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Pharmaceutical Jurisprudence (A Short Handbook)

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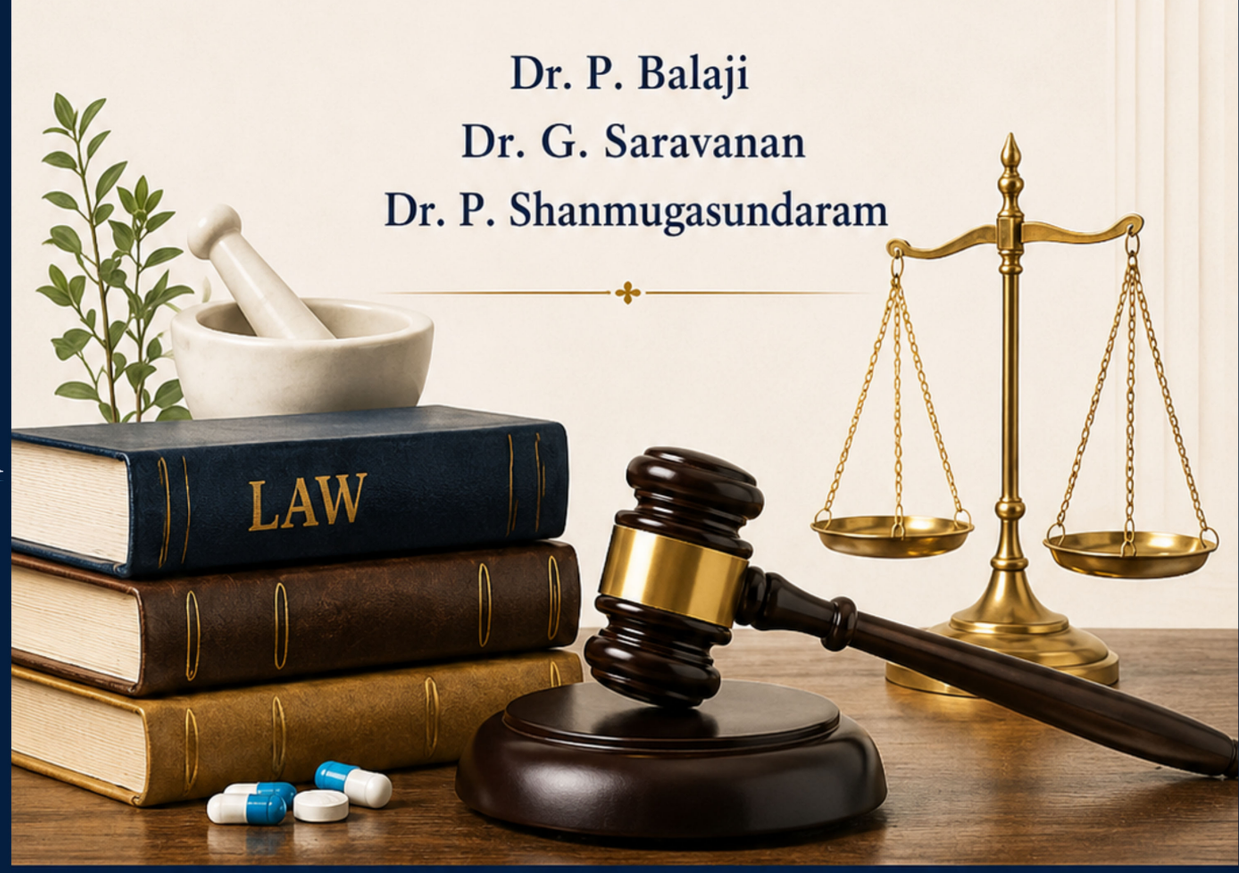
PHARMACEUTICAL JURISPRUDENCE

(A SHORT HANDBOOK)

Dr. P. Balaji
Dr. G. Saravanan
Dr. P. Shanmugasundaram



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Foreword

The field of pharmaceutical sciences is ever-evolving, with laws and regulations playing a crucial role in ensuring the safety, efficacy, and ethical distribution of medicinal products. Understanding pharmaceutical jurisprudence is not only essential for compliance but also for fostering responsible pharmacy practice.

This book, Pharmaceutical Jurisprudence for PharmD 3rd Year, authored by **Dr. P. Balaji** professor department of pharmacology, **Dr**. **K. Karthikeyan** Head of department of pharmacy practice and **Dr. C. Ronald Darwin** Head of department of pharmacology, serves as a comprehensive guide tailored to meet the academic and professional needs of Pharm D students. The authors have meticulously compiled and structured the content to align with the latest legal frameworks governing the pharmaceutical industry, ensuring that readers gain a thorough understanding of drug regulations, ethical considerations, and professional responsibilities.

With a clear and systematic approach, this book provides insights into key legislation, including the Drugs and Cosmetics Act, Pharmacy Act, and other regulatory frameworks that impact pharmacy practice. The inclusion of case studies and real-world applications further enhances its relevance, making it a valuable resource for students, educators, and professionals in the field.

By presenting complex legal concepts in an accessible manner, the authors have successfully created a text that not only aids academic learning but also prepares students for their future roles as responsible pharmacists. This book is a commendable contribution to pharmaceutical education, and it is hoped that it will serve as a reliable reference for years to come.

Acknowledgement

Writing this book has been a collective effort, and we, the authors, would like to express our sincere gratitude to everyone who contributed to its completion.

First and foremost, we extend our sincere appreciation to **VELS INSTITUTE OF SCIENCE AND TECHNOLOGY (VISTAS)** for providing us with the resources, encouragement, and an intellectually stimulating environment that enabled us to carry out this work.

Our special thanks to **Dr. P. Shanmugasundaram Dean, SPS, VISTAS** for his constant support and encouragement.

We are greatly indebted to **Dr. K. Karthickeyan Professor and Head of The Department of Pharmacy Practice, SPS, VISTAS** for his constant encouragement for this kind of academic activity.

We are too delighted to express our gratitude to Dr. C. Ronald Darwin Professor and Head of Department of Pharmacology, SPS, VISTAS for his inspiration to that venture.

We are thankful to **Dr. Malarkodi Velraj,** Professor and Head of The Department of Pharmacognosy, SPS, VISTAS; **Dr. M. Sumithra**, Professor and Head of the Department of Pharmaceutical Chemistry and Analysis; **Dr. D. Akiladevi,** Professor and Head of the Department of Pharmaceutics, SPS, VISTAS for their outstanding support for the successful completion of this book.

We would also like to acknowledge our publishing team, guest authors who contributed significantly to the depth of this work.

We recognize the ideas, concepts and information presented in Pharmaceutical Jurisprudence by **Dr. Rajat Kumar Kar; Dr. T. Purushoth Prabhu; Dr. Kunal N. Patel and The Textbook of Pharmaceutical Jurisprudence by Sundeep. D.S; Dr. R. Narayana Charyulu; Shabana. S**. which has been a constant source of reference and guidance throughout the writing of this book.

Lastly, we extend our sincere appreciation to our readers. Your curiosity and passion for knowledge inspire us to continue writing and sharing ideas. We hope this book servers as a valuable resource and sparks meaningful discussions.

Thank you all for being a part of this journey.

Table of Content

CHAPTER 1
PHARMACEUTICAL LEGISLATIONS

INTRODUCTION

- Legislation is the law which has been promulgated (enacted) by a legislature or that has power to amend, pass, and repeal laws.
- Pharmaceutical legislation is a mixed legislation, which overlappingly covers social, political and economic aspects.

TYPES OF LEGISLATION

There are four basic types of legislation that are handled by Parliament.

- They include **bills, simple resolutions, joint resolutions** and **concurrent resolutions.**
- A bill is the most common type of legislation and can be either permanent or temporary.

PHARMACEUTICAL LEGISLATION

- A society's social and economic aspect can be secured through Pharmaceutical Legislations, denoting mixed type legislation acting as backbone of our healthcare system.
- Pharmaceutical legislation ensures the drug quality, its testing and evaluation criteria, efficacy for its intended use by the patient.

ORIGIN

- In 1811, first chemist shop opened by Mr. Bathgate, who came to India with East India Company in Calcutta.
- Towards the closing of 19th century, manufacturing of modern drug began in India.
- In 1901, Bengal Chemical and Pharmaceutical works was started in Calcutta by Acharya P.C. Ray.

- In 1910 they started manufacture of tincture and spirits.
- In 1903, Prof. T. K. Gajjar opened a small factory at Parel for the development of pharmaceutical units and Alembic chemical works Ltd. at Baroda.
- These units were not sufficient to fulfil the need of Indian public. Hence most of the medicines were being imported from abroad mainly UK, France and Germany.
- After the First World War, there was a drastic change in the import of medicines. Many cheap drugs were imported to India.
- The competition developed between the foreign company drugs and indigenous drugs, as a result, many filthy practices came into picture which resulted in the development of inferior misbranded and spurious drugs. This led to a harmful impact on the public.
- Examples of such conditions are the **Great quinine fraud** which occurred under the British rule in India, Eye drops were replaced with croton oil etc.
- 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 large number of people started dying due to spurious and adulterated drugs, the public started protests inside as well as outside the country. As a result, the British Government was forced to take action for drug legislations.
- 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.
- In 1928 on 4th September, Lt. Col. H.A.J. Gidney asked for immediate control on adulterated drugs in India through the implementation of 'Food and Drugs Act' and 'Pharmacy and Poisons Act'.
- Government of India on 11th August 1930, appointed a committee under the chairmanship of Late Col. R. N. Chopra to see into the problems of Pharmacy in India and recommended the measures to be taken. This committee published its report in 1931. Before this committee was established, there was no such legislation to control the import, manufacture, sale, and distribution of drugs.

SCOPE AND OBJECTIVES

- In 1940, Government brought 'Drugs Bill' to regulate the import, manufacture, sale and distribution of drugs in British India. This Bill was finally adopted as 'Drugs Act of 1940'.
- 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.
- Prof. Mahadeva Lal Schroff (the father of Indian Pharmacy Education) initiated pharmaceutical education at the university level in the Banaras Hindu University.
- Indian Pharmacopeial Committee was constituted under the chairmanship of late Dr. B.N. Ghosh.
- Pharmacy Council of India (P.C.I.) was established under Pharmacy Act 1948.
- Drugs and Magic Remedies (Objectionable Advertisements) Act 1954 was passed to stop misleading advertisements (e.g. Cure all pills).
- Medicinal and Toilet Preparations (Excise Duties) Act 1955 was introduced to enforce uniform duty for all states for alcohol products.
- In 1955, first edition of Indian Pharmacopoeia was published.
- In 1970, Government of India passed the Drugs Price Control Order for regulating the prices of the 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, aimed at amending and setting strict provisions for narcotic and psychotropic drugs.

1.STUDY OF DRUGS ENQUIRY COMMITTEE

- The Chopra Committee chairman was established under the chairmanship of Lt. Col. R. N. Chopra. This committee is also called as DEC or Chopra committee.

Reasons for the formation of Chopra committee

- Drugs were imported form UK, Germany and France.
- During first world war cheaper drugs were imported into India, which increased the demand for indigenous drugs.
- There was no legal and effective control on pharmacy profession.
- Unhealthy competition grew up and Indian market was flooded with inferior quality drugs.
- Hence to have a comprehensive legislation, the Indian government appointed a 'Drug Enquiry Committee' in 1931.

Principles of DEC were to

- 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 different approved medicinal preparations and indigenous drugs preparations.
  3) Enquire the legislations that allow only qualified persons to access the pharmacy profession.

Recommendations

- Formation of Central Pharmacy Council and State pharmacy council which would look after the education and training of professionals. Councils would maintain the register containing names and addresses of the registered pharmacist.
- Creation of drug control machinery (Departments) at the centre and branches in all states.
- Establishment of a well-equipped Central Drug Laboratory (CDL) at Kolkata with competent staff and experts for an efficient and speedy working of Drug Control Department. Small laboratories would work under its guidance.

Implementation

- Due to Second World War in 1939, there was delay in introduction of the legislation.
- Government was reluctant to implement the recommendations of DEC, and the public was pressurizing the government.
- Finally, an Import of Drug Bill was introduced in 1937.
- This bill dealt with only import of drugs and manufacturing and sale of drugs was not included.

HEALTH SURVEY AND DEVELOPMENT COMMITTEE

- This committee, known as the Health Survey and Development Committee, was appointed in 1943 with Sir Joseph Bhore as its Chairman.
- It emphasised on integrating curative and preventive medicine at all levels.
- It made comprehensive recommendations for remodelling of health services in India.

Principles of Bhore Committee

- No individual should be denied to secure adequate medical care because of inability to pay.
- Facilities for proper diagnosis and treatment.
- Health programmes must lay special emphasis on preventive work.
- As much medical relief and preventive health care should be provided to the vast rural population.
- Health services should be located close to the people to ensure maximum benefit to the community.
- Medical services should be free to all, without distinction.

Recommendations

- Integration of preventive and curative services of all administrative levels.
- Development of Primary Health Centres in two stages including Short-term measure and long-term measures.
- Major changes in medical education which include three months training in preventive and social medicine to prepare "social physicians".
- Abolition of the Licentiate in Medical Practice qualifications and their replacement by a single national standard Bachelor of Medicine and Bachelor of Surgery (MBBS) degree.
- Creation of a major central institute for post-graduate medical education and research: which was achieved in 1956 with the All-India Institute of Medical Sciences (AIIMS).

3. HATHI COMMITTEE

- Government of India constituted a committee on 8th February, 1974 consisting of 15 members under the chairmanship of Mr. Jaisukhlal Hathi.
- The purpose was to take comprehensive look into the drug industry and to enquiry in to the various facets of drugs in India.
- After conducting various meetings, the committee submitted its report in the year 1975.
- The report of this committee covered all aspects ranging from licensing, price control, imports, role of foreign sector and quality control.
- It encouraged the development of indigenous industries, it also further controlled price of a large number of drugs in the interest of the consumer.

Principles of Hathi Committee

- It enquires about the development of the industry and the status it has attained.
- 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.
- It recommends measures to support the growth of the drug industry, especially that of the Indian and small-scale industrial sectors.

- It recommends measures for effective quality control of the drugs and for helping the small-scale units.
- It recommends measures to provide the general public (especially in the rural areas) with essential drugs and common household remedies.

Recommendations

- 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.
- The committee recommends to continuously reviewing the packing methods and the packing materials used to develop an appropriate packing standard.

- The committee recommends providing information related to production, stocks, costs, sales, profitability, etc., on a regular basis to government to act in an efficient and rapid way.
- 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.

4. MUDALIAR COMMITTEE

- Government of India appointed a **'Health Survey and Planning committee'** in 1959 towards the end of the 2nd five-year plan to assess the state of the healthcare field and to measure the progress achieved after implementing the suggestions of the Bhore committee of 1946.
- Dr. A. L. Mudaliar was the chairman of the committee. The committee submitted its report in 1962.
- It was appointed to assess the recommendations of Bhore Committee and to suggest the action plan to implement the same.

Principles of Mudaliar Committee

- The Primary Health Centre should provide with all three public health care services namely curative, preventive and promotive services.

- Each Primary Health Centre would cater to population of 40,000 as suggested by Bhore Committee.
- It also suggested that one health worker should be appointed for every 10,000 persons.
- "All India Health Service" body should replace the earlier "Indian Medical Service".
- It suggested that the Employees State Insurance Scheme and the Central Government Health Scheme should be extended to cover more sectors of the population.

Recommendations

- Consolidation of advances made in the first two five-year plans,
- Create an 'All India Health service' similar to 'Indian Administrative service',

- Strengthening of the district hospital with specialist services to serve as central base of regional services,
- Regional organizations in each state between the headquarters organization and the district in charge of a Regional Deputy or Assistant Directors- each to supervise 2 or 3 district medical and health officers.
- Each primary health centre not to serve more than 40,000 population,
- To improve the quality of health care provided by the primary health centres.
- Blood bank services should be available in every district and teaching hospital. The out-patient department should 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.
- Integration of medical and health services recommended by the Bhore Committee; and constitution of All India Health Service on the pattern on Indian administrative service.
- Wealth and political effect should not get privileged treatment in hospitals.

SUMMARY:

1. Drugs and Cosmetics Act, 1940: Regulates the manufacture, sale, and distribution of drugs and cosmetics.
2. Drugs and Magic Remedies (Objectionable Advertisements) Act, 1954: Prohibits misleading advertisements of drugs and remedies.
3. Pharmacy Act, 1948: Regulates the profession of pharmacy and sets standards for pharmacy education.
4. Indian Medical Council Act, 1956: Regulates medical education and practice.
5. Narcotic Drugs and Psychotropic Substances Act, 1985: Regulates the manufacture, sale, and distribution of narcotic drugs and psychotropic substances.
6. National Pharmaceutical Pricing Authority (NPPA) Act, 1997: Regulates drug prices and ensures affordable medicines.
7. Drugs and Cosmetics Rules, 1945: Specifies standards for drugs and cosmetics.
8. Good Manufacturing Practices (GMP) Guidelines: Ensures quality standards for drug manufacturing.
9. Schedule M: Specifies standards for drug manufacturing facilities.
10. Medical Devices Rules, 2017: Regulates the manufacture, sale, and distribution of medical devices.

These legislations aim to

- Ensure safety, efficacy, and quality of drugs and cosmetics
- Regulate the pharmaceutical industry
- Prevent misuse and abuse of drugs
- Promote affordable and accessible medicines
- Set standards for pharmacy education and practice
- Regulate medical devices

Note: These legislations are subject to amendments and updates, and this summary provides a general overview of the key pharmaceutical legislations in India.

CHAPTER 2
CODE OF PHARMACEUTICAL ETHICS

Introduction And Definition:

Ethics:

The code of moral principles or science of moral duty is called ethics. Ethics are rules by which a profession regulates actions and sets standard for all its members.

Pharmaceutical Ethics:

- The ethics in relation to pharmacy profession is called pharmaceutical ethics.
- The profession of pharmacy is noble in its ideals and pious in its character.
- 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.
- The pharmacist works in association with handling, selling, distribution, compounding and dispensing medical substances, including poisons and potent drug, a pharmacist, in collaboration with medical men and others, is charged with the onerous responsibility of safeguarding the health of people.
- Pharmacy practice has been restricted by the Government only to those who have qualified under regulatory requirements.
- Above everything, the pharmacist should be a good citizen and should undertake and defend the laws of the State and the Nation.

Principles:

- Recognising the Consumer's Health and Well-Being as the First Priority.
- Respecting the Consumer's Autonomy and Rights, and Encouraging them to Participate in Decision-Making.
- Upholding the Reputation and Public Trust of the Profession.
- Acknowledging the Professional Roles and Responsibilities to the Wider Community.

- Demonstrating a Commitment to the Development and Enhancing the Profession.
- Maintaining a Contemporary Knowledge of Pharmacy Practice and Ensuring Health and Competence to Practise.
- Agreeing to Practice Only Under Conditions which uphold the Professional Independence, Judgement, and Integrity of Themselves or Others.
- Conducting the pharmacy business ethically and professionally.

The Code of Pharmaceutical Ethics:

The code of pharmaceutical ethics is formulated by Pharmacy Council of India (PCI) for the guidance of Indian pharmacist.

The code of pharmaceutical ethics helps to guide the pharmacist as to how pharmacist should conduct himself/herself in relation to:

- ✓ Job
- ✓ Trade
- ✓ Profession (Pharmacy)
- ✓ Medical profession.

Pharmacist in relation to job:

Scope of pharmaceutical service:

- ➢ When premises are registered under statutory requirements and opened as a pharmacy, a reasonably comprehensive pharmaceutical service should be provided.
- ➢ This involves the supply of frequently required medicines without undue delay.
- ➢ It also involves willingness to furnish emergency supplies at all times.

Conduct of pharmaceutical service:

- ➢ The condition in a pharmacy should be such as to preclude avoidable risk or error or of accidental contamination in the preparation, dispensing and supply of medicines.
- ➢ The appearance of the premises should reflect the professional character of the pharmacy.

- It should be clear to the public that the practice of pharmacy is carried out in the establishment.
- Signs, notices, descriptions, wording on business, stationary and related indications, should be restrained in size, design and terms.
- 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.

Handling Of Prescription:

- A received prescription should be checked for therapeutic efficiency.
- The Pharmacist should not even show any expression on face of alarm or astonishment upon the receipt of a prescription; as such things may cause anxiety in patients or their agents and may lose their faith on physician.
- Any question on a prescription should be answered with very caution and care.
- A guidance should be given on refilling of prescriptions, a pharmacist should solely be guided by the instructions of the prescriber aid, should advise the patient to use medicines or remedies strictly in accordance with the intention of the physician as noted on the prescription.
- The pharmacist cannot add, remove or replace any ingredient or change the prescription's content, without the prescriber's approval.
- 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.

Handling Of Drugs:

- All possible care should be taken to dispense a prescription correctly by weighing and measuring all ingredients in correct proportions by the help of scale and measures: visual estimations must be avoided.
- Always use drugs and medicinal preparations of standard quality available.
- Pharmacist should never fill the prescriptions with spurious, substandard and unethical preparations.
- A Pharmacist should be very Judicious in dealing with drugs and medicinal preparations used for addiction or any other abusive purposes. These

preparations should be supplied to anyone only if it has been prescribed to do so.

Apprentice Pharmacist:

- While in-charge of a dispensary, drugstore or hospital pharmacy where apprentice pharmacists are admitted for practical training, a pharmacist should see that the trainees are given full facilities for their work so that on the completion of their training they have acquired sufficient technique and skill to make themselves dependable pharmacists.
- No certificate or credentials should be granted unless the above criterion is attained and the recipient has proved himself worthy of the same.

Pharmacist In Relation to His trade:

Price Structure:

Prices charged from customers should be fair and in keeping with the quality and quantity of commodity supplied and the labour and skill required in making it ready for use, so as to ensure an adequate remuneration to the pharmacist taking into consideration his knowledge, skill, the time consumed and the great responsibility involved, but at the same time without unduly taxing the purchaser.

Fair Trade Practice:

- No attempt should be made to capture the business of a fellow pharmacist by cut-throat competition, that is, by offering any sort of prizes or gifts or by knowingly charging lower prices for medical commodities than those charged by fellow pharmacist.
- In case any order or prescription, genuinely intended to be served by some dispensary is brought by mistake to another, the latter should refuse to accept it and should direct the customer to the right place.
- Labels, trademarks and other signs and symbols of contemporaries should not be imitated or copied.

Purchase Of Drugs:

Drugs should always be purchased from genuine and reputable sources and a pharmacist should always be on his guard not to aid or abet, directly or indirectly the manufacture, possession, distribution and sale of spurious or sub- standard drugs.

Hawking Of Drugs:

- Hawking of drugs and medicines should not be encouraged nor should any attempt be made to solicit orders for such substances from door to door.
- 'Self-service' method of operating pharmacies and drug - stores should not be used as this practice may lead to the distribution of therapeutic substances without an expert supervision and thus would encourage self-medication, which is highly undesirable.

Advertising And Displays:

No display material either on the premises, in the press or elsewhere should be used by a pharmacist in connection with the sale to the public; medicines or medical appliances which is undignified in style or which contains:

a. Any offer about refund of money
b. Misleading, or exaggerated statements or claims
c. The word "Cure" in reference to an ailment or symptoms of ill-health
d. A guarantee of therapeutic efficacy
e. An appeal to fear
f. Reference to medical practitioner or a hospital, or use of the terms "Doctor" or "Dr" or "Nurse", with the name of a preparation are not allowed
g. Reference to sexual weakness, premature ageing, or loss of virility
h. 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.

Pharmacist In Relation to His Medical Profession:

The pharmacist 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:

Limitation of Professional Activities:

- Pharmacist under no circumstances, take to medical practice i.e. diagnosing drug and prescribing medicines.
- In emergency he can give first aid to the person. Should not recommend a medical practitioner.

Clandestine (Concealed/ Secret) Arrangement:

No pharmacist should enter into the secret agreement and contract with any physician to offer him any commission or any other advantage.

Liaison with Public:

- Being a liaison between medical profession and people, a pharmacist will always keep himself updated with the modern development of pharmacy by regular reading of books, magazines etc.
- Information acquired by the pharmacist during his professional activities should not be revealed to any third person (unless required by law to do so).

Pharmacist In Relation to His Profession:

With relation to profession, the pharmacists should follow the following ethics:

Professional Vigilance:

- A pharmacist should be law-abiding, and should prevent doing activities offensive to the society as well as to the pharmacy profession.
- He should not be afraid of bringing or causing a miscreant (one has done something unlawful) to be brought to book, may be a member of his own profession.
- It is essential for a pharmacist to help and cooperate with a fellow member in his needs or else he should be aware of the undesirable and move them out of the profession.

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.

Relationship With Professional Organisations:

The pharmacist should connect himself with and motivate certain organisations which favour the scientific, moral, and cultural well-being of pharmacists and are not working against the code of pharmacy ethics.

Decorum and Propriety:

A pharmacist should avoid doing activities which are not in accordance with the dignity of pharmaceutical profession or that could bring dishonour to the profession or to him.

Pharmacist's Oath:

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.

SUMMARY:

1. Respect the rights and dignity of patients, healthcare professionals, and colleagues.
2. Ensure the safety, efficacy, and quality of products and services.
3. Maintain confidentiality and privacy of patient information.

4. Provide accurate and unbiased information about products and services.
5. Avoid conflicts of interest and promote transparency.
6. Comply with laws, regulations, and industry standards.
7. Promote ethical business practices and report unethical behavior.
8. Respect the environment and promote sustainable practices.
9. Support continuing education and professional development.
10. Uphold the integrity and reputation of the pharmaceutical profession.

Key principles:

- Respect and dignity
- Safety and quality
- Confidentiality and privacy
- Accuracy and transparency
- Compliance and ethics
- Sustainability and responsibility
- Professional development and integrity

Note: This Code of Pharmaceutical Ethics serves as a guide for professionals in the pharmaceutical industry to maintain high ethical standards and promote trust and confidence in the industry.

CHAPTER 3
DRUGS AND COSMETICS ACT, 1940 AND ITS RULES,1945

INTRODUCTION

The main aim of The Drugs and Cosmetics Act, 1940 and Rules 1945 maintain the import, manufacture, distribution, and sale of drug is to 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.

OBJECTIVES

Following are the objectives of this Act:

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

LEGAL DEFINITIONS:

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.

Misbranded drug

- If it is so coloured, coated, powdered or polished that damage is concealed or if it is made to appear of better or greater therapeutic value than it really is.
- If it is not labelled in the prescribed manner.
- If its label or container or anything accompanying the drugs bears any statement, design or device which makes any false claim for the drug.

Adulterated drug

- If it consists, in whole or in part, of any filthy, putrid or decomposed substance.
- If it has been prepared, packed or stored under insanitary conditions whereby it may have been rendered injurious to health.
- If its container is composed, in whole or in part, of any poisonous or deleterious substance which may render the contents injurious to health.
- If it bears or contains for purposes of colouring only, a colour other than one which is prescribed.

Spurious drug

- If it is imported (manufactured in relation to manufacture, sale and distribution of drugs) under a name which belongs to another drug.
- 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 character and its lack of identity with such other drugs.
- If the label or container bears the name of an individual or com 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;

Misbranded cosmetics

- If it contains a colour which is not prescribed.
- If it is not labelled in the prescribed manner.
- If the label or container or anything accompanying the cosmetic bears any statement which is false or misleading in any particular.

Spurious cosmetics

- If it is imported under a name which belongs to another cosmetic.
- If it is an imitation of, or is a substitute for, or resembles another cosmetic in a manner likely to deceive or bears upon it or upon its label.

S.NO	SCHEDULE	SIGNIFICANCE
1.	**A**	Proforma for application for the licenses, issue and renewal of licenses, for sending memoranda under the Act.
2	**B**	Fee structure for drug analysis by CDL (Central Drug Laboratory) or by the Govt. Analyst.
3.	**C**	List of biological and special products whose import, sale, distribution, and manufacture are governed by special provisions. ***Examples: Serums, Adrenaline Vitamins etc.***
4.	**C 1**	List of other special products whose import, sale, distribution, and manufacture are governed by special provisions. ***Drugs of Vegetable origin: - Bhang, Datura, Jai Phala.*** ***Drugs of Animal origin: - Snake Poison*** ***Drugs of Mineral origin: - Hartala (arsenic), Parada (mercury), etc.***
5.	**D**	List of drugs exempted from the provisions of import of drugs.
6.	**E1**	Poisonous substances under Ayurvedic, Siddha and Unani system of medicines.

7.	**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.
8.	**F – I**	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).
9.	**F – II**	Standards for surgical dressings.
10.	**F – III**	Standards for sterilised umbilical tapes.
11.	**F – F**	Standards for ophthalmic preparations.
12.	**G**	List of substances to be used only under medical supervision and which are to be labelled accordingly. ***Anticancer Dugs*** ***Insulin*** ***Metformin***
13.	**H**	Various drugs to be sold on the prescription of an RMP (Registered Medical Practitioner). ***Antidepressants*** ***Antipsychotics*** ***Analgesics***
14.	**J**	Diseases or ailments which a drug may not prevent or cure/ ***Chlorpheniramine*** ***Antidepressants*** ***4th Generation Antibiotics***
15.	**K**	Drugs exempted from certain provisions of the manufacture of drugs.
16.	**M**	Good Manufacturing Practices (GMP) requirements of factory premises, plants, and equipment.
17.	**M 1**	Requirements of factory premises, etc., for manufacture of homeopathic preparations.
18.	**M 2**	Requirements of factory premises for the manufacture of cosmetics.

19.	**M 3**	Requirements of factory premises for the manufacture of medical devices.
20.	**N**	Regulations and minimum requirements to run a pharmacy.
21.	**O**	Regulations and requirements for disinfectant fluids. ***Part 1: - Provisions applicable to black and white fluids*** ***Part 2: - Provisions applicable to Other Disinfectants.***
22.	**P**	Regulations regarding life period and storage of various drugs. ***The schedule includes antibiotics, vitamins, insulin preparation, normal human plasma, sera toxins, toxoids, other toxins, anti-toxins, miscellaneous drugs.***
23.	**P 1**	Regulations regarding retail package size of various drugs.
24.	**Q**	Part I – List of dyes, colours and pigments permitted in cosmetics and soaps. Part II – List of colours permitted in soaps. (1) ***Natural Colours: - Carotene, Chlorophyll, Red Oxide of Iron, Yellow Oxide of Iron, Titanium Di-oxide, Black Oxide of iron*** (1) ***Artificial Colours: - Caramel*** (2) ***Coal Tar Colours***
25.	**R**	Standards for condoms made of rubber latex intended for single use other mechanical contraceptives ***Eg. Condom, Cu- T, etc***
26.	**R 1**	Standards for medical devices.
27.	**S**	Various cosmetics and toiletries, and directs the manufacturers of cosmetics to confirm to the latest BSI (Bureau of Indian Standards) requirements. *1.* ***Skin Powders*** *2.* ***Tooth Powder*** *3.* ***Toothpaste***

28.	**T**	Regulations and requirements for factory premises and manufacture of Ayurvedic, Siddha and Unani products.
29.	**U**	Particulars to be shown in records of drugs. manufacturing, raw material, and analytical. ***The records or registers shall be retained for a period of 5 years for Drugs & 3 years for Cosmetics from the date of manufacture.***
30.	**U 1**	Particulars to be shown in manufacturing, raw material, and analytical records of cosmetics
31.	**V**	Standards for patent and proprietary medicines.
32.	**W**	List of drugs which can be marketed under generic names only. 1. ***Analgin*** 2. ***Aspirin and its salt*** 3. ***Chlorpromazine and its salt***
33.	**X**	List of drugs which are habit forming, psychotropic and other drugs likely to be misused for addictive purposes.
34.	**Y**	Requirements and guidelines on clinical trials for import and manufacture of new drugs.

IMPORT

IMPORT OF DRUGS

A. Classes of drugs prohibited to import

B. Import of drug under license

- ✓ Specified in Schedule-C/C
- ✓ Specified in Schedule-X
- ✓ Imported for Test/Analysis
- ✓ Imported for personal use
- ✓ Import Of Homeopathic & Cosmetics Drugs

C. Drugs exempted from provisions of import

D. Custom Frontiers.

E. Offences and Penalties

A. CLASSES OF DRUGS PROHIBITED TO IMPORT

- Misbranded drugs.
- Drugs of substandard quality
- Drugs claiming to cure diseases specified in Sch-J
- Adulterated drugs
- Spurious drugs
- Drugs whose manufacture, sale/distribution are prohibited in original country, except for the purpose of test, examination and analysis.
- Drugs not labelled / packed in prescribed manner.
- Drugs of biological products (C/C_1) after the date of expiry
- Drugs not claiming therapeutic values.
- Drugs which is risky to human beings or animals.
- Patent/Proprietary medicines whose true formula is not disclosed.
- Any new drug except with express permission of LIC Authority.

B. IMPORT OF DRUG UNDER LICENSE/PERMIT

1. License is required
2. License is obtaining on application to the proper licensing authority (Customs collection/drug Controller of India)
3. License is valid up to 31st December.
4. License should inform to the licensing authority, if any changes.

1) Import of the biological drugs(C/C_1)

Conditions to be fulfilled:

- Licensee must have adequate facility for the storage.
- Licensee must maintain a record of the sale, showing the particulars of the names of drugs and of the persons to whom they have been sold.
- Licensee must allow an inspector to inspect premises and to check the records.
- Licensee must furnish the sample to the authority.
- Licensee must not sell drugs from which sample is withdrawn and he is advised not to sale, and recall the batch from the market.
- Licensee must comply with undertaking given in Form No. 9

2) Import of the Schedule-X drugs (Narcotic & Psychotropic drugs)

Conditions to be fulfilled:

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

3) Drugs Imported for examination, test or analysis

Conditions to be fulfilled:

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

4) Drugs imported for personal use

Conditions to be fulfilled:

- Up to 100 average doses may be imported without any permit, provided it is part of passenger's luggage.
- More than 100 doses imported with license. Apply on form no.-12- A,12-B
- Drugs must be Bonafide personal use.
- The quantity should be reasonable & covered by R.P.M. prescription.
- Drugs must be declared to the custom collectors if so directed.

5) Import of homeopathic & cosmetics drugs

- In general, Homeopathic cosmetics drugs imported into India without any license.
- New Homeopathic medicines can be imported with license

Cosmetics prohibited to import:

- Misbranded cosmetics, Spurious cosmetics
- Cosmetic containing harmful ingredients
- Cosmetics not of standard quality
- which contains more than-2 ppm Arsenic, 20 ppm lead, 100 ppm heavy metals
- Cosmetics meant for eye and containing coal tar dyes.
- Cosmetics coloured with lead OR arsenic compounds.

C. IMPORT OF DRUGS WITHOUT LICENSE

- Substances not used for medicinal purpose
- Drugs in Sch-C, required for manufacturing and not for medicinal use.

Substances which are both drugs and foods such as:

- ✓ Condensed/Powdered Milk
- ✓ Malt
- ✓ Lactose
- ✓ Farex/Cereal
- ✓ Oats

- Predigested foods - Viral, Bovril, Chickens essence
- Ginger, Pepper, Cumin, Cinnamon
- Drugs transit through India to foreign country.

D. CUSTOM FRONTIERS

ROUTES	PLACES
BY Road/Rail	Ferozepore Cantt, Amritsar Rly Station, (Pakistan) ranaghat, Mohiassan, Bongaon (Bangladesh), Raxaul(Nepal)
BY sea	Madras, Bombay, Calcutta, Cochin, Vishakhapatnam
BY Air	Madras, Bombay, Calcutta, Delhi, Ahmadabad, Hyderabad

E. OFFENCES & PENALTIES

OFFENCES	PENALTIES
Import of spurious OR adulterated drug OR drug which involves risk to human beings or animals OR drug not having therapeutic values	a) 3 years imprisonment and 5000 Rs. fine on first conviction b) 5 years imprisonment OR 1000 Rs. fine OR both for subsequent conviction
Contravention of the provision	a) 6 months imprisonment OR 500 Rs. fine OR both for first conviction. b) 1 year imprisonment OR 1000 Rs. fine for subsequent offence

MANUFACTURE

A. Prohibition of manufacture
B. Manufacture of other than in Sch-C/C_1
C. Manufacture of those in Sch-C/C_1
D. Manufacture of Sch-X drugs
E. Loan license
F. Repackaging license
G. Offences & Penalties

A. PROHIBITION OF MANUFACTURE

- Drug not of standard quality or misbranded, adulterated or spurious.
- Patent or Proprietary medicine
- Drugs in Sch-J
- Risky to human beings or animals
- Drugs without therapeutic value
- Preparation containing cyclamates

B. MANUF. OF DRUGS OTHER THAN IN SCH-C/C_1

PROCEDURE:

- ✓ A Licence is obtained from licensing authority (Food & Drugs Control Administration) on application in prescribed form (No-24) with prescribed fees **(Rs. 6000, 1500)**

- ✓ If the conditions fulfilled, then licence is issued in a prescribed Form (No. 25)

- ✓ There are two types of condition for all manufacturing licence. Condition which are to be satisfied before a licence is granted & conditions which are to be complied with after a licence is granted.

Conditions:

- ➢ Premises should comply with schedule 'M'
- ➢ The manufacture shall be conducted under the acti Slide 102 of 136 directions of competent technical staff.
- ➢ Adequate facility for testing, separate from manufacturing
- ➢ Adequate storage facility
- ➢ Any change in premises, plant or staff, it reported to authority
- ➢ Records maintained for at least 2 years from date of Exp.
- ➢ Licensee Should provide sample to authority
- ➢ On demand Furnish data of stability
- ➢ Maintain the inspection book
- ➢ 10.Maintain reference samples from each batch
- ➢ Accounts of production recorded & maintained for 5 years or 1 year after Expiry.

C. MANUF. OF DRUGS THOSE IN SCHEDULE-C/C$_1$(BIOLOGICAL)

PROCEDURE:

- ✓ A License is obtained from licensing authority (Food & Drugs Control Administration) on application in prescribed form (No-27) with prescribed fees (Rs. 6000, 1500)

- ✓ If the conditions fulfilled, then license is issued in a prescribed Form (No. 28)

Conditions:

- ➢ Drugs must be issued in previously sterilized sealed glass or suitable container
- ➢ Containers should comply with requirement of Sch-F
- ➢ Drugs must comply with standards of Sch-F
- ➢ Some classes tested for aerobic & anaerobic micro-organism.eg. Sera, Insulin, Pituitary hormones.
- ➢ Serum tested for freedom from abnormal toxicity

- Multi dose container for liquids should contain preservatives of spore bearing pathogens.
- Parenteral in doses of 10 ml or more should be tested for freedom from Pyrogens.

D. MANUFACTURE OF SCH-X DRUGS

PROCEDURE:

- ✓ A License is obtained from licensing authority (Food & Drugs Control Administration) on application in prescribed form (No-27 B) with
- ✓ prescribed fees (Rs. 6000, 1500)
- ✓ If the conditions fulfilled, then license is issued in a prescribed Form (No. 28 B)

Conditions:

1) Accounts of all transactions regarding manuf. should be maintained in serially bound & paged register. (Preserved for 5 years)

A) Accounts Of Drugs Used In Manufacture:

- Date Of Issue
- Name Of Drug
- Opening Balance
- Anticipated Yield - Actual Yield
- Wastage
- 6. Qualification

B) Accounts Of Production

- Date Of Manufacture
- Name Of Drug
- Batch No.
- Anticipated Yield - Actual Yield
- Wastage
- Qualification
- Quantity Of Raw Material

2. **Have to send copies of invoice of sale to licensing authority every 3 months.**

3. **Store drugs in direct custody of responsible person.**
4. **Preparation must be labelled with X Rx**
5. **Marketed in packing's not exceeding**

- ✓ 100 units dose-Tablets/Capsules
- ✓ 300 ml- Oral liquid
- ✓ 5 ml – Injection

E. LOAN LICENSE

Definition:

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

Loan licenses are issued for:

1) Drugs other than specified in C/C, & X.

2) Drugs specified in Schedule-C/C_1

PROCEDURE:

- ✓ A License is obtained from licensing authority (Food & Drugs Control Administration) on application in prescribed form (No-24-A, 27-A) with prescribed fees (Rs. 6000, 1500)

- ✓ If the conditions fulfilled, then license is issued in a prescribed Form (No.25-28-A)

Conditions:

1. Application must be supported by parent firm.
2. Drugs inspector inspect the premises of parent firm & assess the spare capacity.
3. Loan licensee is required to test each batch of raw material & finished products.
4. Record of testing should be maintained for 5 years, or 2 years in case of expiry dated drugs.
5. If the licence of the parent firm is cancelled/suspended the loan licensee will also be deemed to be suspended or cancelled.

6. Patent or proprietary medicines should contain the constituents in therapeutic/prophylactic quantities.
7. Patent medicines should be safe for use in the context of vehicles & additives.
8. The ingredients & their quantities must have therapeutic justification.
9. The production must be supervised by competent person of loan licence.

F. REPACKAGING LICENSE

Definition:

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

Repackaging of drugs is granted of drugs other than Schedule-C/C, and X.

PROCEDURE:

- ✓ A License is obtained from licensing authority (Food & Drugs Control Administration) on application in prescribed form (No-24-B,) with prescribed fees (Rs. 500, 200)

- ✓ If the conditions fulfilled then license is issued in a prescribed Form (No.25-B.)

Conditions:

1. Adequate space & equipment should be provided.
2. Repacking must be supervised by competent person.
3. Adequate arrangement for analysis of raw materials & repacked drugs.
4. Maintain records of analysis for at least 3 years from date of manufacture, 3 months for expiry dated drugs.
5. Adequate space for storage of drugs.
6. Licensee should allow an inspector to inspect premises, records & take sample of drugs.
7. Licensee should be displayed on the premises.
8. Factory premises must comply with the condition prescribed in Sch.-M
9. If any change in competent staff immediately informs to authority.

G. PENALTIES RELATED TO MANUFACTURE

OFFENCES	PENALTIES
Manufacture of any spurious drugs OR adulterated drugs cause Death	a) imprisonment not less than 5 Year which may be extend to life imprisonment and not less than 10,000Rs. fine b) 2-6 years imprisonment & Rs.10000 fine on subsequent conviction
Manufacture of adulterated drugs- not cause death	a) 1-3 years imprisonment and Rs.5000 fine b) 2-6 years imprisonment & Rs.10000 fine on subsequent conviction
Manuf. of drugs contravention of the provisions	a) Imprisonment from 1-2 years with time
Person who do not keep record OR disclose information	Imprisonment up to 1 year & Rs.1000 fine
Manufacturer who gives a false warranty, that drugs do not contravene any provision of the Act	Imprisonment up to 1 year & Rs.500 fine or both

SALE

Sale of Drugs

1. Classes of drugs prohibited to be sold
2. Wholesale of biological (C/C_1) drugs
3. Wholesale of other than those specified in C/C, and X
4. Wholesale of Sch-X drugs
5. Retail sale
    - General licences
    - Restricted licences
6. Offences & Penalties

1. CLASSES OF DRUGS PROHIBITED TO BE SOLD

- Misbranded, spurious, adulterated and drugs not of standard quality
- Patent/Proprietary drugs with undisclosed formula
- Sch-J drugs
- Expired drugs.
- Drugs used for consumption by government schemes such as E.S.I.S. Armed force.
- Physician's samples
- Drugs Manufactured/Imported in Contravention of The Provisions of The Act.

2. WHOLESALE OF BIOLOGICAL (C/C_1)

PROCEDURE:

- ✓ A License is obtained from licensing authority (Food & Drugs Control Administration) on application in prescribed form (No-19-C) with prescribed fees (Rs.1500)
- ✓ If the conditions fulfilled, then license is issued in a prescribed Form (No. 21-B)

Conditions:

1. Adequate premises, which should not be less than $10M^2$ Equipped with the facilities for the proper storage of the drugs.
2. Licensee should take precautions while storage
3. The drug should be sold only to those persons who are licensed to retail them.
4. Premises should be in the charge of the competent person who is register pharmacist OR who has passed the matriculation examination with four-year experience in dealing with drug.

EXEMPTION: It does not apply to the sale of drugs to-

- ✓ Hospital institute
- ✓ Medical institute
- ✓ Educational institute
- ✓ Research institute

- ✓ Government authorities

5. For any additional category to sell, licensee should obtain the permission.
6. Record of the purchases and sales should be maintained under following headings:
7. Date of purchases and sales
8. Names/addresses of firms from whom purchased and persons to whom sold.
9. Names, quantities and batch no. of drugs
10. Names of the manufacturers.
11.Records should be preserved for 3 years from the date of sale.
12.Licence should be displayed on premises.

3. WHOLESALE OF OTHER THAN THOSE SPECIFIED IN C/C_1 AND X

PROCEDURE:

A License is obtained from licensing authority (Food & Drugs Control Administration) on application in prescribed form (No-19) with prescribed fees (Rs.1500)

If the conditions fulfilled, then license is issued in a prescribed Form (No. 20- B)

Condition: all the conditions (no.1-7) as discussed above in part(c).

8. The licensee should comply with the provision of the drugs and cosmetics act-1940 and rules there under.

9. The compounding is made by or under the direct and personal supervision of a qualified person.

4. WHOLESALE OF SCH.- X

PROCEDURE:

- ✓ A License is obtained from licensing authority (Food & Drugs Control Administration) on application in prescribed form (No-19-C) with prescribed fees (Rs.500)
- ✓ If the conditions fulfilled, then license is issued in a prescribed Form (No. 20)

Condition: all the conditions (no.1-7) as discussed above in part(c) and 8-9 of part (d) are also applicable to Sch-X

10. The licensee should forward to the licensing authority copies of the invoices of sale made to the retail dealers.

5. RETAIL SALE

Two licences are issued

1. General licences

2. Restricted licences

General licences are granted to persons who have premises for the business & who engaged the services of qualify persons to supervise the sale & do compounding & dispensing.

Issue for following category:

- Other than those specified in sch.-c/c1 & x
- For drugs specified in sch.-c/c1
- For sch.-x drugs

Conditions

1. The licensee must have adequate premises 10 M^2 equipped with facility for storage.
2. Requirement prescribed to run pharmacy as per Sch-N
3. All register & records should be prevented for 2 years.
4. Licensee must allow an inspector to inspect the premises register & records.
5. If any changes in qualified staff report to the licensing authority.
6. Precaution should be taken for the storage of Sch-.c/c1 drug.
7. The licence should be displayed at prominent place.
8. Maintain the inspection book.
9. Drug should be sold only to license holder.
10. Drug should be purchased from license manufacturer.
11. Do not stock & sell expired dated drug.
12. No drug intended for physician sample central govt. health scheme.
13. Veterinary product stored separately & labelled with "NOT FOR HUMAN USE".
14. If drug dispensed after compounding it shall be recorded in prescription register.

Restricted licence granted to those dealers who do not engage the services of the qualified person & only deal with such classes of drugs whose sells can be affected without qualified person & vendors who don't have fixed premise.

Conditions

1. The licence can deal only in such drugs which can be sold without supervision of a qualified person.
2. If licence is vendor, he should buy drugs only from fixed dealer which is specified in his licence.
3. Licensee has to take adequate precautions for preserving the properties of the drugs.
4. The licence should be prominently displayed in the premise. In case of vendor, it should remain on his person.
5. The drugs should be sold in their original containers.
6. Drugs should be purchased only from a duly licensed dealer or manufacturer.

OFFENCES & PENALTIES

OFFENCES	PENALTIES FOR FIRST CONVICTION	PENALTIES FOR SUBSEQUENT CONVICTION
Anyone who sells any adulterated or spurious drugs or drugs which likely to cause death.	5 Years to life time Imprisonment & Rs.10,000 fine	Imprisonment up to 10 years or Rs.20,000 fine or both
Seles of any adulterated or spurious drugs or drugs which is not likely to cause death.	1-3 Years Imprisonment & Rs.5000 fine	2-6 Years Imprisonment & Rs. 10,000 fines
Sales of any drugs in contravention of provision of the Act	1-2 Years Imprisonment & fine	2-6 Years Imprisonment & Rs.5000 fine
If records are not kept & information not disclosed	3 Years Imprisonment or Rs. 1000 fine or both	3-6 Years Imprisonment or Rs. 1000 fine or both

LABELLING AND PACKAGING

1. Labelling general
2. Labelling special

The following are the general requirements of labelling of drugs:

1. Name of drugs with trade name e.g.

PARACETAMOL I.P. TABLETS METACIN - TABLETS

2. Name or synonym specified in the official pharmacopoeias, official compendia or formularies (I.P., B.P., U.S.P., N.F.)
3. Net contents weight, volume or number of units. E.g. 10 tablets
4. Quantities of active ingredients expressed either.

- ✓ Amount per single dose for liquid
- ✓ Amount per millilitre for parenteral
- ✓ Amount per unit (Tablet, capsule)
- ✓ Percentage by weight or volume
- ✓ Unit per gram or per millilitre. E.g.,

PARACETAMOL IP 500 mg. EXCIPIENTS Q.S.

1. Name & address of manufacturer & LIC. No

THEMIS PHARMACEUTICALS
VAPI, GUJARAT. Mfg. LIC. No. G-2104

6. A distinctive batch number, lot number e.g.

Batch no. 5/50, lot No. 6

7. Date of manufacture & date of expiry e.g.

Mfg. dt 5/2/94 Expiry dt. 4/2/99

8. Precautionary information

9. **STORE IN DARK STORE IN COOLPLACE**

10. General information
    - ✓ Shake well before use
    - ✓ (Suspension, Emulsion, lotion)
    - ✓ For external use only (if external preparation)
    - ✓ Not to be sold (if physician sample)

LABELLING SPECIAL

CLASS OF DRUGS	NATURE OF MEDICINES	SPECIFIC PARTICULARS APPEARED ON LABEL
Schedule C/C1	In original form	1) Proper name in addition to patent name 2) Potency in units 3) Name & address of manufacturer 4) Licence No. under which manufacturer 5) Date of manufacture 6) Date of expiry 7) Precaution for preparation
Schedule G	Made up ready for internal use	It is dangerous to take the preparation except under medicinal supervision.
Schedule G	External use	No caution required
Schedule H	Internal use Not narcotic & psychotropic substances	1) Rx symbol on left top corner of the label 2) Schedule H drugs. 3) WARNING: to be sold by retail on the prescription of a R.M.P. only
	Internal use narcotic & psychotropic substances	1) N.Rx symbol on left top corner of the label 2) Schedule H drugs. 3) WARNING: to be sold by retail on the prescription of a R.M.P. only
	External use	External use only
Schedule X	Internal use	1) N.Rx in red ink symbol on left top corner of the label 2) Schedule X drugs. 3) WARNING: to be sold by retail on the prescription of a R.M.P. only
	External use	External use only
Patent and Proprietary containing Vitamin	-	"For Therapeutic Use " OR "For Prophylactic Use" OR: “For Paediatric use"

Nonsterile surgical ligature	-	'Nonsterile" Operation unless sterilised
Mechanical Contraceptives	-	1) As per Schedule- R 2) Date of manufacture 3) storage condition

ADMINISTRATION OF THE ACT AND RULES

A) Advisory:

- Drugs Technical Advisory Board-DTAB
- Drugs Consultative Committee-D.C.C.

B) Analytical:

- Central Drugs Laboratory - CDL
- Drug Control Laboratory in states
- Government Analysts

C) Executives:

- Licensing authorities
- Controlling authorities
- Drug Inspectors

D) Schedule N

E) Schedule M

F) Schedule Y

DRUGS TECHNICAL ADVISORY BOARD (DTAB)

DTAB has the following members:

1) **Ex-Officio Members**

- Director-General of Health Services, who is also the Chairman,
- Drugs Controller of India,
- Director, Central Drugs Laboratory, Kolkata,

- Director, Central Research Institute, Kasauli,
- Director, Indian Veterinary Research Institute, Izzatnagar,
- President, Pharmacy Council of India,
- President, Medical Council of India, and
- Director, Central Drugs Research Institute, Lucknow.

2) Nominated Members

- One person from pharmaceutical industry nominated by the Central
- Government,
- Two government analysts, appointed under the Act, nominated by the
- Central Government, and
- 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

- 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,
- 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,
- One person elected by the Council of the Indian Pharmaceutical Association,
- One person elected by the Council of the Indian Medical Association, and
- One pharmacologist elected by the Governing Body of the Indian Council of Medical Research.

Functions

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

CENTRAL DRUG LABORATORY(CDL)

Established in Calcutta, under the control of a director appointed by the Central Government.

Functions:

- Analysis or test of samples of drugs/cosmetics sent by the custom collectors or courts.
- Analytical Q.C. of the imported samples.
- Collection, storage and distribution of internal standards.
- Preparation of reference standards and their maintenance.
- Maintenance of microbial cultures.
- Any other duties entrusted by Central Government.
- Acting as an appellate authority in matter of DISPUTES.
- Training of drug analysis.
- To advise the central drug control administration in respect of quality & toxicity.
- To work out analytical specification of Monographs for IP & Homeopathic Pharmacopoeia.
- Analysis of cosmetics

  Central drug testing lab (CDLT), CHENNAI, MUMBAI, GUWAHATI.

N.B.:

- Biological & microbiological Test/Analysis are not carried out by C.D.L, sent to Director of central Research Institute-Kasauli.
- Biological for Veterinary use sent to the Director, Indian Veterinary Research
- Institute, Izatnagar Test on condoms are carried out at the central Indian Pharmacopeial laboratory, Ghaziabad

PROCEDURE

- All samples of drugs/cosmetics sent to C.D.L. for analysis by court under registered post & sealed with copy of memorandum.
- A copy of memorandum & specimen of impression of seal on packet sent separately by registration post.
- On receipt of the packet, director/officer should record the conditions of seal on packet
- On completion of test/analysis the director required to supply a report of the analysis.

DRUGS CONSULTATIVE COMMITTEE (DCC)

It is also an advisory body constituted by central government.

Constitution:

- ✓ Two representatives of the Central Government One representative of each State Government
- ✓ Drugs Consultative Committee (DCC)

Functions:

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

GOVERNMENT ANALYST

- ➢ State government appoint persons as government analysts for the purpose of analysis/testing of samples of drugs & cosmetics.
- ➢ The central government may also appoint such person as a government analyst.
- ➢ Government analyst should have NO direct or indirect interest in Import, Manufacture OR Sale of drugs & cosmetics.

QUALIFICATION

A) For the analysis/testing of other than Biological(c/c1)

- ✓ 1.A graduate in Medicine OR Science OR Pharmacy OR Pharmaceutical chemistry & with at least 5 year post graduate experience in testing OR has completed two years training on testing of drugs, including in Sch C in CDL.
- ✓ A postgraduate degree in Medicine OR Science OR Pharmacy OR Pharmaceutical chemistry & with at least 3-year experience in testing OR has completed two years training on testing of drugs, including in Sch C in CDL.
- ✓ Holding associateship Diploma of the Institution of Chemists with Analysis of drugs & Pharmaceuticals with at least 3-year experience in testing OR has completed two years training on testing of drugs, including in Sch C in CDL.

B) For the analysis/testing of Biological (Sch c/c1)

USED FOR HUMAN BEINGS

- ✓ A graduate in Medicine OR Science OR Pharmacy OR Pharmaceutical chemistry. And trained either in physiology or bacteriology, Serology, pathology, pharmacology or Microbiology & with at least 5-year experience in testing of biological products & have at least 6 months training in Approve led Laboratory.
- ✓ A postgraduate degree in Medicine OR Science OR Pharmacy OR Pharmaceutical chemistry or associateship Diploma of the Institution of Chemists with Analysis of drugs & Pharmaceuticals.
- ✓ And trained either in physiology or bacteriology, Serology, pathology, pharmacology or Microbiology & with at least 3-year experience in testing of biological products & have at least 6 months training in Approve led Laboratory has completed two years training on testing of drugs, including in Sch C in CDL.

C) For the analysis/testing of Biological for veterinary use

- ✓ A graduate in veterinary Science OR General Science OR medicine OR Pharmacy.
  And at least 5-year experience of testing.

- ✓ A postgraduate in veterinary Science OR General Science OR medicine OR Pharmacy OR Pharmaceutical Chemistry.
  And at least 3-year experience of testing.

DUTIES

- ✓ To analyse & test sample of drugs & cosmetics sent by inspector or other persons & furnish reports.
- ✓ To engage in any research work & forward the report to the government with a view to publication.

PROCEDURE

- ✓ On receipt of samples the analyst should record the condition or the seal & compare it with the impression of the seal received separately.

- ✓ After completion of the analysis, a report in triplicate with full details should be supplied.

EXECUTIVES

i) LICENSING AUTHORITIES

- ✓ **FOR IMPORT:** the central government appoints licensing authorities to issue licences for the import of drugs.
- ✓ **FOR MANUFACTURE & SALE:** the state governments appoint licensing authorities for respective territories to issues licence for the respective & sale of drugs & for the manufacture & sale of drugs & for manufacture of cosmetic.

The licensing authorities are designated differently in different states. As

- Drug controller
- Director
- Drug control Administration
- Officer in charge Drug control
- Commissioner- FDCA

ii) CONTROLLING AUTHORITIES

- ✓ All inspectors appointed shall be under the control of a controlling authority.

QUALIFICATION

- A graduate in Medicine OR Pharmacy OR Pharmaceutical chemistry (Clinical Pharmacology) OR Microbiology.
- And at least 5-year experience in the manufacture or testing of drugs or enforcement of the Act.

DRUG INSPECTORS

- State government appoint persons as drug inspectors to inspect premises licensed for manufacture of drugs & cosmetics & sale of drugs.
- The central government may also appoint such persons.
- Drug inspectors should have no any financial interest in the import, manufacture or sale of drugs and cosmetics.
- All drug inspectors are public servant within the meaning of Indian Penal Code.
- Inspectors are required to keep all information's confidential & not to disclose.

QUALIFICATION:

A) TO INSPECT PREMISES MANUFACYURE OTHER THAN BIOLOGICAL & PREMISES ANUFACTURE BIOLOGICAL (C/G)

- A degree in Pharmacy
- Science or
- Medicine (Clinical P. ology OR Microbiology)

Any qualification of above and-

- Not less than 18 Months experience in manufacturing OR testing of the substances specified in Sch.C (OR)
- Not less than 3 Years experience in the inspection of firm manufacturing any of the substances specified in Sch C.

B) TO INSPECT PREMISES MANUFACYURE BIOLOGICAL (VETERINARY)

- A graduate in veterinary Science OR General Science OR medicine OR Pharmacy. And 18 months experience in the manufacture OR testing of veterinary biological.
- A graduate in veterinary Science OR General Science OR medicine OR Pharmacy OR Pharmaceutical Chemistry.
- And at least 3-year experience in the inspection of Firm Manufacturing veterinary biological.

DUTIES: classified under 2 heads

- Inspection of premises, licensed for the sale of drugs.
- Inspection of premises licensed for the manufacture of drugs & cosmetics

Inspection of sale premises,

- To inspect not less than once a year all shops within the area assigned to hi
- He checks whether the conditions of licences are being fulfilled or not.
- To obtain & send sale samples for analysis.
- To investigate any complaints
- To institute prosecution
- To maintain record of all inspection.
- To detain packages of imported drugs.
- To enter & search where an offence is believed to be committed.
- To exercise other duties as may be necessary

Inspection Of Manufacturing Premises

- To inspect not less than once a year all shops within the area assigned to him. If manufacturer manufacturing biological drugs (C/C1), inspect plant, process, standardizing & testing of drugs & method of storage & technical qualification of the staff.
- To take sample & send for analysis
- To check all record & registers.
- To institute legal proceeding in case of breach of the Act.
- To send detailed report of each inspection.

POWERS

- Inspect any premises where drugs OR cosmetics being manufactured or sold or if biological product check plant, process & testing
- Take samples of drugs OR cosmetics which are being manufactured or sold.
- Enter and search any premises in which an offence is believed to be committed.
- Examine & seize any records, registers & documents
- 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.
- Stop & search any vehicle, vessel or other conveyance used for carrying any drug or cosmetician respect of which an offence being committed.
- Exercise such other power as may be necessary

PROCEDURE

- Whenever inspector take sample of drugs, he should inform the purpose in writing in the prescribed form (No.17)
- He shall tender the fair price in cash or credit.
- If price is not accepted, he should tender a receipt in prescribed form No.16
- Divide the sample in four parts if sample is taken from sales premises. in three parts if sample is taken from manufacturing premises. If small container or likely to deteriorate, the inspector may take 3 or 4 such containers
- Each part/container sealed & marked.
- Allow the person to add his mark or seal to such part/containers.
- Once part/container of the sample sent to the Govt. analyst, second is reserved for the two warrantor & fourth returned to person from whom sample is taken court, third is sent
- Sample sent to Govt. Analyst by registration post or personally
- After, the report of analysis has been received from Govt. Analyst. Drug inspector will decide any further action.

Salient features of the Drugs and Cosmetics (Amendment) Act, 2008

- Substantial enhancement in punishment
- Life imprisonment for offenders involved in manufacture, sale and distribution of spurious and adulterated drug likely to cause grievous hurt
- Minimum punishment of seven years which may extend to life imprisonment
- Provision for compensation to affected person
- Corresponding enhancement in punishment for repeated offenders
- Cognizance can be taken on the complaint of any gazette officer authorized by Central or State Government
- Cases to be tried by Sessions Court
- Designation of special courts for trial of offences in respect of adulterated and spurious drugs
- All offences relating to adulterated and spurious drugs made cognizable and non bailable
- Restrictions on bail cannot be granted unless public prosecutor is heard
- Certain offences made compoundable.

BRIEF STUDY OF DRUGS WITH REFERENCE TO SCHEDULES
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.

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 be 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 "N Rx" and Schedule H drug warning.
- Schedule H is a list of r 536 drugs. Some examples are Abxicimab, Acylovir, Diclofenac, Baclofen, Carbidopa, Terazosin, Verapamil hydrochloride, Tretinoin, Repaglinide, etc.

SCHEDULE H1

This schedule was introduced under the Drugs and Cosmetics (4th 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.

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 amount 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: Wastewater and other residues from the laboratory may be harmful to the workers or the public health, thus should be disposed of 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 epidemic group of diseases.

7) Working Benches: These are used by the workers for carrying out filling, labelling, packing 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 sparkler filter,
iv) Vacuum or gravity filter, and
v) Water still or deioniser.

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.

8) The following equipment is suppositories: i) required for manufacturing pessaries and 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 vitalized:

i) Mixing equipment, required for manufacturing inhalers and
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 Preparation tanks or other containers made of either glass or such material as will not react with the liquids,
f) Filtering equipment 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.

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 sufficient 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 m2 for a pharmacist working there and additional 2m2 for each additional pharmacist. The premises should have a minimum height of 2.5m2.

3) Furniture and Apparatus: The furniture and apparatus of a pharmacy 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 different label marked with the words „To be diluted“.

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 pharmacy 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.

SCHEDULE P

This schedule deals with the Life Period of Drugs 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 P1 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 listed under this schedule should be marked

DRUGS	DOSAGE FORMS	PACK SIZES
Aspirin	Tablets	14 Tabs
Cholecalciferol	Granules	1 gm sachet
Famotidine	Tablets	14 Tabs
Glyceryl Trinitrate	Capsules	25 Cap

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 lavatory 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 potable 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 residue from the manufacturing section and laboratories should be disposed of properly as it 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 containers. ying of such

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 REJECTED. or APPROVED

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. Their clothing should have proper and clean uniform appropriate to the nature of work and climate. The uniform should have cloth or synthetic covering 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 processing rooms. Facilities for changing 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 Equipment: 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 equipment's should be correctly installed and kept clean.

15) Batch Manufacturing Records: The licensee should maintain batch manufacturing record of each batch of Ayurvedic, Siddha and Unani drugs

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 Pharmacopeial standard.

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 and 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 manufactured under aseptic conditions t o indicate the precautions taken during the 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.

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 Capsules: i) Protocol of tests applied: a) Description, b) Identification, Tablets

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.

SCHEDULE V

This schedule deals with Standards for Patent or Proprietary Medicines. 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, emulsions and suspensions should disperse. Homogeneous solutions should have no sediments. Net content of the product in the container should not be less than the volume mentioned on the label. The ethanol content of pharmaceutical products should be between 90-110% 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 antibiotics, should be, and between 90-110% of the labelled content. In dry formulations of antibiotics, the limit should be 90-130% of the labelled contents. In liquid antibiotics, the limit should be 90-140% of the labelled contents.

SCHEDULE X

This schedule deals with the Substances. List of Narcotic Drugs and Psychotropic 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 stereo-isometric 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.

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 permission to start a phase of clinical trial should also have the investigators brochure, proposed protocol, case record form, study subjects informed consent document(s), investigator undertaking, and ethics committee clearance.

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 investigators skilled in clinical pharmacology who carefully observe and monitor the subjects. Following are the objectives of studies conducted in phase I trials:

- **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.
- **Pharmacokinetics:** It is done to characterise a drug's absorption, distribution, metabolism, and excretion.
- **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 activity and potential efficacy.
- **Early Measurement of Drug Activity:** activity or potential therapeutic benefits are Preliminary studies of 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 indication and recipient population. These studies should suitable basis for marketing approval. a particular provide a

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 comprise 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.

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 buildings 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, and 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 100m2 area to carry out the operations, and an extra 50 m2 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 transmissible 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 experience in the testing of blood and/or its components.

iii) registered nurse(s), and

iv) technical supervisor with: a year's

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 manage d 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 leukapheresis 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 t rash 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 equipment, which should be observed, standardised, and calibrated regularly.

General Equipment 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 maintaining temperature between 2 and untested blood, -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 tubing, and
e) Sahli's Haemoglobinometer/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 Equipment/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 temperatures, to wards and hospitals,
r) Wash bottles,

s) Filter papers,
t) Dielectric tube sealer,
u) Plain and EDTA vials, -10°C
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, compatibility 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 effect 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.

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 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 should 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 should 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 donors or addiction of Self-injected narcotics.

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 recipients, 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.

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 placed on the blood-containing bags. The colour scheme in the table below for the said labels should be used for various blood groups:
vi) The test results for hepatitis B surface antigen and hepatitis C virus antibody, syphilis, freedom from HIV I and II antibodies, and malarial parasite.
vii) The Rh Group.
viii) Total volume of blood, preparation of blood, and nature and percentage of anticoagulant.
ix) The whole human blood and/or components should be kept at 2 Temperature: -6°C
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.

SUMMARY:

1. Regulates the manufacture, sale, and distribution of drugs and cosmetics in India.
2. Ensures the safety and efficacy of drugs and cosmetics.
3. Prohibits the manufacture and sale of adulterated or spurious drugs and cosmetics.
4. Establishes the Central Drugs Standard Control Organization (CDSCO) to oversee enforcement.
5. Sets standards for drugs and cosmetics.
6. Requires licenses for manufacturing and selling drugs and cosmetics.
7. Empowers the government to regulate and prohibit certain drugs and cosmetics.
8. Provides for penalties for offenses, including fines and imprisonment.

Drugs and Cosmetics Rules, 1945:

1. Define "drug" and "cosmetic" and specify categories of drugs.
2. Specify requirements for labeling and packaging of drugs and cosmetics.
3. Set standards for quality, purity, and strength of drugs.
4. Require testing and inspection of drugs and cosmetics.
5. Specify requirements for manufacture, storage, and distribution of drugs and cosmetics.
6. Establish guidelines for clinical trials and approval of new drugs.
7. Require registration of cosmetics and Ayurvedic, Siddha, and Unani drugs.

8. Specify requirements for import and export of drugs and cosmetics.
9. Set standards for medical devices and equipment.
10. Require maintenance of records and reports by manufacturers and sellers.
11. Empower inspectors to seize and confiscate adulterated or spurious drugs and cosmetics.
12. Provide for appeals and revisions of decisions made under the Act and Rules.

Note: These points summarize the main provisions of the Act and Rules, which aim to ensure the safety and efficacy of drugs and cosmetics in India

CHAPER 4
PHARMACY ACT-1948

Introduction:

Until fifth decade of twentieth century, 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 on 4th March 1948 by the Recommendations by DEC committee and Recommendations by Health Survey and Development committee.

Objectives:

- To regulate the profession and practice of pharmacy to raise the status of pharmacy in India.
- **Constitution of Pharmacy Council of India** (PCI) responsible for evolving educational standards and regulations for the courses in Pharmacy.
- Constitution Of State Pharmacy Council of India for registration of pharmacist and for regulation of professional activities.

Definition:

Central Register: Register maintained by the pharmacy council of India (central council).

Medical Practitioner is: A person whose qualification granted by an authority specified under Section 3 of Indian Medical Degrees Act 1916, or specified in the schedules of the Indian Medical Council Act 1956.

A person registered or eligible of practising modern system of medicine and practising veterinary medicine.

A person who does not fall under the above two clauses but declared by a special order made by State Government in the behalf as a person practising the modern scientific system of medicine for the purpose of this Act.

Registered pharmacist: is a person whose name is entered in the register of the state pharmacist in which he is residing or carrying on his profession or business of pharmacy.

Displaced person is: A person who on account of the setting up of the Dominions of India and Pakistan or on account of the civil disturbances or fear of such disturbance after the first day of March 1947, left or been displaced from his place of residence and who has since then been residing in India.

Any person who on account of civil disturbances or the fear of such disturbances now forming part of Bangladesh, has left or displaced from his place of residence after 14th April 1957 but before 25th March 1971, who has since then been residing in India.

Repatriate: is a 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 14th of April 1957, left or has been displaced from his place of residence and who has since then been residing in India.

University Grants Commission: means the University Grants Commission established under section 4 of the University Grants Commission Act, 1956.

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

Pharmacy Council of India:

- Constituted under section 3 of the chapter 1 by the central government
- The first pharmacy council of India (P.C.I) constituted by central government in 1949 and is reconstituted every 5 years.

It consists of three different types of members-

I. Elected member

2.Nominated member

3.EX-Officio Member

MEMBERS	ELIGIBILITY
Six Teachers	Elected members-Elected by University Grant Commission (UGC). At least one teacher of each subject i.e., Pharmacy, Pharmaceutical chemistry, Pharmacognosy and Pharmacology.
One member, elected by Medical Council of India.	Should be elected by the members of the Council.
One member from each state, elected by State Council, who shall be a registered pharmacist.	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/Pharmaceutical Chemistry.
A representative of the UGC	No specific background provided for.
A representative of the AICTE	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 OF CENTRAL COUNCIL:

- Elected by the members of the Council among themselves.
- The President or Vice-President shall hold office as such for a term not exceeding five years and not extending beyond the expiry his term as member of the Central Council.
- He shall be eligible for re-election
- Mode of elections-Elections under this chapter shall be conducted in the prescribed manner, and where any dispute arises regarding any such election it shall be referred to the Central Government whose decisions shall be final.

TERMS OF OFFICE AND CASUAL VACANCIES:

- Subject to the provisions of this section, a nominated or elected member shall hold office for a term of five years from the date of his nomination or election or until his successor has been duly nominated or elected, whichever is longer.
- A nominated or elected member may at any time resign his membership by writing under his hand addressed to the President, and the seat of such member becomes vacant.
- A nominated or elected member shall be deemed to have his seat if he is absent without excuse, from three consecutive meetings of the Central Council.
- A casual vacancy in the Central Council shall be filled by fresh nomination or election and the person nominated or elected to fill the vacancy shall hold office only for the remainder of the term.
- Members of the Central Council shall be eligible for re-nomination or re-election.

STAFF, REMUNERATION AND ALLOWANCES:

The Central Council Shall

(a) appoint a Registrar who shall act as the Secretary to that Council and who may also, act as the Treasurer.

(b appoint such other officers and servants as that Council deems necessary to enable it to carry out its functions under this Act.

(c) with the previous sanction of the Central Government, shall fix the remuneration and allowances to be paid to the President, Vice-President, and other members of that Council, the pay and allowances and other conditions of service of officers and servants of that Council.

FUNCTIONS OF PCI:

1.To prescribe minimum standards of education required for qualification as a pharmacist.

2. To regulate the minimum educational standards.
3. To recognize qualifications granted outside the territories to which Pharmacy Act, 1948 extends for the purpose of qualifying for registration under the said Act.
4. To compile and maintain a central register.

5. All other functions that may be assigned for implementation of the act.

EDUCATION REGULATIONS:

Subject to the provision of Section 10 of the Pharmacy Act 1948, Central Council after approval of central government may make regulations prescribing the minimum standards of education required for qualification as pharmacist called Education Regulations.

EDUCATION REGULATIONS PRESCRIBES:

1.Minimum qualification for admission to the course.
2. Nature and period of course of study.
3. Nature and period of practical training to be undertaken after completion of course.
4. Subjects of examinations and their standard.
5. The equipment's and facilities to be provided by the Institutions to the students.
6. Conditions to be fulfilled by Institutions giving practical training
7. Conditions to be fulfilled by authorities holding approved examinations.

APPROVAL OF INSTITUTION/ AUTHORITIES PROVIDING COURSES OF STUDY AND EXAMINATIONS:

1. Application by Institution/ Authority to the central council
2. Inspection
3. Approval
4. Declaration of Withdrawal of Approval

APPROVAL OF QUALIFICATION GRANTED OUTSIDE INDIA:

1. Qualification in pharmacy granted outside India can be recognized by PCI. This is applicable to Indian citizens.

2. Citizens of foreign nationality can be eligible for registration when an Indian national holding the same qualification is allowed to enter a practice in that country.

CENTRAL REGISTER:

- Under the provision of pharmacy act (1976), the PCI of India is required to maintain a Central Register.
- Each state govt. has to supply five copies of register for a state to the central council, after the first day of April every year.
- The register has to be maintained by the Registrar of PCI. ¬Has to be revised suitably from time to time.
- Published in the gazette of India.

STATE PHARMACY COUNCILS:

Elected members:

- Six members- by registered pharmacist of the state.
- One member elected by the members of MCI Nominated members
- Five members nominated by the State Government from the persons who hold degree or diploma in pharmacy.

Ex-officio members:

- Chief administrative Medical Officer of the state.
- Officer in charge of Drugs Control Organization of the State.
- Government Analyst.

Joint State Pharmacy Council:

Two or more states enter into an agreement to form a joint state pharmacy council

Elected members:

- Registered pharmacist- 3 to 5 from each state.
- Medical council- 1 from each participating state.

Nominated members:

- 2-4 members nominated by each State Government from the persons who hold degree or diploma in pharmacy.

Ex-officio members:

- Chief administrative Medical Officer of each participating state.
- Officer in charge of Drugs Control Organization of each participating State.
- Government Analyst of each participating state.

ELECTION AND TERMS OF OFFICE:

- The president and vice president are elected by the members from amongst themselves.
- Period of 5 years.
- Casual vacancy is filled by nomination or election.
- Members are eligible for re-election.
- Possess an executive committee similar to the central council.

Inspection:

The State Council may appoint Inspectors having the qualifications as per the Act.

Powers:

1. Inspect any premises where drugs are compounded and dispensed.
2. Enquire whether the person engaged in dispensing is a registered pharmacist or not.
3. Institute prosecution under the order of the Executive Committee of the State Council.
4. Other essential powers.

REGISTRATION OF PHARMACIST:

Preparation and maintenance of register

The register shall include the following particulars, namely:

a) the full name and residential address of the registered person;
b) the date of his first admission to the register;
c) his qualifications for registration;
d) his professional address, and if he is employed by any person, the name of such person;
e) such further particulars as may be prescribed.

QUALIFICATIONS FOR ENTRY ON FIRST REGISTER:

- A person who has attained the age of eighteen years shall be entitled on payment of the prescribed fee to have his name entered in the first register if he resides or carries on the business or profession of pharmacy, in the State
- He must (a) holds a degree or diploma in pharmacy or pharmaceutical chemistry or a chemist and druggist diploma of an Indian University or a State Government. OR a prescribed qualification granted by an authority outside India.
- OR (b) holds a degree of an Indian University other than a degree in pharmacy or pharmaceutical chemistry and has been engaged in the compounding of drugs in a hospital or dispensary or other place in which drugs are regularly dispensed on prescriptions of medical practitioners for a total period of not less than three years.
- OR (c) has passed an examination recognized as adequate by the State Government for commoners or dispensers.
- OR (d) has been engaged in the compounding of drugs in a hospital or dispensary or other place in which drugs are regularly dispensed on prescriptions of medical practitioners for a total period of not less than five years prior to the date notified under subsection (2) of section 30.

SPECIAL PROVISIONS FOR "REGISTRATION OF CERTAIN PERSONS":

Notwithstanding anything contained in section 32, a State Council may also permit to be entered on the register:
(a) the names of displaced persons who have been carrying on the business or profession of pharmacy as their principal means of livelihood from a date prior to the 4th day of March 1948, and who satisfy the conditions for registration as set out in section 31.
(b) the names of citizens of India who have been carrying on the business or profession of pharmacy in any country outside India and who satisfy the conditions for registration as set out in section 31 ¬ (c) the names of persons who resided in an area which has subsequently become a territory of India and who satisfy the conditions for registration as set out in section 31

QUALIFICATIONS FOR ENTRY IN REGISTER:

• He/ She should hold a diploma in pharmacy or pharmaceutical chemistry.

• He/ She holds a degree in an Indian University other than pharmacy and has been engaged in the compounding of drugs in hospital or dispensary for a total period not less than 3 years.

• Has passed an examination recognized as adequate by the State Government for commoners or dispensers.

ENTRY AND REMOVAL OF NAMES:

Entry:

• All applicants for the registration should be addressed to the Registrar of SPC.
• If the applicant has the requisite qualifications for registration, he shall direct his or her name to be entered in the register.

• Upon entry, a certificate of registration is issued.

Removal:

• Registration by error.
• If he has been convicted of any offence in any professional aspect.
• 30day period for appealing
• Surrender of certificate of registration and publication in the official gazette.

PRINTING OF REGISTER:

- It is done on the 1st day of April subsequent to the commencement of the Pharmacy (Amendment) Act, 1959 (24 of 1959).
- Thereafter, each year after the first of April, register will arrange for reprinting showing supplements to the registers.
- These supplements and registers are deemed to be proof that the persons whose names are contained therein, are registered pharmacists.

RENEWAL FEES:

- The state govt. by notification in the official gazette, direct that for the retention of the name in the register.
- In order to retain the name in the register, renewal fee shall be paid to the state government as may be prescribed.

- Where a renewal fee is not paid by the due date, the Registrar shall remove the name of the defaulter from the register.
- On payment of the renewal fee, the Registrar shall issue a receipt and such receipt shall be proof of renewal of registration.

OFFENCES AND PENALTIES:

OFFENCES	PENALTIES
Falsely claims to be a registered pharmacist	**First Conviction:** Fine up to Rs.500. Subsequent **Conviction:** Fine up to Rs.1000 and/or 6 months imprisonment.
Dispensing by an unregistered person	6 months of imprisonment or a fine of up to Rs1000 or both.
Failure to surrender the Certificate of registration	Fine of Rs.50
Obstruction of state pharmacy council inspectors	Imprisonment of up to 6 months or a fine up to Rs1000 or both

SUMMARY:

1. Regulates the profession of pharmacy in India, ensuring quality healthcare services.

2. Establishes the Pharmacy Council of India (PCI) to oversee pharmacy education and practice.

3. Defines "pharmacy" and "pharmacist," and sets qualifications for registration as a pharmacist.

4. Requires pharmacists to register with the PCI and obtain a license to practice.

5. Prohibits unqualified persons from practicing pharmacy or using the title "pharmacist."

6. Sets standards for pharmacy education, including curriculum and infrastructure requirements.

7. Recognizes pharmacy degrees and diplomas from approved institutions.

8. Empowers the PCI to inspect pharmacies and enforce compliance with the Act.

9. Provides for disciplinary action against pharmacists for misconduct or negligence.

10. Allows for the framing of rules and regulations to implement the Act and advance the profession of pharmacy.

Note: This Act has undergone amendments and changes over the years, and this summary provides a general overview of its main provisions.

CHAPTER 5
MEDICAL AND TOILET PREPARATION ACT-1955

INTRODUCTION

- Alcohol is an important industrial solvent excellent preservative, and a therapeutic agent. However, it likely to be misused and it could be a drug of addiction (euphoric drink).
- Before enactment of this Act, there was chaotic condition prevailing in the country in relation to price structure of alcohol as a raw material and formulations containing alcohol. Some States were rich in production of alcohol, while others were utilizing this as raw material in manufacture of formulations.
- In the absence of uniform excise policy, the price structure of alcohol containing medicines was varying from State to State within the country. In order to overcome this difficulty and to ensure that uniform structure of excise duty for alcohol products exists, this Act was enacted.
- The Act is effectively implemented throughout India from 15th April,1957.
- The Act has 11 Chapters and 21 Sections.

OBJECTIVE:

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

Definitions Under the Act:

1. **Alcohol:** means ethyl alcohol of any strength and purity having chemical composition C2H5OH.
2. **Dutiable goods:** It includes the Medicinal and Toilet Preparations specified in the schedule as being subject to the duties of excise levied under this act.

3. **Medicinal Preparation:** It includes the drugs used as a remedy or prescription prepared for internal or external use of human being or animals and all substances intended to be used for or in treatment, mitigation or prevention of disease in human being or animals.
4. **Toilet Preparation:** the preparation intended to be used in the toilet of human body or in perfuming apparel of any description, or any substances intended to cleanse, improve or alter the complexion, skin, hair or teeth, and includes deodorants and perfumes.
5. **Bonded manufactory:** means the premises or any part of the premises approved and licensed for the manufacture and storage of medicinal and toilet preparations containing alcohol, opium, Indian hemp and other narcotic drugs or narcotics on which duty has not been paid.
6. **Non-Bonded manufactory:** means the premises or any part of the premises approved and licensed for the manufacture and storage of medicinal and toilet preparations containing alcohol, opium Indian hemp and other narcotic drugs or narcotics on which duty has been paid.
7. **Denatured spirit or denatured alcohol:** means alcohol of any strength which has been rendered unfit for human consumption by the addition of substances approved by the Central Government or by the State Government with the approval of the Central Government.
8. **Spirit Store:** means that portion of the bonded or non-bonded manufactory which is set apart for the storages of alcohol, opium, Indian hemp and other narcotic drugs or narcotic purchased free of duty or at prescribed rates of duty specified in the schedule to the Act.
9. **Sub-standard preparation:** a pharmacopeial preparation in which the amount of any of the various ingredients is below the minimum that the pharmacopeial composition would require, or a proprietary medicine which does not conform to the formula or the list of ingredients disclosed on the label on the container or on the container.
10. **Restricted Preparation:** These are the medicinal preparations which are considered capable of being misused as ordinary alcoholic beverages. 7. Unrestricted Preparation: These are the medicinal preparations which are considered to be not capable of being misused as ordinary alcoholic beverages.

LICENSING:

The Central Government may, by notification in the Official Gazette, provide that from such date as may be specified, no person shall engage in the production or manufacture of any dutiable goods or their ingredients or specified container or labels for such goods except, under the authority and in accordance with the terms and

conditions of a licence granted under this Act. Every licence shall be granted for specific area and period subject to prescribed conditions and restrictions.

CONDITIONS OF LICENCE:

- No licence for alcoholic medicinal is given unless there is a licence issued under Drugs and Cosmetics Act (DCA). A licensee/under DCA can only approach to the Excise Commissioner for issue of alcohol, if the formulations containing alcohol are being manufactured.
- The licence on payment of specified fee can be obtained subject to fulfilment of conditions for manufacture in bond and outside bond of medicinal and toilet preparation, ayurvedic, homeopathic and Unani medicines, as well as, for bonded warehouse.

PROCEDURE FOR LICENSE:

1. Manufacture in Bond: From the Excise Commissioner
2. Manufacture Outside Bond: From the State Govt. authorize officer. The application of grant of licence should be submitted in the prescribed along with fee (Treasury Challan) so as to reach the licensing authority at least 2 months before the proposed date of manufacture.

DETAILS IN APPLICATION:

1. Name and address of applicant
2. If applicant is firm, then name and address of partners
3. If applicant is company, then name address of directors, managers and managing agents and reg. no. of company.
4. Name and address of the Place/site of the bonded/non-bonded laboratory
5. Amount of capital proposed to be invested.
6. Number and full description of vats, stills and other apparatus and machinery which the applicant wishes to setup.
7. Maximum quantities in L. P. litre of alcohol or alcoholic content in the form of finished and unfinished preparations remain at any one time.
8. The kind and number of licences held by the applicant as per D and C act.
9. Approximate date of starting production

10. In case of Bonded laboratory: Statement indicating that excise officer required full time or part time
11. Site and elevation plant of laboratory building showing the locations of room and doors
12. In case of firm, true copy of partnership deed
13. In case of company, list of directors' managers, copies of memorandum of association, articles of association and latest balance sheet.

ENQUIRIES BY LICENSING AUTHORITY:

1. Qualifications and experience of the technical persons.
2. The Equipment in bonded/non-bonded laboratory
3. Suitability of the proposed building for the establishment of a laboratory

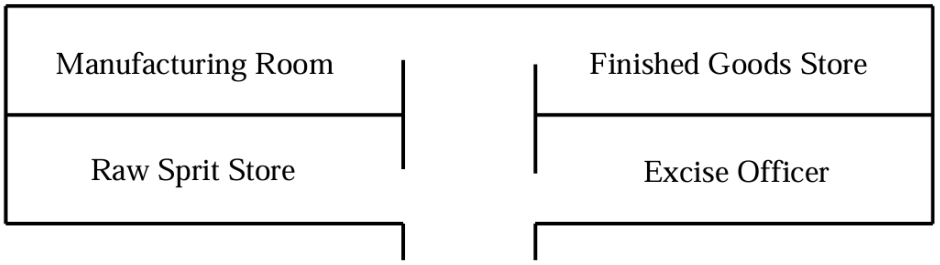
MANUFACTURE IN BOND:

Without payment of duty, rectified spirit is issued with sufficient securities and bond.

Bonded laboratory Ideal requirements:

1. Spirit store
2. Room for manufacturing of medicinal preparations.
3. Room for storage of finished preparations.
4. Room for manufacturing and storage of Toilet preparations
5. Accommodation near the entrance for officer-in-charge with necessary furniture.
6. Every room in bonded laboratory should bear a board indicating the room and serial number.
7. Sinks and wash basins connected to the general drainage of laboratory
8. Gas and Electric supply should be arranged so that they can be easily cut at the end of the day.
9. Windows of the bonded lab should be made up of malleable iron rods of prescribed dimension and should be covered inside with strong wire netting of mesh not exceeding 25 mm.
10. Only one entrance to the bonded laboratory and one door to each of its compartment.
11. All the doors should be secured with excise ticket locks in the absence of officer-in-charge.
12. No alteration in the bonded premises shall be made without Excise commissioner permission.
13. All vessels intended to hold alcohol and other liquid preparations containing alcohol should bear distinctive serial number and full capacity.

14. All the vessels containing medicinal and toilet preparation on which duty has not been paid should bear excise ticket locks.



1. OBTAINING THE RECTIFIED SPIRIT FROM WAREHOUSE:

- The spirit should be obtained from the spirit warehouse approved by the Excise Commissioner.
- The indent should be sent in duplicate in prescribed form counter-signed by the officer in charge of the laboratory.
- Alcohol is issued in duly sealed containers and under intimation to the Excise Officer concerned.
- Cost price of such rectified spirit shall be paid by the licensee to the distiller or warehouse officer.
- No wastage during transshipment is permissible and for any loss due to negligence of the manufacturer, excise duty has to be paid.

2. VERIFICATION AND STORAGE OF SPIRIT RECEIVED:

- On its arrival in bonded laboratory, alcohol is measured in volume and strength.
- Entries are made in register and stored in spirit store room under excise lock with perfect coordination between excise officer in charge and officer of manufacturing unit.
- The alcohol is issued from spirit store from time to time in accordance with the procedure laid down under Rules.

3. ISSUE OF RECTIFIED SPIRIT FROM STORE TO MANUFACTURER:

- The manufacturer should calculate requirement of alcohol and hand it over to the officer in charge.
- Officer in charge then issue the alcohol to the manufacturer
- All ingredients should be kept ready and on receipt of alcohol, the solvent should be mixed immediately in presence of officer in charge.
- The percolators or other vessels containing alcohol during the process of manufacturing and storage should be labelled with the name of the product, batch number, description, quantity of alcohol used, date of manufacture and quantity of preparation removed.
- The preparations should be immediately removed to the finished goods store. Make entry into the register for quantity and given a batch number.
- Up to 200 ml from each batch is permitted to be withdrawn without payment of duty for determination of alcoholic strength of preparation.
- A separate account of number of samples used by the manufacturer for purpose of analysis is maintained.

4. STORAGE OF FINISHED PRODUCTS:

1. Should be store in bulk jars or bottles (more than 2273 ml capacity)
2. Preparation ready for issue shall be filled in containers not less than 57 ml capacity.
3. Every container should be properly labelled.
4. Arranged systematically on the rack for ready identification of batch.
5. Should be stored for period of 3 years or more with permission of Excise commissioner.

5. ISSUE OF PREPARATION FROM BONDED LAB:

1. Application in Prescribed form to the Excise officer in charge
2. He will check the entries and ask the manufacturer to pay the duty accordingly.
3. Then he will issue a permit and allow the required quantities to be removed.

NON-BONDED LABORATORY:

- Manufacture and sale should be conducted between the sunrise and sunset only.
- And only on those days and hours which is fixed by Excise Commissioner.

1. BUILDING ARRANGEMENTS:

1. Separate Unit from other business unit
2. Separate facility for spirit store, laboratory, and finished goods
3. One entrance and one door to each department
4. All the pipes from sinks and wash basins inside the laboratory should be connected with general drainage.
5. Arrangements of gas and electric supply should be able to cut off at the end of the day
6. Separate spirit store for the spirit purchased at different rates of duty.
7. Separate finished goods store for medicinal and toilet preparations

2.OBTAINING THE RECTIFIED SPIRIT-DUTY PAID:

1. Licensee should send the indent along with treasury challan (evidence of duty payable) to the officer in-charge of distillery.
2. The cost of such rectified spirit shall be paid by the licensee to the distillery.
3. After confirmation about correct amount has been paid, officer in charge of distillery order the issue of rectified spirit required along with the permit covering the issue.
4. After making entry in proper register, the obtained spirit transferred to the spirit store.

3.MANUFACTURE AND STORAGE OF PREPARATION:

1. Manufacturing should be carried out in licenced premises only.
2. Registered each manufacturing preparation along with its batch.
3. Transferred finished preparations to the finished store and arrange so that they can easily be checked from the account register.
4. Finished products prepared from alcohol with different duties need to be stored separately.
5. Bulk preparation should be transferred into the vessel of 28 ml capacity and sealed.
6. The quantities from bulk taken by mfg. should be entered time to time

EXEMPTION FROM DUTY:

1. Govt. Hospitals and Dispensary
2. Charitable hospitals and dispensaries
3. Govt. Medical stores

4. Institution certified by District Medical Officer supplying medicine free to poor.
5. Anything in public interest.

EXPORT OF ALCOHOLIC PREPARATIONS:

No duty shall be paid on alcoholic preparations which are exported from India.

1. It has mainly 2 types:
2. Export of duty paid goods (non-bonded) under claim of rebate of duty.
3. Export of non-duty paid goods (under bond).

1.EXPORT OF DUTY PAID GOODS:

1. Should be export under claim of rebate of duty
2. Minimum 48 hours' notice to the concerning Excise Officer.
3. Manufacturer should present the consignment to be exported to the concerning officer who send that samples to the chemical examiner for analysis
4. Chemical examiner gives the report in duplicate
5. Based on the alcoholic content excise duty rebated.

The officer in charge verifies the application for following details:

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

After verifying the applications, the Officer-in-Charge,

1. Seal each pack with his official seal and endorse all copies of application specifying the period within which the goods shall be actually exported.
2. Return duplicate copy to consignor
3. On arrival of the goods at place of export, should be presented to Customs collector for examination with application.
4. After confirmation Excise commissioner sanction the rebate claim.

2. EXPORT OF NON-DUTY PAID GOODS:

1. Application in triplicate to the Excise officer in charge of bonded lab
2. Mention the way of transport (by sea/air/by parcel post)
3. Packages should be marked with ink or oil colour with particulars like serial number, owners name, alcoholic strength and special marks if any.

4. Officer in charge verify the application for details provided
5. Seal all packages with his official seal.
6. The packages then exported by same way as that of duty paid goods.

POWERS OF EXCISE OFFICER:

1. Inspection
2. Entry, search and seizure
3. Detention of person.
4. Suspension-revoke of license.
5. Summons/ notices.
6. Prosecutions.
7. Disposal of seized article/ arrested persons.
8. Power to arrest 9. Power to make rules.

Self-generated alcohol Ayurvedic preparation containing alcohol Alcohol prepared by distillation Alcohol content less than 2% Alcohol content more than 2% Exempted from Duty If capable of consuming as alcoholic beverages Rs. 1/liter If not capable of consuming as alcoholic beverages Exempted from Duty Duty of Rs. 52.8/liter of pure alcohol content Manufacture Of Ayurvedic, Homeopathic And Patent And Proprietary Preparations

OFFENCES AND PENALTIES:

OFFENCES	**PENALTIES**
BY	**LINCESEES**
a. Contravention of any of the provision b. Failure to pay any duty of excise payable under this act c. Failure to supply required information	Imprisonment up to 6 months or Fine Rs. 2000/- or Both
Failure to furnish proof of export	Fine Rs. 2000/- extent to twice the amount of duty
Obstruction to the officer from performing his duty	Fine up to Rs. 500/-
Disorderly keeping of stocks and account	Fine up to Rs. 1000/-
Maintaining False Accounts of stocks	Fine up to Rs. 2000/-

Illegal sale of Dutiable goods	Fine up to Rs. 1000/- and confiscation of the good.
Warehousing related offence	Fine up to Rs. 2000/- and confiscation of the goods
Connivance by any owner or Occupier of land	Imprisonment up to 6 months or Fine Rs. 500/- or Both
BY EXCISE	**OFFICER**
Vexatious search, seizure by officer	Fine Rs. 2000/-
Disclosure of Information	Fine up to Rs. 1000/-
Refusal to perform duty	Imprisonment up to 3 months or fine up to 3 months' pay.

SUMMARY:

Imposes excise duties on medicinal and toilet preparations containing alcohol, narcotics, or other controlled substances.

1. Defines "medicinal preparations" as substances used for medicinal purposes, and "toilet preparations" as substances used for personal hygiene or cosmetics.
2. Specifies the rates of excise duty on various categories of preparations.
3. Exempts certain preparations, like those used for research or educational purposes, from excise duty.
4. Requires manufacturers to obtain a license and maintain records of production and sales.
5. Empowers the Central Government to grant exemptions or reductions in excise duty.
6. Allows for the refund of excise duty on exports or destruction of preparations.
7. Provides for the seizure and confiscation of preparations not complying with the Act.
8. Establishes penalties for offenses, including fines and imprisonment.
9. Authorizes the Central Government to make rules for implementing the Act and regulating the industry.

Note: This Act has undergone amendments and changes over the years, and this summary provides a general overview of its main provisions.

CHAPTER 6
NARCOTIC DRUGS AND PSYCHOTROPIC SUBSTANCES ACT-1985 AND RULES

INTRODUCTION:

- 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'.

OBJECTIVES:

- ➢ To consolidate and amend the law relating to narcotic drugs.
- ➢ To make stringent provisions for the control and regulation of operations relating to narcotic drugs and psychotropic substances

➢ To provide the forfeiture (Financial Penalty) of property derived from, or used in, illicit traffic in narcotic drugs and psychotropic substances

➢ To prohibit, control and regulate the operations relating to NDPS

DEFINITIONS:

1. Addict: means a person who has dependence on any narcotic drug or psychotropic substances. or habitual to regular use of any narcotic drug or psychotropic substances

2. Board: means the Central Board of Excise and Customs constituted under the Central Board of Revenues Act, 1963.

3. Cannabis:

a. Charas, that is, the separated resin, in whatever form, whether crude or purified, obtained from the cannabis plant and also includes concentrated preparation and resin known as hashish oil or liquid hashish.

b. Ganja, that is, the flowering or fruiting tops of the cannabis plant (excluding the seeds and leaves when not accompanied by the tops)

c. Any mixture, with or without any neutral material, of Ganja or Charas or any drink prepared from them.

4. Cannabis plant: means any plant of the genus cannabis.

5. Coco derivative:

a) crude cocaine, that is, any extract of coca leaf which can be used, directly or indirectly, for the manufacture of cocaine;

b) Ecgonine and all the derivatives of ecgonine from which it can be recovered

c) cocaine, that is, methyl ester of benzoyl-ecgonine and its salts;

d) all preparations containing more than 0.1 percent of cocaine

6. Coco leaf:

a) The leaf of the coca plant (except of a leaf from which all ecgonine, cocaine and any other ecgonine alkaloids have been removed)

b) Any mixture thereof with or without any neutral material; but does not include any preparation containing not more than 0.1 per cent of cocaine

7. Opium Poppy: It includes the plant of Papaver somniferum and other species of Papaver from which opium or any phenanthrene alkaloids can be extracted.

8. Illicit traffic:

a) Cultivation of coca plant or gathering any portion of coca plant
b) Cultivation of opium poppy or any cannabis plant
c) Engaged in manufacture, possession, sale, purchase, transportation, warehousing, import, export of NDPS
d) Dealing in NDPS
e) Handling or letting any premises for previously mentioned points
f) Financing any activity related to NDPS
g) Harbouring any person engaged in these activities 8. Abetting or conspiring related to NDPS

AUTHORITIES AND OFFICERS:

AUTHORITIES:

Subject to the provisions of the Act, the Central Government shall take all necessary steps which are necessary for implementation of the act Preventing and combating abuse of narcotic drugs and psychotropic substances and the illicit traffic.

1. Coordinate actions of Central govt. and State govt. officers and other authorities under this act.

2. Fulfil obligations under the International Conventions.

3. Assistance to the concerned authorities in foreign countries and concerned international organizations for prevention and suppression of illicit traffic in narcotic drugs and psychotropic substances.

4. Identification, treatment, education, aftercare, rehabilitation and social re-interaction of addicts.

OFFICERS OF CENTRAL:

Government Under the provision of this act Central Government may appoint the Narcotics Commissioner and such other officers as it thinks fit.

OFFICERS OF CENTRAL GOVERNMENT:

The Narcotics Commissioner shall, either by himself or through officer subordinate to him, exercise all powers and perform all functions relating to;

1. The supervision of the cultivation of the opium poppy and
2. Production of opium
3. Other powers and functions as may be entrusted to him by the Central Government.

OFFICERS OF THE STATE GOVT:

State govt may also appoint officers similar to that appointed by central govt. for the administration of this act

THE NARCOTIC DRUGS AND PSYCHOTROPIC SUBSTANCES CONSULTATIVE COMMITTEE:

Constituted by Central Govt. to advise them in matters related to the administration of this act.

- The committee consist of Chairman, and other members not exceeding 20.
- The committee has power to regulate its own procedure
- This committee can further constitute one or more subcommittee to execute its function.
- The term of office, filling of casual vacancies, remuneration and allowances is as prescribed by central govt.

NATIONAL FUND FOR CONTROL OF DRUG ABUSE:

The Central Government by notification in Official Gazette creates National Fund for implementing various measures to control the drug abuse. The money generated is from:

1. The grant approved by the Parliament,
2. Sale proceedings of property confiscated or forfeited during the raids by the officers.
3. Financial support from individuals or institutes which is usually, income-tax free.
4. Any income from investments of amounts credited. National Fund for Control of Drug Abuse

- The fund is to be used for preventing or combating illicit traffic of NDPS, controlling drug abuse, educating masses, rehabilitation of drug addicts, etc.
- The Central Government constitutes the Governing Body of 6 members out of which one is appointed as Chairman who is not below the rank of additional secretary in Central Government.
- The Annual Report covering the activities of the Governing Body and utilization of the national fund is submitted to the Central Government and placed before the Parliament.

PROHIBITION, CONTROL AND REGULATION:

Section 8 of this act prohibits certain operations i.e. No person shall

1. Cultivate any coca plant or gather any portion of coca plant.
2. Cultivate the opium poppy or any cannabis plant.
3. Produce, manufacture, possess, sell, purchase, transport, warehouse, use, consume, import inter- State, export inter-State, import into India, export from India or trans-ship any narcotic drug or psychotropic substance, except for medical or scientific purposes.

PERMISSION AND REGULATION OF CERTAIN OPERATIONS BY CENTRAL GOVT:

- Cultivation and collection of any portion of coca plant.
- Cultivation of opium poppy and cannabis plant.
- Production and manufacture of opium and production of poppy straw.
- Sale of opium and its derivatives to state govt or manufacturing chemist.
- Manufacture of manufactured drugs.
- Manufacture, possession, sale, purchase, transport, consumption of psychotropic substances.
- Import and export of NDPS.

CONTROL OF CERTAIN OPERATIONS BY CENTRAL GOVT:

- License-time limits for Cultivation of opium poppy
- The land cultivated with the opium poppy, shall be delivered by the cultivators to the officers authorized in this behalf by the Central Government.
- Price fixation
- Forms and conditions for license for Cultivation, mfg., sale etc. and fees to be charged for that.
- Forms and conditions for license for the manufactured drugs.
- Opium shall be weighed, examined and classified according to its quality. Payments should be made accordingly.
- Confiscation of adulterated opium.
- Fees to be charged for Import and export of NDPS.

FACTORIES OF NDPs:

Two govt factories:

1. Neemuch in Madhya Pradesh, near Udaipur

2. Ghazipur in UP, near Varanasi.

CULTIVATION OF OPIUM POPPY FOR POPPY HEADS:

- The license holder should pay duty on the area which he cultivates poppy, at rates fixed by the state govt.
- Licensee Should neither consume any part of the crop himself or to others.
- If doesn't sow before 1st Dec in any year, he should surrender license to officer in charge of tehsil before 15th Dec.
- Shouldn't extract any opium from heads.
- Can sell to any person holding license for retail or whole sale of opium or to person authorized by state govt.
- Licensee should comply with all provisions of the opium act 1878, dangerous drugs act 1930, and NDPS act 1985 and rules.

PRODUCTION AND SUPPLY OF THE OPIUM:

Only on behalf of central govt license granted for following purpose.

➢ Cultivation can be done only in those areas, notified by the govt.

➢ Licenses are granted by district opium officers for cultivation. He appoints one licensed cultivator who performs duties as specified by narcotic commissioner with help of small cultivators under him.

➢ Harvest of each day's collection is weighed and entered in records which is signed by cultivator. The records are checked by the dist. opium officer. The whole opium collected by the dist. Officer is then delivered to opium factory.

➢ The cultivators are paid and they should not dispose of any part of the procedure and adulteration is liable for confiscation.

➢ Cultivator should cultivate full area of land for which he may have received advance amount from the govt.

MANUFACTURE OF MANUFACTURED DRUGS:

Morphine, thebaine, dihydro-morphine, codeine, dihydro codeine and salts are manufactured at govt factory, Ghazipur.

- Manufacture of crude cocaine, cocaine salts, ecgonine, diacetylmorphine and its salt is prohibited.
- Manufacturing of cocaine and its salt is prohibited, except cocaine hydrochloride which can be prepared from confiscated cocaine only.
- Medicinal hemp manufacture shall be under license issued by chief excise authority of the state govt.
- Manufacture of synthetic drugs is prohibited, except it is under the authorized license granted by narcotic commissioner on govt behalf.

SALE OF OPIUM:

- Sale to state govt on order of central govt.
- Sale to manufacturing chemists or other can be affected only under the permit of state govt.
- The permit application includes Purpose, Stock in hand on date, Quantity required, Requirements for 6 months.
- 3 copies of the application is sent to the factory.
- Price fixed by central govt and it shall be per Kg.
- Amount sanctioned to purchase opium shall be sent to the factory by bank draft along with purchase order.
- Sale of opium mixtures are prohibited except in act with rules prescribed by state govt

OFFENSES AND PENALTY:

OFFENCES	PENALTIES
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 Fine between `1 to 2 lacs or more.

ii. Illegal import or export or external dealings in narcotic drugs or psychotropic substances. iii. Allowing use of premises, 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.	
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.
i) Failure to keep accounts or submit returns as required by law or keeping of false accounts or making of false statements. ii) Failure to produce licences, permits, authorisations, etc., on demand by authorised persons. 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.	Rigorous imprisonment for up to 5 years or fine or both. Rigorous imprisonment for up to 3 years or fine or both
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.
i) Illegal possession for personal consumption or consumption of substances other than those mentioned under point 4. Rigorous imprisonment for up to 6 months or fine. ii) Offences for which no punishment is separately provided.	
Abetment/attempt of above	Same punishment as for the main offence.

SUMMARY:

1. Enacted in 1985 to consolidate and amend laws relating to narcotic drugs and psychotropic substances.
2. Aims to prevent and control the abuse of narcotic drugs and psychotropic substances.
3. Defines narcotic drugs and psychotropic substances, including opium, coca, cannabis, and synthetic drugs.
4. Prohibits the production, manufacture, possession, sale, and use of narcotic drugs and psychotropic substances except for medical and scientific purposes.
5. Establishes the Narcotics Control Bureau (NCB) to coordinate and enforce the Act.
6. Sets penalties for offenses, including imprisonment and fines, with stricter penalties for repeat offenders.
7. Provides for the forfeiture of property and assets derived from illicit drug activities.
8. Allows for the detention of individuals suspected of drug-related offenses for up to 180 days without trial.
9. Establishes the Central and State Fund for Controlled Substances to support drug abuse prevention and treatment programs.
10. Empowers the government to make rules and regulations to implement the Act and to amend the schedules of controlled substances as needed.

Note: The NDPS Act has undergone several amendments since its enactment, and this summary is a general overview of the Act's main provisions.

CHAPTER 7
STUDY OF SALIENT FEATURES OF DRUGS AND MAGIC REMEDIES ACT AND ITS RULES

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.
- These tricks are mainly applied on the innocent people, and they end up 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.

OBJECTIVE:

- To control certain types of the advertisements relating to drugs.
- To prohibit certain kinds of advertisements relating to magic remedies which falsely claim and mislead public.
- To provide for matters related therewith.

DEFINITIONS:

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 diagnosis, cure, mitigation, prevention, or treatment of diseases in human beings or animals, 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.

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, atherosclerosis, 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, infantile paralysis, insanity, leprosy, and leukoderma.

2) Advertisements providing false impression about any drug or making false claims for it, or if the advertisements are false and misleading.

3) Advertisement of magic remedies, claiming to be efficient in any conditions produced by the person, who wants to carry on the profession of administering magic remedies.

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 believes 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 advertisement cannot be separated from such document because of being imprinted, without altering its integrity, utility, or saleable value,

iii) Examine any record, register, document, or any other material found in a place mentioned in (i) and seize the same, if he 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.

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 onafide 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 permission 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.

OFFENCES AND PENALTIES:

OFFENCES	PENALTIES
Practicing unauthorized magic remedies	Fine of up to Rs.10,000.
Selling unapproved magic remedies	Fine up to Rs. 20,000
Distributing harmful magical remedies	Fine up to Rs. 50K or imprisonment for up to 15 years.
Advertising false magical remedies	Fine up to Rs.5000 and community service.

Possession of banned magical ingredients	Fine up to Rs. 2000 or imprisonment up to 2 years.
Performing unauthorized magical rituals	Fine up to Rs. 30K or imprisonment for upto 8 years.

SUMMARY:

1. Prohibits advertisements of drugs and remedies that make false or misleading claims.
2. Defines "magic remedy" as any substance or treatment claimed to have miraculous properties.
3. Bans advertisements of drugs and remedies for certain diseases, like cancer, HIV, and infertility.
4. Restricts advertisements of drugs and remedies that claim to enhance sexual performance or fertility.
5. Requires advertisements to comply with specified standards and guidelines.
6. Empowers the government to regulate and prohibit advertisements.
7. Sets penalties for offenses, including fines and imprisonment.
8. Establishes the Central Drugs Standard Control Organization to oversee enforcement.
9. Allows for the seizure of advertisements and materials that violate the Act.
10. Provides for rules and regulations to implement the Act and restrict misleading advertisements.

Key rules:

- No advertisement can claim a drug or remedy can cure diseases like cancer, HIV, or infertility.
- Advertisements must not be misleading or false.
- Advertisements must comply with specified standards and guidelines.
- Advertisements must not promote self-medication or misuse of drugs.

Note: This Act and its rules aim to protect consumers from false or misleading claims about drugs and remedies.

CHAPTER 8
STUDY OF ESSENTIAL COMMODITIES ACT RELEVANT TO DRUGS PRICE CONTROL ORDER

INTRODUCTION:

Commodities:

The term commodities use in the 15th century, which means to benefit or profit.

- The Essential Commodities Act is an act of Parliament of India which was established to ensure the delivery of certain commodities or products
- The supply of which if hoarding or black marketing would affect the normal life of the people. This includes foodstuff, drugs, fuel (petroleum products) etc.

HOLDING OR BLACKMARKETING EXAMPLE:

Petrol bank

Producer receives 10 litres

Petrol demand Chance of black-marketing

Poverty people will not suffer.

PURPOSE OF THE ACT:

- Passed on April 1, 1955
- The main purpose of this Act was to control the production, distribution and supply of these commodities

PRODUCTION, DISTRIBUTION AND SUPPLY:

1.Waste land

central government

Cultivation of rice

environmental

Export rice to Punjab and import wheat from other state to our state.

2.Synthetic or natural Source collected

Manufactured in suitable dosage form

Distributed into our and central Different state government — Central Government

Whole sale retail sale

Central Government

Consumer

HISTORY OF ACT:

- The central government has listed a number of commodities as essential commodities -In 1989, 70 essential commodities were listed under the act and presently only 7 commodities are listed
- From February 2002, 11 commodities were removed
- 31 march 2004, 50 commodities removed.

ESSENTIAL COMMODITIES:

Presently only 7 commodities are listed

- Drugs;
- Fertilizer, inorganic, organic or mixed;
- Foodstuffs, including edible oilseeds and oils;
- Hank yarn made wholly from cotton;

- Petroleum and petroleum products;
- Raw jute and jute textile;
- Seeds:

(i) seeds of food-crops and seeds of fruits and vegetables;
(ii) seeds of cattle fodder; and
(iii) jute seeds. Recently cotton seed was also included in the list

MAJOR AMMENDMENT:

- ✓ 1997-oil seed storage control order
- ✓ 1980 – prevention of black marketing
- ✓ 1981 -Special provision (food material) act
- ✓ 1995 – drug price order
- ✓ 2001 – restriction like license requirement
- ✓ 2005 – consumer affair
- ✓ 1995 – interest amount reduced farmers
- ✓ 1993 – kerosene price control
- ✓ 2000 – regulate supply and distribution petroleum
- ✓ 2010 – sugar price control

FUNCTION OF ESSENTIAL COMMODITIES:

- To ensure the easy availability of essential commodities to consumers
- Regulate production and manufacturing
- Fair price central government can declare it essential commodity
- Increasing suppliers
- Manufacture good quality of the product
- Maintaining proper financial transaction
- Maintain records and documents
- Implemented by the State Governments – Delegated Powers under the Act. Example: food product we need more means government will be increase cultivation

ACT CHECKING:

State Governments/ Union Territories

1. Himachal Pradesh
2. Bihar
3. Maharashtra
4. Uttar Pradesh, etc

- Impose stock or turnover limits for various commodities
- Penalize those who hold in excess of the limit.
- Act fixed the fair price. Everyone is following or not they will check.

POWER UNDER THE ACT:

- Section 3 – Power of Central Government
- Regulate or prohibit the production, supply and distribution, trade and commerce of any essential commodity
- Regulate by licenses, permits or otherwise: the production or manufacture of any essential commodity storage, transport, distribution, disposal, acquisition, consumption
- Cultivate food crops on any waste land
- District Collector will be checking the commodities
- If the Collector is satisfied that there has been a contravention of the order may order confiscation

RULE OF ESSENTIAL COMMODITY ACT:

Animal used for agriculture
Like ox

Animal killed and used to prepare food product or latherer material means

EC act should not accept this product

OFFENCES AND PENALTIES:

OFFENCES	PENALTIES
Hoarding or Black marketing	Imprisonment up to 7 years or fine.
Price manipulation	Imprisonment up to 5 years or fine.
Counterfeiting or adulteration	Imprisonment up to 7 years or fine.
Violation of Price Control Regulations	Fine or imprisonment depending on the severity of breach.
Violation of export or import restrictions	Fine or imprisonment depending on the severity of breach.

CHAPTER 9
DRUG PRICE CONTROL ORDER & NATIONAL DRUG POLICY(CURRENT)

INTRODUCTION:

- Introduced by Central Govt. in order to exercise the powers confirmed by section 3 of the Essential Commodities act, 1955.
- For enabling the Government to declare a ceiling price for essential and lifesaving medicines (as per a prescribed formula) so as to ensure that these medicines are available at a reasonable price to the general public.
- The latest Drug Price Control Order (DPCO-2013) was issued on 15.05.2013.
- Drug prices are monitored and controlled by the National Pharmaceutical Pricing Authority (NPPA).
- All the powers of Government of pricing according to Essential Commodities Act have been delegated to it.
- Under DPCO, 2013 the powers to review are entrusted with the Government. Hence, the Department of Pharmaceuticals is the reviewing authority whenever pharmaceutical companies file review petitions against any price fixation done by NPPA.
- National Pharmaceutical Pricing Policy (NPPP) is the policy governing price control and DPCO is the order by which price control is enforced.
- The Drug Price Control Orders are issued by Ministry of Chemicals and Fertilizers, which is the main nodal administrative ministry for pharmaceutical companies.
- They are issued under the "Essential Commodities Act 1955 whereby certain medicines could be declared to be essential commodities.

OBJECTIVES:

- To achieve adequate production
- To regulate equal distribution
- To maintain and increase supply of bulk drugs and formulations.
- To make these available at fair prices.

DEFINITION:

- **Active pharmaceutical ingredients or Bulk drug-** means any pharmaceutical, chemical, biological or plant product including its salts, esters, isomers, analogues and derivatives, conforming to pharmacopeial standards specified in the Drugs and Cosmetics Act, 1940 and which is used as such or as an ingredient in any formulation.
- **Schedule bulk drug-**means a bulk drug specified in the First Schedule.
- **Scheduled formulation-**means any formulation, included in the First Schedule whether referred to by generic versions or brand name.
- **Brand-**name, term, design, symbol, trademark or any other feature that identifies one seller's drug as distinct from those of other sellers
- **Ceiling price-**means a price fixed by the Government for Scheduled formulations in accordance with the provisions of this Order.
- **Dealer-**person carrying on the business of purchase or sale of drugs, whether as a wholesaler or retailer and includes his agent.
- **Distributor**-means a person engaged in the work of distribution of drugs and includes an agent or a stockist for stocking drugs for resale to a dealer.
- **Generic version of a medicine-**means a formulation sold in pharmacopeial name or the name of the active pharmaceutical ingredient contained in the formulation, without any brand name.
- **Local Taxes-**means any tax or levy (except excise or import duty included in retail price) paid or payable to the 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.
- **Maximum retail price-**means the ceiling price or the retail price plus local 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.
- **Pharmacoeconomics-**means a scientific discipline that compares the therapeutic value of one pharmaceutical drug or drug therapy to another.
- **Price to retailer-** means the price of a drug at which it is sold to a retailer which includes duties and does not include local taxes.
- **Scheduled formulation-**means any formulation, included in the First Schedule whether referred to by generic versions or brand name.

- **Sale turnover-**means the product of units of formulations sold by manufacturer or an importer in an accounting year multiplied by retail price inclusive of sales tax, if any paid on direct sales by the manufacturer or importer. It does not include excise duty and local taxes.

PRICE OF BULK DRUGS:

1. Govt. has right to fix the maximum sale price of the drugs

2. While fixing the price govt. shall take into consideration following-

I. Post tax return of 14% on net worth OR
II. Return of 22% on capital employed OR
III. For new plant, a rate of return of 12% based on long term marginal costing.
IV. In case of production is from basic stage, a post tax return of 18% on net worth or 26 % on capital employed.

3.Provided further that the option with regard to the rate of return once exercised by a manufacturer shall be final and no change of rates shall be made without the prior approval of the Government.

4. No person shall sell a bulk drug at a price exceeding the maximum sale price fixed as per the provision of this order plus local taxes if applicable.

RETAIL PRICE OF FORMULATION:

Formulation for calculation: -

R.P = (M.C+ C.C+ P.M+ P.C) *(1+MAPE/100) +E.D.

where, R.P =retail price

M.C =material cost
C.C =conversion cost
P.M =packing material cost
P.C =packing charges
E.D =excise duty
MAPE =maximum allowable post manufacturing expenses.

1. **R.P-**means retail price.
2. **M.C-**means material cost and includes the cost of drugs and other pharmaceutical aids used including overages, if any, plus process loss there on specified as a norm from time to time by notification in the Official Gazette in this behalf.
3. **C.C-**means conversion cost worked out in accordance with established procedures of costing and shall be fixed as a norm every year by notification in the Official Gazette in this behalf.

4. **P.M-**means cost of the packing material used in the packing of concerned formulation, including process loss, and shall be fixed as a norm every year by notification in the Official Gazette in this behalf.
5. **P.C-**packing charges worked out in accordance with established procedures of costing and shall be fixed as a norm every year by notification in the Official Gazette in this behalf.
6. **MAPE (Maximum Allowable Post-Manufacturing Expenses)-means** all costs incurred by a manufacturer from the stage of ex- factory cost to retailing and includes trade margin and margin for the manufacturer and it shall not exceed one hundred per cent for indigenously manufactured Scheduled formulations.
7. **E.D-**means excise duty- in the case of an imported formulation, the landed cost shall form the basis for fixing its price along with such margin to cover selling and distribution expenses including interest and importer's profit which shall not exceed fifty per cent of the landed cost.

CALCULATION OF CEILING PRICE OF A SCHEDULED FORMULATION:

Step1.- Calculation of Avg. price P(s) to retailer

Average Price to Retailer, P(s) = (Sum of prices to retailer of all the brands and generic versions of the medicine having market share more than or equal to one percent 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 one percent of total market turnover on the basis of moving annual turnover for that medicine.)

Step2- Calculation of ceiling price

P(c) P(c) = P(s)* (1+M/100),

where P(s) = Average Price to Retailer for the same strength and dosage of the medicine as calculated in step1 above.

M = % Margin to retailer and its value =16.

The ceiling price calculated as per sub-paragraph (1) and notified by the Government shall be applicable to scheduled imported formulations also.

CALCULATION OF RETAIL PRICE OF A NEW DRUG FOR EXISTING MANUFACTURERS OF SCHEDULED FORMULATIONS:

(1) The retail price of the new drug (Ps) available in domestic market shall be calculated as provided in sub-paragraph (1) of paragraph 4.

(2) (i) the price to retailer of a new drug, not available in domestic market, shall be fixed by the Government on the principles of "Pharmacoeconomics" of the new drug, on the recommendation of a Standing Committee of Experts.

(ii) the retail price of such new drug shall be fixed by adding 16% margin to retailer on the price to retailer as fixed in item (i).

OFFENCES AND PENALTIES:

OFFENCES	PENALTIES
Selling goods above the prescribed price	Fine up to Rs. 10000
Hoarding or black-marketing essential goods	Fine up to Rs. 20000
Falsifying price tags or labels.	Fine up to Rs. 50000
Refusing to comply with price regulations.	Fine up to Rs. 15000

SUMMARY:

- Introduced by the Central Government under the Essential Commodities Act, 1955, to regulate the pricing of essential and lifesaving medicines.
- Aims to ensure that these medicines are available at reasonable prices to the public.
- The latest order, DPCO 2013, was issued on May 15, 2013.
- The National Pharmaceutical Pricing Authority (NPPA) monitors and controls drug prices.
- The Department of Pharmaceuticals reviews pricing decisions when pharmaceutical companies file petitions.

Objectives:

- Achieve adequate production of medicines.
- Regulate fair distribution and maintain adequate supply.
- Ensure availability of medicines at reasonable prices.

Key Definitions:

- **Active Pharmaceutical Ingredients (API): The** main component of a drug, which is regulated.
- **Ceiling Price:** Maximum price set by the government for scheduled formulations.
- **Retail Price:** The price at which drugs are sold to consumers, including taxes and duties.
- Scheduled Formulations: Medicines listed in the First Schedule of the DPCO.
- **Pharmacoeconomics:** A discipline comparing the therapeutic value of different drugs.

Price of Bulk Drugs:

Government has the right to fix maximum sale prices for bulk drugs, considering post-tax return, capital employed, or production costs.

The manufacturer must seek approval for any price changes.

Retail Price Calculation:

Formula: R.P = (M.C + C.C + P.M + P.C) * (1 + MAPE/100) + E.D
M.C: Material cost.
C.C: Conversion cost.
P.M: Packing material cost.
P.C: Packing charges.
MAPE: Maximum allowable post-manufacturing expenses (up to 100%).
E.D: Excise duty.

Ceiling Price Calculation for Scheduled Formulations:

Average Price to Retailer (P(s)) is calculated based on market share.

Ceiling Price (P(c)) is determined by adding a 16% margin to the average price.

Retail Price of New Drugs:

For existing drugs: Retail price is calculated based on the average price.

For new drugs not available domestically, the price is set using Pharmacoeconomics principles, with a 16% margin added for retailers.

Offences and Penalties:

- Selling goods above prescribed price: Fine up to ₹10,000.
- Hoarding or black-marketing: Fine up to ₹20,000.
- Falsifying price tags/labels: Fine up to ₹50,000.
- Refusing to comply with price regulations: Fine up to ₹15,000.
- This framework ensures that drug prices remain controlled, with penalties for violations to protect public health interests.

CHAPTER 10
PREVENTION OF CRUELTY TO ANIMALS ACT-1960

INTRODUCTION:

The Prevention of Cruelty to Animals Act, 1960 (59 of 1960) amended by Central Act 26 of 1982.

(1) This Act may be called the Prevention of Cruelty to Animals Act, 1960.

(2) It extends to the whole of India except the State of Jammu and Kashmir.

(3) It shall come into force on such date as the Central Government may, by notification in the official Gazette, appoint, and different dates may be appointed for different States and for the different provisions companied in this Act.

LAWS FOR ANIMALS:

- ✓ The Indian Penal Code,1860
- ✓ The Criminal Procedure Code,1973
- ✓ The Prevention of Cruelty to Animals Act, 1960
- ✓ The Wildlife Protection Act, 1972

OBJECTIVE:

To prevent the infliction of unnecessary pain or suffering on animals as well as to prevent cruelty to animals.

DEFINITION:

1. Domestic animal-means any animal which is tamed or which has been or is being sufficiently tamed to serve some purpose for the use of human or which, although it neither has been nor is intended to be so tamed, is or has become in fact wholly or partly tamed.

2. Captive animal-any animal (not being a domestic animal) which is in capacity or confinement, whether permanent or temporary, or which is subjected to any appliance

of contrivance for the purpose of hindering or preventing its escape from captivity or confinement or which is pinioned or which is or appears to be maimed.

3. Experimentation of animals-advancement by new discovery of physiological knowledge or II. knowledge which will be useful for saving or III. for prolonging life or IV. alleviate suffering or V. for combating any disease, whether of human beings, animals or plants.

COMMITTEE FOR THE PURPOSE OF CONTROL AND SUPERVISION OF EXPERIMENTS ON ANIMALS (CPCSEA):

➢ Constituted by Central Govt

➢ CG nominates one of the members as chairman

➢ Committee has power to regulate its own procedure

➢ CG gives grants and funds to CPCSEA

➢ Subcommittee can be formed to execute various functions

➢ Committee may appoint staff members, officers and other employee.

DUTIES AND POWERS OF THE COMMITTEE:

- To take all such measures as may be necessary to ensure that animals are not subjected to unnecessary pain or suffering before, during or after the performance of experiments on them.
- the registration of persons or institutions carrying on experiments on animals is essential;
- the reports and other information which shall be forwarded to the Committee by persons and institutions carrying on experiments or, animals.

OBJECTIVES OF THE RULES MADE BY CPCSEA:

➢ In particular, and without prejudice to the generality of the foregoing power, rules made by the Committee shall be designed to secure the following objects, namely
I. In cases where experiments are performed in any institution, the responsibility therefore is placed on the person in charge of the institution. In cases where experiments are performed outside an institution by individual responsibility therefore is placed on the person. The individual person must be technically qualified and competent.

II. Experiments should care and humanity and that as far as possible experiments involving operations are performed under the influence of some anaesthetic of sufficient power to prevent the animals feeling pain.

III. that experiments on animals are avoided wherever it is possible to do so; as for example; in medical schools, hospitals, colleges etc. if other teaching devices such as books, models, films may equally suffice.

IV. that experiments on larger animals are avoided when it is possible to achieve the same results by experiments upon small laboratory animals like guinea-'pigs, rabbits, frogs and rats.

V. As for as possible, experiments are not performed merely for the purpose of acquiring manual skill.

VI. animals intended for the performance of experiments are properly looked after both before and after experiments.

VII. suitable records are maintained with respect to experiments performed on animals

➢ All rules made by the Committee shall be binding on all individuals performing experiments outside institutions and on persons in-charge of institutions in which experiments are performed

INSTITUTIONAL ANIMAL ETHICS COMMITTEE:

Functions:

To review and approve research proposals involving lab animals

1. To provide suggestions for modification of the proposals wherever necessary
2. To conduct periodic supervision of Institute's animal facility
3. To ascertain ethical use of animals and protection of well-being of animals during and after research. When research activity is not found in accordance with CPCSEA guidelines to help adopt correct measures.
4. To see that all those persons involved in animal care and research are adequately trained to handle the animals.
5. To ensure that GLP guidelines are followed in animal facility to protect the researchers and all others involved in animal handling.

CONSTITUTION OF IAEC:

I. Biological Scientist, Chairperson
II. Scientist In charge of Animal House Facility- Member Secretary
III. Scientist from different discipline (From different institute and from same institute)
IV. Veterinarian

V. CPCSEA Main Nominee
VI. Socially Aware Nominee
VII. Link Nominee

The IAEC is valid for a period of five years and is renewed after that period.

- Any change in IAEC members can be made only with prior approval of CPCSEA.
- IAEC is required to be reconstituted at the time of renewal of registration as per CPCSEA guidelines.
- It is required to convene the meeting of the reconstituted IAEC within a period of 30 days and upload the same on the website of the CPCSEA.
- Only above approved IAEC members shall sign, with date, on the attendance sheet of the IAEC meetings, and decisions will be taken only in meetings where quorum is complete.
- The quorum for holding IAEC meeting is six (6), and CPCSEA Nominees must be present in such meetings.
- Link Nominee can attend in case main nominee conveys his unavailability in writing to the chairman IAEC.
- Socially aware member's presence is compulsory in cases referred to CPCSEA and at least in one meeting in a calendar year.
- Any decision taken in the meetings of IAEC without quorum shall be considered invalid.
- Before commencing any research on large animals, it is required to send research protocols with due recommendation of IAEC to CPCSEA for further approval.
- The Main Nominee is requested to ensure that the IAEC meetings are held regularly as stipulated in the SOP of CPCSEA and submit the Annual Inspection Reports of the Animal House Facility regularly on the website of CPCSEA.

CRUELTY OF ANIMALS:

Treating animals cruelly

(1) If any person

a. Beats, kicks, over-rides, over-drives, over-loads, tortures or otherwise treats any animal so as to subject it to unnecessary pain or suffering; or

b. Wilfully and unreasonably administers any injurious drug or injurious substance to (any animal) or wilfully and unreasonably causes or attempts to cause any such drug or substance to be taken by (any animal;)

c. Conveys or carries, whether in or upon any vehicle or not, any animal in such a manner or position as to subject it to unnecessary pain or suffering; or

d. Keeps or confines any animal in any cage or other receptacle which does not measure sufficiently in height, length and breadth to permit the animal a reasonable opportunity for movement; or

e. Keeps for an unreasonable time any animal chained; or

f. Being the owner, neglects to exercise or cause to be exercised reasonably any dog habitually chained up or kept in close confinement; or

g. Being the owner of (any animal) fails to provide such animal with sufficient food, drink or shelter; or

h. Without reasonable cause, abandons any animal in circumstances which tender it likely that it will suffer pain by reason of starvation thirst; or

i. Wilfully permits any animal, of which he is the owner, to go at large in any street, while the animal is affected with contagious or infectious disease or, without reasonable excuse permits any diseased or disabled animal, of which he is the owner, to die in any street; or

j. Offers for sale or without reasonable cause, has in his possession any animal which is suffering pain by reason of mutilation, starvation, thirst, overcrowding or other ill treatment; or

k. Promotes or takes part in any shooting match or competition wherein animals are released from captivity for the purpose of such shooting

OFFENCES AND PENALTIES:

OFFENCES	PENALTIES
Intentional cruelty	Fine up to Rs. 10,000 or imprisonment up to 5 years.
Neglect or Abandonment	Fine up to Rs. 50000 or imprisonment up to 2 years.
Animal Fighting	Fine up to Rs. 20000 or imprisonment up to 7 years.
Transporting inhumane conditions	Fine up to Rs. 2,500 or imprisonment up to 6 months.
Torture or Maiming	Fine up to Rs. 15,000 or imprisonment up to 3 years.
Failure to provide adequate care	Fine up to Rs. 3000 or imprisonment up to 1 year.

SUMMARY:

1. Aims to prevent cruelty to animals and promote animal welfare.
2. Defines "animal" to include all living creatures except humans.
3. Prohibits cruelty to animals, including beating, kicking, or torturing.
4. Bans animal fighting, baiting, and organized animal races.
5. Regulates the use of animals for scientific research and experimentation.
6. Requires humane treatment and housing of animals in captivity.
7. Sets standards for animal transportation and slaughter.
8. Prohibits the use of animals for entertainment, like circuses and zoos.
9. Empowers animal welfare organizations to inspect and report cruelty.
10. Establishes the Animal Welfare Board of India to oversee enforcement.
11. Provides for penalties, including fines and imprisonment, for cruelty offenses.
12. Allows for the seizure and rehabilitation of animals subjected to cruelty.
13. Regulates the sale and use of animal traps and snares.
14. Promotes education and awareness about animal welfare.
15. Enables the government to make rules and regulations to implement the Act.

Key aspects:

- Protects animals from cruelty and promotes welfare
- Regulates animal use in research, entertainment, and transportation
- Empowers animal welfare organizations and government agencies
- Provides penalties for cruelty offenses
- Promotes education and awareness about animal welfare

Note: This Act aims to prevent animal cruelty and promote welfare in India, and its provisions have been amended and updated over the years.

CHAPTER 11
PATENTS & DESIGN ACT-1970

THE PATENT ACT AND RULES:

- A patent is intellectual property right relating to inventions and is the grant of exclusive right, for Limited period by the government to the patentee, in exchange for full disclosure of his invention, for excluding others from making, using, selling, importing the patented product or process producing that product for those purposes.
- The purpose of this system is to encourage inventions by promoting their protection and utilisation so as to contribute to the development of industries, which in turn, contributes to the promotion of technological Innovation and to the transfer and dissemination of Technology.
- The Patent Act 1970 came into force on the 20th April, 1972 and extends to the whole of India.

DEFINITIONS:

1. "assignee" includes an assignee of the assignee and the legal representative of a deceased assignee and references to the assignee of any person Include references to the assignee of the legal representative or assignee of that person.

2. "Patent" means a patent for any invention granted under this act.

3. "patentee"means the person for the time being entered on the register as the grant for proprietor of the patent.

TYPES OF PATENTS: There are four types of patents under the act,

1. ordinary patents
2. patents of addition
3. convention application with priority date claiming on the basis of filing in convention countries and
4. National phase applications under PCT.

PATENT COOPERATIVE TREATY (PCT):

PCT is a law which is filed by one member and it is equally valid in all PCT member states. Patentable invention: an invention to be patentable should be technical in nature and should meet the following criteria;

a) novelty: The matter disclosed in the specification is not published in India or elsewhere before the date of filing of the patent application in India.

b) inventive step: the invention is not obvious to a person skilled in the light of the friar publication/ knowledge/document.

c) industrially applicable: invention should possess utility so that it can be made or used in the industry.

INVENTIONS NOT PATENTABLE: the following are not invention within the meaning of this act and hence are not patentable-

a) An invention which is frivolous or which claims anything obviously contrary to well established natural laws;

b) And invention, the primary or intended use or commercial exploitation of which would be contrary to public order or morality or which causes serious prejudice to human, animal or plant life for health or to the environment.

c) The main discovery of a scientific principle is the formulation or discovery of any living thing or non-living substance occurring in nature.

d) A substance obtained by a mere admixture resulting only in the aggregation of the properties of the components thereof for a process for producing substance;

e) method of agriculture for horticulture;

f) plants or animals is whole or any part thereof other than microorganisms but including seeds, varieties and species and essentially biological processes for production or propagation of plants and animals;

g) A mathematical or business method or a computer program algorithm;

h) scheme for rule or method of performing mental act or method of playing game;

i) representation of information;

j) topography of integrated circuits;

k) An invention which, in effect, is traditional knowledge or which is an aggregation or duplication of known properties of traditionally known components of components.

APPLICATION FOR PATENTS: an application for a patent for an invention may be made by any one of the following persons either alone or jointly with any other person-

a) any person claiming to be the true and first inventor of the invention;

b) any person being the assignee of the person claiming to be the true and first inventor in respect of the right to make such an application;

c) the legal representative of any deceased person who immediately before his death was entitled to make such an application.
Every application for a patent shall be for one invention only and shall be made in the prescribed form and filed in the patent office. Every application shall be accompanied by a professional or complete specification.

PROVISIONS AND SPECIFICATION: an application for the patent is accompanied by a provisional specification, a complete specification or shall be filed within 12 months in this duration the controller may, if the applicant so request within 12 months from the date of filing of the application that such specification shall be treated as a provisional specification that shall be done.

CONTENTS OF SPECIFICATION: Every specification, whether provision or complete, shall describe the invention and shall begin with the title sufficiently indicating the subject matter to which the invention relates. Every complete specification shall-

a) fully and particularly describe the invention and its operation or use and the method by which it is to be performed;

b) disclose the best method of performing the invention which is known to the applicant and for which he is entitled to claim protection and

c) End with the claim or claims defining the scope of the invention for which production is claimed;

d) be accompanied by an abstract to provide technical information on the invention. Priority dates of claims of complete specification: there shall be priority date for each claim of complete specification where a complete specification is filed and claim then it is fairly based on undisclosed matter and specification. the priority date of the claims shall be the date of relevant specification.

PATENT OFFICE: The patent office has its head office at Kolkata and branch offices at Mumbai, Delhi and Chennai.

PUBLICATION AND EXAMINATION OF APPLICATION: For patent shall be open to the public for such period until the controller permits for the publication of patent. No detailed disclosure of the patent should be done before the expiry of the prescribed period.

RIGHTS OF PATENTEES: A patent granted under this act shall confirm upon the patentee-

a) Where the subject matter of a patent is a product, the exclusive right to prevent third parties from the act of making, using, offering for sale, selling or importing for those purposes that products in India.

b) where the subject matter of a patent is the process, the exclusive right to prevent third parties from the act of using that process and from the act of using offering for sale, selling for importing for those purposes.

TERMS OF PATENT: The term of every patent which has not expired or ceased from the date of commencement 20 years will be counted from the date of filing.

PATENTS OF ADDITION: "Patent of addition" means a patent granted in accordance with section 54; a patent of addition shall not be granted before the grant of the patent for the ' main invention'.

REVOCATION OF PATENTS: Patent, whether granted before or after the commencement of this act may be revoked by the appellate board/ High Court or any e one of the following grounds-

a) that the invention, so far as claimed in any claim of the complete specification, was claimed in a valid claim of earlier priority date contained in the complete specification of another patent granted in India;

b) that the patent was granted on the application of a person not entitled to apply therefor;

c) that the person was obtained wrongfully in contravention of the rights of the petitioner or any e person under through whom he claims;

d) For want of sufficient disclosure where any claim of complete specification is not vary based on the matter disclosed in the specification;

e) that the patent was obtained on a false suggestion for representation;

f) that leave to amend complete specification was obtained by fraud.

REGISTER OF PATENTS: Register of patents is kept at the patent office in which are entered- a) the names and addresses of the grantees of patent;

b) notification of assignments and of transmission of patents, of licences Under patents amendments, extensions, and revocation of patents; and

c) particulars of such matters affecting the validity or proprietorship of patents as may be prescribed.

THE DESIGN ACT AND RULES:

In 1911, the deigns act was passed by the British government in India. Since then, extensive amendments have been made in the designs act. To provide more effective protection to registered designs and to promote design activity in order to promote design elements in an article of production it became necessary to make the legal system of providing protection to industrial designs more efficient.

REGISTRATION OF DESIGNS: The controller general of patents, designs and trademarks appointed under the trade and Merchandise marks act shall be the controller of designs for the purposes of this act.

The central government can appoint as many examiners and other officers with such designations as it may think fit.

Proprietor of any new or original design, not previously published in any country, and which is not contrary to public order or morality, should file his application for registration to the controller general of patents, designs and trademarks.

Four copies of the Representation of the design and the application shall accompany such an application and each copy of representation of the design shall be dated and signed by the applicant for his agent.

The registered proprietor of a design shall have power absolutely to assign, grant licences as to, or otherwise deal with, the design and to give effectual results for any consideration for any set assignment, licence or dealing.

Copyright in registered designs: when a design is registered the registered proprietor of the design shall have copyright in the design during 10 years from the date of registration. this period of copyright may be extended further for a second period of 5 years if application in prescribed manner is made to the controller.

The controller could restore registration of lapse design if the register had ceased to have effect by reason of failure to pay the fee; on receipt of necessary application, statement verified in the prescribed manner and on payment of prescribed fee.

During the existence of copyright in a design, any person furnishing such information may enable the controller to identify the designed and non-payment of the prescribed fee may inspect the designs, certified copy of any registered design may be obtained on an application to the controller and on payment of prescribed fee.

PROHIBITION OF REGISTRATION OF CERTAIN DESIGNS:

The following designs cannot be registered-

a) a design which is not new original or

b) has been disclosed to the public in India aur any other country by Publication in tangible form or by use or in any other way prior to the filing date, or where applicable, the priority date of the application for registration, or

c) is not significantly distinguishable from known designs for combination of known designs; or d) Comprises or contains scandalous or obscene matters.

CANCELLATION OF DESIGN:

Petition for the cancellation of a registered design may be presented by any interested person to the controller on any of the following grounds-

a) that the design has been previously registered in India; or

b) that it has been published in India or in any other country prior to the date of registration; or

c) that the design is not a new or original design or

d) that the design is not registrable under this act or

e) That it is not a design as defined under the act Appeal against any order of controller under this section can be made to the high court.

Piracy of registered designs: during the existence of copyright in any design it shall not be lawful for any person –

a) for the purpose of sale to apply or cause to be applied to any article in any class of articles in which the design is registered, the design or any fraudulent obvious limitation thereof, except with the licence or written consent of the registered proprietor, or to do anything with a view to enable the design to be so copied or applied, or

b) to import for the purposes of sale coma without the consent of the registered proprietor, any article belonging to the class in which the design has been registered, and having applied to it the design or any fraudulent obvious limitation thereof, or

c) knowing that the design or any fraudulent obvious limitation thereof has been applied to any article in any class of articles in which the design is registered without the consent of the registered proprietor, to publish or expose or cause to be published or exposed for sale that article.

PENALTY:

OFFENCES	PENALTIES
Making a false representation to the patent office.	Fine up to Rs. 50K or imprisonment up to 6 months.
Patent infringement	Civil damages or fines determined by the court.
Design infringement	Fine up to Rs. 10K or imprisonment up to 3 years.
Filling a false application.	Fine up to Rs. 10K or imprisonment up to 1 year.

PROTECTION OF SECURITY IN INDIA:

Security of India means any action necessary for the security of India which relates to the application of any design registered under this act to any article used for war for Applied directly Ee or indirectly for the purposes of military establishments or for the purposes of War or other emergency in international relations. Notwithstanding anything contained in this act, the controller shall- a) not disclose any information relating to the registration of design or any application relating to the registration of a design under this act, which he considers prejudicial to the interest of the security of India; and b) Take any action regarding the cancellation of registration of such designs registered under this act which the central government may, by notification in the official gazette, specify in the interest of the security of India.

POWER TO MAKE RULES:

This act with the central government may, by notification in the official gazette in the interest of the central government may, by notification in the official gazette, make rules for carrying out the provisions of this act. every rule made act shall be laid before each house of parliament.

SUMMARY:

Patent Definition: A patent is an intellectual property right granted by the government for a limited period, allowing the patentee exclusive rights to prevent others from making, using, selling, or importing the invention.

Purpose: To encourage innovation, technological development, and industrial growth by protecting inventions.

Patent Types:

Ordinary Patents

Patents of Addition

Convention Applications (priority date based on foreign filings)

National Phase Applications under PCT (Patent Cooperation Treaty)

- **Patentable Inventions:** Must be novel, involve an inventive step, and be industrially applicable.

- **Non-patentable Inventions:** Includes scientific discoveries, methods for agriculture/ horticulture, computer programs, mathematical methods, traditional knowledge, and certain living organisms.

- **Application for Patents:** Can be filed by the true inventor, assignee, or legal representative of a deceased inventor. The application must include a specification describing the invention.

- **Patent Rights:** Grant the patentee exclusive rights to use or prevent the use of the invention in India for a 20-year period.

- **Revocation Grounds**: Includes lack of novelty, false representation, insufficient disclosure, and wrongful acquisition.

- **Patent Office:** Headquartered in Kolkata, with branches in Mumbai, Delhi, and Chennai.

- **Publication and Examination:** Patent applications are open to the public after a specified period for examination.

- **Patent of Addition:** Granted after the main patent is granted for improvements or modifications to the original invention.

Design Act and Rules:

- **Purpose:** To provide protection for new, original industrial designs, and to encourage design activity.
- **Registration:** Design applications should be filed with the Controller of Patents, Designs, and Trademarks. The design must be new, original, and not contrary to public morality.
- **Design Copyright:** The registered design owner has copyright protection for 10 years, which can be extended by an additional 5 years.
- **Prohibited Designs:** Designs that are not new, are scandalous, or are not significantly distinguishable from known designs cannot be registered.
- **Cancellation:** Designs can be cancelled if they were previously registered, not original, or if they fail to meet the legal criteria.
- **Piracy of Registered Designs:** Unauthorized use, sale, or importation of articles with the registered design is prohibited.

Penalties:

False Representation: Fine up to Rs. 50,000 or imprisonment up to 6 months.

- **Patent Infringement**: Civil damages or fines.
- **Design Infringement:** Fine up to Rs. 10,000 or imprisonment up to 3 years.
- **False Application:** Fine up to Rs. 10,000 or imprisonment up to 1 year.

Security of India:

The Controller may withhold information related to the design registration if it's deemed prejudicial to national security.

Rule-Making Power:

The central government can make rules to implement the provisions of the act, which must be laid before Parliament.

This summary provides an overview of the key points related to patents and designs under Indian law.

CHAPTER 12
BRIEF STUDY OF PRESCRIPTION AND NON-PRESCRIPTION PRODUCTS

INTRODUCTION:

- Medications include over-the-counter drugs (OTC) as well as prescription drugs.
- People often think drugs that do not require a doctor's prescription cannot be harmful.
- Over-the-counter drugs also can create problems if not used in the right way or sometimes if used at the same time as prescription medications.
- Because over-the-counter drugs are used so frequently and can have harmful effects, it is important to know the differences between prescription and over-the-counter drugs.

PRESRICPTION DRUGS:

- Require a written order or prescription from a physician, dentist, or nurse practitioner. This prescription tells a pharmacist to dispense a particular medication.
- Are prescribed to treat a specific medical problem.
- Are usually more powerful than over-the-counter drugs.

OVER-THE -COUNTER DRUGS:

- 'OTC drugs' means drugs legally allowed to sold over the counter by pharmacist.
- Over-the-counter (OTC) drugs are those available without a prescription.
- Are intended for things patients can treat with self- care.
- Are considered safe if warnings and directions are followed.

OTC DRUGS CATAGORIES:

COMMONLY USED OTC DRUGS:

- ✓ NORFLOX-TZ
- ✓ IBUPROFEN
- ✓ I-PILL
- ✓ REVITAL
- ✓ PARACETAMOL
- ✓ BENADRYL

INTERESTING FACTS OF OTC:

- Over-the-counter drug market in India ranks eleventh in the global OTC market and is expected to reach the ninth position within the next five years.
- The Indian OTC market is estimated to be worth $19 billion with an annual growth rate of 23%.
- An estimated 3 out of 4 people routinely self-medicate with these drug products.

SWITCHING POLICY OF FDA:

- The FDA is attempting to make more drugs available to the general public by switching some frequently used and safe prescription drugs to OTC status.
- More than 700 OTC products on the market today use ingredients or dosages, that were available only by prescription, less than 30 years ago.

OTC MEDICATIONS ARE SFE BUT NOT RISK-FREE:

- As with all medications, there can be risks with use. The risks of OTC use include:
- Delay in seeking medical advice for a serious illness.
- Risk of drug-drug/herbal/dietary supplement interactions.

- Risk of adverse events.
- Potential for dependence, misuse and abuse.

IN WHAT WAYS THE OTC DRUGS CAN BE HARMFUL:

- OTC drugs can change the effect of prescription medications.
- OTC drugs can mask symptoms of disease.
- OTC drugs can lead to overdose.
- If misused even common over-the-counter drugs, such as aspirin, vitamins, or cold remedies can be harmful.

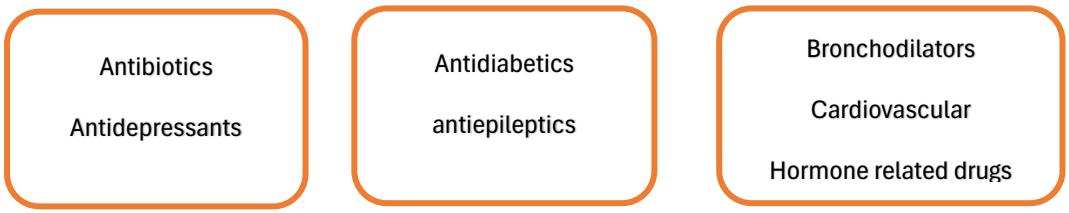
MISUSE AND ABUSE:

Recent Survey have reported that:

i. In one survey it has been found that only 16% reads the entire product label.
ii. If they read them, they do not follow the directions on the label.
iii. Abuse is most common in adolescents aged 10-17 years.
iv. Adolescents are 18% times more likely to dies from an OTC overdose than from a illicit drug dose overdose.

ABOUT PRESCRIPTION DRUGS:

- According to the Durham-Humphrey Amendment of 1951, drugs are controlled with prescription if they are:
- Habit-forming.
- Not safe for self-medication.
- Intended to treat ailments that require the supervisions of a health professional.
- New and without an established safe track record.



ECOMMONLY USED PRESCRIPTION DRUGS:

- ✓ AMOXICILLIN
- ✓ DIAZEPAM
- ✓ ATENOLO
- ✓ FRUSEMIDE
- ✓ LOSARTAN
- ✓ IMPRAMINE

SUMMARY:

1. Require a prescription from a licensed healthcare professional to obtain.
2. Used to treat a wide range of medical conditions, from mild to severe.
3. Examples include antibiotics, blood pressure medications, and antidepressants.
4. Regulated by government agencies, such as the FDA in the US.
5. Must meet strict standards for safety, efficacy, and quality.
6. Often have stronger dosages and more potential side effects than OTC medications.
7. Can only be dispensed by licensed pharmacies and pharmacists.
8. May require ongoing monitoring and follow-up appointments with a healthcare professional.
9. Can interact with other medications, including OTC drugs and supplements.
10. Should only be used under the guidance of a healthcare professional.

Key characteristics:

1. Require a prescription
2. Treat various medical conditions
3. Regulated by government agencies
4. Meet strict standards
5. Stronger dosages and potential side effects
6. Dispensed by licensed pharmacies and pharmacists
7. Require ongoing monitoring
8. Potential interactions with other medications
9. Should only be used under healthcare professional guidance

Note: Prescription drugs play a crucial role in treating medical conditions, but their use requires careful supervision and monitoring to ensure safety and effectiveness.