in creating moving image and also includes sounds. Though, no precise level of innovation is needed in it, but the major portion of the movie should not violate any previously done work. The copyright is not provided to the artist, but is acquired by the producer of the movie, and the right of public performance is conferred to the music director and lyricist.

6) **Sound Recordings:** This work includes all recordings of sounds irrespective of the medium used or method employed for generation of sounds. Such rights generally accrue to the performers of the music, i.e., musicians, singers, and directors of music under the category of related rights which is ascribable to producers of recordings and broadcasters.

13.1.6.2. Rights Conferred by Copyright

The owner of the copyright has liberty to use the work in his desired way. But he should pay due respect to the interests and rights of other people and should adopt proper mechanism for restricting others to use his work without his permission. The rights granted to a copyright owner are:

1) **Statutory Rights:** According to these rights, the copyright owner has the authority to forbid some actions of others related to his /her own work. The copyright owner can prohibit or forbid others in the following ways:
   i) Its duplication in any form, like printed or recording.
   ii) Circulation of copies of the work.
   iii) Performance in front of the general public.
   iv) Publically broadcasting or communicating the work.
   v) Translation of the work in other languages.
   vi) Adapting the work from one form to another, like turning a novel into a play.

2) **Economic Rights:** These are the monetary or financial gains which a person derives from the use of his work. The owner may exercise his /her economic rights by exploiting the work or may license the work to others in return of payment of some amount by way of royalty or other payment methods.

3) **Moral Rights:** The copyright owner is allowed to take some steps for protecting his/her association with the work. Moral rights include the right to claim the authorship and right to object to any sort of twisting or alteration of the original work, or any other offence related with the work which might harm his/her reputation or honour. This right should be kept separate from the monetary rights and is enjoyed by the owner even when the work is being licensed to others.

4) **Copyright is a Negative Right:** The negative nature of copyright originates from the fact that it forbids others from using the original creation of a person for his/her own gains without getting due permission or authorisation by its creator.

13.1.6.3. Registration of Copyright

Copyright may or may not be registered. Copyright office ma intains a register of copyright, containing the applications for copyright. This register acts as a *prima facie* evidence with regard to ownership and possession of the matter/substance. It is open for public inspection. Any information can be gathered from this register.

The register of copyright is kept in the copyright office of the Department of Education. The register is divided into the following parts:

Part 1: Literary works and dramatic works.

Part 2: Musical works.

Part 3: Artistic works.

Part 4: Cinematographic films.

Part 5: Sound recordings.

Part 6: Computer programs, tables and compilations, including computer databases.

For the purpose of registration, all the details sh ould be mentioned. Both published and unpublished works are eligible for registration. Other requirements include submission of a copy of the work and the issue of notice for submitting an application. The objections may be submitted to the Registrar. Upon satisfactory completion of all the requireme nts and validating the material, the work is registered with the is sue of a certificate, named as **certificate of registration**.

13.1.6.4. Importance of Copyright

The importance of copyright can be evaluated from the following points:

1) **Creation of Public Record:** By registering for copyright, the owner gets protection of his /her intellectual property. The registration of the innovation helps in the creation of public records which forbids other individuals or firms to use the intellectual property of the company without due permission. The copyright also helps in recognising the originator of the innovation.

2) **Right to Sue for Copyright Violation:** The registration of a particular work for copyright helps the owner to sue for cop yright violation. An innovator cannot sue those who try to replicate his /her work, unless the work is registered for the copyright. A copyright empowers the owner to file a legal suite against violator of the copyright. The product of the offender can be completely banned or he /she may be asked to pay due compensation to the sufferers for the losses and damages.

3) **Acts as Clear-Cut Evidence:** Registration of copyright acts as an evidence to support the authenticity of the copyright and the associated facts. Hence, it is vital to register a work for copyright within 5 years of publication.

4) **Recovery of Damages:** Only timely registration of the copyright helps in recovery of the damages associated with the violation of the copyright. "Timely registration" means registering the work within the first 3 months of its publication, or before its violation. This stands as a proof of legitimacy of the copyright. An owner can claim only actual damages and not exemplary damages in case the copyright is not registered.

5) **Protection against Import of Copyright Product:** Registered copyright owner can further serve notice of registration to customs service. This provides safety a gainst importation of the copyright material that may infringe the owner's rights under copyright.

13.1.7. Trade Secrets

Any piece of information that is important with respect to the business and is not shared with the general public, and which the businessman tries to keep confidential or secret is termed as a **trade secret** . It serves as a competitive advantage to the business and helps in beating the market competition. Thus, any information or process which a business owner attempts to hide and which necessarily involves monetary benefit can be regarded as a trade secret. **For example**, some procedures might be followed by a firm on daily basis which help it to offbeat the competitors; such procedures can be considered as trade secret.

A trade secret refers to a practice, formula, tradition, method, plan, tool, prototype, or an assortment of data which is usually concealed or is practically difficult to comprehend. It helps the companies to win customer loyalty by gaining a competitive edge over other market players.

13.1.7.1. Features of Trade Secrets

Following are the main features of trade secrets:

1) **Can Cover Non -Patentable Data:** The category of trade secrets is wider than that of the patents. Besides including the innovation, it can also contain secret information which the business owners do not want to share with the competitors. Trade secret s often include information which cannot be patented. **For example,** list of clients may not be patentable but it can be regarded as a trade secret for a service-provider company.
2) **Must be a Secret:** The trade secret should not be disclosed and kept as a secret, so as to gain advantages from court protection.
3) **Have Indefinite Duration:** A trade secret usually has indefinite duration and may never expire. Its benefits can be reaped by the owner till it is unknown to the world and as long as the owner is willing to use it.
4) **Can be Non -Exclusive:** Trade secrets are non -exclusive in the sense that more than one business owners can use similar trade secret, in cases where the other business owner d evelops the same trade secret . **For example,** suppose Company X formulated a unique process of plating steel plates and acquired competitive edge over all others. After many years, Company Y also develops the same process for plating steel plates. Since, company X has not disclosed its trade secrets to anyone, it cannot forbid company Y to use it, if the method is formulated by Company Y through rightful means and by putting individual efforts.
5) **Can be Reverse Engineered:** The process of reverse engineering is considered legally fair and justified in trade secrets. **For example,** two competing firms can obtain each other's product, open it apart, explore it to determine its working , and can compete successfully by using the acquired information.

13.1.7.2. Tools to Protect Trade Secrets

It is quite vital for the organisation to check whether the ir trade secrets are not being misused, stolen, lost, or damaged. Following are the ways for safeguarding the trade secrets:

1) **Agreement with the Employees:** It is vital to sign a confidentiality agreement with the employees for non -disclosure or non -competence clause, depending upon the degree of secrecy needed. It should clearly specify the kind of information which can be leaked, the ways for using the information and prohibition on revealing the secret information after job termination.

2) **Trade Secret Policy:** It is a necessity for businesses, especially those which mainly depend on their trade secrets. One of the fundamental ways for developing such a policy is to recognise and arrange the trade secrets in the order of their worthiness and degree of sensitivi ty. It is vital to inform the employees regarding the policy and the resultant action on violation of the policy, prior to asking them to sign the agreement.

3) **Non-Disclosure Agreements (NDAs):** One of the other ways of protecting the trade secrets is to sign a NDA with third parties at the time of discussing any project or business plan. This can be used as a tool for preventing the third party from disclosing particular information or trade secret.

4) **Sufficient Documentation and Records:** Developing and maintai ning records for the trade secret is quite vital to show its formulation and possession. In case any dispute arises, it would act as evidence. Time ly audit and maintaining up -to-date records (implying changes) could be beneficial for any business.

5) **Security Systems:** The trade secrets and related confidential information should be allowed to access by a few personnel only (who can be relied upon) having undergone through the security checks. Various safety measures are specifically needed for an enterprise w ith electronic background, like electronic surveillance, virus scanners, firewalls, etc.

13.1.7.3. Importance of Trade Secrets

The importance of trade secret is as follows:

1) **Only Alternative for Non-Patentable:** Trade secret is the sole alternative in cases when the secret data covers information which is non -patentable. It is specifically true in case the trade secret consist s of items, like list of loyal customers, business tactics, or sources of supply. It also happens because of the occurrence of items which are p atentable and held for sale widely for the past few years.

2) **Provides Long-Term Competitive Advantage:** The next best advantage of trade secrets is that it provides benefits for the technology which would be obsolete within a short span. Due to this, patent can be an issue, or may be of no use, if one wants to gain competitive edge by being "first-to-market". Another benefit of trade secrets is due to its infinite existence. Hence, it is a better choice to opt for trade secrets in cases of patents for technol ogies

which would help in conserving their competitive advantage for longer duration than the tenure of a patent.

3) **Free of Cost:** One of the major advantages of a trade secret is that it does not incur any official expenditure on prosecution or maintenance a t the time of establishing or retaining its power.

13.1.8. Licensing

Most of the entrepreneurs may be inclined towards starting a new venture, business expansion (expanding the market coverage or the type of business), quality enhancement of goo ds and services , and improvement in their market position. All of these business objectives can be accomplished with the help of licensing of intellectual property rights.

In case of a licensing agreement, the licensor permits the rights to intangible properties to the licensee for a certain period of time in return of a royalty paid by the licensee. These property rights may either be non -exclusive or exclusive. In case of trademarks, patents, copyrights , and unpatented technology, the concept of licensing is widely adopted, since there is no risk for the licensor to place its tangible assets such as plant and equipment in foreign countries. Also, the licensee enjoys lesser costs of arrangement as there is no need to spend huge amount in developing the required intangible property.

13.1.8.1. Types of Licensing

The main types of licensing are as follows:

1) **Technology Licensing Agreement:** This type of licensing helps in:
   i) Enhancing the product's quality or producing new products whose patent rights, utility model, or know-how are protected through a trade secret by other firms. Technology licensing agreements are used in such situations for obtaining the rights held by others.
   ii) Entering in a new market segment or expanding the cur rent market for a certain product whose patent rights are owned by SME s (Small and Medium Enterprises) in the form of utility model or know -how. These SMEs can authorise other firms to utilise these products or processes with the help of this licensing.
   iii) With the help of this licensing, the licensor transfers the rights of using a particular technology to the licensee, under certain terms and conditions. Thus, this can be seen as a free contract between two parties agreed upon pre-specified terms and conditions.

2) **Franchise or Trademark Licensing Agreements :** This type of licensing helps in:
   i) Marketing the product or service or using the trademark or design of any product whose property rights are owned by other person or firm, and
   ii) Entering into a new market or expanding the current market for a product/service whose property rights are owned by SME.

   With the help of franchise agreements, the owner of a particular technical firm (i.e., the franchiser) who is reputed for connecting with the right use of service or trade mark often collaborates with other firms (i.e., the franchisee) who have their

own financial resources for facilitating the distribution of the products directly to the end-customers. With the help of management skills and technical knowledge, proper maintenance of quality and other standards can be ensured and controlled by the franchisor with reference to the trademark or service mark associated with some specific standardised characteristics such as similar trade dress.

3) **Copyright Licensing Agreements:** This type of licensing helps:
   i) When literary and/or artistic efforts of creators are to be produced, distributed, or marketed, or
   ii) When literary and/or artistic efforts of creators need market expansion or a new market.

In case of artistic or literary efforts, one has to maintain the copyright license agreement. Since, it is quite difficult for some owners to properly manage these rights, they have developed collective management organisations which are responsible for representing and managing their rights. If any member wishes to utilise his rights, the organisation authorises their rights when they address themselves to the organisation.

13.1.8.2. Advantages of Licensing

The various advantages of licensing are stated below:

1) **Revenue:** Instant and guaranteed revenues can be earned by the licensor by issuing licences to other firms. There are a number of payments required under licensing agreements which mainly involve a guaranteed licence payment or the payments depending upon the profits earned from the business. In both the ways, the licensee has to pay certain amount to the licensor for holding the license.
2) **Brand Recognition:** The licensing company gains brand recogn ition and brand credibility due to the increased awareness in the public that the products are made by the licensee for the licensing firm.
3) **Inventive Incentive:** Best incentives and design solutions are unleashed for the product's inventor by having the main part in the commercial success of the product. Through licensing agreements, incentives in the form of a suitable royalty are given to the inventor as a mark of appreciation for his/her innovation, creativity, and development investment.
4) **Licensing, T ried and True:** Different industries make use of licensing agreements successfully. Such contracts are well -defined and clearly specify the roles and responsibilities of the involved parties along with the terms and conditions. They also forecast every emergency situation and how it should be dealt with by both the parties.
5) **Fair and Balanced:** Different products can have different royalty depending upon the licensee's tooling manufacturing, and promotional expenses so that a proper and fair balance of profit can be maintained between the parties.
6) **Product Exclusivity:** A license permits the manufacturer to produce and sell license-related goods along with the linked patents. This provides a great advantage by discouraging other market players from launching new products which can violate the patent.

7) **Production Head Start:** Licensing provides a head -start in production as a lot of time spent on R&D can be saved by the firm and used in production processes. The saved time and money can also be invested in other important activities such as market analysis, focus -group testing, tooling, production planning, and promotion.
8) **Resource for Future Projects:** A creative resource as well as a trusted partner is gained with the help of licensing relationship. This will help the organisation to be more creatively involved in product development and promotional activities as it will become more familiar with the future demands.

13.1.8.3. Disadvantages of Licensing

Following are the major disadvantages of licensing:

1) **Competition:** One of the most important limitations of licensing is that it creates competition for the licensing firm. It creates an equal level of competition as similar production process can now be used by the competitor as that of the original firm. However, by controllin g the scope of licensing, this competition can be controlled by the licensing firm. **For example,** some kind of restrictions related to the geographical location, time or quantities can be imposed under the license, which can help the licensing company.
2) **Confidentiality:** A production process becomes a valuable property right if a firm pays some amount to another firm for using that process under a license. This mainly has the disadvantage of disclosure of confidential and proprietary production process. There are greater chances of breaching the confidentiality when more numbers of people are involved in the process. This becomes more of a threat when there is no control of the licensing firm on the manpower and contractors working with the licensee business.
3) **Increases Business Costs:** Licensing increase the operating costs of the firm. Depending upon the conditions mentioned in intellectual property license and related filing fees, the cost of licenses can be quite high. For confirming whether the products/services are meeting the specified needs of intellectual property license, many firms seek help from other service -provider firms which involves sub-contracting costs.
4) **Creates Legal Issues:** Various legal issues, like copying of products/services by other market players, payment of renewal fees in future, and other costs associated with maintenance of the license, can be created by the intellectual property licenses. The firms will also be required to have a legal firm on retainer or hire a lawyer every time when such issues related to intellectual property licenses occur. A lot of time and money is wasted on these legal issues and consequently, lesser revenues are generated by the firms.
5) **Limits Potential Revenue Streams:** Firms that have the license for a certain product/service can also think of franchising their business operations to future licensees. Despite having a large market share, this practice can reduce the revenue generating opportunity for the firms as they will become dependent upon the franchisee for their revenue generation. Thus, the main focus of franchisor firm should be on managing its franchisees.

13.1.9. Franchising

An agreement between two entities where the owner (i.e., the franchisor) of a company grants the right to the o ther party (i.e., the franchisee), to use its trade name or trademark and also specific business processes and techniques for producing and marketing goods or services, is termed as **franchising**. In general, the franchisor lists all the terms and conditions to the franchisee on the basis of which the entire business is conducted. The franchisor provides all these facilities to the franchisee in return of a fee. For this purpose, the franchisee willing to do a business then provides the required time and capi tal to the franchisor in order to utilise all the available resources.

Franchising is a method through which one firm gets permission to use business model and brand of another firm for a specified time period. This method involves transfer of the intell ectual property rights such as patents governing the design of manufactured product (**e.g.,** Honda and BMW cars have patents and no one can copy their design) , trademark (**e.g.,** Bata, Nike, Reebok, Coca -cola), trade secret (**e.g.,** recipe of Barista Coffee Chai n, Dominos, Pizza Hut , and McDonald's), or copyright (**e.g.,** in case of merchandising agreements). From the above examples, we can conclude that intellectual property lincen se forms the core in franchising. Therefore, franchising laws are greatly dependent on intellectual property lincense laws.

13.1.9.1. Features of Franchising

Following are the distinct features of franchising:

1) **Well-Established Business:** A franchise is a well -established and successful business which seeks to expand its market share with the help of a local representative.
2) **Needs Limited Investment:** The investment required for entering a franchise is reasonably low as it is already established by the franchisor.
3) **Easy Entry in New Markets:** It is very easy for a franchisor to enter a new market as the company has already established its reputation and goodwill in other markets.
4) **Business has Large Establishments:** Generally, franchise is a large -scale establishment which operates globally through a network of local representatives in different market segments.
5) **Facilitates in Diverting Business Risks:** The owner of a company can diversify his risks by settingup various outlets in different markets across the world.
6) **Results in Large Turnover:** The management of franchisor and service ability of franchisee benefits the society and results in high sales volume. The turnover is also influenced by the brand name and publicity.
7) **Division of Labour and Specialisation:** In franchising, division of labour and specialisation is followed. Where the franchisor focuse s on the production system, at the same time, franchisee is responsible for distribution and services at unit. This work pattern is beneficial for the franchisor and the franchisee.

8) **Allows Use of Brand Name and Trademark:** In a franchise, the franchisee is free to use the trademark and brand name of the franchisor for managing and developing the franchise business around the world.

9) **Business Based on Mutual Agreement:** A franchising business is based on certain terms and conditions or a mutual agreement on which the franchise business is based upon. This agreement is drafted in detail to avoid any kind of disputes, and is held on mutual understanding between the franchisor and the franchisee.

10) **Long-Term Relationship to Meet Success:** A long-term relationship between the franchisor and the franchisee is essential for the functioning of a franchise business. It ensures the growth and profitability of business. It also enables the franchisor to sell a franchise more effectively, implement the necessary changes into the system, and motivate the franchisee and its staff members to improve the quality of products and services.

13.1.9.1. Types of Franchising

Various types of franchising options are as follows:

1) **Product Franchise:** Product franchise is the most elementary and simple form of franchise. In this kind of set-up, a franchisor can be seen as a distributor, who distributes the goods to the retailers having the authority to sell the products and goods in a specific location. In common practice, these kinds of markets are associated with a certain geographical locations. Car dealership, gas stations, and many fashion organisations are typical **examples** of this category. The older **examples** of franchising are the beer franchises in England and Germany running since early 1800s.

2) **Manufacturing Franchise:** This is the second form of franchise system which is derived from the first type of franchise. In this type of franchise, a certain type of element or particular specification is provided by the franchisor, which is used by the franchisee in the production of the goods. Medicine and soft drinks are the **examples** of this type of system. Other **examples** are companies having a retailer's label can manufacture private label goods, and companies having license of a designer label can manufacture fashion apparels.

3) **Business-Format Franchise:** This is the third form of franchise developed in the post-war scenario of mid 1950s. In this type of system, an extensive, detailed, operating setup is provided to the franchisee by the franchisor. Each franchisee should follow all the rules and norms of the franchisor; else franchisor has a right to withdraw the franchise. These franchises can be food centres, restaurants, travel agencies, etc. **For example,** Pizza Hut, McDonalds, Holiday Inn, 24-7 convenience store, etc.

13.1.9.2. Advantages of Franchising

Advantages of franchising are as follows

1) **Proven Market for Product or Service:** A well-known market already exists for the franchiser's products or services. Facts and figures about the

performance of existing franchises can be easily attained from the franchisee. This helps the franchisor to make future decisions.

2) **Services Provided by the Franchisor:** A franchisor provid es the following valuable services to the franchisee:
   i) **Assistance in Location Selection:** A franchisor provides assistance to the franchisee in selecting an appropriate location for doing business. It is very important for the success of a business, especial ly off -reserve businesses in service and retail industry.
   ii) **Purchase or Construction of Site, Buildings, and Equipment:** Franchisor provides assistance in purchase and construction of business site, buildings, or equipment. This also saves a lot of time and money.
   iii) **Provision of Financing:** Many franchisors financially support their franchisee by providing the required capital. The association of franchisor and franchisee also helps in obtaining financial support.
   iv) **Standardised Methods of Operating:** All the sta ndard procedures for operating a franchise is provided by the franchisor. It mainly includes standards for customer service, control system, cost accounting, etc.
   v) **Advertising:** Franchisors also provide advertising -related services by advertising nationwide.

3) **Advantages of Purchasing:** The franchisor purchases large inventories for franchisee. In these cases, the franchisees need not have to purchase several items as they are already provided by the franchisor, which results in cost savings.

4) **Advantages of T raining:** New franchisees are o ften trained by the franchisors by thorough training sessions or instruction manuals. This has a positive impact on the growth of franchisee's business.

5) **Advantages of Marketing and Management:** Franchising business offers a product which is already known and tested in the market. Customers believe the franchisees due to the goodwill and brand name of the franchisors. Hence, it is easy for franchises to launch and manage a product in the market.

6) **Quality Control Standards:** Certain quality control standards, essential for maintaining the quality of the products, are imposed by the franchisors on the franchisee. Thus, the goodwill of the business in the market is maintained. The franchisee also identifies these standards as guide lines for developing and maintaining high standards and considers these as a key reason for the success of business.

7) **Less Operating Capital Requirement:** Usually, franchisees require very less capital for establishing their business. They do not have to spe nd much on the infrastructure of the business as it is provided by the franchisor at a nominal cost. Having a prior knowledge about the market also helps the franchisee to spend less on inventories, as they are already aware of what product is in demand and what is not.

8) **Growth Opportunities:** Several growth opportunities are provided to new franchisees by the franchisors in the form of setting up initial franchise unit and further purchasing additional franchise locations. Because of this, franchisee faces no competition from other franchisees or other outlets in a certain geographic area. This facilitates the new franchisee to start and develop new stores within the specified locations.

13.1.9.3. Disadvantages of Franchising

Disadvantages of franchising are as follows

1) **Lack of Independence:** When a franchisee signs a franchise contract with a firm, some kind of assistance and help is expected from the franchisor. The franchisor will analyse the performance of business to ensure the realisation of franchise agreement. This constrains the liberty and freedom of the franchisee.

2) **Cost of the Franchise:** There is a particular price for acquiring a franchise which includes a start-up fee and royalties based on operations. A person has to pay a specific amount of money either as a fee or has to create the infrastructure in order to take the franchise of a business organisation.

3) **Unfulfilled Promises:** In most of the cases, the franchisor provides services like training in operational skills and marketing activities. But, in some cases, such a support is not provided by the franchisor.

4) **Constraints of the Contract:** There may be several clauses of franchise agreement which can limit the liberty of franchisee. They are stated as follows:
   i) **Product or Service Offered:** The franchisee may not have the right to sell the product of any other manufacturer.
   ii) **Line Forcing:** The franchisee has to maintain the whole range of product line produced by the franchisor despite the fact that many products may not be having any market in the area covered by the franchisee.
   iii) **Termination:** Without facing the penalties, a franchisee cannot surrender the franchise and he is also not permitted to transfer franchise to his family member or friends and is restricted to sell the product of other companies.
   iv) **Demand Sa turation:** It has been observed that in many locations, a franchisor gives many franchise which results in the saturation of demand for a certain franchisee and thus many franchisees which are working in that area face financial drawback.
   v) **Security:** In case of any violation of agreement conditions, the franchisor has the authority of either terminating the agreement before the contract period is over or not renewing it once it is terminated.
   vi) **Price of Merchandise:** Sometimes, the franchisor sells products to t he franchisee at higher prices than all the other places. But the franchisee is bound to buy products from the franchisor as per the agreement conditions.

13.2. SUMMARY

The details given in the chapter can be summarised as follows:

1) Intellectual property corresponds to **ideas owned by a person or a firm**, and thus subjected to legal protection under the law.
2) There are several **legislations** regulating and developing the concept of IPRs in India.
3) An exclusive and absolute right granted to the owner or inventor of an invention to create, utilise, produce, and market the invention is termed as **patent**.
4) For all the types of products, the **validity of patent** is **20 years** from the date on which the patent application is filed.
5) Not every product or invention is patentable.
6) Patent rights in India are allowed on the basis of first-to-apply.
7) Assignment of rights involves the transfer of one's rights and interests in the property in favour of another.
8) The patentee may surrender his/her patent at any time by giving notice to the controller.
9) Certain products or services are recognised as those manufactured or provided by a specific individual or business enterprise by means of an exclusive sign, that sign is termed as **trademark**.
10) The uniqueness of the trademark can be either inherent or acquired.
11) **Inherent uniqueness** refers to the dissimilar features in itself and it could not be rationally claimed by anyone else.
12) **Acquired uniqueness** means that the trademark has attained uniqueness by continuous usage.
13) The availability of the trad emark should be verified before the application is made.
14) A right available for developing an original work related to the fields of literature, art, music, or drama is termed as **copyright**.
15) The **term of a copyright** is **60 years** from the starting of the cale ndar year succeeding the year in which the work was published.
16) The owner of the copyright has liberty to use the work in his desired way.
17) Copyright may or may not be registered.
18) Franchisor lists all the terms and conditions to the franchisee on the basi s of which the entire business is conducted.
19) Product franchise is the most elementary and simple form of franchise.

13.3. EXERCISE

13.3.1. True or False

1) Every product or invention is patentable.
2) The term of a copyright is 60 years from the starting of the calendar ye ar succeeding the year in which the work was published.
3) Acquired uniqueness refers to the dissimilar features in itself and it could not be rationally claimed by anyone else.
4) Trademarks can be the name of a place.
5) The uniqueness of the trademark can be either inherent or acquired.

13.3.2. Fill in the Blanks

6) A right available for developing an original work related to the fields of literature, art, music, or drama is termed as _____.
7) _____ refers to the dissimilar features in itself and it could not be rational ly claimed by anyone else.
8) For all the types of products, the validity of patent is _____ years from the date on which the patent application is filed.
9) _____ means that the trademark has attained uniqueness by continuous usage.
10) Patent rights in India are allowed on the basis of _____.

Answers:

1) False 2) True 3) False 4) False 5) True
6) Copyright 7) Inherent uniqueness 8) 20 years
9) Acquired uniqueness 10) First-to-apply

13.3.3. Very Short Answer Type Questions

1) What is main purpose of intellectual property right?
2) Name the various legislations which are regulating and developing the concept of IPRs in India.
3) Define the terms patent and trademark.
4) Write the different types of work covered under copyright.
5) Write the types of licensing.
6) Explain the importance of trade secrets.

13.3.4. Short Answer Type Questions

1) Write the advantages and disadvantages of licensing.
2) What is franchising? Also, give their types.
3) Explain the features of trade secrets.
4) Give the procedure for registration of trademark.
5) Mention the conditions of patentability.

13.3.5. Long Answer Type Questions

1) Write a note on patents and trademark.
2) Discuss the types and importance of copyright.
3) Define franchising. Also, mention its features, types, advantages and disadvantages.
4) Explain about trade secrets and licensing in details.

Index

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About the Book

This textbook introduces Pharmaceutical Jurisprudence. Chapter 1 & 2 details on Drugs and Cosmetics Act. Chapter 3, 4 & 5 discusses Pharmacy Act, Medicinal and Toilet Preparations Act, and Narcotic Drugs & Psychotropic Substances Act. Chapter 6, 7 and 8 illustrates Drugs and Magic Remedies Act, Prevention of Cruelty to Animals Act, & National Pharmaceutical Pricing Authority. Chapter 9, 10 & 11 introduces Pharmaceutical Legislations, Pharmaceutical Ethics, and Medical Termination of Pregnancy Act. Chapter 12 and 13 introduces Right to Information Act & IPR.

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Pharmaceutics-I	160	Physical Pharmaceutics I	185	Industrial Pharmacy I
Human Anatomy and Physiology-I	195	Pharmaceutical Microbiology	215	Pharmacology II
Pharmaceutical Analysis-I	160	Pharmaceutical Engineering	190	Pharmacognosy and Phytochemistry II
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