CBS Confident Pharmacy Series

Second Edition

Pharmacy Law and Ethics

for Second Year Diploma in Pharmacy

Course Code: **ER20-26T**

As per the latest syllabus prescribed by Pharmacy Council of India

Including
Board Examination Question Papers and Specimen Answer Papers

VN Raje



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Preface to the Second Edition

Second edition of this book includes Board Examination Question Papers and Specimen Answer Papers. These additional contents are of great importance to the students which gives an exact idea about the framework of Question Paper Pattern and Specimen Answers as per the format of Pharmacy Council of India (PCI ER-2020).

The book builds self-confidence in students which helps to get success in the examinations. The book has been written to meet the requirements of students of Diploma in Pharmacy (D Pharm) in accordance with the new revised syllabus ER-2020 prescribed by Pharmacy Council of India.

This book is small and humble effort has been put in for compiling necessary information on the subject. An attempt has been made to demystify and simplify the basic concepts for the students of pharmacy and to enable them get an evergreen success in all the board examinations.

The salient features of the present book are:

- Lucid and easy language
- To the point answers
- Remembering facts in the simplest way
- Infusing confidence in the reader to appear in the board examinations

Hence, the series is named

CBS Confident Pharmacy Series

I am confident that this book will be useful to both the students and the teachers of Diploma in Pharmacy as well as the candidates desiring to succeed in competitive examinations for better job opportunities in pharmacy profession such as hospital pharmacists in PHCs, civil hospitals, etc.

Raje Vijay N

to

my beloved family

Acknowledgements

I express my heartfelt thanks to Prof Madan Jagtap, Chairman, Gourishankar Education Society, Satara, Maharashtra, for consistent encouragement and inspiration for writing this book.

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I am also thankful to Shri Satish Kumar Jain, Chairman & Managing Director, and Shri Shantanu Sarkar, General Manager, Mumbai Branch, CBS Publishers and Distributors Pvt Ltd, for their sustained efforts and keen interest in the publication of this book.

I wish all my beloved students to have a great success in the board examinations.

Raje Vijay N

Syllabus

(As per PCI New ER 2020)

Pharmacy Law and Ethics

Course Code: ER20-26T **75 Hours (3 Hours/week)**

1. General Principles of Law, History and various Acts related to Drugs and Pharmacy profession.
2. **Pharmacy Act, 1948 and Rules:** Objectives, Definitions, Pharmacy Council of India; its constitution and functions, Education Regulations, State and Joint State Pharmacy Councils, Registration of Pharmacists, Offences and Penalties.

   Pharmacy Practice Regulations 2015
3. **Drugs and Cosmetics Act, 1940 and Rules 1945 and New Amendments:** Objectives, Definitions, Legal definitions of schedules to the Act and Rules, **Import of drugs:** Classes of drugs and cosmetics prohibited from import. Import under license or permit.

   Manufacture of drugs: Prohibition of manufacture and sale of certain drugs. Conditions for grant of license and conditions of license for manufacture of drugs, manufacture of drugs for test, examination and analysis, manufacture of new drug, loan license and repacking license.

   Study of Schedule C and C1, G, H, H1, K, P, M, N, and X.

   ***Sale of Drugs*:** Wholesale, Retail sale and Restricted license, Records to be kept in a pharmacy

   Drugs Prohibited for manufacture and sale in India

   ***Administration of the Act and Rules*:** Drugs Technical Advisory Board, Central Drugs Laboratory, Drugs Consultative Committee, Government analysts, licensing authorities, controlling authorities, Drug Inspectors.
4. **Narcotic Drugs and Psychotropic Substances Act, 1985 and Rules:** Objectives, Definitions, Authorities and Officers, Prohibition, Control and Regulation, Offences and Penalties.
5. **Drugs and Magic Remedies (Objectionable Advertisement) Act, 1954:** Objectives, Definitions, Prohibition of certain advertisements, Classes of Exempted adverisements, Offences and Penalties.

6. **Prevention of Cruelty to Animals Act, 1960:** Objectives, Definitions, CPCSEA—brief overview, Institutional Animal Ethics Committee, Breeding and Stocking of Animals, Perfomance of Experiments, Transfer and Acquisition of animals for experiment, Records, Power to suspend or revoke registration, Offences and Penalties.
7. **Poisons Act, 1919:** Introduction, objective, definition, possession, possession for sales and sale of any poisons, import of poisons.
8. **FSSAI (Food Safety and Standards Authority of India) Act and Rules:** Brief overview and aspects related to manufacture, storage, sale and labelling of Food Supplements.
9. **National Pharmaceutical Pricing Authority:** Drugs Price Control Order (DPCO) 2013: Objectives, Definitions, Sale prices of bulk drugs, Retail price of formulations, Retail price and ceiling price of scheduled formulations, Pharmaceutical Policy 2002, National List of Essential Medicines (NLEM).
10. **Code of Pharmaceutical Ethics:** Definition, ethical principles, ethical problem solving, registration, code of ethics for Pharmacist in relation to his job, trade, medical profession and his profession, Pharmacist's oath.
11. **Medical Termination of Pregnancy Act and Rules:** Basic understanding, salient features and Amendments.
12. **Role of all the government pharma regulator bodies:** Central Drugs Standards Control Organization (CDSCO), Indian Pharmacopoeia Commission (IPC)
13. **Good regulatory practices** (documentation, licenses, renewals, e-governance) in Community Pharmacy, Hospital Pharmacy, Pharma Manufacturing, Wholesale business, Inspections, import, export of drugs and medical devices.
14. **Introduction of BCS system of classification**, Basic concepts of Clinical Trials, ANDA, NDA, New Drug development, New Drugs and Clinical Trials Rules, 2019. Brand v/s Generic, Trade name concept, Introduction to Patent Law and Intellectual Property Rights, Emergency Use Authorization.
15. **Blood bank:** Basic requirements and functions.
16. **Clinical Establishment Act and Rules:** Aspects related to Pharmacy.
17. **Biomedical Waste Management Rules, 2016:** Basic aspects and aspects related to pharma manufacture to disposal of pharma/medical waste at homes, pharmacies and hospitals.

18. **Bioethics:** Basic concepts, history and principles, Brief overview of ICMR's National Ethical Guidelines for Biomedical and Health Research involving human participants.
19. **Introduction to the Consumer Protection Act**.
20. **Introduction to the Disaster Management Act**.
21. **Medical Devices:** Categorization, basic aspects related to manufacture and sale.

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Chapter

1

General Principles of Law, History and Various Acts related to Drugs and Pharmacy Profession

Q.1. Define the terms "jurisprudence" and "pharmaceutical jurisprudence".

Jurisprudence

It is the study of fundamental legal principles and is also science and philosophy of law.

Pharmaceutical Jurisprudence

It is a branch of pharmacy which deals with the knowledge of laws relating to drugs and pharmaceuticals and about pharmacy profession.

Q.2. Write a note on origin and nature of pharmaceutical legislation in India.

Origin and Nature of Pharmaceutical Legislation in India (History)

- At first time in India a chemist shop was opened in about 1811 by Mr Bathgate who came to India with East India Company in Calcutta.
- The manufacturer of modern drugs in India was started at the end of 19th century.
- At that time drugs were mostly exported in crude form and imported in the finished form.
- There was no control on the drugs and therefore, anything under the name of drug could be made, sold or imported.
- As there was no restriction on the import of the drugs and also quality of drugs, many adulterated and spurious drugs have got entry in India.
- To that effect Sir Haroon Zaffer moved a resolution on March 9, 1927 in the council of state, recommending the Governor-General to take immediate steps to control the quality and standard of drugs.

- Accordingly council of state adopted resolution and recommended to the governments to take such steps as may be necessary so as to control quality of drugs.
- As per the recommendations "Import Drugs Bill" was introduced in 1937 in the legislative assembly to control import of drugs.
- This bill did not contain any provision about the manufacture, sale and distribution of drugs.
- Thus drugs bill was introduced in 1940 in the legislative assembly and the Drugs and Cosmetics Act, 1940 came into force.
- Presently Drug Act, 1940 covers the provisions relating to drugs and cosmetics, Ayurvedic, Siddha and Unani drugs.

Q.3. What is DEC? Give the recommendations of DEC. (S. 24)

Drug Enquiry Committee (DEC)

Chopra Committee

Government of India appointed drug enquiry committee under the chairmanship of Col. RN Chopra in 1931. It is also known as Chopra Committee.

Recommendations of Chopra Committee

1. Central legislation to control drugs and pharmacy.
2. Setting up of testing laboratories in all the states so as to control quality of production of drugs and pharmaceuticals and also imported drugs.
3. To appoint an Advisory Board to advise the government in making rules.
4. Setting up of courses for training in pharmacy and prescribing minimum qualification as a pharmacist.
5. Registration of every patent and proprietary medicine.
6. Development of drug industries in India.
7. Steps should be taken to comply Indian pharmacopoeia.

Q.4. Give the scope of pharmaceutical legislation in India.

Scope of Pharmaceutical Legislation in India

1. The pharmaceutical legislation is related with legal system which regulates the conduct of pharmacy business and practice of profession of pharmacy.
2. A thorough understanding of all laws pertaining to pharmacy is essential and all legal aspects must be satisfied by those who wish to practise the pharmacy business.

3. The pharmaceutical legislation helps the pharmacists to understand their legal and ethical responsibility and thereby avoid the danger of unnecessary legal proceedings.
4. The patient should get the drugs of good quality which are tested and evaluated for safety and efficacy.
5. It also covers the legal aspects relating to manufacture of drugs in pharmaceutical industries, their storage, sale and distribution, etc.
6. The pharmaceutical legislation safeguards the health of the people by making right medication by controlling pharmacy business and profession.

Q.5. Give the objectives/purposes of pharmaceutical legislation in India.

Objectives of Pharmaceutical Legislation in India

1. To promote health care by regulating the manufacture, supply and distribution of good quality drugs.
2. To make these drugs available to public at reasonable prices and through qualified person.
3. To safeguard the people from misleading and false advertisements relating to the drugs and magic remedies.
4. To regulate the profession of pharmacy.
5. To promote the indigenous research technology.

Q.6. Explain the role of pharmacist in health care system. OR What is the contribution of pharmacist to health care system? OR "Pharmacy is an integral part of health care system." Comment on this statement.

Pharmacy and Health Care System

- Pharmacy is an integral and essential part of health care system.
- In olden days, men developed remedies based on experience. Then physician used to diagnose the diseases and treat them in an improvised manner. The pharmacy was not in existence.
- Later on some physicians gave the responsibility of preparing medicines to their assistants known as compounders (apothecaries). The profession of medicine was concerned with both medicine and pharmacy.
- Hindu system of medicine began with 'Atharva-veda' followed by 'Ayurveda' and 'Rigveda'. The ayurvedic system was greatly affected by 'Unani Tibb system' which was brought by Muslims in India. The Britishers brought the most popular system of medicine—"Allopathic system". With the advancement of allopathic system in India, medicine and pharmacy profession got separated.

- With the developing trends in the science and technology, pharmacist's responsibility was increased to give the feedback information to the physician and the patient regarding the drugs.
- Thus, the health care system is not only medical care but also includes services provided to individual or communities by agent of the health services or profession for the purpose of promoting, maintaining or restoring health.
- Pharmacy occupies an important position in the health care system. Thus, the pharmacist should be well equipped with knowledge of drugs, their handling system and legal aspects as well as principles of quality assurance applied to medicines, price structure of medicinal products.
- They provide a link between physician and patient.
- They are able to advise the patients with minor illness.
- The profession of pharmacy in our country presently consists of:
  i. Industrial pharmacist
  ii. Hospital pharmacist
  iii. Academic pharmacist
  iv. Community pharmacist.
- Pharmacist has to play an important role in the areas such as:
  i. Prescription adherence
  ii. Storage and distribution of drugs
  iii. Drug choice
  iv. Drug monitoring
  v. Information and education
  vi. Clinical pharmacokinetics
  vii. Research and development.

In the chain of health care, the pharmacist is responsible for ensuring that the right patient is receiving the right medicine in the right dose for the right condition in the right dosage form and at right frequency and hence pharmacist is considered as an integral part of the health care system.

OBJECTIVE QUESTIONS WITH ANSWERS IN BOLD LETTERS

1. DEC is appointed under chairmanship of **Col RN Chopra** in 1931.
2. In India first chemist shop was opened in Calcutta in 1811, by Scottish chemist and druggist called **Mr. Bathgate**.
3. **Pharmacist** is considered as an integral part of health care system.

4. 'Import of Drugs Bill' was introduced in **1937** in the legislative assembly to control import of drugs.
5. **Jurisprudence** is the study of legal principles and also science of philosophy of law.
6. The Drug Bill is introduced in year **1930**.
7. Sixth edition of Indian Pharmacopoeia was published in year **2010**.
8. The pharmaceutical Society of India was established in **1923**.
9. In 1937, the Government of India introduced **Import of Drugs Bill**.
10. A small factory at Parel (Bombay) was initiated by **Prof TK Gajjar** in 1903.

Chapter

2

The Pharmacy Act, 1948 and Rules

Q.1. Give objectives of Pharmacy Act, 1948.

Objectives

The Pharmacy Act, 1948 was passed with objectives:

1. To provide uniform education and training to the 'would be' pharmacist.
2. To maintain control over the persons entering in the profession of pharmacy, by providing their registration in the states.

Q.2. Define the terms.

1. **Central Council:** It means Pharmacy Council of India constituted under Section 3 of the Pharmacy Act, 1948.
2. **State Council:** It means State Pharmacy Council constituted under Section 19 and also includes Joint State Pharmacy Council constituted under Section 20.
3. **Registered pharmacist:** A person whose name for the time being is entered in the register of pharmacist of the state, in which he is for the time being residing or carrying on his profession or business of pharmacy.
4. **Displaced person:** It means:
   i. Any person who on account of setting up of the dominion of India and Pakistan or on account of civil disturbances or fear of such disturbances in the area, now forming the part of Pakistan, has left after March 1, 1947 or has been displaced from such place of his residence and since then residing in India.
   ii. Any person who on account of civil disturbances or fear of such disturbances in the area now forming the part of Bangladesh, has left after April 14, 1957 but before March 25, 1971 or has been displaced from such place of his residence and since then residing in India.

5. **Repatriate:** It means any person of Indian origin who on account of civil disturbances in any area now forming the part of Burma, Sri Lanka or Ugenda or any other country has left after March 14, 1957 or has been displaced from such place of his residence and since then been residing in India.
6. **First register:** It means the register of pharmacist prepared under chapter IV of the Pharmacy Act, by the state government before constitution of state council.
7. **Subsequent register:** It means the register of pharmacist prepared under chapter IV of Pharmacy Act, by the state council after first register.
8. **Central register:** It means the register of pharmacist maintained by the central council.
9. **UGC:** It means University Grants Commission established under Section 4 of the University Grants Commission Act, 1956.

Q.3. What is PCI? Give the constitution and functions of PCI. (W. 23)

Pharmacy Council of India (PCI/Central Council)

- PCI was constituted under Section III of Pharmacy Act, 1948.
- The first PCI was constituted by central government in 1949 and council is reconstituted every 5 years.

Constitution of PCI/Central Council

The council consists of elected nominated and ex-officio members.

A. *Elected Members*
   1. Six persons elected by UGC from amongst the teaching staff of a university or affiliated college granting degree or diploma in pharmacy. Amongst these, there shall be one teacher each of pharmacy, pharmaceutical chemistry, pharmacognosy and pharmacology.
   2. One person elected by Medical Council of India from amongst its members.
   3. One registered pharmacist elected by each state pharmacy council from amongst its members.

B. *Nominated Members*
   1. Six persons nominated by central government of whom at least four should possess degree or diploma in pharmacy or shall be engaged in the practice of pharmacy or pharmaceutical chemistry.
   2. One registered pharmacist nominated by each state government.
   3. One representative of UGC and AICTE.

C. *Ex-officio Members*
   1. Director General of Health Services.

2. The Drugs Controller of India.
3. The Director of Central Drug Laboratory.

Functions of PCI/Central Council

1. To prescribe the minimum standards of education required for qualification as pharmacist.
2. To frame the course of study for the pharmacist.
3. To regulate the minimum educational standards.
4. To maintain central register of the pharmacists.
5. To fix the powers and duties of president, vice-president, secretary, etc. of the council.
6. To fix the rates of remunerations and other allowances, payable to its members.
7. To prepare education regulations.
8. To inspect the institutions by appointing inspectors.
9. To give approval to the institution running pharmacy course.
10. Any other function given by central government.

Q.4. Give the constitution and functions of executive committee of PCI.

The executive committee of PCI consists of:

A. Ex-officio Members

1. President who shall be the chairman of the committee.
2. Vice-President.

B. Five Members

Elected by central council from its members.

Functions

1. Executive committee is authorised to observe the efficacy of present education regulation.
2. To recommend amendment in the present education regulation.
3. To carry out such other functions as may be entrusted to it by the central council.

Q.5. What are education regulations? Describe different education regulations. OR Write a note on ER. (S. 24)

The Pharmacy Council of India has laid down minimum standards of education required for qualification as a pharmacist. These standards are known as education regulations.

These education regulations are:

i. Minimum qualification for admission to the course.
ii. The nature and period of course of study.
iii. The nature and period of practical training that shall be undertaken after the completion of regular course.
iv. Subjects of the examination and standards to be attained in such examinations.
v. Equipments and facilities to be provided for the student by the institution running approved course of study.
vi. Conditions to be fulfilled by the institution giving practical training.
vii. Conditions to be fulfilled by the authorities holding approved examination.
viii. Latest Education Regulation is ER 2020.

Q.6. How are amendments in education regulations done?

The present ER is framed by PCI with the approval of central government.

Amendments to these regulations are first circulated to the state governments for their comments. If the comments are received within three months, then they may be taken in consideration by the central council and then amendment are send to central government for its approval. After approval by central government it is published in the official gazette. Executive committee shall report to the council from time to time about the efficacy of regulations and may recommend amendments in the present regulation.

Q.7. Give the constitution of state pharmacy council and joint state pharmacy council.

State pharmacy council	*Joint state pharmacy council*
A. Elected members	
1. Six registered pharmacists elected among themselves. each participating state.	1. 3 to 5 registered pharmacists elected from amongst the pharmacists of
2. One person elected by medical council of state from amongst its members.	2. One person elected by medical council of each participating state from amongst its members.
B. Nominated members	
5 persons nominated by state government of whom at least 3 possess a degree/diploma in pharmacy or pharmaceutical chemistry or be the registered pharmacist.	2 to 4 members nominated by each participating state government and more than half should possess a degree/diploma in pharmacy or pharmaceutical chemistry or be the registered pharmacists.

Contd.

Contd.

State pharmacy council	*Joint state pharmacy council*
C. Ex-officio members 1. Chief administrative medical officer of the state. 2. A government analyst appointed under the D&C Act, 1940. 3. Officer in-charge of the drug control organisation in the state.	1. Chief administrative medical officer of the each participating state. 2. A government analyst of each participating state. 3. Officer in-charge of the drug control organisation of each participating state.

Q.8. How is approval given to the institutions running the course of pharmacy? OR How are the institutions running pharmacy course approved?

1. **Application:** Any institute or authority which conducts the course of study or examination for the pharmacy has to apply the central council for its approval of the course or examination.
2. **Inspection:** On the receipt of application, the central council appoints inspectors to visit the institution and to satisfy whether the institution has prescribed facilities or not. Inspector may attend any examination during the course of inspection to judge its standard.

   After inspection inspectors prepare a detailed report of inspection and send it to central council.
3. **Approval:** If the central council is satisfied on the report of the inspector that the institution possesses the prescribed facilities as per ER, it may give approval to such institution, conducting pharmacy course.
4. **Declaration:** Declaration of the approval is made by passing the resolution in the meeting of the council and then it is published in the official gazette.

Q.9. Under what circumstances/conditions/grounds approval of institution can be withdrawn?

If it comes to the notice of PCI that any approved course of study or examination does not continue as per ER, then council may give notice to such institution indicating its intention to withdraw the approval.

In such case the concerned institute should make representation through the state government within 3 months from the date of receipt of notice.

If central council satisfies on the report of state government, it may give approval conditionally.

Q.10. What is central register? How is it prepared? (S. 24)

Central Register

It is the register of pharmacist maintained by PCI, containing names of all persons registered as pharmacists in different states of India.

This register has to be maintained by the registrar of the council as per the directions of the council and has to revise from time to time and published in the official gazette.

Preparation of Central Register

For the preparation of central register each state council is required to supply 5 copies of its register to central council after April 1, of each year along with amendments if any for updating the central register.

Q.11. Define state council. Give the functions of state council.

State Council

It means state pharmacy council constituted under Section 19 and also includes joint state pharmacy council constituted under Section 20 of the Act.

Functions of State Council

1. To register the names of all persons who have approved qualification.
2. To maintain state register of pharmacist.
3. To appoint suitable number of inspectors for the inspection of premise where drugs are dispensed and compounded.
4. To fix the powers and duties of President, Vice-President, Secretary, etc.
5. To send five copies of state registers to central council after April 1, of each year for the preparation of central register.

Q.12. What is interstate agreement? Give the provisions under interstate agreement.

Interstate Agreement

When two or more states may enter into agreement (under Section 20) whereby the state council of one state will serve the needs of other states, such agreement is called interstate agreement.

Provisions

1. Under interstate agreement the membership of the state council may be increased by not more than two persons, out of these one should possess degree/diploma in pharmacy or pharmaceutical chemistry or be registered pharmacist.

2. Agreement provides for the distribution of expenditure between the participating states.
3. It shall also provide which of the state government shall exercise various functions of the participating state governments.
4. It also provides for the consultation between the participating state governments on the general or special matter arising under Act.
5. Such agreement is required to be published in the official gazette of all the participating states.

Q.13. What are the powers of inspector appointed by state council?

1. To inspect premise where drugs are compounded or dispensed.
2. To enquire weather a person who is engaged in compounding and dispensing of drugs is registered pharmacist.
3. To investigate any complain made to him in writing, regarding contravention of the Act.
4. To institute prosecution under the order of executive committee of the state council.
5. To exercise such other powers as may be entrusted to him under the Act.

Q.14. Define first register. How is it prepared? What qualification is required to enter the name in first register? (S. 23)

First Register

It means the register of pharmacists prepared under chapter IV of the Pharmacy Act by the state government before constitution of state council.

Preparation of First Register

The first register is required to be prepared in the following manner:

1. The state government appoints the 'Registration Tribunal' consisting of 3 persons and also appoints a secretary and registrar of the tribunal.
2. The tribunal then appoints the date before which all applications for registration along with prescribed fees should reach the tribunal.
3. The tribunal examines all applications received within a given date and if it is satisfied that an applicant is duly qualified for registration, it will direct his or her name to enter in the register.
4. The first register so prepared, is then published in a manner directed by state government.
5. The registration certificates in prescribed format are issued to persons whose names are entered in first register.

Qualifications for Entry into First Register

A person for registration should be of at least 18 years of age, and should reside or carry on the business in the state and should have following qualifications:

1. A degree or diploma in pharmacy or pharmaceutical chemistry or a chemist/druggist diploma of an Indian University or a state government or a prescribed qualification granted by an authority outside India.
2. A degree of an Indian University other than a degree in pharmacy or pharmaceutical chemistry and has engaged in the compounding of drugs in a hospital or dispensary or other places in which drugs are regularly dispensed on prescription of medical practitioners for the total period of not less than three years.
3. Has passed an examination for compounders and dispensers recognised by state government.
4. Has not less than 5 years experience of compounding and dispensing in a hospital or dispensary or other place in which drugs are regularly dispensed on prescription of medical practitioners.

Q.15. Define subsequent register. What qualifications are required for entry of name of the person into subsequent register?

Subsequent Register

It means the register of pharmacist prepared under chapter IV of the Pharmacy Act by the state council after first register.

Qualifications Required Before ER Taken Effect in the State

A person for registration should be of at least 18 years of age and should reside or carry on the business in the state and should have qualification:

i. Those who possess the qualification required for first register and are at least matriculate.
ii. Are registered pharmacist in another states.
iii. Possess qualification for registration recognised by central council and are at least matriculate.

Qualifications Required After ER Taken Effect in the State

A person for registration should be of at least 18 years of age and should reside or carry on the business in the state and should have qualifications for entry into subsequent register:

i. Those who have passed an approved examination.

ii. Those who possess the qualifications granted by an authority outside India, and which is recognised by central council for the purpose of registration.
iii. Those who are registered pharmacist in another state.

Q.16. Under what circumstances/conditions/grounds the name of pharmacist can be removed from the register of the state? OR When did the name of pharmacist can be removed from the register of the states?

The name of the pharmacist may be removed from the register on the following grounds:

i. If his name has been entered in the register due to error, misrepresentation, or suppression of material facts.
ii. If he has been convicted of an offence in any professional respect or has been held guilty of infamous conduct in the professional respect.
iii. If the person employed by the register pharmacist has been convicted of an offense and such person is registered pharmacist his name may be removed from the register.
   - However, the name of pharmacist can be removed from the register only after an order passed by executive committee of state council after making due enquiries and giving opportunity to the person concerned to explain his conduct.
   - The removal of name may be either permanent or only for the specified period of time.
   - The order passed by executive committee shall be confirmed by the state council and it will take effect only after 3 months from the date of passing order.
   - A person who is dissatisfied by the order about the removal of his name may appeal to the state government within 30 days of the order.
   - Any person whose name has been removed from the register has to surrender the certificate of registration to the registrar of the state of the council.

Q.17. Give the offences and penalties under Pharmacy Act, 1948.

1. Falsely Claiming to be a Registered Pharmacist

Any person whose name is not entered in the register of pharmacist and uses the words like "pharmacist", "chemist", "druggist", "dispenser" or combination of such words like "chemist and druggist", "dispensing

chemist", etc. which likely suggest that the person is registered pharmacist. Such person is said to be falsely claiming to be a registered pharmacist.

Defense

However, if a person is the registered pharmacist of another state and has made application for registration in the state is not deemed to be falsely claiming as a registered pharmacist.

Penalty

Any person who is falsely claimed to be a registered pharmacist is punishable with a fine up to ₹ 500/- on first conviction and to a fine up to ₹ 1000/- or imprisonment up to 6 months or both on any subsequent conviction.

2. Dispensing by Unregistered Person

Any person who is not registered pharmacist but engages in the compounding and dispensing of drugs on prescription of RMP is punishable with a fine of ₹ 1000/- or imprisonment up to 6 months or both.

3. Obstructing the State Council Inspectors in their Duties

Anyone who obstructs state council inspectors from discharging their duties is punishable with the fine of ₹ 500/- on first conviction and fine of ₹ 1000/- or imprisonment up to 6 months or both on any subsequent conviction.

4. Failure to Surrender the Certificate of Registration

Anyone who fails to surrender the certificate of registration after removal of his name from the register is punishable with the fine of ₹ 50/-.

Q.18. What are the duties of the PCI inspectors?

PCI inspectors may

i. Inspect any institution which provides an approved course of study.
ii. Attend at any approved examination.
iii. Inspect any institution whose authorities have applied for the approval of its course of study or examination.
iv. An inspector attending at any examination without interference with the conduct of the examination and report to the Executive Committee.

Q.19. When the seat of PCI member is deemed to be vacated and how is it filled?

i. A nominated or elected member may resign his membership at anytime by writing to President and the seat of such member shall become vacant.

ii. A nominated or elected member should have to vacate his seat if he is absent without excuse, in the opinion of the Central Council, for three consecutive meetings of the Central Council.

iii. A causal vacancy in the Central Council shall be filled by fresh nomination or election as the case may be, and the person nominated or elected to fill the vacancy shall hold office 'only for the remainder of the term'.

OBJECTIVE QUESTIONS WITH ANSWERS IN BOLD LETTERS

1. First register is prepared by **state government** under chapter IV of the Pharmacy Act, 1948.
2. Registration of pharmacist is done by the State PCI under **Section 19** of the Pharmacy Act, 1948.
3. For the preparation of central register, each State Pharmacy Council is required to supply **05 copies** of its register to central council after 1 April of each year.
4. Penalty for failure to surrender the certificate of registration is **₹ 50** as per Pharmacy Act, 1948.
5. Education Regulations are framed by **PCI** with the approval of central government.
6. Joint State Pharmacy Council is constituted under **Section 20** of the Pharmacy Act, 1948.
7. Central register is maintained by **Registrar** of the Pharmacy Council of India.
8. The minimum qualification for registration as pharmacist is **D Pharm**.
9. Name of the pharmacist can be removed from the register of the state only by an order of the **Executive Committee of the state**.
10. Central register is maintained under **Section 15A** by the Pharmacy Council of India as per Pharmacy Act, 1948.
11. **PCI** is a final authority to approve courses of study and examination for the purpose of qualifying for registration as a pharmacist.
12. PCI is reconstituted in every **5 years**.
13. Pharmacy Council of India has laid down minimum standards of education required for qualification as pharmacist is called **Education Regulations**.
14. The Pharmacy Act was come into force on **4th March 1948**.
15. For registration of pharmacist in the various states, the Pharmacy Act provides for the constitution of **State Pharmacy Councils**.

16. First Pharmacy Council of India was constituted in **1949**.
17. Minimum age limit for registration as a pharmacist is **18 years**.
18. **500 hours** of training to be undertaken by a student pharmacist in medical shop or pharmacy.
19. PCI was constituted under **Section III** of the Pharmacy Act, 1948.
20. When two or more states enter into an agreement under **Section 20** of the Pharmacy Act, such agreement is called **interstate agreement**.
21. The Joint State Pharmacy Council was constituted under **Section 20** of the Pharmacy Act, 1948.
22. Registration of the pharmacist is done by the State Pharmacy Council under **Section 19** of the Pharmacy Act, 1948.
23. The Central Register of pharmacists is maintained by **Central Council/ Pharmacy Council of India**.
24. Total area required for retail and whole sale drug store together is **15 sq.m**.
25. The first PCI was constituted in year **1949**.
26. For registration of pharmacist in various States, the Pharmacy Act provides for the constitution of **State Pharmacy Council**.
27. The institutions running pharmacy course are approved by **Pharmacy Council of India (PCI)**.
28. Joint State Pharmacy Councils are constituted for **indefinite period**.
29. The Education Regulations (ER) were laid down by **Pharmacy Council of India (PCI)**.
30. Education Regulation is published in official gazette by **central government**.
31. Registration Tribunal for first register consists of **3 persons**.
32. PCI is constituted by **central government**.
33. Interstate agreement is made for the constitution of joint **State Pharmacy Councils**.
34. A person who is aggrieved with the decision of Registration Tribunal may appeal within **60 days**.
35. State Council is constituted by **state government**.
36. The members of PCI hold office for a period of **5 years**.
37. The prescribed renewal fees should be paid before **31st December** of every year.
38. Registration of pharmacist is essential for maintaining **the standard of pharmacy profession**.

39. Registrar of the Central Council shall, on receipt of the report of registration of a person in the register for a state, enter his name in the **Central Register**.
40. In the preparation of first register, a registrar acts as a **Secretary**.
41. Education Regulation 2020 cancelled **ER 1991**.
42. The Director, General of Health Service is an **Ex-officio member** of PCI.
43. Executive Committee of PCI consists of **7** members.
44. For the preparation of First Register, state government appoints **'Registration Tribunal'** consisting of 3 persons.

Chapter

3

The Drugs and Cosmetics Act, 1940 and Rules thereunder 1945 and New Amendments

Q.1. Give the aims and objectives of the Drugs and Cosmetics Act, 1940.

Objectives

The Drugs and Cosmetics Act, 1940 was passed.

1. To regulate the import, manufacture, distribution and sale of drugs and cosmetics.
2. To regulate the import of drugs into India so that no substandard or spurious drugs get imported in India.
3. To regulate manufacture of drugs so that no substandard or spurious drugs get manufactured in the country.
4. This act also provides for the control over the sale and distribution of the drugs by only trained and qualified person.
5. This act also provides for the control over the manufacture, sale and distribution of Ayurvedic, Siddha, Unani and Homeopathic drugs.
6. This act also provides provisions relating to import, manufacturing and sale of cosmetics.

Q.2. Define the terms as per D&C Act, 1940.

1. **Drug (S. 23):** It includes:
   i. All medicines for internal or external use of human being or animals and all the substances intended to be used for or in the diagnosis treatment, mitigation or prevention of any disease or disorder in the human being or animal including the preparation applied on human body for the purpose of repelling insects like mosquito.
   ii. Such substances other than food, intended to affect the structure or any function of the human body or intended to be used for the destruction of vermin or insects which causes disease in human beings or animals.

iii. All substances intended for use as a component of drug including empty gelatin capsules.
iv. Such devices intended for internal or external use in diagnosis, treatment, mitigation or prevention of the diseases or disorders in human beings or animals.

2. **Ayurvedic, Siddha and Unani drugs:** It includes all medicines intended for internal or external use for or in the diagnosis, treatment, mitigation or prevention of disease or disorder in the human beings or animals and manufactured according to formulae described in books of Ayurveda, Siddha and Unani system of medicine specified in first schedule of the Drugs and Cosmetics Act, 1940.
3. **Homeopathic medicines:** It includes drugs recorded in homeopathic literature and their therapeutic efficacy has been established through long clinical experience and which are prepared according to homeopathic technique but does not include medicines for parenteral use.
4. **Patent and proprietary medicines:** It means medicines for internal or external use of human beings or animals and prepared according to formulae other than those included in IP or any other book of standards.
5. **New drug (S. 23):** It means the drug whose composition is generally not recognised as a safe for use under the conditions recommended or suggested in the label and the drugs whose composition is recognised as a safe but which have not been used to any large extent for any appreciable period of time.
6. **Manufacture:** It means any process or part of process for making, altering, ornamenting, finishing, labelling, breaking up of any drug or cosmetic for the purpose of their sale and distribution but does not include compounding or dispensing of any drug or the packing of any drug or cosmetic in the ordinary course of retail business.
7. **Misbranded drug (S. 23, W. 23):** It means a drug which is:
   i. Coloured, coated, powdered or polished so as to conceal the damage or if it is made to appear of a better therapeutic value than it really is.
   ii. If it is not labelled in the prescribed manner.
   iii. Its label or container bears the statement which is false and misleading or makes the false claim.
8. **Adulterated drug (S. 23):** A drug shall be deemed to be adulterated:
   i. If it consists, in whole or in part, of any filthy or putrid or decomposed substance.

ii. If it has been prepared, packed or stored under insanitary conditions, which are likely to make them injurious to health.
iii. If it is packed in the container composed of poisonous substances.
iv. If it contains a colour other than prescribed.
v. If it contains any harmful or toxic substance which may render it injurious to health.
vi. If any substance is mixed with it, so as to render its quality or strength.

9. **Spurious drug:** It means a drug:
   i. Imported under the names of other drugs.
   ii. The drugs which are an imitation or substitute of the other drugs.
   iii. It resembles other drugs in a manner likely to cause deception.
   iv. It bears the name of manufacturer which is fictitious or does not exist.
   v. Which is supposed to be the product of manufacturer of whom it is not truly a product.
10. **Drug store:** It means the licensed premises for the sale of drugs which do not require the services of a qualified person.
11. **Chemist and druggist (S. 24):** It means premises licensed for sale of drugs which require the services of qualified person but where the drugs are not compounded against the prescription of RMP.
12. **Pharmacy:** It means the premises licensed for sale of drugs which require services of qualified persons and where drugs are compounded against the prescription of RMP.
13. **Qualified person:** Qualified person is a person who:
   i. Holds a diploma/degree in pharmacy or pharmaceutical chemistry.
   ii. Is a registered pharmacist (under Pharmacy Act, 1948).
   iii. Has minimum 4 years experience of dispensing and has been approved by licensing authority as a 'qualified person' on or before December 31, 1969.
14. **Drug inspector:** It means:
   i. In relation to Ayurvedic, Siddha or Unani drug, an inspector appointed by central or state government under Section 33 G of the Act.
   ii. In relation to other drugs and cosmetics an inspector appointed by central or state government under Section 21 of the Act.

15. **Government analyst:** It means:
    i. In relation to Ayurvedic, Siddha or Unani drugs a person appointed under Section 33 F.
    ii. In relation to any other drugs and cosmetics a person appointed by central or state government under Section 20 of the Act.
16. **Repacking of drugs:** It means the process of breaking up any drug from a bulk container into small packages and the labelling of each package with a view to its sale and distribution, but it does not include the compounding, dispensing and packing of drugs in the ordinary course of retail business.
17. **Repacking licence:** It is the licence for repacking of drugs and granted for breaking up any drug from the bulk container into small packages and labelling of each package with a view to its sale and distribution.
18. **Loan licence:** It means a licence issued by licensing authority to a person who does not have his own arrangement for manufacture but who intends to avail of the facilities owned by another manufacturer.
19. **Restricted licence:** It is the licence for retail sale of drugs whose sale does not require the supervision of qualified person, it is issued to the travelling agents of the firms or venders of the drugs.
20. **General licence:** It is the licence for retail sale of drugs and issued to the person who has fixed premise for the business and engages the services of qualified persons for sale and compounding, dispensing of drugs.
21. **Retail sale:** It means a sale other than a sale by the way of wholesale dealing.
22. **Sale by the way of wholesale dealing:** It means a sale to a person for the purpose of selling again and also includes the sale to hospitals, dispensaries or medical educational or research institutions.
23. **Cosmetic:** It means any article intended to be rubbed, poured, sprinkled or sprayed on or introduced into or applied to any part of the human body for cleansing, beautifying, promoting attractiveness or altering the appearance and includes any article intended for use as a component of cosmetic.
24. **Misbranded cosmetic:** It means a cosmetic:
    i. Which contains a colour other than prescribed.
    ii. It is not labelled in a prescribed manner.
    iii. Makes any false or misleading claim.

25. **Spurious cosmetic:** It means:
    i. A cosmetic which is imported under the name of other cosmetic.
    ii. Cosmetics which are imitations or substitutes for other cosmetics.
    iii. Resembles other cosmetics in a manner likely to cause deception.
    iv. Bears the name of manufacturer who does not exist.
    v. It is claimed to be the product of manufacturer of whom it is not a truly product.

Q.3. What are the schedules to the Drugs and Cosmetics Act, 1940? OR What does the first and second schedule of D&C Act, 1940 prescribe?

1. **First schedule:** It prescribes the list of Ayurvedic, Siddha or Unani drugs.
2. **Second schedule:** It deals with the standards to be complied by the imported drugs and by drugs manufactured for sale, sold, stocked or exhibited for sale or distribution.

Q.4. Give the contents/meaning of the following schedules.

- **Schedule 'A':** List of forms used for making application for issuing licences, granting licences, sending memorandum, etc.
- **Schedule 'B':** Fees for test or analysis by the central drug laboratory or government analyst.
- **Schedule 'C':** List of biological and special products whose import, manufacture and sale are governed by a special provision.
- **Schedule 'C_1':** Other special products whose import, manufacturing and sale are governed by special provisions.
- **Schedule 'D':** List of Drugs exempted from a certain provision of the import of drugs.
- **Schedule 'E':** List of Ayurvedic, Siddha and Unani poisonous substances.
- **Schedule 'F':** Provisions applicable to blood bank requirement and licensing to process blood components.
- **Schedule '$F_{(I)}$':** Provisions applicable to production of bacterial and viral vaccines, sera and diagnostic agents.
- **Schedule '$F_{(II)}$':** Standards for surgical dressings.
- **Schedule '$F_{(III)}$':** Standards for umbilical tapes.
- **Schedule FF:** Standards for ophthalmic preparations.

- **Schedule 'G':** List of substances required to be taken only under supervision of RMP.
- **Schedule 'H':** Prescription drugs which are required to be sold by retail only on the Rx of RMP.
- **Schedule 'J':** List of diseases or ailments, which a drug may not claim to prevent or cure.
- **Schedule 'M':** Current good manufacturing practices (cGMP) and requirements of factory premises, equipment, etc. for the manufacturing of **drug**.
- **Schedule '$M_{(I)}$':** Requirements of factory premises, plant and equipment for the manufacturing of **homeopathic** medicines.
- **Schedule '$M_{(II)}$':** Requirements of factory premises, plant and equipments for the manufacturing of **cosmetic**.
- **Schedule '$M_{(III)}$':** Requirements of factory premises, plant and equipments for the manufacturing of **medical devices**.
- **Schedule 'T':** Requirements of factory premises and hygienic conditions for the manufacturing of **Ayurvedic, Siddha and Unani medicines**.
- **Schedule 'N':** List of minimum equipments for the efficient running of pharmacy.
- **Schedule 'O':** Standards for disinfectant fluids.
- **Schedule 'P':** Life period of drugs.
- **Schedule 'P_1':** Pack sizes of drugs.
- **Schedule 'Q':** List of coaltar colours permitted to be used in the cosmetics and soaps.
- **Schedule 'V':** Standards for patent and proprietary medicines.
- **Schedule 'R':** Requirements for condoms made of rubber latex intended for single use.
- **Schedule 'S':** Standards for cosmetics.
- **Schedule 'U':** Particulars to be shown in the manufacturing and analytical records of drugs.
- **Schedule 'W':** List of drugs shall be marketed under generic names only.
- **Schedule 'X':** List of habit forming, psychotropic and other such drugs.

Q.5. Give the examples of drugs belonging to following schedules.

Schedule 'C'

Sera, toxins, antigens, antitoxins, vaccines, adrenaline, penicillin, streptomycin, tetracyclines, chloramphenicol, ophthalmic preparation, erythromycin.

Schedule 'C_1'

Digitalis, adrenaline, vitamins, hormones, vaccines, penicillins, tetracycline, oxytetracycline, chloramphenicol, bacitracin.

Schedule 'G'

Chlorthiazide, bleomycin, ethacrynic acid, glibenclamide, phenytoin, insulin, tolbutamide, chlorpheniramine, diphenhydramine.

It includes anticancer, diuretic, antidiabetic, antihistaminic, antiepileptic drugs.

Schedule 'H'

Analgin, barbituric acid and its salts, betamethasone, bromhexine, chlorpromazine, cimetidine, dapsone, diazepam, ibuprofen, imipramine, mebendazole, metronidazole, oxytocin, paracetamol, phenyl butazone, sulpha drugs.

Schedule 'X'

Amylbarbitone, amphetamine, barbitone, glutethimide, meprobamate, methaqualone, pentobarbitone, phenobarbitone, secobarbitone.

Schedule 'W'

Analgin, aspirin, chlorpromazine, ferrous sulphate, piperazine, paracetamol.

Q.6. Write a note on 'Schedule M'.

Schedule 'M'

It deals with current good manufacturing practices and requirements of factory premises, plant, equipments, etc. for the manufacture of drugs.

Quality of drug is basically responsibility of manufacturer and GMP provides guidelines so as to assure the quality. To achieve the objectives of GMP the licensee shall comply with the requirements of GMP as laid down in Schedule 'M'.

Schedule 'M' consists of two parts:

Part I

It deals with GMP relating to factory premises.

General Requirements

1. **Location:** It shall be free from contaminants like sewage, drain, soot, dust, smoke, etc.
2. **Construction:** The premises shall be well built, well ventilated. It shall prevent entry of insects and rodents.

3. Manufacturing operations shall be conducted in such a way that mix up and cross-contamination shall be avoided.
4. **Working space:** Adequate space shall be provided for working and keeping the materials, etc.
5. Health clothing, and sanitation of workers, medical services like first aid facility, vaccination facility, etc.
6. Requirement of raw material.
7. **Sterile product area:** It shall be separate unit, provided with air locks, well ventilated air supply through HEPA filter.
8. **Master formula records (MFR):** It shall be maintained by licensee which contains all procedures for each product and it shall be prepared and maintained by competent technical staff.
9. Product containers, closures, labels and other printed material.
10. Batch manufacturing records as per schedule 'U'.

Part II

It deals with plant, equipment, etc. for manufacturing of drugs.
It includes the equipments for manufacturing of drugs in sections like:

i. Ointments, emulsions, lotion and suspension
ii. Syrup, elixir, solutions
iii. Ophthalmic preparations
iv. Oral liquid preparations
v. Tablet, capsule
vi. Injectables
vii. Granules
viii. Powders.

Minimum area required for parenteral section: 60 sq. metre.
For other sections: 30 sq. metre.

Q.7. Write a note on Schedule 'N'. (S. 23)

Schedule 'N'

It prescribes the list of minimum equipments for the efficient running of pharmacy.

The schedule 'N' prescribes the following minimum requirements.

1. **Entrance:** Front portion of pharmacy shall be indicated as 'PHARMACY'.
2. **Premises:** The premises shall be well built, dry, well ventilated with sufficient dimensions for stocking goods. Poisons shall be

stored separately. Dispensing department shall not be less than 6 sq. metre for each pharmacist. The height of premise shall be at least 2.5 metre. The floors and walls should be free from holes, cracks, and surfaces shall be easily washable.

3. **Furniture and apparatus:** Pharmacy shall contain furniture of required size and suitable apparatus. The drugs and chemicals shall be kept in suitable containers to prevent their deterioration. Every container shall be labelled as the name of drug as per pharmacopoeia. Dispensing bench shall be impervious and washable. Poisonous drugs shall be stored in cupboard with lock and key and marked with the word 'POISON' in red letters on white backgrounds.

   Containers containing water-soluble solutions shall be marked with the words "To Be Diluted".

4. **List of minimum equipment/apparatus:** Dispensing balance minimum 30 mg sensitivity, beakers, bottles, evaporating dish, filter paper, glass funnel, measuring cylinder of 10, 25, 100 ml and 500 ml, mortar and pestle, ointment slab, spatula, spirit lamp, waterbath, wire gauze, suppository mould, thermometer, etc.
5. **Books**
   i. The pharmacopoeias
   ii. National formulary
   iii. Drugs and Cosmetics Act, 1940 and Rules, 1945
   iv. The Pharmacy Act, 1948
   v. NDPS Act, 1985.
6. **General provisions:** The conduct of pharmacy shall be under continuous personal supervision of registered pharmacist and his name shall be displayed prominently in the premise. He shall wear white apron. He shall maintain records, registers as per the Act.

Q.8. Mention different administrative bodies of Drugs and Cosmetics Act, 1940.

1. Advisory

i. Drugs Technical Advisory Board (DTAB)
ii. Drugs Consultative Committee (DCC).

2. Analytical

i. Government analyst
ii. Central Drug Laboratory (CDL)
iii. Drug control laboratories in the states.

3. Executive

i. Licencing authorities
ii. Drug Inspectors (DI)
iii. Custom collectors.

Q.9. What is DTAB? Give the ex-officio members and functions of DTAB. (S. 24, W. 23)

DTAB (Drug Technical Advisory Board)

It is constituted by central government and consists of ex-officio, nominated and elected members.

Ex-Officio Members of DTAB

1. The Director General of Health Services (Chairman).
2. The Drugs Controller of India.
3. The Director, Central Drug Laboratory Kolkata.
4. The Director, Central Research Institute, Kasauli.
5. The Director, Central Drug Research Institute, Lucknow.
6. The Director, Indian Veterinary Research Institute, Izzatnagar.
7. The President, Pharmacy Council of India.
8. The President, Medical Council of India.

Functions of DTAB

1. To advise the central and state governments on the technical matters arising out of the administration of the Act.
2. To carry out such other functions as may be entrusted to it by the central government.

Q.10. What is Drugs Consultative Committee? Give its constitution and functions.

Drugs Consultative Committee (DCC)

DCC is constituted under Section 7 of the Act by the central government.

Constitution

It consists of:

1. Two representatives of central government nominated by central government.
2. One representative of state government nominated by each state government.

Functions of DCC

1. To advise the central government, state government and DTAB, on any matters so as to secure uniformity in the administration of the Act.

2. To carry out such other functions as may be entrusted to it by the central government.

Q.11. Give the functions of CDL. What procedure is to be followed for the dispatch of samples to CDL? (S. 23, 24)

Central Drug Laboratory (CDL)

Functions

1. To analyse or test the samples of drugs or cosmetics sent to it by the court or custom collectors or any other authorized officer.
2. To carry out such other functions as may be entrusted to it by the central government or state government after consultation with DTAB.
3. In case of the following drugs or classes of drugs, function of CDL are carried out at the Central Research Institute, Kasauli and such functions are exercised by the Director of the said institute: Sera, vaccines, toxins.
4. The functions regarding oral polio vaccine are exercised by the Deputy Director and Head of the Polio Vaccine Testing Laboratory in case of Central Research Institute, Kasauli.
5. In case of condoms the functions of CDL are carried out at the Central Indian Pharmacopoeia Laboratory, Ghaziabad and such functions are exercised by the Director of the said Laboratory.

Procedure of Dispatch of Samples to CDL

The samples for test or analysis shall be sent by registered post in a sealed packet along with a copy of memorandum (Form I) and with prescribed fee.

A specimen impression of seal used for sealing the package is also sent separately along with a copy of memorandum by registered post.

On the receipt of package the authorised officer compares the seal with the specimen impressions of seal and then opens the packet and conduct the test or analysis.

After completion of text or analysis the report is supplied in Form II and it is signed by the director or the authorised officer on his behalf.

Q.12. Define government analyst. Give the qualifications required for government analyst. Mention the duties of government analyst. What procedure is to be followed by government analyst on the receipt of sample? (W. 23)

Definitions

It means:

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

2. In relation to any other drugs and cosmetics a person appointed by central or state government under Section 20 of the Act.

Qualifications

A person appointed as a government analyst should have following qualifications:

1. A graduate in medicine, science, pharmacy or pharmaceutical chemistry from the recognised university with not less than 5 years experience in testing of drugs or cosmetics.
2. A postgraduate degree in medicine, science, pharmacy or pharmaceutical chemistry from recognised university with not less than 3 years experience in the testing of drugs.
3. Has passed Associateship Diploma of Institution of Chemist (India) with 'Analysis of Drugs and Pharmaceuticals' as one of the subjects and not less than 3 years experience in the testing of drugs under the control of:
   i. A government analyst.
   ii. Head of an institution/approved testing laboratory for this purpose.

Duties of Government Analyst (Functions)

1. To analyse or test the samples of drugs or cosmetics sent to him by drug inspectors or private persons and furnish the report in the prescribed format.
2. To engage in a research or analytical work and send it from time to time to the government with a view of its publication at the discretion of the government.

Procedure Followed by Government Analyst on Receipt of Sample

On the receipt of package of sample, government analyst will record the condition of seal and compare with specimen impression of seal received separately.

On the completion of test or analysis he shall supply the report of analysis in triplicate in Form 13 together with full protocols of the test applied.

If the purchaser wants to analyse or test his sample, he has to make application in Form 14 A along with prescribed fees and report will be supplied in Form 14 B.

Q.13. Define drug inspector. Give the qualifications required for drug inspector. (S. 23, W. 23)

Drug Inspector

It means:

1. In relation to Ayurvedic, Siddha or Unani drugs, an inspector appointed by central or state government under Section 33 G of the Act.

2. In relation to other drugs and cosmetics, an inspector appointed by central or state government under Section 21 of the Act.

Qualifications

1. A graduate in pharmacy, pharmaceutical sciences or medicine with specialisation in clinical pharmacology or microbiology from the recognised university.
2. Provided for the inspection of premises licensed for manufacture of Schedule 'C' drugs a person appointed as drug inspector should have:
   a. Not less than 18 months experience in the manufacture of at least one substance specified in Schedule 'C'.
   b. Not less than 18 months experience in the testing of any one of the substances specified in Schedule 'C' in the approved laboratory.
   c. Not less than 3 years experience in the inspection of firms licensed for manufacture of Schedule 'C' drugs during the course of their service as drug inspector.

Q.14. Discuss various powers of drug inspectors as per D&C Act, 1940. (W. 23)

Powers of Drug Inspector

1. **To inspect:**
   i. The premise licensed for sale of drugs.
   ii. The premises licensed for manufacture of drugs.
2. **To take samples:** To take samples which are manufactured, sold, exhibited for sale or distributed or imported.
3. **To search:** To search any person in connection with the offence at all reasonable times.
4. **To enter and search:** To enter and search any premises in which he has reason to believe that an offence is being committed or has been committed.
5. **To stop and search:** To stop and search any vehicle or other conveyance which he has reason to believe that it used for carrying any drug or cosmetic in respect of which offence has been committed or being commited.
6. **To give order:** To give order in writing to the person in possession of drugs or cosmetics in respect of which offence has been committed, not to dispose off stock of such drug or cosmetic for specific period not exceeding 20 days.
7. **To examine:** The registers, records or other documents which are required to be maintained under the provisions of the Act.

Q.15. Give the duties of drug inspector as per D&C Act, 1940.

Duties of Drug Inspector

A. ***Duties in Relation to Sale of Drugs***

1. To inspect at least twice a year all the premises licensed for sale of drugs.
2. To take samples of drugs or cosmetics and send them for test or analysis.
3. To investigate any complain made to him in writing.
4. To examine the register, record and other documents required to be maintained as per the Act.
5. To institute prosecution in respect of breach of the Act and rules.
6. To submit the detail report of inspection and actions taken by him to the controlling authority.

B. ***Duties in Relation to Manufacture of Drugs and Cosmetics***

1. To inspect at least twice a year all the premises licensed for manufacture of drugs or cosmetics.
2. To inspect premises licensed for manufacture of schedule C and C_1 drugs and observe the process of manufacture, the means employed for standardisation, testing, storage, qualification of technical staff and also the location, construction and administration which are likely to affect potency of the product.
3. To take the samples of drugs or cosmetics and send them for test or analysis.
4. To investigate any complain made to him in writing.
5. To examine the register, record and other documents required to be maintained under the Act.
6. To institute prosecution in respect of breach of the Act and rules.
7. To submit the detail report of inspection and actions taken by him to the controlling authority.

Q.16. Give the procedure of drug inspector for taking the samples of drugs or cosmetics and their dispatch to the government analyst.

Whenever drug inspector takes any sample of drug or cosmetic:

1. He shall intimate the purpose of taking the sample in the prescribed form (Form 17).
2. He shall tender a fair price of the sample, if the price is refused the inspector shall give receipt in the prescribed form (Form 16).
3. He shall divide the sample in 4 parts in the presence of the person from whom the sample is taken and seal and mark each part. If manufacturer wants to sign and mark, he is also allowed to do so. However, if the

sample is taken from manufacturing unit it shall be divided into 3 parts only.

4. The four parts of sample shall be disposed off in the following manner:
   i. One part shall be sent to the government analyst for testing or analysis.
   ii. One part shall be given to the person from whom sample is taken.
   iii. One part shall be retained by the drug inspector or the production before court if legal proceedings are to be instituted.
   iv. One part shall be sent to the warranter, if any.

On the receipt of report from the government analyst drug inspector will decide whether further action in this matter is required or not.

If the person is dissatisfied with the report of government analyst, it can be challenged within 28 days from the receipt of report. In such case the sample shall be sent to the central drug laboratory and the report supplied by director of CDL is considered to be final.

Q.17. Give the form numbers of licences for the grant of various licences. (S. 23)

- Form 19: For sale of drugs other than Schedule 'X'.
- Form 19A: For restricted licence.
- Form 19AA: Wholesale or distribute the drugs from motor vehicle.
- Form 19C: For sale of Schedule 'X' drugs.
- Form 19B: For sale of homeopathic drugs.

Licence issued		*Form numbers*		
		For the drugs other than Sch. C, C_1 and X	*For the drugs specified in Sch. C and C_1*	*For Schedule 'X' drugs*
1.	Retail sale	20	21	20F
2.	Restricted	20A	21A	–
3.	Wholesale	20B	21B	20G
4.	Wholesale of drugs through motor vehicle	20BB	21BB	–

Q.18. Write a note on restricted licence.

Restricted Licence

It is a licence for the sale and distribution of drugs whose sale does not require the supervision of qualified person, and it is issued to the travelling agents of the firms or vendors of drugs.

Conditions for the Grant of Restricted Licence

1. Licensee shall have adequate arrangement for the proper storage of drugs.
2. Licensee shall deal only such drugs that can be sold without supervision of qualified person.
3. The licence shall be displayed at the prominent place of the premise open to the public.
4. In case of vendors of drug they shall possess the licence and should be produced on the demand of inspector.
5. Drugs should be sold in the original containers.

Q.19. What are the conditions to be fulfilled for the grant of general licence?

General Licence

It is the licence for retail sale of drugs and issued to the person who has fixed premise for the sale of drugs and engages the services of qualified person and also do compounding and dispensing of drugs.

Conditions for the Grant of General Licence

1. Licensee must have adequate premise and proper storage facilities for the drugs.
2. Sale and distribution of drugs shall be conducted under the supervision of qualified person.
3. The requirements prescribed for pharmacy should be as per Schedule 'N'.
4. Licensee should allow inspector to inspect premise, register, records, etc.
5. Any changes in qualified staff shall be reported within 1 month to the licensing authority.

Q.20. Define wholesale of drugs. Mention general conditions required for the grant of licence for wholesale of drugs.

Wholesale of Drugs

It means sale of drugs to the hospitals, dispensaries, medical, educational and research institutions and to the person who purchases it for selling again.

General Conditions for the Grant of Wholesale Licence

1. Licensee must have adequate premise which should not be less than 10 sq. metre and which is well equipped for the storage of Schedule C and C_1 and Schedule 'X' drugs.

2. Incharge of the premise should be competent person.
3. Licence shall be displayed at the prominent place of the premise open to the public.
4. Drugs should be purchased only from licensed dealer or manufacturer.
5. The record of purchase and sale of drugs shall be maintained as per the provisions of the Act.
6. The drug should be sold only to those persons who are licensed to sale the drug by retail.

Q.21. Write in brief about storage of schedule 'X' drugs.

Storage of Schedule 'X' Drugs

The substances specified in Schedule 'X' kept in the retail shop shall be stored.

1. Under lock and key in the cupboard or drawer separately reserved for the storage of these substances.
2. In the part of premise which is separate from the remaining premise where responsible persons are allowed to enter.

Q.22. Write in short about storage of drugs for veterinary use.

Storage of Drugs for Veterinary Use

The medicines for treatment of animal should be labelled as "**Not for Human Use**, **For the Treatment of Animal Use Only**."

Veterinary drugs should be stored in the cupboard or drawer separately reserved for the storage of veterinary drugs or in the part of premise separated from the remaining part of the premise where customers are not permitted to enter.

Q.23. Name the classes of drugs prohibited for import, manufacture and sale and distribution as per Drugs and Cosmetics Act, 1940.

The following are the classes of drugs which are prohibited for import, manufacture and sale and distribution as per Drugs and Cosmetics Act, 1940:

1. Any drug which is not of standard quality.
2. Adulterated, misbranded or spurious drug.
3. Any patent and proprietary medicine whose true formula is not disclosed on the label.
4. Any drug which claims to cure or prevent any of the diseases specified in Schedule 'J'.
5. Any drug in contravention of any of the provisions of the Act and rules.
6. Physician samples are also prohibited for distribution.

Q.24. Name the places/routes through which drug may be imported into India.

	Route of import	*Places*
1.	By air	Mumbai, Delhi, Kolkata, Chennai
2.	By sea	Mumbai, Kolkata, Chennai, Visakhapatnam
3.	By rail	Ferozpur, Amritsar

Q.25. Write a note on loan licence.

Loan Licence

It is the licence for manufacture of drugs and issued to the person who does not have his own premises and facilities for the manufacturing of drugs but who intends to avail of facilities owned by another person or licensee.

Loan licence is issued for the manufacture of drugs other than those specified in Schedule 'X'.

Conditions for the Grant of Licence

1. The applicant should submit the documentary consent of the licensee whose facilities are to be availed for the manufacturing.
2. The requirements of factory premises, plant, equipment, etc. shall be as per Schedule 'M'.
3. The licensee shall provide for testing of batch of raw materials and finished goods and maintain the records as per Schedule 'U'.

Q.26. Write a note on repacking licence. (S. 23, 24)

Repacking Licence

It is the licence for breaking of any drug from the bulk container into small packages and labelling of these packages with a view to sale and distribution.

Repacking licence is issued for the drugs other than Schedule 'C' and 'C_1'.

Conditions for the Grant of Repacking Licences

1. Repacking shall be conducted under supervision of at least one "competent person".

   Competent person: It means:

   i. Who holds diploma in pharmacy or is registered pharmacist under Pharmacy Act, 1948.

   ii. Has passed matriculation examination or its equivalent examination and with not less than 4 years experience in the manufacturing, dispensing or repacking of drugs.

2. The factory premises should comply with requirements of Schedule 'M'.
3. The licensee should maintain adequate arrangement for testing of each batch of raw material and repacked drugs.
4. The licence should be kept in the licensed premise and should be produced to inspector on his demand.
5. The repacked drugs in addition to other particulars should be labelled with repacking licence number.

Q.27. State the general conditions for labelling of drugs as per Drugs and Cosmetics Act, 1940.

General Conditions for Labelling of Drugs

1. Proper name of the drug along with trade name (if any).
2. Statement of net contents in terms of weight, volume, number of units, etc.
3. Quantity of active ingredient expressed in terms of amount per single dose. For example:
   i. For oral liquid content per single dose or per 5 ml or multiple thereof.
   ii. For liquid parenterals content per ml or content per single dose or % by volume.
   iii. For any dosage forms like tablet, capsule, contents per tablet or capsule, etc.
4. Name and address of the manufacturer.
5. Distinctive batch number: It can be written as batch number or lot number.
6. Manufacturing licence number: Mfg Lic. No.
7. Date of manufacture.
8. Date of expiry or potency.
9. Alcoholic preparation should be labelled with percentage of alcohol by volume in the product.
10. If the drug is distributed as a free sample to medical practitioners, it shall be labelled as "physician sample, not to be sold".

Q.28. Give the labelling conditions for following schedules.

Labelling conditions for the given schedules are as follows:

1. Schedule 'G'

Caution

It is dangerous to take the preparation except under medical supervision.

It should be conspicuously printed and surrounded by a line.

2. Schedule 'H'

Warning

i. To be sold by retail on the R_x of RMP.
ii. Symbol R_x conspicuously displayed on the left top corner of the label.

3. Schedule 'H' Drugs (Under NDPS Act)

i. Symbol NR_x displayed on left top corner of the label.
ii. Schedule 'H' drug.

Warning

"To be sold by retail only on the R_x of RMP."

4. Schedule 'C' Drugs

i. Proper name of the drug.
ii. Statement of potency in units.
iii. Name and address of manufacturer.
iv. Date of manufacture.
v. Batch number.
vi. Date of expiry.
vii. Name and percentage of preservative, if added.
viii. Precautions regarding preserving the potency of product.
ix. When the test for maximum toxicity is prescribed a statement that the drug has passed such test.

5. Schedule 'X' Drugs

i. *Warning*: "To be sold by retail only on the R_x of RMP."
ii. Symbol XR_x in a red on left hand top corner of the label.

6. Ophthalmic Preparations (S. 24)

Ophthalmic Solutions and Suspensions

i. For external use only.
ii. Not for injection.
iii. *Warning*:
   a. If irritation persists or increases discontinue the use of drug and consult the physician.
   b. Do not touch the tip of dropper or any other dispensing tip to any surface, since it may contaminate the solution.
   c. Use the solution within 1 month after opening the container.

Ophthalmic Ointment

i. For external use only.

ii. *Warning*: If irritation persist or increases discontinue the use of drug and consult the physician.

Q.29. Give the specimen labels for certain drugs.

a. Give the specimen label for 10 × 10 tab of Analgin IP

10 × 10 Tablets ANALGIN TABLETS I.P.
Rx Each tablet contains Analgin IP ..... 500 mg Date of mfg Mfg LIC No. Batch No. Date of Expiry RP (not to be exceeded) Schedule 'H' drug
Warning: To be sold by retail on the prescription of RMP only.
Dosage: As directed by physician
ABC PHARMA PVT. LTD., SATARA

b. Prepare a specimen label for vial of Insulin 80 units/cc.

10 cc INSULIN 80 Units/cc
Date of mfg Date of Expiry Mfg LIC No. RP (not to be exceeded) Batch No. (LT Extra) Schedule 'G' Drug
Caution: It is dangerous to take the preparation except under medical supervision.
Dosage: As directed by physician
PQR PHARMA PVT. LTD., MUMBAI

c. Prepare a specimen label for 100 tablets of Phenobarbitone sodium.

10 × 10 Tablets PHENOBARBITONE SODIUM TABLETS
XRx Each tablet contains Phenobarbitone sodium ..... 30 mg Date of mfg Date of Expiry Mfg LIC No. RP (not to be exceeded) Batch No. (LT Extra) Schedule 'X' Drug
Warning: To be sold by retail only on the prescription of RMP.
Dosage: As directed by physician
XYZ PHARMA PVT. LTD., PUNE

d. Prepare a specimen label for 100 tablets of Ethyl morphine hydrochloride.

10 × 10 Tablets ETHYL MORPHINE HCl TABLETS
NRx Date of mfg Date of Expiry Mfg LIC No. RP (not to be exceeded) Batch No. (LT Extra) Schedule 'H' Drug
Warning: To be sold by retail on the prescription of RMP.
Dosage: As directed by physician
UPS PHARMA PVT. LTD., PUNE

Q.30. Give specimen label for hair dye containing paraphenylene diamine 4% or coal tar colour.

40 ml HAIR DYE	
Date of Mfg.	Expiry date
Mfg LIC No.	MRP Rs.....
Batch No.	(inclusive of all taxes)
It contains: Paraphenylene diamine	4%
POISON FOR EXTERNAL USE ONLY	
Caution: This product contains ingredients which may cause skin irritation in certain cases and so a preliminary test according to accompanying direction should first be made. This product should not be used for dying eyelashes eyebrows as such use may cause blindness.	
Warning: Keep the product away from reach of children.	
Direction: Apply as directed.	
COLOURS PVT. LTD., MUMBAI	

Preliminary Test

This preparation may cause serious inflammation of the skin in some cases and so a preliminary test should always be carried out to determine whether or not special sensitivity exists.

To make the test cleanse a small area of skin behind the ear or upon the inner surface of the forearm using soap and water or alcohol.

Prepare the dye as per the instructions and apply a small quantity of hair dye to the area and allow it to dry for 24 hours. After that wash the area with soap and water. If no irritation or inflammation exists, it may be assumed that their is no hypersensitivity to the dye.

Q.31. Give the offences and penalties under Drugs and Cosmetics Act, 1940.

1. **Penalty for the use of government analyst report for advertising:** Any one who uses the report of test or analysis supplied by CDL or government analyst for advertising, shall be punishable with fine up to ₹ 500/-, on first conviction and with imprisonment up to 10 years or fine or both on any subsequent conviction.
2. **Penalty for nondisclosure of the name of manufacturer:** Any one who does not disclose the name of the manufacturer or his agent when

asked by inspector shall be punishable with imprisonment up to 1 year or fine up to Rs. 1000/- or both.

3. **Offences and penalty for manufacture for sale or for distribution of stocks or exhibits for sale or offers for sale or distribution of cosmetics:**
   i. Any spurious cosmetics, shall be punishable with imprisonment up to 3 years and with fine.
   ii. Any cosmetic in contravention of the provisions of the Act and rules thereunder shall be punishable with imprisonment up to 1 year or fine up to Rs.1000/- or with both, on first conviction and with imprisonment up to 2 years and with fine up to Rs. 2000/- or with both on subsequent conviction.

Q.32. What does the Schedule 'J' prescribe for? Give examples.

Schedule 'J' prescribes the list of diseases and ailments to which the drug may not claim to prevent or cure.

Examples: Cancer, blindness, leprosy, epilepsy, plague, diabetes, obesity, deafness, paralysis, rheumatism.

Q 33. Mention the Schedules to which the following drugs fall.

	Drugs	*Schedule*
1.	Diazepam	Schedule H
2.	Phenobarbital	Schedule X
3.	Chlorpheniramine	Schedule G
4.	Insulin	Schedule G
5.	Cyclobarbital	Schedule X
6.	Analgin	Schedule H
7.	Streptomycin	Schedule P
8.	Secobarbital	Schedule X
9.	Erythromycin	Schedule C_1
10.	Vasopressin	Schedule H
11.	Penicillin	Schedule C
12.	Amphetamine	Schedule X
13.	Toxins	Schedule C
14.	Chloral hydrate	Schedule H
15.	Tolbutamide	Schedule G

	Drugs	*Schedule*
16.	Heparin	Schedule H
17.	Meprobamate	Schedule X
18.	Ampicillin	Schedule H
19.	Sera	Schedule C
20.	Chlorpropamide	Schedule G
21.	Ibuprofen	Schedule H
22.	Salbutamol sulphate	Schedule H
23.	Chlordiazepoxide	Schedule H
24.	Pituitary extract	Schedule C
25.	Fish liver oil	Schedule C_1
26.	Polio vaccine	Schedule P
27.	Methaquinolone	Schedule X
28.	Dexamphetamine	Schedule X
29.	Primidone	Schedule G
30.	Tetracycline	Schedule C_1

OBJECTIVE QUESTIONS WITH ANSWERS IN BOLD LETTERS

1. The drugs which are imported under the names of other drug are called as **spurious drugs.**

2. **Drug store** means the licensed premises for the sale of **drugs** which don't require the services of qualified person.
3. **Schedule 'J'** includes the list of diseases and ailments which a drug may not claim to prevent or cure.
4. Insulin belongs to **Schedule G** drugs.
5. Schedule 'P' stands for **pack size of drugs**.
6. Diazepam belongs to **Schedule 'H'.**
7. **Schedule 'W'** contains the list of drugs shall be marketed under generic names only.
8. **Schedule 'FF'** stands for standards of ophthalmic products
9. **Schedule N** prescribes for the list of minimum equipment for the efficient running of pharmacy.
10. CDL stands for **Central Drug Laboratory**
11. **Form 19** is to be submitted for an application related to the sale of drugs specified in the Schedule C and C1 excluding Schedule X.
12. Penalty for using Government Analyst report for advertising is ₹ **500**.
13. Schedule 'P' stands for **life period of drugs.**
14. Licence for the retail sale of Schedule C and C1 drugs is given in the **Form 21**.
15. **Schedule A** is related to the issue and renewal of license.
16. Drugs exempted from the provisions of import come under **Schedule D.**
17. **Schedule X** prescribes the list of habit forming, psychotic and such other drugs.
18. A drug which is manufactured under the name which belongs to another drug is called as **spurious drug**.
19. DTAB stands for **Drug Technical Advisory Board.**
20. The chairman of DTAB is **Director, General Health Services.**
21. The sample taken by the Drug Inspector from the retail premises should be divided into **03** parts.
22. The particulars to be shown in manufacturing and analytical records of the drugs are dealt under **Schedule U.**
23. Application to manufacture of cosmetics is made to the licensing authority is in **Form 31**.
24. The area specification required for retail sale premises is **10 sq.m**
25. The Sera comes under the **Schedule C.**
26. The drug samples taken by Drug Inspectors for analysis are sending to **Government Analyst.**

27. If the drug contains a colour which is not prescribed as per D&C Act, 1940 is called as **Misbranded drug.**
28. GMP requirements of factory premises, plants and equipment are given in **Schedule M.**
29. Standards for patents and proprietary medicines are laid down in **Schedule V.**
30. If the product has been substituted partly or wholly by another drug substance is known as **spurious drug.**
31. Drug samples are sent from Magistrate for analysis to the **State Drug Control Laboratory.**
32. **DCC committee** advises DTAB and various governments.
33. Joint State Pharmacy Council was constituted under **Section 20** of the Pharmacy Act, 1948.
34. **XRx** is the symbol used on the left hand top corner of the label of **Schedule X** drugs.
35. Standards for mechanical contraceptives are given in the **Schedule R.**
36. **Drug store** means the licensed premises for the sale of drugs which do not require the services of qualified person.
37. **Chemist and Druggist** means the premises licensed for the sale of drugs which require the services of qualified persons and where the drugs are not compounded against the prescription of RMP.
38. **Schedule B** prescribes the fees for test or analysis by the Central Drug Laboratory or Government Analyst.
39. **Schedule G** prescribes the list of substances required to be taken only under supervision of RMP.
40. DCC is constituted under **Section 7** of the D&C Act, by the central government.
41. **Pharmacy** means the premises licensed for sale of drugs which require services of qualified person and where the drugs are compounded against the prescription of RMP.
42. The **First schedule** of D&C Act prescribes the list of Ayurvedic, Siddha and Unani drugs.
43. The Ayurvedic, Siddha, Unani, DTAB comes under **Section 33** of D&C Act, 1940.
44. The Government Analyst has to submit his report of drug analysis in 3 copies in the **Form 13**.
45. The Government Analyst compares the seals on the package with the **specimen impression.**

46. Penalty for the use of Government Analyst report is **500 Rs**.
47. Drug Inspector shall be deemed to be a public servant under **Section 21** of Indian Penal Code (IPC).
48. DTAB is purely a **central government body**.
49. For the import of drugs specified in Schedule X, the licence shall be granted in **Form 10A.**
50. In pharmacy a separate cupboard should be provided for **storage of poisons.**
51. Diazepam belongs to **Schedule H.**
52. Tolbutamide belongs to **Schedule G**.
53. Drug samples are sent from Magistrate for analysis to the **State Drug Control Laboratory.**
54. If the product has been substituted partly or wholly by another drug substance, it is known as **spurious drug.**
55. Standards for patents are laid down in **Schedule V.**
56. The schedule of standards for cosmetics is **Schedule S**.
57. **Form 20B** is used to issue licence for wholesale of drugs other than specified in Schedule C, C_1 and X.
58. Biologicals are tested at **Kasauli**.
59. Licence for wholesale of drug specified in Schedule C and C_1 is issued in **Form 21B**.
60. The Drug Inspector is appointed under the Act of **21 of Indian Penal Code (IPC).**
61. If a drug contains a colour which is not prescribed is called **Misbranded drug.**
62. The drug samples taken by Drug Inspector for analysis are sending to **Government Analyst.**
63. List of coal tar colours permitted under to be used in cosmetics comes under **Schedule Q.**
64. **Schedule FF** prescribes standards for ophthalmic preparations.
65. The Central Drug Laboratory (CDL) is situated at **Calcutta.**
66. The person in-charge of State Drugs Laboratory is **Government Analyst.**
67. **DCC** is the advisory committee of DTAB and various governments.
68. The Chairman of DTAB is **Director General of Health Services**.
69. Antisera are tested at **Izzatnagar.**
70. DTAB and DCC are purely **advisory** agencies/bodies.

71. The Drugs and Cosmetics Act was passed in 10th April 1940, with a main object to **regulate the import, manufacture, distribution and sale of Drugs and Cosmetics.**
72. Chapter number III of Drugs and Cosmetics Act, 1940 contains **import of drugs and cosmetics.**
73. Schedule R (I) prescribes the standards for **medical devices**.
74. Licence of import of drug is obtained in application to **Drug Controller of India**.
75. Warning for **Schedule H** is "To be sold by retail only on the R_x of RMP."

Chapter

4

Narcotic Drugs and Psychotropic Substances Act, 1985 and Rules

Q.1. Give the objectives of Narcotic Drugs and Psychotropic Substances Act, 1985.

1. The Act was passed to fight against the fast increasing use of addictive materials.
2. The Act provides very stringent provisions for the control and regulation of operations relating to the narcotic and psychotropic substances and concerned matters.

Q.2. Define the terms.

1. **Addict:** It means a person addicted to any narcotic drugs and psychotropic substances.
2. **Psychotropic substances:** It means any substance, natural or synthetic or any salt or preparation of such substances or material, which is included in the list of psychotropic substances in the schedule. For example, mescaline, diazepam, nitrazepam, phenobarbitone, chlordiazepoxide, amphetamine.
3. **Narcotic drugs:** It means coca leaf, cannabis, opium, poppy straw and includes all manufactured drugs.
4. **Medicinal cannabis (hemp):** It means any extract or tincture of cannabis (hemp).
5. **Coca plant:** It means the plant of any species of genus Erythroxylon.
6. **Coca leaf:** It means:
   i. The leaf of coca plant except a leaf from which all ecgonine and cocaine have been removed.
   ii. Any mixture with or without neutral material except any preparation containing not more than 0.1% of cocaine.

7. **Coca derivative**
   It means:
   i. Crude cocaine
   ii. Ecgonine and all its derivatives
   iii. Cocaine and its salts
   iv. All the preparations containing more than 0.1% of cocaine.
8. **Opium**
   It means:
   i. Coagulated juice of opium poppy
   ii. Any mixture with or without neutral materials of coagulated juice but not includes any preparation containing not more than 0.2% of morphine.
9. **Opium poppy:** It means the plant of *Papaver somniferum* and other species of papaver from which opium or any phenanthrene alkaloids can be extracted.
10. **Poppy straw:** It means all parts of opium poppy (except seeds) after harvesting whether in their original form, or cut, crushed or powdered and whether or not juice has been extracted from it.
11. **Poppy straw concentrate:** It means the material obtained when poppy straw is subjected for the concentration of its alkaloids.
12. **Opium derivatives**
    It means:
    i. *Medicinal opium*: It is the opium confirming with requirement as per Indian Pharmacopoeia or any other pharmacopoeia and mixed with or without neutral materials.
    ii. *Prepared opium*: It means the opium manipulated to make it suitable for smoking and the residue left after it has been smoked.
    iii. Morphine, codeine, thebaine and their salts.
    iv. Heroin and its salts.
    v. Preparation containing more than 0.2% of morphine.
13. **Cannabis (hemp):** It means:
    i. *Charas*: The resin in the crude or purified state obtained from cannabis plant including concentrated preparations and the resin known as Hashish oil or liquid Hashish.
    ii. *Ganja*: Means flowering and fruiting tops of cannabis plant except seeds and leaves.
    iii. Any mixture with or without neutral material of the above forms or any drink prepared from them.

14. **Illicit traffic (S. 23):** It includes:
    i. Cultivating any coca plant or gathering any portion of coca plant.
    ii. Cultivating the opium poppy or any cannabis plant.
    iii. Engaging in production, manufacture, possession, sale, purchase, transport, warehousing, consumption, interstate import or export, import into India, export from India, transhipment of narcotic drugs or psychotic substances.
    iv. Engaging in the activities in the narcotic drugs or psychotic substances other than those specified in (i) to (iii) above.
    v. Giving premises for the above activities except as permitted under the Act.
    vi. Financing directly or indirectly for any of the above activities.
    vii. Harbouring the persons engaged in the above activities.

Q.3. Give the operations controlled and regulated by central government as per NDPS Act, 1985. (W. 23)

Central government by making rules controls and regulates following operations:

1. Cultivation and gathering of any portion of coca plant, only on behalf of central government.
2. Cultivation of opium only on behalf of central government.
3. Production and manufacture of opium and production of poppy straw.
4. Manufacture of manufactured drugs except prepared opium and medicinal hemp.
5. Sale of opium and opium derivatives.
6. The manufacture, possession, transport, interstate export, import, sale, purchase, consumption or use of psychotropic substances.

Q.4. What are the operations controlled and regulated by state government?

State government by making rules controls and regulates following operations:

1. Possession, transport, interstate import, export, warehousing, sale, purchase, consumption and use of poppy straw.
2. Cultivation of any cannabis plant, production, manufacture, possession, transport, interstate import, export, sale, purchase, use of cannabis (except charas).
3. Manufacture of medicinal opium or preparation containing manufactured drugs.

4. Possession, transport, purchase, sale, interstate import, export, use or consumption of manufactured drugs.
5. The manufacture and possession of prepared opium from opium lawfully possessed by an addict registered with state government on medical advice or his personal consumption.

Q.5. Give the offences and penalties under NDPS Act.

1. Offences

i. Operations relating to poppy straw.
ii. Cultivating coca plant and gathering its portion.
iii. Operations relating to prepared opium.
iv. Operations relating to opium poppy and opium.
v. Operation relating to cannabis plant except ganja.

Penalties

i. Rigorous imprisonment for not less than 10–25 years and fine not less than 1 to 2 lakhs on first conviction.
ii. With rigorous imprisonment for not less than 15 to 30 years and fine not less than 1.5 to 3 lakhs.

2. Offences

i. Operations of manufactured drugs and their preparations.
ii. Operations relating to psychotropic substances.
iii. Illegal import–export or transhipment of narcotic drugs and psychotropic substances.
iv. External dealing in narcotic drugs and psychotropic substances.
v. Allowing premise, vehicle, vessel, etc. to be used for the commission of offences.

Penalties

i. Rigorous imprisonment not less than 10 to 20 years and fine not less than 1 to 2 lakhs on first conviction.
ii. With rigorous imprisonment for not less than 15 to 30 years and fine not less than 1.5 to 3 lakhs.

3. Penalty for Illegal (Unlawfully) Possession in Small Quantity of any Narcotic Drugs and Psychotropic Substances for Personal Consumption under NDPS Act, 1985

Shall be punishable with:

i. Imprisonment up to 1 year or fine or both where narcotic drugs or psychotropic substances consumed is—cocaine, morphine, heroin, etc.

ii. Imprisonment up to 6 months or fine or both where narcotic drugs or psychotropic substances consumed is other than above.

OBJECTIVE QUESTIONS WITH ANSWERS IN BOLD LETTERS

1. NDPS Act provides very stringent provisions for the control and regulation of operations relating to the **Narcotic Drugs and Psychotropic Substances.**
2. Narcotic Drugs and Psychotropic Substances Consultative Committee has been formed by **central government.**
3. Charas is obtained from the **Indian hemp plant.**
4. **Prepared opium** means the opium manipulated to make it suitable for smoking and the residue left after it has been smoked.
5. The NDPS Act was passed to fight against **the fast increasing use of addictive materials.**
6. The Narcotic Drugs and Psychotropic substances Act was passed in **1985.**
7. Cannabis includes both **charas and ganja.**
8. Medicinal cannabis is also known as **hemp.**
9. Coca derivatives include both **ecgonine and cocaine.**
10. The Narcotic Drugs and Psychotropic substances Consultative Committee consist of **20 members.**
11. Diacetylmorphine is also known as **herion**.
12. **Charas** is the resin obtained from the Cannabis (Indian hemp).
13. Punishment for illegal possession of a small quantity of cocaine, morphine, diacetylmorphine for personal consumption is **imprisonment up to 1 year or fine or both.**
14. Opium poppy includes plant of ***Papaver somniferum***.
15. Dangerous Drugs Act was passed in **1930.**
16. The NDPS ordinance was passed to provide prevention of **illict traffic** in NDPS.
17. Under the provisions of NDPS Act, the government may appoint **Narcotic Commissioner.**
18. The extract of tincture of cannabis is called **medicinal cannabis and medicinal opium**.
19. *Cannabis sativa* yields **hemp.**
20. The second International Opium Conference was held on **27th Sept. 1924 at Geneva.**

21. Opium straw includes all parts except **seed.**
22. Operations related to Narcotic Drugs under Section 8 are controlled by **state government.**
23. Coca leaf contains **more than 0.1% cocaine.**
24. Cocaine is **methyl ester of benzoyl ecgonine.**
25. Heroin is also known as **Diamorphine.**
26. A person habitual to regular use of any Narcotic Drugs or Psychotropic Substances is known as **addict.**
27. Narcotic Drugs and Psychotropic Substances Consultative Committee has been formed by **central government.**
28. Geneva Convention was held on Narcotic Drugs in **March 1972.**
29. Opium means **coagulated juice of opium poppy** (*Papaver somniferum*).
30. Licence for cultivation of opium poppy is granted by **District Opium Officer.**
31. Opium can be manufactured by **Government Opium Factory.**
32. The licence for the manufacture of medicinal hemp is granted by **state government.**
33. The price of opium is fixed by **central government**.

Chapter

5

The Drugs and Magic Remedies (Objectionable Advertisement) Act, 1954

Q.1. Give the objectives of the Drugs and Magic Remedies (Objectionable Advertisement) Act, 1954.

Objectives

i. This Act is passed to control and prohibit the advertisements related to drugs and magic remedies which make false claim and mislead the public.

ii. This Act covers all the advertisements which are objectionable and unethical and which are used to promote self-medication and self-treatment.

Q.2. Define the terms as per DMR (OA) Act, 1954.

a. **Advertisement**
   It means:
   i. Any notice, circular, label, wrapper or other document.
   ii. Any announcement made orally or by means of producing or transmitting light, sound or smoke.

b. **Drug:** It includes:
   i. The medicines for internal or external use for human beings or animals.
   ii. Any substance intended to be used for the diagnosis, cure, mitigation, treatment or prevention of diseases in human beings or animals.
   iii. Any article other than food, if affects any structure or organ function of the body of human beings.
   iv. Any article used as a component of any medicine or substances used in (i), (ii) and (iii) as above.

c. **"Magic remedy":** It includes Talisman, mantras, Kavachas and other charm of any kind which claim to possess miraculous power, for diagnosis, cure, mitigation, treatment and prevention of any diseases in human beings or animals or altering any organic function of human or animal bodies.

d. **"Taking part in the publication of any advertisement"**
It includes:
i. The printing of advertisement.
ii. The publication of any advertisement in the area to which this Act extends.

Q.3. State the classes of prohibited advertisement as per OA Act, 1954. OR Give the classes of advertisement which are prohibited under the DMR Act, 1954. OR What are the classes of advertisement to which provisions of Act are applicable? OR Name the classes of advertisement of which import and export are totally prohibited under DMR (OA) Act, 1954. (S. 24)

Following classes of advertisements are prohibited under the Act:

I. **Advertisements relating to drugs** which are likely to be used in the following diseases or conditions for:
   a. The procurement or miscarriage (abortion) or the prevention of conception (pregnancy) in women.
   b. The correction of menstrual disorders in women.
   c. The maintenance or improvement of capacity of human being for sexual pleasure.
   d. Diagnosis, cure, mitigation, treatment or prevention of any disease or disorder specified in Schedule 'J' of the Act.
   Schedule 'J' diseases:
   Appendicitis, blindness, cataract, cancer, deafness, diabetes, epilepsy, gallstone, kidney stone, leprosy, obesity, paralysis, sexual impotence, smallpox, tuberculosis, venereal diseases, etc.

II. **Advertisements relating to drug**
   i. Which directly or indirectly give false impression regarding true character of the drug.
   ii. Make false claim for it.
   iii. Are otherwise false and deceptive.

III. **Advertisements relating to magic remedies** claiming their efficacy mentioned in clause (I) by the person who carries on the profession of administering magic remedies.

Q.4. Give the classes of advertisements and displays which are exempted from the provision of DMR Act, 1954. OR Name the classes of advertisements to which DMR Act, 1954 is not applicable. (W. 23)

The following classes of advertisements are exempted from the provisions of DMR Act:

a. Any notice, signboard displayed by RMP on his premise indicating that the treatment is undertaken for disease.
b. Any book or treatise dealing with matter relating to the disease or conditions and which is published from bona fide scientific or social standpoint.
c. Advertisements relating to drugs which are sent confidentially in the prescribed manner to the RMP.

   Such advertisements are required to be sent confidentially and if sent by post then following matter should be written at the top.

   "For the use of registered medical practitioner or hospital."
d. Advertisements relating to drugs which are printed or published by government or by any other person with previous permission of government.
e. Any advertisements, labels or sets of instructions which are permitted under the Drugs and Cosmetics Act and rules thereunder.
f. Any advertisement which is prohibited under Act, and central government feels that particular advertisement shall be in the interest of public, then it may be permitted by notification in the official gazette.

Q.5. How scrutiny of misleading advertisements relating to the drugs is done as per DMR (OA) Act, 1954?

- The scrutiny of misleading advertisement is done by person authorised by state government.
- If the person authorised feels that a particular advertisement has been made in contravention of the provisions of the Act, he may order to the manufacturer, packer, distributor or seller to submit the information regarding composition of drug or its ingredient.
- Such other information which may be necessary for scrutinising the advertisement.
- The manufacturer, packer, or seller shall bound to comply with order.
- The publishers and advertising agencies shall furnish the information like name and address of manufacturer, packer and seller, etc.
- From the above information advertisement is scrutinised and if it is found misleading then it shall be punishable under this Act.

Q.6. Give the offences and penalties under DMR (OA) Act, 1954. (S. 23)

1. Anyone who contravenes any of the provisions of Act shall be punishable with imprisonment up to 6 months or a fine or both on first conviction and with imprisonment up to 1 year or a fine or both on subsequent convictions.

2. If company contravenes any of provisions of Act, every person who at the time of offence was incharge of company or responsible person shall be deemed to be guilty and punishable under the Act.

Q.7. Enlist any 10 diseases or ailments of which advertisements are prohibited under DMR (OA) Act, 1954. OR Mention any seven diseases or ailments of which no advertisement should be made to claim their cure as per Drugs and Magic Remedies (OA) Act. (S. 24)

1. Tuberculosis
2. Epilepsy
3. Leprosy
4. Cancer
5. Smallpox
6. Paralysis
7. Deafness
8. Appendicitis
9. Obesity
10. Deafness
11. Blindness
12. Rheumatism
13. Kidney stone
14. Cataract
15. Heart diseases.

OBJECTIVE QUESTIONS WITH ANSWERS IN BOLD LETTERS

1. **Magic Remedy** includes: Talisman, mantras, kavachas and other such treatments for cure of diseases in human or animal bodies.
2. Advertisement relating to drugs for the procurement of or miscarriage or prevention of conception in women comes under the **prohibited classes of advertisement.**
3. Magic Remedies Act was passed in **1954.**
4. Taking part in the publication of advertisement means **printing and publication of the advertisement in any country.**
5. Hakkims, pandits, vaids claiming to cure of diseases referred to **magic remedy.**

Chapter

6

The Prevention of Cruelty to Animals Act, 1960

Q.1. Give in brief introduction of the Prevention of Cruelty to Animals Act, 1960.

Prevention of Cruelty to Animals Act, 1960

In modern medical pharmaceutical sciences, animals are widely used to perform experiments to study the safety, toxicity and therapeutic efficacy of drugs as they are much similar to human systems.

The animals like frogs, rabbits, guinea pigs, rats, dogs, etc. were used for experimentation. It was observed that animals may be subjected to injury, pain or suffering and even death due to careless handling during experimentation.

Therefore, the Prevention of Cruelty to Animals Act came into existence to minimize the unnecessary pains or suffering on the animals.

Q.2. Give the objectives of the Prevention of Cruelty to Animals Act, 1960.

The Prevention of Cruelty to Animals Act, 1960 was passed with the following main objectives:

a. This Act prevents the infliction of unnecessary pain or suffering on the animals.
b. The Act prevents the human from behaving cruel towards animals.

Q.3. Define the following terms.

1. **Animal**
   Animal means any living creature other than a human being.
2. **Domestic Animals**
   It means any animal which is tamed or which has been or is being sufficiently tamed to serve some purpose for the use of man or which, although it neither has been nor is being or is intended to be so tamed, is or has been in fact wholly or partly tamed.

3. **Captive Animals (S. 23)**
   It means 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.
4. **Local Authority**
   It means a municipal committee, district board or other authority for the time being invested by law with the control and administration of any matter within a specified local area.
5. **Cruelty**
   It means the infliction of unnecessary pain or suffering on the animals.
6. **Phooka or Doom Dev**
   It includes any process in which any substance or air is introduced into the female organ of milch animal with the intention of drawing of any secretion of milk.
7. **Breeder**
   It means a person including an institution which breeds animal for the purpose of transfer to other authorized institution for performing experiments.
8. **Establishments**
   It means any individual, company, firms, corporation and institution other than school up to higher secondary level, which performs experiments of animals.
9. **Experiments**
   It means any programme/project involving experiments on animals for the purpose of advancement by new discovery of physiological knowledge which will be for saving or prolonging life or alleviating suffering or for combating any disease whether on human being or animals.
10. **Owner**
    Owner means a person with reference to animals, includes not only the owner but also any person for the time being in possession or custody of the animal, whether with or without the consent of the owner.

Q.4. Give the constitution and functions of Animal Welfare Board.

Animal Welfare Board

Animal Welfare Board is established by central government in order to:

a. Protect the animal from the unnecessary pain or suffering.
b. Promote the animal generally.

Constitution of Animal Welfare Board

Animal Welfare Board consists of the various members. central government nominates one of the members to be its Chairman and another member to be its Vice-Chairman.

Central government may also appoint Secretary of the Board.

Functions

1. To prevent cruelty to the animals by keeping the laws in force and advise government regarding the amendments to be undertaken in this Act from time to time.
2. To suggest the government any improvement in the design of the vehicle so as to lessen the burden on draught animals.
3. To advise central government on making of the rules for preventing infliction of unnecessary pain especially when they are being transported or when they are kept in captivity or confinement.
4. To take the steps for the amelioration of animals by providing facilities like shades, water, troughs, etc. along with veterinary assistance.
5. To encourage the animals welfare associations by providing financial assistance or forming rescue homes, shelter to the old animals and birds.
6. To advise the government on medical care and attention to be provided in animal hospitals.
7. To cooperate with the various associations established to prevent the infliction of unnecessary pains or sufferings to the animals.
8. To impart the education relating to the handling of animals by human beings by means of lectures, books, posters, etc.
9. To advise the government on any other such matters relating to animal welfare.

Q.5. Write a note on "Experimentation on Animals". Give the constitution of committee which control and supervise the experiments performed on animals and mention the rules made by them.

Experimentation on Animals

The experimentation on animals are carried out to develop a new drug molecule, biological like vaccines, sera and hormones which will be useful for saving or for increasing life or treating diseases of human beings, plants or animals.

Experimental animals should be handled with due care and humanity. Animals should not suffer from any pain or any harm to the health of the animals during experimentation.

Therefore, central government has constituted a committee to control and supervise the experiments performed on animals.

Constitution of the Committee

It consists of the following members:

a. *Nominated Members*
   1. Two members nominated by central government from each of the:
      i. Indian Council of Medical Research
      ii. Indian Council of Agricultural Research
      iii. Council of Scientific and Industrial Research
   2. Two members from Universities giving medical and veterinary degrees nominated by central government.
   3. Five non-official members from the persons who are actively engaged in the promotion of animal's welfare are nominated by central government.

b. *Elected Members*

   One member each of Lok Sabha and Rajya Sabha is to be elected by the Houses respectively.

Rules Made by the Committee

The committees shall make the following rules to supervise the animals during experimentation.

1. If possible, the experiments on the animals shall be avoided, if other teaching aids like books, models, films, etc. are available.
2. If possible, the use of large animals shall be avoided, if same results can be obtained by using small animals like rats, frogs, rabbits, etc.
3. Usually the experiments on the animals shall not be performed to have a practice.
4. The experiments on the animals shall be performed under the influence of anesthetic with due care and humanity.
5. Where the experiments are performed under the influence of anesthetic and if the animal is so injured that if they cannot be recovered shall be destroyed still unconscious.
6. The animals used for experimentation shall be looked before and after the experiments.
7. The proper records regarding experimentation shall be maintained.

Q.6. What is CPCSEA? Give its objectives.

CPCSEA

It means the Committee for the Purpose of Control and Supervision of Experimental Animals.

CPCSEA is a statutory committee which is established under Chapter 4, Section 15(1) of the Prevention of Cruelty to Animals Act, 1960.

Objective/Purpose of the Act

The objective of CPCSEA is to ensure that animals are not subjected to unnecessary pains or suffering before, during or after performance of the experiments on them. For this purpose, the government has made "Breeding of and Experiments on Animals (Control and Supervision) Rules, 1998 as amended during 2001 and 2006, to regulate the experimentation on animals.

Q.7. What are the functions of CPCSEA? (W. 23)

All establishments in research and education involving animals are required to comply with the various guidelines, norms and stipulations set out by CPCSEA.

Functions of CPCSEA

1. Registration of establishments conducting animal experimentation or breeding of animals for this purpose.
2. Selection and appointment of nominees in the Institutional Animal Ethical Committees of registered establishments.
3. Approval of animal house facilities on the basis of reports of inspections conducted by CPCSEA.
4. Permission for conducting experiments involving the use of animals.
5. Recommendations for import of animals for use in experiments.
6. Actions against establishments in case of violation of any legal norms.
7. Conduct of training programmes for the nominees of CPCSEA.
8. Conduct/support of conferences/workshops on animal ethics.

Q.8. What is IAEC? Give the objectives of IAEC.

IAEC means Institutional Animal Ethical Committee

Objectives of IAEC

1. To receive, review and approve research proposals involving experiments on small laboratory animals.

2. To receive, review and recommend research proposals involving experiments on large laboratory animals to CPCSEA.
3. To monitor the research activity on laboratory animals.
4. To regulate the housing, breeding, transport of laboratory animals and maintenance of animal house as per guidelines of CPCSEA.

Q.9. Give the constitution/composition of IAEC.

Institutional Animal Ethical Committee (IAEC) shall include eight members as follows:

1. A biological scientist.
2. Two scientists from different biological disciplines.
3. A veterinarian involved in the care of animals.
4. Scientist in charge of animal facility of the establishment concern.
5. A scientist from, outside the institute.
6. A non-scientific socially aware member.
7. A nominee of CPCSEA.
8. Specialist co-opted while reviewing special project using hazardous agents such as radioactive substance and deadly microorganisms.

The chairperson of the committee and member secretary would be nominated by the institution from amongst the eight members. The members against serial number 5, 6 and 7 will be nominated by CPCSEA, with a provision of a link nominee for CPCSEA.

Q.10. What are the functions of IAEC?

Functions of IAEC

1. IAEC monitors the research throughout the study and after completion of study through periodic report and visit animal house and laboratory where the experiments are conducted.
2. The IAEC committee ensures compliance with all regulatory requirements, applicable rules, guidelines and laws.
3. It reviews proposed use of animals in research and require any modification necessary for approval or withhold approval prior to use of animals.
4. It approves research involving animals which conform to the various guidelines for use of animals in research.
5. It reviews periodically the institute's animal facility.
6. It reviews and investigates legitimate concern involving the care and use of animals during research.

7. It suspends the research activity which does not adhere to the guidelines for use of animals in research and take corrective action.
8. It ensures that all personnel involved in animal care and use are appropriately qualified to perform their duties and conduct proposed activities.

Q.11. Write in brief about "Breeding and Stocking of Animals".

Breeding and Stocking of Animals

Breeding and stocking of animals for experimentation is regulated under Breeding of and Experiments on Animals (Control and Supervision) Rules of 1998, 2001 and 2006 framed under the PCA Act, 1960.

Breeding of Animals

"Breeder" means a person including an institution, which breeds animals for the purpose of transfer to other authorized institution for performing experiments.

Provisions for Breeding of Animals as per Rules

i. No establishment shall carry on the business of breeding of animals or trade of animals for the purpose of experiments unless it is registered.
ii. Every breeder/establishment carrying on the business of breeding animals or trade of animals for the purpose of experiments, shall apply for registration within sixty days from the date of commencement of these rules and, stop breeding of animals if registration is subsequently refused to it by the committee.

Stocking of Animals

The animals shall be stocked by the breeder and the establishment in the following manner:

a. Animal houses shall be located in a quiet atmosphere, undisturbed by traffic and the premises kept tidy, hygienic and the animals protected from drought and extreme of weather.
b. Animal cages for small animals and stables for large animals shall be such that animals can live in comfort and overcrowding is avoided.
c. Animal's attendants must be suitably trained experienced in the duties allotted to them.
d. Animals shall be looked after, before and after the experiments by trained and experienced attendants.
e. There shall be satisfactory arrangement for looking after the animals during off hours and on holidays.

Q.12. What do you mean by "Cruelty to Animals"?/What is the concept of "Cruelty to Animals"?

Cruelty to Animals Generally Means

If any person:

a. Beats, kicks, over-rides, over-loads, tortures or otherwise treats any animal so as to subject it to unnecessary pain or suffering or causes, or being the owner permits, any animal to be so treated; or
b. 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
c. 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
d. Keep for an unreasonable time any animal chained or tethered upon an unreasonable short or unreasonably heavy chain or cord; or
e. Being the owner, neglects to exercise or cause to be exercised reasonably a dog habitually chained up or kept in close confinement; or
f. Being the owner (of any animal) fails to provide such animal with sufficient food, drink or shelter; or
g. Without reasonable cause, abandons any animal in circumstances which tender it likely that it will suffer pain by reason of starvation thirst; or
h. Willfully 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 reasonably excuse permits any diseased or disabled animal, of which he is the owner, to die in any street; or
i. Offers for sale or without reasonable cause, has in his possession any animal which is suffering pain by reason of starvation, thirst, overcrowding or other ill treatment; or
j. Kills any animal (including stray dogs) by using the method of strychnine injections in the heart or in any other unnecessary cruel manner; or
k. Solely with a view to providing entertainment; or
l. Keeps uses or acts in the management or, any place for animals fighting or for the purpose of baiting any animal or permits or offers any place to be so used or receives money for the admission of any other person to any place kept or used for any such purposes; or
m. Promotes or take part in any shooting match or competition wherein animals are released from captivity for the purpose of such shooting.

Q.13. What precautions should be taken during performance of the experiments on the animals?

Performance of Experiments

During conduction of experiments on animals following precautions should be taken:

a. Experiments shall be performed under the supervision of duly qualified person, i.e. Degree or Diploma holders in Veterinary Science or Medicine or Laboratory animal science of a University or an institution recognized by government.
b. Experiments shall be performed with due care and humanity.
c. Animals used for performance should be properly looked before and after the experiments.
d. Anesthesia shall be administered to the animals under experiment by a veterinary surgeon trained in methods of anesthesia, and shall remain present near the animal till the completion of the experiment.
e. Animal suffering abnormal or severe pain at any stage of a continuing experiment, it shall be destroyed at that stage without proceeding with experiment.
f. Experiments on animals shall not be performed for the purpose of attaining or retaining manual skills except in schools, colleges and recognized training institutions.
g. Experiments shall not be performed as a public demonstration.
h. Experiments shall not be repeated if the result of which is already conclusively known.

Q.14. What are the provisions for transfer and acquisition of animals for experiment?

Transfer and Acquisition of Animals for Experiment

a. A breeder shall not transfer any animal by a sale or establishment which is not registered under these rules.
b. An establishment shall not acquire any animal by sale or otherwise except from a registered breeder/establishment.
c. Every establishment after acquisition of animal or animals shall not transfer such animal or animals by sale or otherwise to any other establishment or person except to a registered breeder/establishment.
d. The animals used for experimentation in a production/breed improvement programme may be given out by the breeder's institution for domestic use.

e. No animal shall be imported by a breeder or an establishment which is available in the country.
f. A breeder or establishment shall comply, with the directions given by the Committee for the purpose of controlling and supervising experiments on the animals.

Q.15. How the records of animals are maintained as per Rules of PCA, 1960, Act?

Maintenance of Records of Animals

a. Every, establishment/institutional Animals Ethics Committee shall maintain a record of the animals under its control and custody in the specified format.
b. Every, establishment/institutional Animals Ethics Committee shall furnish such information, as the Committee may from time to time require in the specified format.
c. All laboratories shall inform the exact number/species of animals to the Members Secretary or any officer authorized in this regard by the Committee as per the specified format.

Q.16. What are the provisions for suspension/revocation of registration of an establishment or breeder by CPCSEA?

The Suspension/Revocation of Registration of an Establishment or Breeder by CPCSEA

The following are provisions as per the Rule 14 of the Breeding of and Experiments on Animals (Control and Supervision), for the suspension/revocation of registration of an establishment or breeder:

a. If the committee found that:
    1. The rule made by it is not being complied with by an establishment or breeder; or
    2. A violation of the directions of the Committee has been committed by any establishment or breeder and the Committee's directions to rectify such violation have not been complied within the period so specified.
b. The Committee may, by order in writing, suspend or revoke the registration of the establishment or breeder and/or direct the closure of the animal house facility for such a period as may be specified in the order:

Provided that no order under this clause shall be made without giving the establishment or breeder opportunity of being heard in the matter.

Provided further that no order for suspension or revocation of registration or closure of the animal house facility shall be issued in a case of minor violation.

Q.17. What are the offences and penalties under Prevention of Cruelty to Animals Act,1960?

Offences and Penalties

1. Any person who is treating the animal cruelly shall be punishable with fine not less than ₹10/- which may extend up to ₹ 50/- on first conviction and on subsequent conviction, he shall be punishable with fine not less than ₹ 25/- which may extend up to ₹ 100/-.
2. Any person who is performing operations like phooka doom dev or any other operation to improve the lactation which is injurious to the health of the animal is punishable with a fine up to ₹ 1000/- or imprisonment up to two years or with both. The animal subjected to such operation is liable to forfeiture to the government.
3. Any person who contravenes any condition imposed by Committee or contravenes any order made by the Committee shall be punishable with fine up to ₹ 200/-.

OBJECTIVE QUESTIONS WITH ANSWERS IN BOLD LETTERS

1. The prevention of Cruelty to Animals Act was passed in the year **1960.**
2. **Cruelty** means the infliction of unnecessary pain or suffering on the animals.
3. **Phooka or Doom Dev** includes any process in which any substance or air is introduced into the female organ of milch animal with the intention of drawing of any secretion of milk.
4. CPCSEA means **Committee for the Purpose of Control and Supervision of Experiments on Animals.**
5. IAEC stands for **Institutional Animal Ethical Committee.**
6. Animal Welfare Board is established by **central government.**
7. CPCSEA is a statutory committee which is established under Chapter 4, Section 15(1) of the **Prevention of Cruelty to Animals Act, 1960.**
8. **"Breeder**" means a person including an institution, which breeds animals for the purpose of transfer to other authorized institution for performing experiments.

Chapter

7

The Poison Act, 1919

Q.1. Give the aims and objectives of Poison Act, 1919.

Objective

The Poison Act, 1919 was passed with a view to regulate and control import, possession for sale and sale of a poison.

Q.2. Define 'poison' as per Poison Act, 1919. Give examples of list A and list B poisons. (S. 24)

Poison

It means all the substances notified as a poison under the Poison Act, 1919.

List A

Morphine, atropine, arsenic, heroin, potassium cyanide, belladonna, coca, strychnine, barbituric acid, cyanide, ecgonine, lead, aconite digitalis, aconine, ergot.

List B

Chloroform, zinc chloride, oxalic acid, carbolic acid, barium sulphate.

Q.3. Write a note on "import of poison".

Import of Poison

- Central government regulates import of poisons in India.
- The import of poisons into India is permitted only under the authority of licence issued by the central government.
- The persons licensed to import poisons must observe the conditions of licence.
- The person licensed to import poisons, should import them across one of the defined customs frontiers and in accordance with the conditions of the licence.

Q.4. How does state government regulate possession for sale and sale of poison under Poison Act, 1919? OR Explain in brief the restrictions imposed by the Poison Act on possession for sale and sale of poison in India. OR Mention different conditions to be satisfied for wholesale or retail sale of poison in a state. (S. 23, W. 23)

Possession for Sale and Sale of Poison

The rules made by state government for possession and sale of poison.

1. To grant of licences to possess any specified poison for wholesale or retail.
2. Fixing the fees for the licence.
3. The classes of persons to whom licences may be granted.
4. The classes of persons to whom the poison may be sold.
5. The maximum quantity of poison that can be sold to any one person.
6. Maintenance of sale register by the vendors of poisons, particulars to be entered in the register and its inspections.
7. Safe custody of such poisons and labelling of vessels, packages or coverings in which the poison is sold or possessed for sale.
8. Inspection and examination of such poison by the inspectors appointed by state government when poison is possessed for the sale by the vendors.

Q.5. Give the offences and penalties under Poisons Act, 1919.

1. **Penalty for unlawful (illegal) importation, possession for sale and sale of any poison:** Anyone who unlawful imports, possesses or sells any poison, shall be punishable with imprisonment up to 3 months or fine up to ₹ 500/- or both on first conviction and with imprisonment for 6 months or a fine up to ₹1000/- or both on any subsequent conviction.
2. **Penalty for illegal possession of any poison:** Anyone who possesses any poison whose possession is banned by the state government is punishable with imprisonment up to 1 year or a fine up to ₹1000/- or both.
3. Any poison in respect of which offence has been committed is liable to confiscation along with any vessel packages, coverings, etc. in which the poisons have been stored.

OBJECTIVE QUESTIONS WITH ANSWERS IN BOLD LETTERS

1. **Poison** means all the substances notified as a poisons under the Poison Act, 1919.

2. The Poison Act was passed to regulate **import, sale and possession of poisons.**
3. **Central government** regulates import of poison in India.
4. Insecticide Act was passed in **1968.**
5. Penalty for the import of poison without licence is punishable with fine up to ₹ **500** on first conviction.
6. Poison Act came into existence in **1919.**
7. The possession and possession for sale of poison is regulated by **state government.**
8. Import of poison is regulated by **central government.**

Chapter

8

Food Safety and Standards Authority of India (FSSAI) Act and Rules

Q.1. What is FSSAI? Give the objectives and functions of FSSAI.

FSSAI means Food Safety and Standards Authority of India.

FSSAI has been established under Food Safety and Standards Act, 2006 which consolidates varies Acts and orders that have handled food related issues in various Ministries and Departments.

Objectives of FSSAI

FSSAI has been created for laying down science based standards for articles of food and to regulate their manufacture, storage and import to ensure availability of safe and wholesome food for human consumption.

Functions of FSSAI

1. Laying down procedures and guidelines for accreditation of laboratories and notification of the accredited laboratories.
2. To provide scientific advice and technical support to central government and state government in the matters of framing the policy and rules in areas which have a direct or indirect bearing of food safety and nutrition.
3. Collect and analyze the data regarding food consumption, incidence and prevalence of biological risk, contaminants in food and food products.
4. Creating an information network across the country so that the public, consumers, panchayats, etc. receive rapid, reliable and objective information about food safety and issues concern.
5. Provide training programs for persons who are involved or intended to get involved in food businesses.

6. Contribute to the development of international technical standards for food, sanitary standards.
7. Promote general awareness about food safety and food standards.

Q.2. Define the following terms under FSSAI Act and Rules.

1. **Food Authority:** It means the Food Safety and Standards Authority of India established under Section 4 of the Act.
2. **Functional food:** Functional food shall have the meaning assigned to it in Section 22 of the Act.
3. **Health supplements:** Health supplements have the meaning assigned to it in the Section 22 of the Act.
4. **Commissioner of food safety:** It means the commissioner of food safety appointed under Section 30 of the Act.
5. **Food safety:** It means assurance that food is acceptable for human consumption according to its intended use.
6. **Food safety officer:** It means an officer appointed under Section 37 of the Act.
7. **Food safety audit:** It means a systematic and functionally independent examination of food safety measures adopted by manufacturing units to determine whether such measures and related results meet with the objective of food safety and the claims made in that behalf.
8. **Food safety management:** It means the adoption of Good manufacturing practices, Good Hygienic practices, Hazard Analysis and critical control point and such other practices as may be specified by regulation, for the food business.
9. **Food analyst:** It means an analyst appointed under Section 45 of the Act.
10. **Food:** Food means any substance, whether processed, partially processed or unprocessed, which is intended for human consumption and includes primary food, genetically modified or engineered food or food containing such ingredients, infant food, packaged drinking water, alcoholic drink, chewing gum and any substance, including water used into the food during its manufacture, preparation or treatment but does not include any animal feed, live animals unless they are prepared or processed for placing on the market for human consumption, plants, prior to harvesting, drugs and medicinal products, cosmetics, narcotics or psychotropic substances.
11. **Adulterant:** It means any material which is or could be employed for making the food unsafe or substandard or mis-branded or containing extraneous matter.

Q.3. How FSSAI is established?

Establishment of FSSAI

1. The central government shall, by notification, establish a body to be known as Food Safety and Standards Authority of India to exercise the powers conferred on, and to perform the functions assigned to it under this Act.
2. The Food Authority shall be a body corporate by the name aforesaid, having perpetual succession and a common seal with power to acquire, hold and dispose of property, both movable and immovable, and to contract and shall, by said name, sue or to be sued.
3. The head of the Food Authority shall be at Delhi.
4. The Food Authority may establish its offices at any other place in India.

Q.4. Write in brief about "packaging and labeling of foods and food products".

Packaging and Labeling of Foods and Food Products

1. No person shall manufacture, distribute, sell or expose for sale or dispatch or deliver to any agent or broker for the purpose of sale, any packaged food products which are not marked and labelled in the manner as may be specified by regulations.
   Provided that the labels shall not contain any statement, claim, design or device which is false or misleading in any particular concerning the food products contained in the package or concerning the quantity or the nutritive value implying medicinal or therapeutic claims or in relation to the place of origin of the said food product.
2. Every food business operator shall ensure that the labeling and presentation of food, including their shape, appearance or packaging, the packaging materials used, the manner in which they are arranged and the setting in which they are displayed, and the information which is made available about them through whatever medium, does not mislead consumers.

Q.5. What is food safety officer? Give the powers of food safety officer.

Food Safety Officer

1. The commissioner of Food Safety shall, by notification, appoint such person as he thinks fit, having the qualification prescribed by the Central Government, as Food Safety Officers for such local area as he may assign to them for the purpose of performing functions under this Act and the rules and regulations made thereunder.

2. The state government may authorize any officer of the state government having the qualifications prescribed under sub-section (1) to perform the functions of a Food Safety Officer within specified jurisdiction.

Powers of Food Safety Officer

1. The Food Safety Officer may:
   a. Take sample:
      i. of any food, or any substance, which appears to him to be intended for sale, or to have been sold for human consumption; or
      ii. of any article of food or substance which is found by him on or in any such premises; which he has reason to believe that it may be required as evidence in proceeding under any of the provisions of this Act or of the regulations made thereunder; and
   b. Seize any article of food which appears to the Food Safety Officer to be in contravention of this Act or the regulations made thereunder; and
   c. Keep it in the safe custody of the food business operator such article of food after taking a sample.

   Provided that where the Food Safety Officer keeps such article in the safe custody of the food business operator, he may require the food business operator to execute a bond of sum of money equal to the value of such article with one or more sureties as the Food Safety Officer deems fit and the food business operator shall execute the bond accordingly.
2. The Food Safety Officer may enter and inspect any place where the article of food is manufactured, or stored for sale, or stored for the manufacture of any other article of food, or exposed or exhibited for sale and where any adulterant is manufactured or kept, and take samples of such articles of food or adulterant for analysis.
3. Where any sample is taken, its cost calculated at the rate at which the article is usually sold to the public shall be paid to the person from whom it is taken.
4. Where any article of food seized under clause (b) of sub-section (1) is of a perishable nature and the Food Safety Officer is satisfied that such article of food is so deteriorated that it is unfit for human consumption, the Food Safety Officer may, after giving notice in writing to the food business operator, cause the same to be destroyed.
5. Food Safety Officer shall, in exercising the powers of entry upon, and inspection of any place under this section, follow, as far as may be, the provisions of the Code of Criminal Procedure, 1973 (2 of 1974) relating to the search or inspection of a place by a police officer executing a search warrant issued under that Code.

6. Any adulterant found in the possession of a manufacturer or distributor of, or dealer in, any article of food or in any of the premises occupied by him as such and for the possession of which he is unable to account to the satisfaction of the Food Safety Officer and any books of account or other documents found in his possession or control and which would be useful for, or relevant to, any investigation or proceeding under this Act, may be seized by the Food Safety Officer and sample of such adulterant submitted for analysis to a Food Analyst.
7. Where the Food Safety Officer takes any action under clause (a) of sub-section (1), or sub-section (2), or sub-section (4) or sub-section (6), he shall, call one or more persons to be present at the time when such action is taken and take his or their signatures.
8. Where any books of account or other documents are seized under sub-section (6), the Food Safety Officer shall, within a period not exceeding thirty days from the date of seizure, return the same to the person from whom they were seized after copies thereof or extract there from as certified by that person in such manner as may be prescribed by the Central Government have been undertaken.
9. The commissioner of Food Safety may from time to time issue guidelines with regards to exercise of powers of the Food Safety Officer, which shall be binding.

Q.6. Define Food Analyst. Give the functions of food analyst.

Food Analyst: It means an analyst appointed under Section 45 of the Act.

The commissioner of Food Safety shall may, by notification, appoint such person as he thinks fit, having the qualification prescribed by the Central Government, to be Food Safety Analyst for such local area as he may assign to them by the commissioner of Food Safety.

Functions of Food Analyst

1. On the receipt of a package containing a sample for analysis from a Food Safety Officer or any other person, the Food Analyst shall compare the seal on the container and the outer cover with specimen impression received separately and shall note the conditions of the seal thereon;
2. The Food Analyst shall cause to be analysed such samples of articles of food as may be sent to him by Food Safety Officer or by any other person authorized under this Act.
3. The Food Analyst shall within a period of fourteen days from the date of receipt of any sample for analysis, send:

i. Where such sample is received under Section 38 or Section 47, to the Designated Officer, four copies of the report indicating the method of sampling and analysis; and
ii. Where such sample is received under Section 40, a copy of the report indicating the method of sampling and analysis to the person who had purchased such article of food with a copy to the Designated Officer.

4. An appeal against the report of Food Analyst shall lie before the Designated Officer who shall, if he so decides, refer the matter to the referral food laboratory as notified by the Food Authority for opinion.

Q.7. Give the offences and penalties under FSSAI Act and Rules.

Offences and Penalties Under FSSAI Act and Rules

1. Penalty for sub-standard Food

Any person who whether by himself or by any other person on his behalf manufacture for sale or stores or sells or distributes or imports any article of food for human consumption which is sub-standard, shall be liable to a penalty which may extend to five lakh rupees.

2. Penalty for Misbranded Food

i. Any person who whether by himself or by any other person on his behalf manufactures for sale or stores or sells or distributes or imports any article of food for human consumption which is misbranded, shall be liable to a penalty which may extend to three lakh rupees.
ii. The Adjudicating Officer may issue a direction to the person found guilty of an offense under this section, for taking corrective action to rectify the mistake or such article of food shall be destroyed.

3. Penalty for Misleading Advertisement

i. Any person who publishes, or is a party to the publication of an advertisement, which
   a. falsely describes any food; or,
   b. is likely to mislead as to the nature or substance or quality of any food or gives false guarantee, shall be liable to a penalty which may extend to ten lakh rupees.
ii. In any proceedings the fact that a label or advertisement relating to any article of food in respect of which the contravention is alleged to have been committed contained an accurate statement of the composition of the food shall not preclude the court from finding that the contravention was committed.

4. Penalty for Food Containing Extraneous Matter

Any person whether by himself or by any other person on his behalf manufactures for sale or stores or sells or distributes or imports any article of food for human consumption containing extraneous matter, shall be liable to a penalty which may extend to one lakh rupees.

5. Penalty for Failure to Comply with the Directions of Food Safety Officer

If a food business operator or importer without reasonable ground, fails to comply with the requirements of the Act or the rules or regulations or orders issued thereunder, as directed by the Food Safety Officer, he shall be liable to a penalty which may extend to two lakh rupees.

6. Penalty for Unhygienic or Unsanitary Processing or Manufacturing of Food

Any person who, whether by himself or by any other person on his behalf, manufactures or process any article of food for human consumption under unhygienic or unsanitary conditions, shall be liable to a penalty which may extend to one lakh rupees.

7. Penalty for Unsafe Food

Any person who, whether by himself or by any person on his behalf, manufacture for sale or stores or sells or distributes or imports any article of food for human consumption which is unsafe, shall be punishable:

i. Where such failure or contravention does not result in injury, with imprisonment for a term which may extend to six months and also with a fine which may extend to one lakh rupees;
ii. Where such failure or contravention results in a non-grievous injury, with imprisonment for a term which may extend to one year and also with fine which may extend to one lakh rupees.
iii. Where such failure or contravention results in a grievous injury, with imprisonment for a term which may extend to six years and also with fine which may extend to five lakh rupees.
iv. Where such failure or contravention results in death, with imprisonment for a term which shall not be less than seven years but which may extend to imprisonment for life and also with fine which shall not be less than ten lakh rupees.

OBJECTIVE QUESTIONS WITH ANSWERS IN BOLD LETTERS

1. Food and Adulteration Act was passed in **1954.**
2. FSSAI means **Food Safety and Standards Authority of India.**
3. FSSAI has been established under **Food Safety and Standards Act, 2006.**

4. Food Authority means the Food Safety and Standards Authority of India established under **Section 4** of the Act.
5. Food Officer means an officer appointed under **Section 37** of the Act.
6. Food Analyst means an analyst appointed under **Section 45** of the Act.
7. Penalty for manufacture for sale or stores or sells or distributes or imports any article of food for human consumption which is sub-standard, is extended to **five lakh** rupees.

Chapter

9

National Pharmaceutical Pricing Authority (NPPA) (Drug Price Control Order 2013)

Q.1. What is NPPA?

- NPPA means National Pharmaceutical Pricing Authority.
- NPPA was constituted by Government of India in 29th August 1997.
- NPPA is a government regulatory agency that controls the prices of pharmaceutical drugs in India.
- NPPA was built to fix/change the cost of bulk medications and to uphold cost and accessibility of the medicines in the nation under the Drug Price Control Order, 1995.

Q.2. Give objectives of Drug Price Control Order 2013. (S. 24)

The government has notified the DPCO 2013 under Essential Commodities Act, 1955, which will give power to the NPPP 2012, to regulate prices of 348 essential drugs along with their specified strengths and dosages under NLEM 2011.

Objectives of DPCO 2013

i. To improvise the basic health care facilities and availability of basic medicines at an affordable price across the country.
ii. The DPCO 2013 empowers the National Pharmaceutical Pricing Authority (NPPA) to regulate prices of 348 essential drugs.
iii. As per new DPCO 2013, all strengths and dosages specified in National List of Essential Medicines (NLEM) will be under price control.

Q.3. What are the main features of the DPCO 2013?

Main Features of DPCO 2013

1. The new order will bring 348 drugs and their 652 formulations under price control.
2. The new policy uses market-based pricing mechanism against the earlier proposed cost-plus method.

3. The ceiling price would be calculated by taking the simple average of prices of all brands of a drug with a market share of 1% or more.
4. Margins of wholesalers and retailers have been cut down 8% and 16% respectively.
5. Companies selling medicines above the government mandated ceiling rated would have to slash price to meet the demands of new rules, but those selling drugs below the ceiling price would not be allowed to raise prices.
6. Firms that launch new medicines can sell them at or below government set price caps.
7. Existing firms will not be allowed to stop production of any drug without permission from the government.
8. Drug producers will be permitted an annual increase in the retail price in sync with wholesale price index.

Q.4. Define the terms.

1. **Active pharmaceutical ingredient or bulk drug (S. 23):** It means any pharmaceutical, chemical, biological or plant product including its salts, esters, isomers, analogues and derivatives, confirming to standards specified in the Drugs and Cosmetics Act, 1940 (23 of 1940) and which is used such or as an ingredient in any formulation.
2. **Ceiling price:** It means a price fixed by government for Scheduled formulations in accordance with the provisions of this order.
3. **Dealer:** It means a person carrying on the business of purchase or sale of drugs whether as a wholesaler or retailer and includes his agents.
4. **Wholesaler:** It means a dealer or his agent or stockist engaged in the sale of drugs to a retailer, hospital, dispensary, medical, educational, or research institution or any agency.
5. **Retailer:** It means a dealer carrying on the retail business of sale of drugs to customers.
6. **Distributor:** It means a person engaged in the work of distribution of drugs and includes an agent or stockist for stocking of drugs for sale to dealer.
7. **Formulation (S. 23):** It means medicine processed out of or containing one or more bulk drugs with or without the use of any pharmaceutical aids, for internal or external use or in the diagnosis, treatment, mitigation or prevention of disease in human beings or animals but does not include:
   i. Any medicine included in any bonafide Ayurvedic (including Siddha) or Unani (Tibb) systems of medicines.
   ii. Any medicine included in the homeopathic system of medicine.

iii. Any substance to which the provisions of Drugs and Cosmetics Act, 1940 do not apply.

8. **Retail price:** It means the price fixed by the government for a new drug under paragraph 5.
9. **Existing manufacturer:** It means manufacturer existing on the date of publication of this order in the Official Gazette.
10. **Generic version of a medicine:** It means a formulation sold in pharmacopoeial name or the name of active pharmaceutical ingredient contained in the formulation, without any brand name.
11. **Local taxes:** It means any tax or levy (except excise or import duty included in retail price) paid or payable to the government or any local body under any law for the time being in force by the manufacturer or his agent or dealer.
12. **Manufacturer:** It means any person who manufactures or imports or markets drugs for distribution or sale in the country.
13. **Market share:** It means the ratio of domestic sales values (on the basis of moving turnover) of a brand or a generic version of a medicine and the sum of total domestic sales value of all brands and generic versions of that medicine sold in the domestic market having same strength and dosage form.
14. **Margin of retailer:** It means a percentage of prices to retailer.
15. **Maximum retail price (S. 23):** It means ceiling price or 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.
16. **Moving annual turnover:** It means cumulative sales value for twelve months in domestic market, where the sales value of that month is added and the corresponding sales of the same month in the previous year are subtracted.
17. **National List of Essential Medicines (NLEM):** It means National List of Medicines, 2011 published by Ministry of Health and Family Welfare as updated or revised from time to time and included in the first schedule of this order by the government through a notification in the Official Gazette.
18. **New Drug:** It means formulation launched by an existing manufacturer of a drug of specified dosages and strengths as listed in the National List of Essential Medicines by combining the drug with another drug either listed or not listed in the National List of Essential Medicines or a formulation launched by changing the strength or dosages or both of the same drug of specified dosages and strengths as listed in the National List of Essential Medicines.

19. **Pharmacoeconomics:** It means scientific discipline that compares the therapeutic value of one pharmaceutical drug or drug therapy to another.
20. **Price to retailer:** It means the price of a drug at which it is sold to a retailer which includes duties and does not include local taxes.
21. **Scheduled formulation:** It means any formulation, included in the First Schedule whether referred to by generic versions or brand name.
22. **Non-scheduled formulations:** It means a formulation, which is not included in Schedule 1.
23. **Wholesale price index:** It means annual wholesale price index of all commodities as announced by the Department of Industrial Policy and Promotion, Government of India, from time to time.

Q.5. How ceiling price of the scheduled formulation is calculated?

The ceiling price of a scheduled formulation shall be calculated as follows:

Step 1. Calculate Average Price to Retailer, P(s)

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 medicines having market share more than or equal to one percent of total market turnover on the basis of moving annual turnover for that medicine).

Step 2. 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 step 1 above.

M = % Margin to retailer and its value = 16

Q.6. How fixation of ceiling price of scheduled formulations is done?

1. The government shall fix and notify the ceiling prices of the scheduled formulations in accordance with the provisions of the paragraphs 4 and 6 as the case may be, and no manufacturer shall sell the scheduled formulation at a price higher than the ceiling price (plus local taxes as applicable) so fixed and notified by the government.

2. Where any manufacturer sells a scheduled formulation at a price higher than ceiling price (plus local taxes as applicable) fixed and notified by the government, such manufacturers shall be liable to deposit the overcharged amount along with interest thereon from the date of such overcharging.

Q.7. Write a note on drug price equalisation account (DPEA).

1. Government may, by notice, ask manufacturer, importer or distributor, as the case may be, to deposit the amount which has accrued under the provisions of the Drugs Price Control Order, 1979 on or before the commencement of this order into the Drugs prices equalisation account and the manufacturer, importer or distributor, as the case may be, shall deposit the said amount into the said account within such time as the government may specify in the said notice.
2. The existing amount, if any, in the Drugs Prices Equalisation Account on or before the date of commencement of this order, and the amount deposited under sub-paragraph shall be utilized for:
   a. Paying to the manufacturer, importer or distributor the shortfall between his retention price and the common selling price for the purpose of increasing production, proper distribution and availability at fair prices of drugs.
   b. Meeting expenses of government during discharging its functions under this paragraph.
   c. Promoting higher education and research in pharmaceutical sciences and technology or the purposes incidental thereto.

Q.8. What do you mean by 'Sale of split quantities of formulations'?

'Sale of Split Quantities of Formulations' Means

No dealer shall sell loose quantity of any formulation at a price which exceeds the pro-rata price of the formulation.

Q.9. What is National Pharmaceutical Policy, 2002? Give its objectives.

The drug and pharmaceutical industry in the country today faces new challenges an account of liberalization of the Indian Economy, the globalization of the world economy and on the account of new obligations undertaken by India under WTO Agreements.

These challenges require a change in emphasis in the current pharmaceutical policy and the need for new initiatives beyond those enumerated in the Drug policy 1986, as modified in 1994, so that policy inputs are directed more towards promoting accelerating growth of the pharmaceutical Industry and towards making it more internationally competitive.

To face these issues National Pharmaceutical Policy, 2002 is formed.

Objectives of National Pharmaceutical Policy, 2002

a. To ensure availability of good quality essential pharmaceuticals for mass consumption at reasonable prices within the country.
b. To strengthen the indigenous capability for cost effective quality production and exports of pharmaceuticals by reducing barriers to trade in the pharmaceutical sector.
c. To strengthen the system of quality control over drug and pharmaceutical production and distribution to make quality an essential attribute of the Indian pharmaceutical industry and promoting national use of pharmaceuticals.
d. To encourage R&D in the pharmaceutical sector in a manager compatible with the country's need and with particular focus on diseases endemic or relevant to India by creating an environment conductive to channelizing a higher level of investment into R&D in pharmaceuticals in India.
e. To create an incentive framework for the pharmaceutical industry that promotes new investment into pharmaceutical industry and encourages the introduction of new technologies and new drugs.

Q.10. What is NLEM? Mention the objective/purpose/uses of NLEM.

- NLEM means National List of Essential Medicines as per World Health Organization (WHO).
- NLEM is a list of medicines prepared by the Ministry of Health and Family Welfare based on essentiality and made a part of the Drug Price Control Orders (DPCO), 2013.
- Essential medicines are those that satisfy the priority health care needs of the population.
- The list is made with consideration to disease prevalence, efficacy, safety and comparative cost effectiveness of the medicines.
- NLEM is the basis for the National Pharmaceutical Pricing Authority (NPPA) to revise the list of medicines that should come under government price control.

- The First National List of Essential Medicines (NLEM) of India is prepared and released in 1996. This list was subsequently revised in 2003, 2011 and 2015.

Objective/Purpose/Uses of NLEM

1. To guide safe and effective treatment of priority disease conditions of a population.
2. To promote the rational use of medicines.
3. Optimize the available health resources of a country.

Q.11. How is "Retail price" of formulation calculated as per DPCO, 1995? (S. 24, W. 23)

By applying the following formula, the retail price of the formulation is calculated by the government.

$$\mathbf{RP = (MC + CC + PM + PC) \times [1 + MAPE/100] + ED}$$

where,

RP: Means retail price.

MC: Means material cost which includes the cost of drug and other pharmaceutical aids with averages, if any plus process thereon in accordance with the norms specified from time to time by notification in the Official Gazette.

CC: Means conversion cost worked out in accordance with such norms as may be specified by the government from time to time by notification in the Official Gazette.

PM: Means cost of packing material including process loss thereon worked out in accordance with such norms as may be specified by the government from time to time.

PC: Means packing charges worked out in accordance with such norms as may be specified by government every year by notification in the Official Gazette.

MAPE: Maximum Allowable Post-manufacturing Expenses. It means all the cost incurred by the manufacturer from the stage of ex-factory cost of retailing. If also included trade margin and margin of the manufacturer. MAPE shall not exceed 100% for indigenously scheduled formulations.

ED: Excise Duty.

OBJECTIVE QUESTIONS WITH ANSWERS IN BOLD LETTERS

1. NPPA means **National Pharmaceutical Pricing Authority**.
2. NPPA was constituted by government of India in **29th August 1997**.

3. NPPA is a government **regulatory agency** that controls the prices of pharmaceutical drugs in India.
4. The government has notified the DPCO 2013 under **Essential Commodities Act, 1955**.
5. Retail price means the price fixed by the government for a **new drug** under paragraph.
6. **Pharmacoeconomics** means scientific discipline that compares the therapeutic value of one pharmaceutical drug or drug therapy to another.
7. Margin of retailer means a **percentage of prices to retailer.**
8. NELM means **National List of Essential Medicines**.
9. NELM is a list of medicines prepared by the **Ministry of Health and Family Welfare.**
10. The first National List of Essential Medicines of India was prepared and released in **1996.**
11. **Ceiling Price** means the price fixed by government for scheduled formulations according to the provisions of DPCO.
12. DPEA means **Drug Price Equalization Account.**
13. DPCO means **Drug Price Control Order.**
14. The latest Drug Price Control Order is **2013**.
15. MAPE means **Maximum Allowable Post Manufacturing expenses.**
16. Sale of **'Split quantity of formulation'** means no dealer shall sell the loose quantity of formulation at a retail price exceeding prices of formulation plus **5%** thereof.
17. Drug Price Control Order (DPCO) was passed under the **Essential Commodity Act, 1955.**
18. In DPCO 2013 ceiling price is calculated on the basis of **Market Based Pricing** Method.
19. NPPA is a regulatory authority of **Government of India**.
20. Only **16%** margin of the price is allowed to a retailer.
21. WPI means **wholesale price index**.

Chapter

10

The Code of Pharmaceutical Ethics

Q.1. Define the terms.

- **Ethics:** Ethics means rules by which a profession regulates actions and sets standards for all its members.
- **Law:** Law is defined as the rules of human conduct binding to all persons in the state or nation.
- **Pharmaceutical ethics:** The ethics in relation to pharmacy profession is called pharmaceutical ethics.

Q.2. What do you mean by code of pharmaceutical ethics?

- The code of pharmaceutical ethics is formulated by PCI for the guidance of Indian pharmacist.
- The code of pharmaceutical ethics helps to guide the pharmacist as to how he should conduct himself in relation to:
  1. His job
  2. His trade
  3. His fellow pharmacist
  4. His physician
  5. With medical profession
  6. With his profession (pharmacy)
  7. With general public.

Q.3. How should a pharmacist handle the prescription as per ethics? OR Describe the ethics for pharmacist in relation to his job during his service. (S. 24, W. 23)

- Pharmacist shall supply commonly required medicines without undue delay.
- Pharmacist also provides emergency supply of drug at all times.

- The premise of pharmacy should be clean in appearance.
- During compounding and dispensing there should not be any type of contamination in the medicines.
- There should be good conduct of owner of pharmacy and pharmacist.
- Pharmacist should receive the prescription and read it carefully and should not discuss merits and demerits of prescription.
- Pharmacist should not show any surprising expression, otherwise it may cause anxiety in patients and it may loose faith in their physician.
- Any question asked by the patient should be answered carefully.
- Pharmacist should not disclose any information which may be kept secrete by the physician.
- Pharmacist should not add, omit or substitute any ingredient in the prescription without consulting the doctors.
- If any overdose, or error is in the prescription, it is send back for correction to the prescriber.
- Pharmacist should advise the patient about use of medicines as per directions of physician.
- Pharmacist should compound the drugs by taking accurate quantities of ingredients.
- Pharmacist should use the drugs of standard quality.
- Pharmacist should not dispense the drugs which are poisonous or addictive to any person without prescription.
- Pharmacist should give full training to his apprentice pharmacist.

Q.4. Explain the ethics for pharmacist in relation to his trade.

- Pharmacist should charge a fair price from the customer for the medicines.
- Pharmacist should give adequate remuneration to fellow pharmacist.
- Fair trade practice:
  - Pharmacist should not attempt to capture the business of fellow pharmacist by cut throat competition, i.e. offering any sort of prizes, gifts to the physician.
  - He should not sell the medicines at low prices than those charged by fellow pharmacist.
  - If the prescription contains the name of other than his, he should direct the customer to right place.
  - Labels, trademarks, other signs and symbols of the fellow pharmacist should not be imitated or copied.
- Pharmacist should not attempt for selling the drugs from door to door or obtain the orders for medicines.

- He should not carry self-service method for medicines.
- Pharmacist should purchase the drugs from genuine source.
- Pharmacist should not directly or indirectly help the manufacturer for the sale of spurious or substandard drugs.
- Pharmacist should not make advertisement or display of materials which is unethical.

Q.5. How should pharmacist behave with his fellow pharmacist as per ethics?

- Pharmacist should not attempt to capture the business of fellow pharmacist by cut throat competition, i.e. by offering any sort of prizes or gift to the physician.
- He should not charge lower prices for medicines than those charged by fellow pharmacist.
- If the prescription contains name of other dispensary or pharmacy than his, he should not accept such prescription, but should direct the customer to the right place.
- Labels, trademarks and other signs and symbols of the fellow pharmacist should not be imitated or copied.

Q.6. How should pharmacist behave with physician as per code of ethics? OR Give the relation of pharmacist with physician as per code of ethics.

- When pharmacist receives the prescription, he should not discuss the merits and demerits of the prescription.
- Pharmacist should not show any surprising expression on his face, otherwise it may loose faith in their physician.
- Pharmacist should not add, omit, substitute or alter the composition of prescription without the permission of prescriber.
- If there is an error in the prescription like overdose, incomplete direction, etc. then such prescription is referred back for correction to the prescriber.
- Pharmacist should not enter into the secret contract with the physician by offering him any sort of prizes, gifts or commission.
- Pharmacist should not recommend any particular physician to the patient unless it is asked to do so.

Q.7. Give relation of pharmacist to the medical profession. OR Explain how pharmacist is liaison between medical profession and public.

- Pharmacist should not undertake medical practice, i.e. diagnosis of disease, prescribing of drugs.

- In emergency cases like accidents, he can give first aid to the victims.
- Pharmacist should not recommend a particular medical practitioner unless asked to do so.
- Clandestine arrangement: Pharmacist should not enter into any secret contract with the physician to offer him any commission, gifts or prizes. This is known as clandestine arrangement.
- Pharmacist is a liaison between medical profession and the people.
- Pharmacist shall obtain the knowledge about the modern developments in the pharmacy.
- Pharmacist should advise the physician, nurses, compounders about new drugs and pharmaceutical matter.
- Pharmacist may be able to educate the people for maintaining healthy and sanitary conditions of living.

Q.8. Describe the code of ethics for pharmacist in relation to his profession (pharmacy).

- Pharmacist should increase the status of profession of pharmacy by giving cooperation to fellow members of scientific and technical fields.
- Pharmacist should join the professional organisations, study their aims, objects, etc.
- Pharmacist should not do any unfair deed which is harmful to pharmaceutical profession and discredit the profession.
- Pharmacist should fulfil the provisions of pharmaceutical matters and other laws and regulations.

Q.9. Give the relation of pharmacist with general public as per code of ethics.

- Pharmacist shall supply commonly required medicines without undue delay.
- Pharmacist shall provide emergency supply at all times.
- He shall charge a fair price on medicines.
- Pharmacist shall educate the people for maintaining healthy and sanitary conditions of living.
- In case of emergency or accidents he shall provide first aid treatment to the victims.
- He shall play an important role in family planning programmes and programmes organised by the government and social organisation.
- He shall take part in various social activities, join various organisations and contribute his share in the nation-building activities.

Q.10. Differentiate between law and ethics. (S. 23)

Law	*Ethics*
1. Law is the rules of human conduct binding to all persons in a state or nation.	1. Ethics means the rules by which profession regulates actions and sets standards for all its members.
2. Law deals with actions that are punishable.	2. Ethics deals with right or wrong.
3. Laws are written and approved documents.	3. Ethics is also written words but they are not carrying legal status.
4. Law will punish anyone, who happens to violate it.	4. Ethics does not carry any punishment to anyone who violates it.
5. The laws are made with ethics as a guiding principles.	5. Ethics comes from within a person's moral values.
6. A law is something you must obey.	6. Ethics is how society expects you to behave.
7. Law is a set of rules and regulations.	7. Ethics is a set of guidelines.
8. The laws are rules developed by government in order to provide balance in society and protection to its citizens.	8. Ethics are rules of conduct.

Q.11. Define law. State the importance of pharmaceutical law.

Law

Law is defined as rules of human conduct binding on all persons in a state or nation.

Importance of Pharmaceutical Law

1. Pharmaceutical law covers legal aspects relating to manufacture of drugs in pharmaceutical industries, their storage, sale, distribution.
2. It helps the pharmacists to understand their legal and ethical responsibilities and thereby avoid danger of unnecessary legal proceedings.
3. The pharmaceutical law safeguards the health of the people by making right medication by controlling pharmacy business and profession.
4. The patient should get the drugs of good quality which are tested and evaluated for safety purposes.
5. Pharmaceutical laws relate to the creation, sale, distribution and use of pharmaceutical drug.
6. Another important role is in product safety and marketing.

7. To promote health care by regulating the manufacture, supply and distribution of good quality drugs.
8. To safeguard the people from misleading and false advertisement relating to drugs and magic remedies.

Q.12. What are various ethical principles in pharmacy profession?/Write a note on 'ethical principles in pharmacy profession'. (S. 23, W. 23)

Ethical Principles in Pharmacy Profession are:

Principle 1: Consumer First Priority

A pharmacist must consider the health and well-being of the consumer as the first priority.

Principle 2: Freedom of Decision-making

A pharmacist should respect the rights of consumers and actively participate in decision-making.

Principle 3: Public Trust

A pharmacist should build a good reputation and public trust of the profession.

Principle 4: Quality Use of Medicines

A pharmacist is responsible for supply of therapeutic good and enhancing the quality use of medicines in partnership with individuals and the wider community.

Principle 5: Enhance the Profession

A pharmacist should be involved in the development, advancement and enhancement of the profession of pharmacy.

Principle 6: Lifelong Learning

A pharmacist should update the knowledge of pharmacy practice and utilize it to ensure good health of the community.

Principle 7: Professional Accountability

A pharmacist should provide professional service to their consumers. The professional service delivery depends on successful team work derived from respect, good communication and co-operation.

Principle 8: Ethical Business Practice

A pharmacist should conduct the business of pharmacy in an ethical and professional manner. There should not be any setting during business practices.

Principle 9: Collaboration

A pharmacist should work collaboratively with other health professional to improve the health outcomes of the consumers. Collaborative care can be possible only through good communication and co-operation among the members of health care team.

Q.13. Explain various steps to be taken for ethical problem solving./ Write in brief about "essential steps for ethical problem solving".

Essential steps to be taken for ethical problem solving involves following steps:

1. Determine whether there is an ethical issue, i.e. identify the problem as you see it.
2. Identify the key values and principles involved.
3. Rank the values or ethical principles with your professional judgement most relevant to the issue.
4. Develop an action plan that is consistent with the ethical priorities and gather the relevant data.
5. Implement your plan, utilizing the most appropriate practice skill to take appropriate action.
6. Make a list of possible actions and their positive and negative effects.
7. Make a plan that you can defend professionally and ethically and that meets the requirement of the regulations.
8. Evaluate your plan and take the actions to solve the problem.

Q.14. Write in brief about 'Ethics and Law'.

Ethics

- Ethics may be defined as the code of moral principles or as the science of morals.
- These principles are based on moral obligations and virtues and are established to guide pharmacists in relationship with patients, health professionals and society.
- Ethics comes from within a person's moral sense and desire to preserve himself respect.
- A code of ethics is a carefully formulated system of principles or rules of practice for guidance of a particular group of individuals, such as the members of profession.
- The development of code of ethics is an indication of the evolution and growth of moral consciousness.

Law

- Laws are made by government in order to protect its citizens.
- Law is the rules of human conduct binding to all persons in the nation.
- Law may prevent one from causing injury to another, but it cannot force him to help his neighbour in hours of need. Helping the neighbour is a function of ethics.
- Law deals with actions that are punishable.
- Law is a set of rules and regulations.

Ethics and laws are therefore necessary to provide guidance and stability to people and society as a whole.

Q.15. What is pharmacist oath?/State the pharmacist oath.

Pharmacist's Oath

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 health care team.

I shall uphold the laws and standards governing my profession.

I shall strive to perfect and enlarge my knowledge to contribute to the advancement of pharmacy and public health.

I shall follow the system which I consider the best for pharmaceutical care and counselling of the patients.

I shall endeavour to discover and manufacture drugs of quality to alleviate sufferings of humanity.

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.

I shall associate with organizations having their objectives for betterment of profession of pharmacy and make contribution to carry out the work of those organizations.

While I continue to keep this oath inviolated, may it be granted to me to enjoy life and practice of pharmacy respected by all, at all times!

Should I trespass and violate this oath, may the reverse be my lot!

OBJECTIVE QUESTIONS WITH ANSWERS IN BOLD LETTERS

1. **Pharmacist** is a liaison between physician and patient.
2. Clandestine arrangement means **secret agreement**.
3. **Ethics** is defined as "Rules by which a profession regulates actions and sets standards for all its members.

4. Clandestine arrangement is also called as **Underhand arrangement.**
5. The code Pharmaceutical Ethics is formulated by **PCI** for the guidance of Indian Pharmacists.
6. Fair trade practice is also known as **cut-throat competition**.
7. The rules of human conduct binding to all persons in state or nation is called **Law.**
8. Clandestine arrangement is also called **underhand arrangement.**
9. Ethics is study of **moral duties/principles.**
10. If the pharmacist is making an attempt to capture the business of fellow pharmacist is said to be **cut-throat competition**.
11. If the pharmacist has made a secret contract with the doctor, it is called **clandestine arrangement.**

Chapter

11

Medical Termination of Pregnancy Act, 1971 and Rules thereunder 1975

Q.1. Give the aims and objectives of the Medical Termination of Pregnancy Act, 1971.

Objectives of MTP Act, 1971

The Medical Termination of Pregnancy Act, 1971 was passed to provide for the termination of pregnancies of women by Registered Medical Practitioners (RMP) for bonafide medical reason and for the matter concerned therewith.

- The termination of pregnancy during certain period is harmful to the health of pregnant woman or it may cause serious effects on the child of such woman.
- Pregnancy should be terminated under hygienic conditions along with the required facilities in specified premises under the supervision of Registered Medical Practitioners.

Q.2. Define the terms under MTP Act, 1971.

1. **Guardian:** It means a person having care of minor or lunatic.
2. **Minor:** It means a person who is deemed to be not attending the age of minority under the provisions of Indian Majority Act.
3. **Lunatic:** It means as specified under Section 3 of the Indian Lunacy Act, 1912.
4. **Admission Register:** It means a register maintained as per regulation V of the MTP Act, 1971 and rules thereunder.
5. **Owner:** Owner in relation to place means any person who is the administrative head or otherwise responsible for the working or maintenance of such hospital or clinic.
6. **Place:** It is a building, tent, vehicle or vessel or part thereof used for the establishment or maintenance therein of a hospital or clinic which is used or intended to be used for the termination of any pregnancy.

7. **Approved place:** It means a place approved under rule IV of the MTP Act, 1971 and Rules thereunder.

Q.3. Name the approved places for the termination of pregnancies./ Name the places where termination of pregnancy is done as per MTP Act, 1971.

Termination of pregnancy should be made only at:

1. Hospital established and maintained by government.
2. Any place approved by the government for this purpose.
3. A place approved by 'District level committee'

Those places should provide:

a. Operation theater and surgical instruments for performing abdominal and gynecological surgery
b. Anesthetic equipment, resuscitation equipment and sterilized equipment
c. Drugs and parenteral fluids for emergency use.

Q.4. How are the places for termination of pregnancy are approved as per the provisions of MTP Act, 1971?

Approval of place for termination of pregnancy:

- For the approval of the place, application shall be made to the Chief Medical Officer (CMO) of the district.
- The CMO shall verify and inspect the premise and if he satisfies that applicant has prescribed facilities for the termination of pregnancies, he will submit the report to the government.
- If government satisfies on the report of CMO, it may approve such place and issue a certificate of approval.
- This certificate shall be displayed at the prominent place of the premise.
- CMO inspects the approved place whenever necessary and submit the report to the government.
- If the CMO report not complying with the conditions under the Act, government may suspend the approval until specified conditions are satisfied.

Q.5. What are the facilities/equipment provide at approved place as per MTP Act, 1971?

The owner of the approved place shall provide the following facilities for the termination of pregnancies:

i. Operation table
ii. Instruments for abdominal and gynaecological surgery.
iii. Anaesthetic equipment
iv. Sterilization equipment
v. Resuscitation
vi. Emergency drugs
vii. Parenteral fluids, IV fluids, dextrose solution, etc.

Q.6. What is Admission Register? How is it maintained?

Admission Register

It means a register maintained under regulation V of the MTP Act, 1971.

- MTP Rules, 1975 provides for the maintenance of Admission Register.
- Every head of the hospital or owner of the approve place shall maintain the admission register in prescribed form of the admissions of women for the termination of their pregnancies.
- The entries in the admission register shall be made serially and year-wise.
- A fresh serial number should be given to each calendar year.
- The admission register is a secrete document and the information contained in it should not be disclosed to any person.
- The register shall be kept in the custody of Head of the hospital or owner of the approved place.
- No entry shall be made in any case sheet, operation theatre register, follow-up card or any other document or register except the admission register maintained at any hospital or approved place regarding the medical termination of pregnancy of a woman.
- Every admission register shall be destroyed on the expiry of a period of five years from the date of last entry in that register.
- Other papers shall be destroyed on the expiry of a period of three years from the date of the termination of the pregnancy concerned.

Q.7. Under what circumstances/conditions/grounds pregnancy of a woman can be terminated by RMP as per MTP Act, 1971? Or What are the provisions under which the RMP may terminate the pregnancy of a woman as per the MTP Act, 1971? (S. 24, W. 23)

The provisions under which RMP may terminate the pregnancies of women are as follows:

i. Those who are 18 years of age or more with their written consent.
ii. Those who are less than 18 years of age or more than 18 years but are lunatic, with the written consent of their guardians.
iii. The pregnancy may be terminated if it is not more than 12 weeks old and RMP is of opinion that continuation of pregnancy is dangerous to the life of the woman or it may affect the physical or mental health of the pregnant woman or child to be born may suffer with physical or mental abnormalities.
iv. Further pregnancy which is more than 12 weeks but less than 20 weeks old may also be terminated if at least two RMPs are of above opinion.
v. If pregnancy is caused because of rape can be terminated by RMP as per provisions.
vi. If pregnancy is caused because of failure of contraceptive used by woman or her husband such unwanted pregnancy is found to affect physical and mental health of pregnant woman and therefore, it may be terminated.
vii. The pregnancy of any duration may be terminated by RMP, if it is immediately necessary to save the life of a pregnant woman.

Q.8. Give the offences and penalties under MTP Act, 1971.

1. Termination of pregnancy by person other than RMP is an offence and is punishable under Indian Penal Code (IPC).
2. Anyone who purposefully contravenes or fails to comply with the requirements of any regulation, shall be liable to be punished with a fine extending up to ₹ 1000.

Q.9. Whether termination of pregnancy at the residence of a Registered Medical Practitioner will be supposed to be legal? If not, state the places where it will be legal.

The termination of pregnancies at the residence of a Registered Medical Practitioner will not be legal, because residential place does not come under the approved place as per the provisions of MTP Act, 1971.

It will be legal at the following places:

i. Any hospital established and maintained by government.
ii. Any place approved by the government for this purpose.
iii. A place approved by 'District Level Committee'.

Q.10. What type of training and experience is required to RMP for termination of pregnancies as per the MTP Act, 1971? (S. 23)

The Medical Termination of Pregnancy Rules, 1975, prescribes the experience or training in gynaecology and obstetrics that a Registered Medical Practitioner should have to terminate any pregnancy.

a. A Medical Practitioner registered in a State Medical Register immediately before the commencement of the Act, should have not less than 3 years experience in the practice of gynaecology and obstetrics.
b. A Medical Practitioner registered in a State Medical Register on or after the date of the commencement can terminate the pregnancy:
   i. If he has completed six months of house surgery in gynaecology and obstetrics.
   ii. If he has experience at any hospital for a period of not less than one year in the practice of gynaecology and obstetrics, or
   iii. If he has assisted a Registered Medical Practitioner in the performance of 25 cases of medical termination of pregnancy in hospital established or maintained, or a training institute approved by the government for this purpose.
c. In case of Registered Medical Practitioner who holds a postgraduate degree or diploma in gynaecology and obstetrics, the experience or training gained during the course of such degree or diploma is considered.

OBJECTIVE QUESTIONS WITH ANSWERS IN BOLD LETTERS

1. The Medical Termination of Pregnancy Act was passed in **1971.**
2. **Minor** means a person who is deemed to be not attending the age of Majority Act.
3. Admission register is maintained to record the **termination of pregnancies** under the MTP Act, 1971.
4. **Lunatic** means as specified under Section 3 of the Indian Lunacy Act, 1912.
5. **Admission register** means a register maintained as per regulation V of the MTP Act, 1971.
6. RMP may terminate a pregnancy of women of **18 years** of age or more with her written consent.
7. Guardian means a person having care of **minor or lunatic.**
8. **Approved place** means a place approved under Rule IV of the MTP Act, 1971 and Rules thereunder.

9. MTP Rules, 1975 provides for the maintenance of **admission register.**
10. The admission register is **a secret document** and the information contained in it should not be disclosed to any person.
11. The **admission register** shall be kept in the custody of head of the hospital or owner of the approved place.
12. Every admission register shall be destroyed on the expiry of a period of **five years** from the date of last entry in that register.
13. Termination of pregnancy by person other than RMP is an offence and is punishable under **Indian Penal Code (IPC)**.
14. A 12 weeks pregnancy can be terminated with the consent of **2** RMPs.
15. Registered Medical Practitioner (RMP) in the context of Medical Termination of Pregnancy Act has experience in **obstetrics and gynaecology.**
16. Every head of the hospital or owner of the approved place shall maintain **admission register.**
17. The admission register and its maintenance are regulated under **MTP Regulations, 1975.**
18. Any person wilfully fails to comply regulations of MTP Act, 1971, is punishable with fine up to ₹ **1000**.
19. **MTP Act, 1971** promotes access to safe abortion services to women.
20. As per MTP Act, 1971, the pregnancy may be terminated up to **20 weeks** gestation.

Chapter

12

Central Drugs Standards Control Organization (CDSCO) and Indian Pharmacopoeia Commission (IPC)

Q.1. What is Central Drugs Standards Control Organization (CDSCO)? Give the role/objectives of CDSCO.

CDSCO

The Central Drugs Standards Control Organization (CDSCO) is India's National Regulatory body for drugs, cosmetics, medical and diagnostic devices and clinical trials.

Role of (CDSCO)/Objectives

1. CDSCO is responsible for approval of drugs.
2. For conduct of clinical trials.
3. To prepare the standards for drugs.
4. To control over the quality of imported drugs in the country.
5. Co-ordination of the activities of the State Drug Control Organizations by providing expert advice.
6. CDSCO is the main regulatory body for pharmaceuticals and medical devices.
7. CDSCO establishes safely, efficacy and quality standards for pharmaceuticals and medical devices.
8. It publishes and updates the Indian Pharmacopoeia.
9. To participate in WHO GMP certification scheme.
10. Testing of drugs by central laboratories.

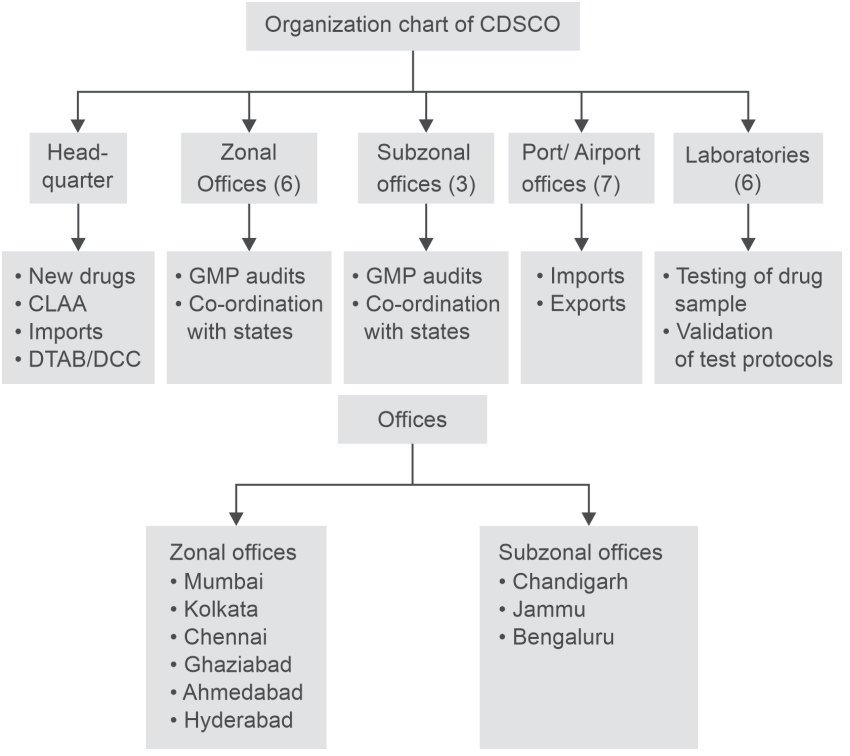
Q.2. Write a note on CDSCO. Mention the functions of CDSCO.

CDSCO

The CDSCO of India is main regulatory body for regulation of pharmaceutical medical devices and clinical trials:

- The head office of CDSCO is located in New Delhi and functioning under the control of Directorate General of Health Services, Ministry of Health and Family Welfare, Government of India.
- CDSCO is headed by Drug Controller General of India (DCGI).

- The DCGI is responsible for approval of new devices and drugs, medical clinical trials to be conducted in India.
- The DCGI is advised by the Drug Technical Advisory Board (DTAB) and the Drug Consultative Committee (DCC).
- The licensing and classification of medical devices are handled by the Central Licensing Approval Authority (CLAA).



Central Drug Testing Laboratories

- Central Drug Laboratory, Kolkata,
- Central Drug Testing Laboratory, Mumbai
- Central Drug Testing Laboratory Chennai
- Central Drug Laboratory, Kasauli
- Regional Drug Testing Laboratory, Guwahati
- Regional Drug Testing Laboratory, Chandigarh.

Functions of CDSCO

The main functions of the CDSCO include control of the quality of drugs imported into the country, coordination of the activities of the States Drug Control Authorities, approval of new drugs, etc.

A. Functions Undertaken by Central Governments:

1. Laying down standards of drugs, cosmetic diagnostics and devices.
2. Laying down regulatory measures, amendments to the Acts and Rules.
3. To regulate market authorization of New Drug.
4. Work relating to the DTAB and DCC.
5. Testing of drugs by CDLS.
6. Publication of Indian Pharmacopoeia.
7. Coordinating the activities of State Drug Control Organizations.
8. Guidance on technical matter.
9. Participation in the WHO GMP certification scheme.
10. Screening of drug formulations available in Indian Market.

B. Functions Undertaken by State Governments:

1. Licensing of drug manufacturing and sales establishments.
2. Licensing of drug testing laboratories.
3. Approval of drug formulations for manufacture.
4. Monitoring of quality of drugs and cosmetics manufactured by respective state units and those marketed in the state.
5. Investigation and prosecution in respect of contravention of legal provision.
6. Administrative actions.
7. Pre- and post-licensing inspection.
8. Recall of sub-standards drugs.

Q.3. What is IPC? Give the objectives and functions of IPC.

Indian Pharmacopoeia Commission (IPC): IPC is an autonomous institution of Ministry of the Health and Family Welfare which sets standards for all drugs that are manufactured, sold and consumed in India.

Formation of IPC

The Indian Pharmacopoeia Commission has been established as an Autonomous Institution under Ministry of Health and Family Welfare, Government of India on 9th Dec. 2004.

Mission of IPC

To promote public health in India by bringing out authoritative and officially accepted standards for quality of drugs including active pharmaceutical ingredients, excipients, and dosage forms, used by health professionals, patients.

Vision of IPC

To promote the highest standards of drugs for the use in humans and animals within practical limits of the technologies available for manufacturing and analysis.

Aims and Objectives of IPC

1. To publish new editions and supplements of the Indian Pharmacopoeia.
2. To accelerate the process of preparation, certification and distribution of IP.
3. To establish working and relations with various professional organizations.

Functions of IPC

1. To create a set of standards of drugs in India.
2. To update regularly the standards of drugs commonly required for treatment of diseases occurring in India.
3. Timely publication of Indian Pharmacopoeia and its Addenda.
4. Characterization and certification of IP Reference Substances.
5. Synthesis and characterization of impurities degradation products, etc.
6. International recognition and acceptance of Indian Pharmacopoeia.
7. To develop as an institution of excellence for Analytical Development Research, and Pharmacopoeia related matters.
8. To create a Library with state-of-the-art facilities to cater the needs of South East Asia Region for dissemination of information.

OBJECTIVE QUESTIONS WITH ANSWERS IN BOLD LETTERS

1. **CDSCO** is India's National Regulatory body for drugs, cosmetics, medical and diagnostic devices and clinical trials.
2. Indian Pharmaceutical Committee was appointed in **1948.**
3. CDSCO is responsible for **approval of drugs.**
4. CDSCO is the main regulatory body for **pharmaceuticals and medical devices.**
5. CDSCO is headed by **Drug Controller General of India (DCGI)**.
6. CLAA means **Central Licensing Approval Authority**.
7. The Indian Pharmacopoeia Commission (IPC) has been established as an Autonomous Institution under **Ministry of Health and Family Welfare, Government of India** on 9th Dec. 2004.
8. **Indian Pharmacopoeia Commission** create a set of standards of drugs in India.

Chapter

13

Good Regulatory Practices (GRPs)

Q.1. What do you mean by Good Regulatory Practices (GRPs)? Mention various regulatory requirements in India. What are the key considerations of regulatory requirements? (W. 23)

Good Regulatory Practices (GRPs)

Good Regulatory Practices include administrative procedures that govern intergovernmental co-ordination of rule making activity, impact assessment, regulatory transparency, participation and accountability.

Regulatory Requirements in India

1. To safeguard health and safety, Government of India frames regulatory requirements for manufacture and sale of goods and services including those imported.
2. Regulations are stipulated through various Acts/Rules and Regulations by different ministries under Government of India.
3. Enactment of Acts, Rules and Regulations is done taking consideration of the relevant WTO Agreements.

Key Considerations of Regulatory Requirements

- Regulatory measures should be minimum required.
- Regulatory measures should have minimum compliance cost.
- Regulatory measures should benefit society.
- Regulatory measures should comply with the laws of the country.
- Regulations should be made and enforced in a transparent manner.
- Regulations should be fair and treat all equitably.
- Regulation should be drafted in clear and simple language for understanding of all.
- Regulatory measures should be flexible for amendments/revisions, if required due to changed circumstances.

Q.2. What are the principles of Good Regulatory Practices?

Principles of Good Regulatory Practices (GRPs)

1. Legality
2. Consistency
3. Independence
4. Proportionality
5. Flexibility
6. Clarity
7. Efficiency
8. Transparency
9. Impartiality

1. **Legality:** Regulatory system and the decisions that flow from them must have a sound legal basis.
2. **Consistency:** Regulatory oversight of medical products should be consistent with existing government policies and legislation and be applied in consistent and predictable manners.
3. **Independence:** Institutions implementing regulations of medical products should be independent.
4. **Proportionality:** Regulation and regulatory decision should be proportional to risk and the regulators capacity to implement and enforce.
5. **Flexibility:** Regulatory oversight should be flexible for responding to changing environment and unavoidable circumstances. Responsiveness in a timely manner to public health emergencies should be built into the regulatory system.
6. **Clarity:** Regulatory requirements should be assessable to and understood by the users.
7. **Efficiency:** Regulatory system should achieve their goals within the required time and at reasonable effort and cost.
8. **Transparency:** Regulatory system should be transparent, requirement and decision should be made known.
9. **Impartiality:** All regulated parties should be treated equitably, fairly and free from bios.

Q.3. Write a note on Good Pharmacy Practice (GPP) in Community and Hospital Pharmacy. (S. 24, W. 23)

Good Pharmacy Practice (GPP)

- Good Pharmacy Practice defines pharmacists that provide quality pharmacy service to every patient.
- GPP is the practice of pharmacy that responds to the needs of the people, who use the pharmacist's services to provide optimal, evidence-based care.

Good Pharmacy Practice (GPP) Organizes Following Major Roles for Pharmacists

1. To prepare, obtain, store, secure, distribute, administer, dispense and dispose the medical products.

2. To provide effective medication therapy.
3. To maintain and improve professional performance.
4. Contribute to improve effectiveness of health care system and public health.

Requirements for the Good Pharmacy Practice (GPP)

1. Premises/layout/furniture
2. Equipment
3. Manpower
4. Storage
5. Inventory control
6. Services
7. Documentation

1. Requirements of Premises/Layout/Furniture:

- The location of pharmacy should be such that it is easily identified by the public.
- The environment in the pharmacy should be neat and clean.
- It should have clearly and marked word "Pharmacy"
- The pharmacy should also be accessible to disabled people or peoples using wheelchairs.
- It should have display counter, shelves, for medicine storage, counseling area, waiting area, billing area, adequate space for movement and waste collection boxes.
- Counselling area should have furniture (table and chairs) and cabinets for keeping Patients Medication Records (PMR).

2. Requirements of Equipment:

- The pharmacy should be equipped with refrigerator for storage and medicine in cold temperature and validated from time to time.
- Counseling area should be equipped with demonstration chart, patient information leaflets, reference materials, etc.
- It should contains basic equipments such as thermometer, sphygmomanometer, glucometer, stethoscope weight and height scale.
- It should have telephone, computer software facilities.

3. Requirements of Manpower:

- The pharmacy should be managed under the supervision of pharmacist and other personnel working in pharmacy should be well trained.
- The pharmacy should have well-documented guidelines and procedures for personnel set by management with pharmacist consultation.

- The personnel in the pharmacy should wear neat apron/coat and wear a badge displaying his name and designation.
- All pharmacy personnel should be medically examined and adequately immunized periodically.
- The chief pharmacist must be bachelor/master in pharmacy.
- Assistant pharmacist must be at least diploma pharmacy.

4. Requirement for Storage:

- All the medicines coming into the pharmacy should initially be quarantined and then checked for quantity, batch number, expiry, integrity, etc. After checking they should be transferred to their respective storage location.
- All the medicines should be stored at appropriate temperature protecting from excessive light, dust and humidity.
- The medicines and shelves should be clean and dust free following Standard Operating Procedures (SOPs).
  Narcotics and psychotropic should be stored and of labelled as per norms.
- Shelves should be checked periodically for expiry medicines and expired medicines should be kept separately labeling a "Expired Goods" "Not for Sale" .
- Expired medicines unused and unopened medicines are either returned to the suppliers or destroyed as per in-house protocol.

5. Requirements for Inventory Control:

- The pharmacy should develop and maintain safe, effective, operational and socio-economically acceptable procurement and inventory management.
- Pharmacist should ensure medicines and health care products readily available in the pharmacy in sufficient quantities.

6. Requirements of Services:

- Service strategies include home delivery of medicine special care and attention to patients like elderly patients, regular patients, etc.
- Service manual should state in detail service offered, service time and pharmacy operation schedule.

7. Requirements of Documentation:

- Documentation is one of the activities for maintaining and achieving quality.
- Pharmacist shall maintain all necessary documents like registration, permissions, etc.
- All operational documents like purchase invoices, sales invoices, etc.

Q.4. What are the Good Regulatory Practices in pharmaceutical manufacturing?/Write a note on Good Manufacturing Practices in pharmaceutical industries.

Good Manufacturing Practices (GMP)

Good manufacturing practice is a set of regulations, codes, and guidelines for the manufacture of drug substances and drug products, medical devices *in vivo* and *in vitro* diagnostic products and foods.

Objectives of GMP

1. A basic principle of GMP is that quality cannot be tested into a batch of product but must be built into each batch of product during all stages of the manufacturing process.
2. GMP is designed to minimize the risks involved in any pharmaceutical production that cannot be eliminated through testing the final product.

General Requirements of GMPs

- Avoid risks and possibilities of mix-up at all stages of manufacturing, labeling, packing and testing.
- Comfort of the personnel working and regular monitoring of temperature and humidity, particle count, DOP testing, etc.
- Proper drainage system which prevents backflow.
- Avoid open channels and if provided must be able to clean and disinfect.

Ten Principles of GMPs

1. Design and construct the facilities and equipments properly.
2. Follow written procedures and instructions
3. Document work.
4. Validate work.
5. Monitor facilities and equipment.
6. Write the step by step operating procedures and work on instructions.
7. Design, develop and demonstrate job competence.
8. Protect against contamination.
9. Control components and product related processes.
10. Conduct planned and periodic audits.

Following are the GMP Categories

1. **Sale:** No distributor and no importer shall sell a drug unless it has been fabricated packaged/labeled, tested and stored.

2. **Premises and equipment:** It includes effective cleaning, prevention of contamination and goods of repair and maintenance.
3. **Personnel:** It includes appropriate educated, trained and experienced staff with sufficient numbers and received GMP training.
4. **Sanitation:** It includes proper sanitation program to prevent contamination. Cleaning procedures for facilities and equipments, pest control, and environmental monitoring must be done.
5. **Raw material, packaging material and finished product testing:** It includes testing of each lot or batch of material. Approved test methods and specifications are used. Transportation and storage records must be maintained as per standard operating procedures.
6. **Manufacturing control:** It includes written procedures to be followed, master formula, manufacturing order and packaging order should be in a sequence. The validation, verification, self-inspections should be carried out.
7. **Quality control department:** It includes testing of bulk components, testing of finished product, stability program, and review of batch records, labels, auditing, and customer complaints.
8. **Records:** It includes documents of all GMP activities, use of good documentation practices (GDPs).
9. **Good documentation practices (GDPs):** Documentation must be permanent (black or blue ink) legible, clear, concise, accurate, timely and complete.
10. **Samples:** Retain the samples of each lot of raw material and finished products for specified period of time.
11. **Stability:** Establish the length of time in which the product meets all specifications.
12. **Sterile products:** Sterile products should be packaged in a separate enclosed area by trained personnel using method to ensure sterility.

OBJECTIVE QUESTIONS WITH ANSWERS IN BOLD LETTERS

1. GRPs means **good regulatory practices**.
2. GPP means **good pharmacy practice.**
3. **Good pharmacy practice** defines pharmacists that provides quality pharmacy service to every patient.
4. PMRs means **patients medication records**.
5. GMP means **good manufacturing practice**.
6. GDP means **good documentation practice**.

Chapter

14

Introduction to BCS System of Classification

Q 1. Define biopharmaceutical classification system (BCS). Explain different classes of BCS for drugs. Give the importance/role of BCS classification. (S. 24, W. 23)

Biopharmaceutical Classification System (BCS)

Definition

The biopharmaceutical classification system is a schematic framework for classifying a drug substance based on its aqueous solubility, intestinal permeability and a dissolution rate.

The BCS was first developed in 1995 by Amidon et al and his colleagues.

Biopharmaceutical Classification System for Drugs

Class	*Solubility*	*Permeability*	*Examples*
Class I	High	High	Metoprolol, Propranolol
Class II	Low	High	Nifedipine, Naproxen
Class III	High	Low	Cimetidine, Metfomin
Class IV	Low	Low	Taxol, Chlothiazide

Features of Class I to IV:

Class I

- Ideal for oral route administration.
- Drug absorbed rapidly.
- Drug dissolved rapidly.
- Rapid therapeutic action.
- Bioavailability problem not expected for immediate release drug products, e.g. Metoprolol, Propranolol, Diltiazem.

Class II

- Oral route for drug administration.
- Drug absorbed rapidly.
- Drug dissolves slowly.
- Bioavailability is controlled by dosage form and rate of release of the drug substance, e.g. Nifedipine, Naproxes.

Class III

- Oral route for drug administration.
- Drug absorbance is limited.
- Drug dissolved rapidly.
- Bioavailability is incomplete if drug is not released/dissolved in absorption window, e.g. Cimetidine, Metformin, Insulin.

Class IV

- Poorly absorbed by oral administration.
- Both solubility and permeability limitation.
- Low dissolution rate.
- Slow and low therapeutic action.
- An alternate route of administration may be needed, e.g. Taxol, Cefixime, Trihydrate, Chlorthiazide.

Importance/Role/Applications of Biopharmaceutical Classification System (BCS) of Drugs

1. To characterize the drugs for which products of those drugs may be eligible for biowaiver of *in vivo* bioequivalence studies.
2. To aid in earliest stages of drug discovery research.
3. To predict *in vivo* performance of drug product using solubility and permeability measurements.
4. Useful for the regulation of bioequivalence of the drug product during scale-up and post-approval.
5. Useful for research scientist to decide upon which drug delivery technology to follow or develop.

Q.2. Define BCS. Explain factors affecting on BCS.

BCS

The Biopharmaceutical classification system is a schematic framework for classifying a drug substance based on its aqueous solubility, intestinal permeability and a dissolution rate.

Factors Affecting on BCS

1. Solubility

- The maximum amount of solute dissolved in a given under standard conditions of temperature, pressure and pH.
- Solubility is the ability of the drug to be soluble after dissolution.
- The higher single unit dose is completely soluble in 250 ml at pH 1–6.8 (37°C).

2. Permeability

- Permeability of the drug means to pass the drug through biological membrane which is the lipophilic.
- Permeability is indirectly based on the extent of absorption of a drug substance.
- Drug substance is considered to be highly permeable, when the extent of absorption in human determined to be 90%.

3. Dissolution

- Dissolution is the process in which solid substance solubilises in a given solvent.

Dissolution test can be done:

- By using dissolution test USP apparatus I at rpm or USP apparatus at 50 rpm.
- Dissolution media.

Q.3. What are clinical trials? Give importance of a clinical trial. Mention types of clinical trials. (S. 24, W. 23)

Clinical Trials

Clinical trials are scientific investigations that examine and evaluate safety and efficacy of different therapies in human subjects.

Importance/Significance of Clinical Trials

1. Important for discovering new treatments for diseases
2. Important for new ways to detect, diagnose and reduce the chance of developing the disease.
3. Clinical trials benefit the participants as well as the investigators, the sponsorers, and the medical community.
4. Clinical trials provide a scientific basis for advising and treating patients.

5. Clinical trials help to determine the most effective dosages, and best method delivery.
6. Clinical trial is a research study that tests a new medical treatment or a new way of using an existing treatment.

Types of Clinical Trials

1. Treatment trials
2. Prevention trials
3. Diagnostic trials
4. Screening trials
5. Quality of life and supporting care screening
6. Genetic trials
7. Compassionate use clinical trials: Critical ill patients.

Q.4. Explain different phases of clinical trials. (S. 24, W. 23)

Phases of Clinical Trials

Clinical trials involving new drugs are commonly classified into four phases (I, II, III, and IV):

- ***Pre-clinical trials*:** It involves *in vitro* (test tube or cell culture) and *in vivo* (animal) experiments using wide ranging doses of the study drug to obtain preliminary efficacy, toxicity and pharmacokinetic information.

1. ***Phase I trials*:** It involves initial studies to determine the metabolism and pharmacologic actions of drugs in humans, the side effects associated with increasing doses and to gain early evidence of effectiveness may include healthy participants and/or patients.
2. ***Phase II trials*:** It involves controlled clinical studies conducted to evaluate the effectiveness of drug for a particular indication or indications in patients with the disease or conditions under study and determine the common short-term side effects and risks.
3. ***Phase III trials*:** It involves expanded controlled and uncontrolled trials after preliminary evidence suggesting effectiveness of the drug has been obtained and are intended to gather additional information to evaluate the overall benefit–risk relationship of the drug and provide adequate basis for physician labeling.

4. ***Phase IV trials*:** Phase IV trials are 'post-approval' studies. It includes post-marketing studies to describe additional information including drug's risks, benefits and optimal use.

Q.5. What do you mean by NDA, ANDA and INDA?

1. **NDA (New Drug Application):** NDA is a critical component for drug approval process which is required to submit to USFDA before drug commercialization.
2. **ANDA (Abbreviated New Drug Application):** An Abbreviated New Drug Application (ANDA) contains data which when submitted to FDA office of general drugs, provides for the review and ultimate approval of a generic drug product.
3. **INDA (Investigational New Drug Application):** An INDA is a submission to the food and drug administration (FDA) requesting permission to initiate a clinical study of a new drug product.

Q.6. Define New Drug. Enlist different steps involved in the New Drug Development. (S. 23)

New Drug (as per Schedule Y)

New drug means:

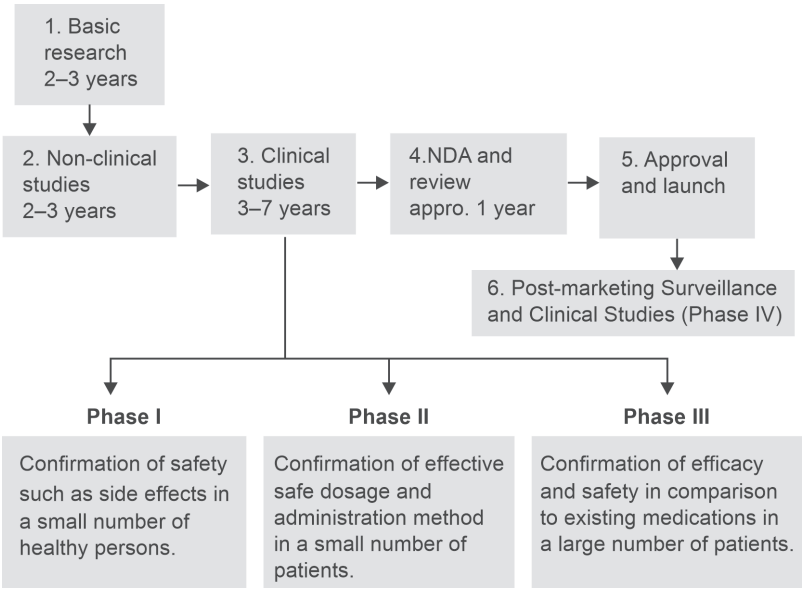
i. New substance which except during local clinical trials, has not been used ever before in the country.

ii. Drug already approved for certain claims but which is now proposed to be marketed with modified or new claims (indications, dosage, dosage forms, route of administration).

Steps in New Drug Development

1. Idea or basic research
2. New drug discovery
3. Screening
4. Preclinical studies
5. Formulation development
6. IND application
7. Clinical studies
8. Official license/regulations/marketing

Flowchart/Diagram of New Drug Development



Q.7. Write in brief about Brand Drug v/s Generic Drug.

Brand Name Drugs

These drugs are also called innovator drugs invented by pharmaceutical companies to prevent them from being copied as reverse engineered by this companies.

Generic Drugs

A generic drug is defined as "A drug product that is comparable to brand/ innovator drug in dosage form, strength, route of administration, quality and performance, characteristics and intended use".

- It should contain the same active ingredients as the original formulation.
- According to FDA, generic drugs are identical or within an acceptable bioequivalent range to the brand name counterpart with respect to pharmacokinetics and pharmacodynamics properties.

Examples of Generic and Branded Drugs

Category	*Generic drug*	*Price*	*Branded drug*	*Price*
Analgesic	Paracetamol	₹ 2.45	Crocin	₹ 11.00
Antibiotic	Amoxycillin	₹ 13.2	Remox	₹ 38.7
Vitamin	B-complex	₹ 1.8	Becosule	₹ 11.00
Antihypertensive	Atenolol	₹ 7.0	Aten	₹ 23.8

Comparison between Generic and Brand Drugs

Similarities	*Dis-similarities*
• They must contain the same active ingredients. • They must have the same dosage strength (e.g. 20 mg, 40 mg). • They must be the same dosage forms. • They must have the same route of administration. • They must deliver similar amounts of drug to the blood stream.	• They could have different sizes, shapes colours. • They might have different inactive ingredients. • The generic costs are less than brand drug name.

Q.8. Give the difference between Generic Drugs and Brand Name Drugs. (S. 23, 24)

Sr No.	*Features*	*Generic drugs*	*Brand name drugs*
1.	Patent	Off patent	Patent protected
2.	Manufactured by	Manufactured by several pharmaceutical companies after patents expiration of the relevant brand name drugs	Developed and manufactured by an innovator company only.
3.	Animal and clinical study	Not required to perform	Essential to perform.
4.	Price	Cheaper	Costly than generic drugs.
5.	Appearance (colour, size, shape)	Look different from relevant brand name drugs.	Unique look as per design during product development.
6.	Name variation	Same generic name in any country.	Same or different brand names in different countries.
7.	Excipients	Same or altered but acceptable excipients.	Uses acceptable excipients.
8.	Availability	After expiration of patents and exclusivities.	From product launch after proving the safety and effectiveness.
9.	Examples	Paracetamol	Crocin, Calpol, Paracetamol.

Q.9. Define Trademark. Give its types. Mention functions of trademarks./ Write a note on trademark.

Trademark/Brand Name

Trademark or brand name is any distinctive word, Phrase, logo, symbol, design, picture, styling or a combination of one or more of these elements. Trademark Act, 1940 was the first statute law or trademarks in India.

Types of Trademarks

1. A name (including personal and surname of the applicant or predecessor in business or the signature of the person).
2. Alphanumeric as letters or numerals or any combination thereof.
3. Image, symbol, monograms, letters, etc.
4. Sound marks in audio format.

Functions/Uses/Importance of Trademark

1. It distinguishes one company's goods or services from another to protect consumers from confusion.
2. It indicates the source and origin of the producer—primary functions and establishes a connection between goods and people.
3. It identifies the products. The products are recognized on the basis of trademarks.
4. It guarantees and assures of a certain quality.
5. Trademark is a standard of quality. Customer expects that goods bearing the same mark will be of the same quality.

Q.10. Define the terms.

1. ***Intellectual Property (IP):*** Intellectual property refers to creation of mind inventions literacy and artistic works and symbols, names and images used in commerce.
   Intellectual property means ideas owned by a person or a firm. The main purpose of IP is to give encouragement to the innovators of new concepts by giving them the opportunity to make sufficient profits from their inventions and recovery their manufacturing cost and effects.
2. ***Patent:*** A patent in relation to inventions is an exclusive right granted by the government to the patentee in exchange a full disclosure of his invention, for excluding others from making, using, selling, importing the patented products or process producing that product for those purposes.
3. ***Intellectual Property Rights (IPRs):*** Intellectual property rights are legal rights that protect creations and/or inventions resulting from intellectual activity in the industrial, scientific, literacy or artistic field.

Types of IPRs:

i. Patents
ii. Trademarks
iii. Copyright
iv. Trade secrets

v. Licensing
vi. Franchising

Q.11. What is Indian Patent Act? Give the object of Indian Patent Act.

Indian Patent Act

- The Patent Act in India was implemented in 1970 which came into force on 20th April 1972 and extended to the whole of India.
- This act was amended in March 1999 and June 2002 to meet India's obligations under the agreement on Trade Related Aspects of Intellectual Property Rights (TRIPS) which forms part of the agreement establishing the World Trade Organization (WTO).

Scope/Object/Purpose of Patent Act

- To encourage inventors to make great contribution to their field by granting them exclusive rights to their inventions.
- To improve the recognition and credibility of the inventor or his startup as a company in the market.

Q.12. What is IPRs? Give objectives or importance of IPRs.

IPRs

Intellectual Property Rights are legal rights that protect creations and/or inventions, resulting from intellectual activity in the industrial, scientific, literacy or articles field.

Objectives of Intellectual Property Rights (IPRs)

1. To create public awareness about the benefits of intellectual property among all sections of society.
2. To stimulate and create the growth of intellectual property by undertaking relevant measures.
3. To have a strong or effective laws with regards to IP rights, consistent with international obligations.
4. To modernise and strengthen Intellectual property administration
5. To catalyse commercialization of IP rights.
6. Capacity development by strengthening and expanding human resources, institution for training research and skill building in intellectual property.

Significance/Importance of IPR

- To provide exclusive rights and to protect the interest of the creator and encourage investment in research and information creation.

- IPR is a right which gives monopoly of any intellectual creation of mind.
- IPR is a combination of science and technology both.
- It is given for any new creation such as composition of music, writing a book, new invention.
- IPRs have a significant influence on economic progress.
- IPR gives recognition to the efforts employed by the person, firms or organization.
- IPRs promote further inventions and research activities.

Q.13. Define.

a. *Patent*: Patent means a patent granted under Indian Patent Act.
b. *Patent agent*: It means a person for the time being registered under the Indian Patent Act as patent agent.
c. *Patentee*: It means a person for the time being entered on the register as the guarantee or the proprietor of the patent.
d. *Patented article and patented process*: It means respectively an article/process in respect of which patent is in force.
e. *Exclusive licence*: It means licence from a patentee who confers on the licence or on the license and the person authorized by him, to the exclusion of other persons (including the patentee), any right in respect of the patented invention, and "exclusive license" shall be constructed accordingly.
f. *Invention*: It means any new and useful:
   i. Art, process, method or manner of manufacture
   ii. Machine, apparatus another article
   iii. A substance produced by the manufacturer and includes any new and useful improvement of any of them and an alleged invention.

Q.14. Enlist patentable and not patentable inventions.

A. Inventions which are Patentable

An invention to be patentable should be technical in nature and should meet the following criteria:

a. *Novelty*: The invention should be new and original.
b. *Inventive step*: The invention is not obvious to person skilled in the light of the prior publication/knowledge /document.
c. *Industrially applicable*: Invention should possess utility so that it can be made or used in the industry.

B. Inventions not Patentable

The following are not inventions 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. An invention, the primary or intended use or commercial exploitation of which would be contrary to which causes serious prejudice to human, animal or plant life or health or to the environment.
c. The mere discovery of a scientific principle or formulation of or discovery of any living thing or non-living substance occurring in nature.
d. The mere discovery of a new form of a known substance which does not result in the enhancement of any known efficacy of that substance or the mere discovery of any new property or new use for a known substance or of the mere use of a known process, machine or apparatus unless such known process results in a new product or employs at least one new reactant.
e. A substance obtained by a mere admixture resulting only in the aggregation of the properties of the components thereof or a process for producing such substance.
f. The mere arrangement, rearrangement or duplication of known devices each functioning independently of one another in a known way.
g. A method of agriculture or horticulture.
h. Any process for the medicinal, surgical, curative, prophylactic, diagnostic, therapeutic or other treatment of human beings or any process for a similar treatment of animals to render them free of disease or increase their production or propagation of plants and animals.
i. Plants or animals in 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.
j. A mathematical or business method or a computer programme.
k. A literary, dramatic, musical or artistic work or any other aesthetic creation whatsoever including cinematographic works and television productions.
l. A mere scheme or rule or method of performing mental act or method of playing the game.

m. A presentation of information.
n. The topography of integrated circuits.
o. An invention which, in effect, is traditional knowledge or which is an aggregation or duplication of known properties of a traditionally known component or components.

Q.15. What are Intellectual Property Rights (IPRs)? Give its types/ examples.

Intellectual Property Rights are legal rights that protect creations and/or inventions, resulting from intellectual activity in the industrial, scientific, literacy or articles field.

Forms/Types/Examples of Intellectual Property Rights Include:

- Patents
- Domain names
- Industrial design
- Confidential information
- Inventions
- Moral rights
- Database rights
- Works of authorship
- Service marks
- Logos
- Trademarks
- Design rights
- Business or trade names
- Commercial secrets
- Computer software.

Q.16. Describe various types of intellectual property.

There are four main types of intellectual property.

1. Patents

- Patent is a limited monopoly to a particular invention and as a legal monopoly, it is therefore a very valuable form of property.
- Patents are available for any new and useful process, machine, and manufacture of composition of matter or any new and useful improvement thereof.
- Patent law protects inventions from the use by others and gives exclusive rights to one or more inventors.

- There are three types of patents:
  a. *Design patent*: Design patent may be granted for any new original and ornamental design for an article of manufacture.
     A design patent essentially protects the visual appearance of the design shown in the drawing of the patent, e.g. a pharmaceutical manufacturer may wish to protect the appearance of its drug tablet so that ornamental appearance may not be copied, The pharmaceutical manufacturer may obtain design patent covering the tablets appearance.
  b. *Plant patents*:
     – This type of patent safeguard for new varieties of plants.
     – An example of a plant patent is pest-free version of fruit trees.
  c. *Utility patent*:
     – It covers mechanical inventions such as machines.
     – It also covers chemical formulations and biotechnology.
     – A utility patent protects a functional aspect of an invention.
     – A process or method patent is a part of utility patent which involves a series of steps directed to producing useful results.

2. Trademarks

- Trademark or brand name is any distinctive word, Phrase, logo, symbol, design, picture, styling, colours, sounds or a combination of one or more of these elements.
- Trademarks are also important in distinguishing one company's goods or services from another to protect the consumers from confusion.
- Trademark is used by a business to identity itself and its products or services to consumers and set itself and its products or services apart from other business.
- Trademark Act of 1946, governs trademarks infringement and services marks.

3. Copyrights

- A right available for developing an original work related to the field of literature, art, music, or drama is termed Copyright.

4. Trade Secrets

- Any piece of information that is important with respect to the business and is not shared with the general public and which the businessman tries to keep confidential or secret is termed a "trade secret".
- Trade secret is the company intellectual property that is not public, which has economic value and carries information.

- Trade secrets may be a formula, recipe or process used to gain a competitive advantage.

Q.17. Define Patent. Give importance of Patents.

Patent

A patent in relation to inventions is an exclusive right granted by the government to the Patentee in exchange of full disclosure of his invention, for excluding others from making, using, selling, importing the patented products or process producing that product for those purposes.

Importance of Patents

- They provide the right to the patentee to restrict others from manufacturing the product.
- The right of exclusivity allows the patentee to market his product without competition for a considerable period of time enabling him to obtain higher prices for his invention.
- They enable the patentee to legally sue anyone who attempts to make patentee's product without his permission.
- They allow the patentee to generate money by selling or licensing his product to someone else, who may economically exploit the patentee's invention.
- They provide a negative right to the inventor, which prevents others from making. selling, or importing the product for a certain period of time. This gives enough time to the patentee to economically exploit his invention.
- They encourage incremental changes in the existing product by recognising innovation besides invention as such patents are more interested in 'evolution' rather than 'revolution'.
- The rights granted under the patent law are territorial in nature. The rights of a patent holder having his invention registered in India are limited to India only.
- They promote technological innovations by recognising and protecting new inventions and innovations.
- They safeguard the creation and the resources spent on making the invention by awarding appropriately the creative endeavour.
- They help in safeguarding all the technological innovations related to the industry, like mechanical and electronic devices and chemical compositions.

Q.18. Give the aims, objectives and features of "New Drugs and Clinical Trials" (NDCT Rules, 2019).

New Drugs and Clinical Trials Rules, 2019

Ministry of Health and Family Welfare has notified the "New Drugs and Clinical Trials" Rules, 2019 on 25th March 2019.

Aims and Objectives of NDCT Rules, 2019

- To promote clinical research in the country and will change the regulatory landscape for the approval of new drugs and conduct of clinical trials in the country.
- The rules will apply to all new drugs, investigational new drugs for human use, clinical trial, bioequivalence study, bioavailability study, and ethics committee.

Features of New Drugs and Clinical Trial Rules

- The new rules aim to promote clinical research in India by providing for predictable transparent and effective regulation for clinical trials and by ensuring faster accessibility of new drugs to the Indian population.
- New rules have reduced the time for approving applications which has now come down to 30 days for drugs manufactured in India and 90 days for those developed outside the country.
- In case of no communication from Drugs Controller General of India, the application will be deemed to have been approved.
- Drugs Controller General of India will decide the compensation in cases of death and permanent disability of the injury to a trial subject.
- The requirements of a local clinical trial may be permitted for approval of a new drug if it is approved and marketed in any of the countries specified by the Drugs Controller General with the approval of the government.

Q.19. What do you mean by "Emergency Use Authorization" (EUA)?

Emergency Use Authorization (EUA)

EUA is a tool used by FDA to authorize the temporary use of products that fulfil urgent medical needs during public health emergencies.

- These products are authorized for use only in specific circumstances and expire once those conditions end.
- The Emergence Use Authorization (EUA) authority allows FDA to help strengthen the nation's public health protections against chemical, biological, radiological and nuclear threats by facilitating the availability and use of medial countermeasures needed during public health emergencies.

The Process of Issuing EUA

It involves the following five steps:

1. Determination of an emergency.
2. Declaration of an emergency.
3. Review of the request for EUA by the FDA.

4. Issuance of the EUA or denial of the request.
5. Termination of EUA.

OBJECTIVE QUESTIONS WITH ANSWERS IN BOLD LETTERS

1. BCS means **Biopharmaceutical classification system**.
2. The BCS was first developed by in **1995 by Amidon et al**.
3. **Phase IV** trials are 'Post-approval' studies.
4. NDA means **New Drug Application**.
5. ANDA means **Abbreviated New Drug Application**.
6. INDA means **Investigational New Drug Application**.
7. FDA means **Food and Drug Administration**.
8. Patents are protected for **brand name drugs**.
9. **Trademark or brand** name is any distinctive word, Phrase, logo, symbol, design, picture, styling or a combination of one or more of these elements.
10. Trade Mark Act, **1940** was the first statute law or trademarks in India.
11. **Intellectual property** refers to creation of mind inventions literacy and artistic works and symbols, names and images used in commerce.
12. **Intellectual property** means ideas owned by a person or a firm.
13. IPRs means **Intellectual Property Rights**.
14. Patents, Trademarks, Copyright, Trade secrets, Licensing, Franchising are the types of **Intellectual Property Rights**.
15. The Patent Act in India was implemented in **1970** which came into force on 20th April 1972.
16. TRIPS means **Trade Related Aspects of Intellectual Property Rights**.
17. WTO means **World Trade Organization**.
18. IPR is a right which gives **monopoly** of any intellectual creation of mind.
19. A right available for developing an original work related to the field of literature, art, music, or drama is termed **Copyright**.
20. Trade secret is the **company** intellectual property.
21. NDCT means **New Drugs and Clinical Trials**.
22. **Ministry of Health and Family Welfare** has notified the "New Drugs and Clinical Trials" Rules, 2019 on 25th March 2019.
23. EUA means **Emergency Use Authorization**.
24. The Patent System was first introduced in India in **1856**.
25. Topography of integrated circuit is **non-patentable** type of invention.

Chapter

15

Blood Bank: Basic Requirements and Functions

Q.1. What is Blood Bank? Give its objectives, importance and functions.

Blood Bank

Blood bank is a bank of blood or blood components, gathered as a result of blood donation, stored and preserved for later use in blood transfusion.

Charles Richard Drew is pioneer/father of the blood bank.

Objectives of Blood Bank

1. To collect, process, store the blood for research and medical purposes.
2. To make sure that donated blood or blood products are safe before they are used in blood transfusions.
3. To save the lives of the people by providing blood.
4. To separate various components of blood which can be used effectively according to the needs of the patient.
5. To identify the patient and blood products during transfusion of blood.
6. To bridge the gap between blood banks, hospital volunteer, donors and needy people through this system.

Importance/Functions of Blood Bank

1. Blood banks are responsible for the collections, processing, safety and storage of blood for research and medical purposes.
2. To give rapid service to urgent request for blood components.
3. To check pre-transfusion samples and requests.
4. To assess immunological compatibility between donor and patients.
5. To select a suitable blood component for each clinical condition.
6. To perform blood group matching.
7. To safe delivery and handling of blood components

8. The primary function of the blood bank is to provide blood components for transfusion.
9. Blood bank is a major component of hospital, concerned with activities from donors registration to collection, storage, etc.

Q.2. What are the general guidelines for the setting/establishment of a blood bank?

General Guidelines for Blood Bank

- The blood bank or blood transfusion services should have its own constitution, which defines the responsibility and authority of the management.
- The blood bank should function under the direction of a licensed physician qualified by training and experience as transfusion medicine specialist (medical officer of blood bank) who should be responsible for all medical, technical and administrative services.
- All blood banks should be licensed by State Drug Controller and approved by Drugs Controller General (India) and should be regulated by Drugs and Cosmetics Act and rules thereunder.
- Blood bank should comply with laid down standards in Drugs and Cosmetics Rules in recruitment and selection of blood donars, Collection, processing, storage and distribution.
- All blood banks should have their own quality policy and prepare a quality manual that addresses the system in use.
- Each blood bank should maintain a detailed standard operating procedure manual, as well as records in a prescribed formate prescribed by Drugs and Cosmetics Rules.
- There should be an adequate and competent staff as prescribed in the schedule F, part XII B and C of Drugs and Cosmetics Rules.
- Suitable space, environment and equipment should be available to maintain safe and acceptable standards of housekeeping.
- The records of calibration, maintenance and validation of equipment should be maintained as per the norm.
- All materials of blood collection and transfusion should be sterile, pyrogen free and disposable and should be stored in an air conditioned area.
- All the containers and coagulants used for storage, preservation of blood and blood components should meet the standards of Drugs and Cosmetics Acts and Rules and Bureau of Indian Standards (BIS).
- The blood banks should establish and maintain a quality assurance system.

Q 3. What are the basic requirements of blood banks?

Basic Requirements of Blood Banks

The requirement of blood banks is given under Schedule F Part XII B of the Drugs and Cosmetics Rules.

Schedule F Part XII B describes the requirement for the functioning and operation of a blood bank and for preparation of blood components.

I. Blood Bank/Blood Components

1. General
2. Accommodations for blood bank
3. Personnel
4. Maintenance
5. Equipment
6. Supplies and reagents
7. GMPs and SOPs
8. Criterion for blood donation
9. General equipment and instruments
10. Special reagents
11. Testing of whole blood
12. Records
13. Labels

II. Blood Donation Camps

1. Premises, personnel, etc.
2. Personnel for outdoor blood donation camps
3. Equipment

III. Processing of Blood Components from whole blood by a blood bank

1. Accommodation
2. Equipment
3. Personnel
4. Testing facilities
5. Categories of blood components
6. Plasmapheresis, plateletpheresis

1. General Space

- The blood bank Unit shall have a minimum requirement floor area of 100 m^2 and an additional 50 m^2 for preparation of blood products.
- All floors and walls in processing area must be smooth impervious and easily cleaned.

2. Location

- Ideally blood bank should be located on the ground floor.
- Direct access from the main entrance.
- Easy visibility.
- It should be near to emergency department, operation theater.

3. Accommodation

It includes following separate rooms:

- Registration and medical examination room
- Blood collection room (air conditioned)
- Room for blood component preparation (air conditioned)
- Room/Lab for blood group serology (air conditioned)

4. Personnels

A Bachelor's Degree is a must for aspiring blood bank specialist. A degree in biology, a certification work experience in any blood bank are the key requirements and to become a blood bank specialist. Medical officer of the blood bank along with all competent technical staff should follow the Standard Operating Procedures (SOPs) for the efficient running of blood bank.

5. Equipment

The major equipment of the blood bank include blood storage refrigerator, donor couches, blood mixer and collector, platelet incubator, platelet agitator, plasma expressor, ELISA reader with washer, refrigerated centrifuge, binocular microscope, centrifuge, universal hot air oven, bacteriological incubator.

6. Criterion for Blood Donation

- Donor should be in good health.
- Age 18–60 years, Hb not less than 12.5 gm/dL, normal HR, pulse, BP, temperature, body weight.
- Skin at the vein puncture site should be free from any lesion.
- Should not have any disease or disorder.

7. Other Facilities

Water supply, electric supply, sewage disposal system, storage system, steam, supply of distilled water, high pressure air vacuum, intercom system, mobile van, etc.

OBJECTIVE QUESTIONS WITH ANSWERS IN BOLD LETTERS

1. **Charles Richard Drew** is pioneer/father of the blood bank.
2. BIS means **Bureau of Indian Standards**.
3. The requirement of blood banks is given under **Schedule F Part XII B** of the Drugs and Cosmetics Rules.
4. The blood bank unit shall have a minimum requirement floor area of **100 m^2**.

Chapter

16

Clinical Establishment Act and Rules

Q.1. Give the objectives of Clinical Establishment Act.

Objectives of Clinical Establishment Act

The Clinical Establishment (Registration and Regulation) Act, 2010 has been enacted by the central government to provide for registration and regulation of all clinical establishments in the country with a new to prescribe the minimum standards of facilities and services provided by them.

Q.2. What are the categories under which a hospital can be registered under Clinical Establishment Act?

1. District Hospital
2. Corporate Hospital
3. Referral Hospital
4. Regional State Hospital
5. Nursing Home and private hospitals.

Q.3. Define the term as per Clinical Establishment Act and Rules.

1. **Certificate:** It means certificate of registration issued under Section 30.
2. **National Council:** It means the National Council of Clinical Establishments established under Section 3.
3. **Register:** It means the register maintained by the authority, state government under Sections 37, 38 and 39 respectively of this Act containing the number of Clinical Establishments registered.
4. **Clinical Establishment:** It means:
   i. A hospital, maternity home, nursing home, dispensary, clinic sanatorium or an institution by whatever name called that offers services facilities requiring diagnosis, treatment or care for illness, injury, deformity, abnormality or pregnancy in any recognised system of medicine established and administered or maintained by any person or less body of person, whether incorporated or not; or

ii. A place established as an independent entity or part of an establishment referred to in subclause (i), in connection with diagnosis or treatment of diseases where pathological, bacteriological, genetic, radiological, chemical, biological investigations or other diagnostic or investigative services with the aid of laboratory or other medical equipment, are usually carried on, established or administered or body of persons, whether incorporated or not, and shall include at clinical establishment owned, controlled or managed by:
   a. The government or a department of the government;
   b. A trust, whether public or private;
   c. A corporation (including a society) registered under a Central Provincial or State Act, whether or not owned by the government
   d. A local authority, and
   e. A single doctor, but does not include the clinical establishments owned controlled as managed by the armed forces.

Q.4. What is National Council? Give the Constitution of National Council.

National Council

National Council means National Council of Clinical Establishments established under Section 30.

Constitution of National Council

The National Council shall consist of:

a. Director-General of Health Service, Ministry of Health and family Welfare, ex-officio, who shall be the chairperson,
b. Four representatives out of which one each to be elected by the:
   i. Dental Council of India Constituted under Section 3 of the Dentist Act, 1948.
   ii. Medical Council of India Constituted under Section 3 of the Indian Medical Council Act, 1956.
   iii. Nursing Council of India Constituted under Section 3 of the Indian Nursing Council Act 1947.
   iv. Pharmacy Council of India, under Section 3 of the Pharmacy Act 1948.
c. Three representatives to be elected by the Central Council of Indian Medicine representing the Ayurveda, Siddha and Unani systems of medicines constituted under Section 3 of the Indian Medicine Central Council Act, 1970.
d. One representative to be elected by the Central Council of Homeopathy, constituted under Section 3 of the Homeopathy Central Council Act, 1973.

e. One representative to be elected by the Central Council of Indian Medical Association.
f. One representative of Bureau of the Indian Standards Constituted under Section 3 of the Bureau of Indian Standards Act, 1986.
g. Two representatives from the Zonal Council setup under Section 15 of the Reorganisation States Act, 1956.
h. Two representatives from the North Eastern Council setup under Section 3 of the North-Eastern Council Act, 1971.
i. One representative from the line of paramedical systems excluding systems that have been gives representation under clause (b).
j. Two representatives from National Level Consumer group to be nominated by the central government.
k. One representative from the Associations of Indian Systems of Medicine relating to Ayurveda, Siddha and Unani to be nominated by the central government.
l. The Secretary General of the Quality Council of India, ex-officio.

Q.5. What are the functions of National Council? (S. 24, W. 23)

Functions of National Council

The National Council shall:

a. Compile and publish a National Register of clinical establishments within two years from the commencement of this Act.
b. Classify the clinical establishments into different categories.
c. Develop the minimum standards and their periodic review.
d. Determine within period of two years from its establishment, the first set of standards for ensuring proper health care by the clinical establishments.
e. Collect the statistics in respect of clinical establishments.
f. Perform any other function determined by the central government from time to time.

Q.6. Give the Constitution of State Council for Clinical Establishments.

Every state government shall by notification constitute a State Council for clinical establishments or the Union Territory Council for clinical establishments as the case may be.

The constitution of State Council for clinical establishments.

It consists of the following members, namely:

a. Secretary, Health ex-officio, who shall be the Chairman.
b. Director of Health Services ex-officio, member Secretary.

c. Directors of different streams of Indian systems and Medicine ex-officio members.
d. One representative each to be elected by the Executive Committee of:
   i. State Medical Council of India
   ii. State Dental Council of India
   iii. State Nursing Council of India
e. Three representative to be elected by the Executive of the State Council of the Union Territory Council, as the case may be of Indian medicine representing the Ayurveda, Siddha and Unani systems of medicine.
f. One representative to be elected by the State Council of the Indian Medical Association.
g. One representative from the line of paramedical systems.
h. Two representatives from state level consumer groups as reputed or non-governmental organizations working in the field of health.

Q.7. Write in brief about "Authority for Registration of Clinical Establishments".

Authority for Registration of Clinical Establishments

1. The state government shall by notification, set-up an authority to be called the District Registering Authority for each district for registration of clinical establishments with the following members, namely:
   a. District Collector—Chairperson,
   b. District Health Officer—Convener,
   c. Three members with such qualifications and on such terms and conditions as may be prescribed by the central government.
2. Notwithstanding anything contained in sub-section (1), for the purposes of provisional registration of clinical establishments under Section 14, the District Health Officer or the Chief Medical Officer shall exercise the powers of the authority as per procedure that may be prescribed.

Q.8. What are various conditions for "Registration of the Clinical Establishments"? (S. 23)

Conditions for Registration of Clinical Establishments

1. For registration and continuation, every clinical establishment shall fulfil the following conditions, namely:
   i. The minimum standards of facilities and services as may be prescribed,
   ii. The minimum requirement of personnel as may be prescribed,
   iii. Provisions for maintenance of records and reporting as may be prescribed,
   iv. Such other conditions as may be prescribed.

2. Clinical establishment shall undertake to provide within the staff and facilities available, such examination and treatment as may be required to stabilize the emergency medical condition of any individual who comes or is brought to such Clinical Establishment.

OBJECTIVE QUESTIONS WITH ANSWERS IN BOLD LETTERS

1. The Clinical Establishment (Registration and Regulation) Act, 2010 has been entacted by **the central government**.
2. National Council means National Council of Clinical Establishments established under **Section 30**.

Chapter

17

Biomedical Waste Management Rules, 2016

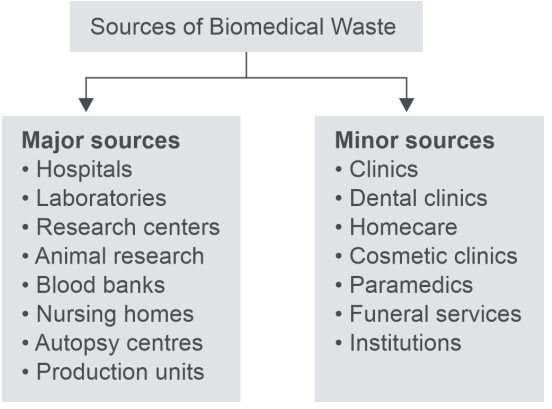
Q1. What is Biomedical Waste (BMW)? Give its sources. Give the classification of biomedical wastes.

Biomedical Waste (BMW)

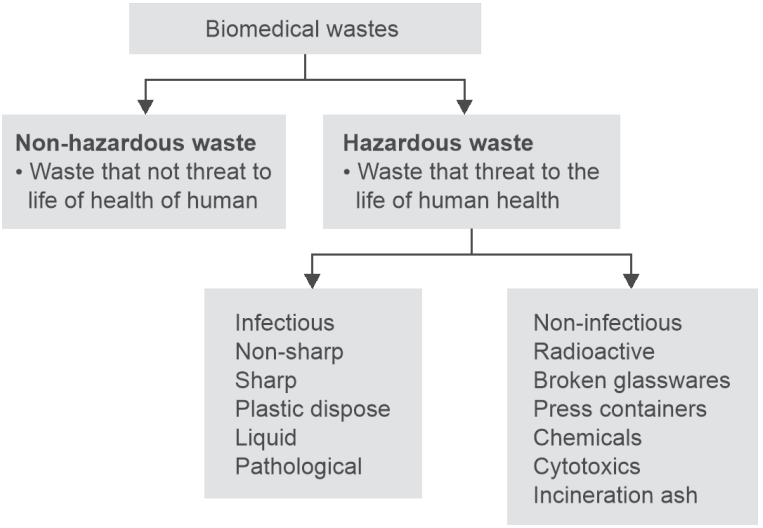
The waste generated in the diagnosis, treatment or immunization of human beings or animals, in research or in the production of material or testing of biological products.

It also includes waste coming out of medical treatment given at home.

Sources of Biomedical Waste



Classification of Biomedical Wastes (BMW)



Q.2. What are the benefits/advantages of biomedical waste management?

Benefits/Advantages of Biomedical Waste Management

1. It helps to keep clean and healthy surrounding.
2. It helps to reduce the incidence of hospital acquired and general infections.
3. It helps to reduce cost of infection control within the hospital.
4. It reduces the possibility of disease and death due to reuse and repackaging of infectious disposable.
5. It lowers incidence of community and occupational health hazards.
6. It reduces cost of waste management and generation of revenue through appropriate treatment and disposal of waste.
7. It helps to improve the image of the health care establishment and increase the quality of life.

Q.3. How biomedical waste segregation is done? Mention various categories of biomedical wastes.

Segregation of Biomedical Waste (BMW)

- Segregation refers to the base separation of different categories of waste generated at sources and thereby reducing the risks as well as cost of handling and disposal.

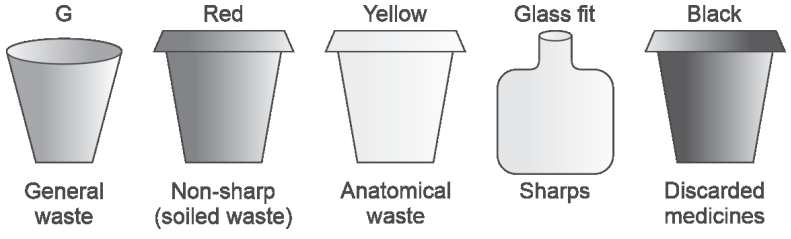
- Segregation is most important step in biomedical waste management. Effective segregation alone can ensure effective biomedical waste management.
- The BMWs must be segregated in accordance to guidelines laid down under Schedule 1 of BMW Rules, 2016.

Segregation of biomedical waste: Segregation of BMW is done in the following categories:

Category	*Type of waste*	*Method of disposal*
Category 1	Human anatomical waste	Incineration, deep burial
Category 2	Animal waste	Incineration, deep burial
Category 3	Microbiology and biotechnology waste	Local autoclaving, microwaving, incineration
Category 4	Waste sharps	Autoclaving, microwaving
Category 5	Discarded medicines and cytotoxic drugs	Incineration, landfilling
Category 6	Solid waste (dirty liver, etc.)	Incineration, autoclaving, microwaving
Category 7	Solid waste (tubing catheters, etc.)	Chemical disinfection, autoclaving, microwaving
Category 8	Liquid waste (waste from cleaning)	Discharge into drain
Category 9	Incineration ash	Disposal in municipal landfill
Category 10	Chemical waste discharge into drains for liquid	Chemical treatment and and secure landfill for solids.

Note

- Biomedical waste should not be mixed with any other kind of waste.
- The containers should be labelled according to schedule.



Q 4. What are various hazards associated with hospital waste?

Hazards Associated with Hospital Waste

1. **Ignitability:** Waste capable of burning or causing fire can irritate the skin, eyes and lungs and may give harmful vapours, e.g. gasoline, industrial alcohols.

2. **Corrosivity:** Waste capable of corroding metals and burning human tissues on contact, e.g. alkaline cleaners, some chlorides.
3. **Reactivity:** Materials capable of reacting with other chemicals in air causing an explosion as release of poisonous fumes, e.g. peroxides, isocynides, cyanides and chlorine.
4. **Toxicity:** Toxic wastes are harmful or fatal when ingested or absorbed, e.g. heavy metals such as lead and mercury and pesticide wastes.
5. Infectious waste can get cause diseases like hepatitis B, AIDS, typhoid, etc.
6. Exposure to hazardous hospital waste can result in diseases or injury.

Q.5. Explain different methods of disposal of biomedical wastes.

Methods of Disposal of Biomedical Wastes

1. Incineration Technology

- This is a high temperature thermal process employing combustion of the waste under controlled condition for covering them into inert material and gases.
- Incinerators can be oil, fire or electrically powered or a combination thereof.
- Three types of incinerators are used for hospital waste disposal—multiple hearth type, rotary kiln and controlled air type.

2. Non-incineration Technology

- Non-incineration treatment includes four basic processes such as thermal, chemical, irradiative and biological.
- The majority of non-incineration technologies employ the thermal and chemical processes.
- The main purpose of the treatment technology is to decontaminate waste by destroying pathogens.

3. Autoclaving

- This process involves use of steam at high temperatures.
- Autoclaves used may be of gravity type, prevacuum type.
- These methods are used for microbiology and biotechnology waste, waste sharps, soiled and solid wastes.

4. Microwave Irradiation

- The microwave is based on the principle of generation of high frequency waves.

- These waves cause the particles within the waste material to vibrate generating heat.
- This heat generated from within, kills all pathogens.

5. Chemical Method

1% hypochlorite solution can be used for chemical disinfection.

6. Plasma Pyrolysis

- Plasma pyrolysis is a state-of-the-art technology for safe disposal of medical waste.
- It is an environment-friendly technology which converts organic waste into commercially useful byproducts.
- The intense heat generated by the plasma enables it to dispose all types of waste including municipal biomedical waste and hazardous waste in a safe and reliable manner.
- Medical waste is pyrolyse into CO, H_2 and hydrocarbon when it comes in contact with the plasma-arc. These gases are burned and produce a high temperature (around 1200°C).

Q.6. What do you mean by pharmaceutical waste? Give the methods of disposal of pharmaceutical wastes.

Pharmaceutical Waste

It means drug waste, unused or expired drugs, unused or expired prescription and OTC human drugs, veterinary drugs, diagnostic agents, and nutritional supplements.

It also includes:

1. Scrap (e.g. rejected foils, bottles, cans, tins, etc.)
2. Trash (e.g. dust, unsalable materials)

Methods of Disposal of Pharmaceutical Wastes

1. Return to the manufacturer
2. Incineration: At high temperature (>1200°C) and medium temperature (max. 850°C)
3. Immobilization, e.g. waste encapsulation, inertization
4. Landfill: It includes:
   a. Highly engineered sanitary landfilling
   b. Engineered landfill
   c. Open uncontrolled nonengineered dump
5. Sewer and fast-flowing water course
6. Burning in open containers
7. Chemical decomposition

Q.7. What is hospital waste? Give the methods of disposal of hospital waste.

Hospital Waste

Hospital wastes are the wastes produced in the course of health care activities in hospital during treating, diagnosing and immunizing human being or animals or while doing study/research activities.

Treatment and Disposal of Hospital Wastes

1. Incineration
2. Chemical disinfection
3. Wet and dry thermal treatment
4. Microwave irradiation
5. Land disposal
6. Inertization.

1. Incineration

- It is a high temperature dry oxidation process that reduces organic and combustible waste into inorganic combustible matter.
- This results in significant reduction in waste volume and weight.
- Incinerators used are: Double chambered, single chambered, rotatory kilns.
- Incineration process is selected to treat waste that cannot be recycled, reused or cannot be disposed in land.

2. Chemical Disinfection

- This method is commonly used for treatment of liquid infectious waste, e.g. blood, urine, stool and hospital sewage.
- Chemicals are added to waste to kill or inactivate the pathogen it contains.

3. Wet and a Dry Thermal Treatment

- Wet thermal treatment: It is based on exposure of high infectious waste to high temperature and to high steam similar to process of autoclaving.
- Dry thermal treatment (screw feed technology):
  a. In this type the waste is shredded and heated in rotating auger.
  b. 80% volume and 20–35% weight is reduced.
  c. This method is suitable for infectious waste and sharp.

4. Microwave Irradiation

- Microwave of frequency 2450 MHz and wavelength 12.24 cm is used to destroy the microorganism,

- Water contained in the waste is rapidly heated by microwave and infections components are destroyed by heat conduction.

5. Land Disposal

Sanitary landfills are designed and constructed to prevent contamination of soil, surface, groundwater and direct contact with public.

6. Inertization

- It is the method of mixing waste with cement and other substances before disposal in order to minimize the risk of toxic substances migrating into surface water or groundwater and to prevent scavenging.
- Proportion of 65% waste, 15% time, 15% cement and 5% water is used.

OBJECTIVE QUESTIONS WITH ANSWERS IN BOLD LETTERS

1. BMW means **biomedical waste**.
2. **Segregation** refers to the base separation of different categories of waste generated at sources.
3. Chemical waste comes under **Category 10** of the BMW.
4. Autoclaving process involves use of **steam at high temperatures**.
5. The **microwave** is based on the principle of generation of high frequency waves.
6. **Plasma pyrolysis** is a state-of-the-art technology for safe disposal of medical waste.
7. **Inertization** is the method of mixing waste with cement and other substances before disposal.
8. In inertization the proportion **of 65% waste, 15% time, 15% cement and 5% water** is used.

Chapter

18

Bioethics

Q.1. Define the term 'Ethics' and 'Bioethics' .

Ethics

The branch of knowledge that deals with moral principles.

Bioethics (S. 23, 24, W. 23)

Bioethics is the study of ethical issues emerging from advances in biology and medicines.

Q.2. Give the history, principles and scope of bioethics. (S. 23, 24, W. 23)

Bioethics

- Bioethics is the study of ethical issues emerging from advances in biology and medicines.
- Bioethicists are concerned with the ethical questions that arise in the relationship among life sciences, biotechnology, medicine, politics, law and philosophy.
- Bioethics includes the study of values relating to primary care and other branches of medicine.
- Bioethics also helps to establish a common ground for different views, the democratic process being facilitated by the principle of giving equal and fair consideration to all sides or aspects of a given issue concerning human, animal as environmental rights.

Principles of Bioethics

1. **Justice:** Patients should share equally in the costs and benefits of the health care system.
2. **Autonomy:** The rights of the individual to make decisions regarding their own health must be respected.
3. **Beneficence:** Health care providers must strive to benefit their patients.
4. **Non-malfeasance:** Health care providers must not hurt their patients.

Scope of Bioethics

The scope of bioethics has expanded to include the ethical questions raised by:

1. Human genome project
2. Stem cell research
3. Artificial reproductive technologies
4. Pre-implantation genetic diagnosis
5. The synthesis of new-life forms
6. The possibility of successfully reproductive cloning.

Ethical Issues are:

- Abortion
- Euthanasia
- Suicide
- Cloning
- Human experimentation
- Birth control
- *In vitro* fertilization
- Stem cell technology
- Homosexuality

Q.3. What are ICMR's National Ethical Guidelines for biomedical and health research involving human participants?

ICMR

- Indian Council of Medical Research is one of the oldest medical research bodies in the world and is the apex body in India for the formulation, co-operation and promotion of biomedical research.
- ICMR's guidelines are meant to safeguard the dignity rights, safety and well-being of human participants involved in biomedical and health research.
- The statement of Ethical Guidelines for Biomedical Research on human participants shall be known as the ICMR Code.

General Principles of ICMR

1. Principle of Essentiality

The use of human participants is considered to be essential for the proposed research. This should be duly examined by an ethics committee (EC) independent of the proposed research.

2. Principle of Voluntariness

Voluntariness of the participants is well respected. The informed consent process ensures that participants rights are safeguarded.

3. Principle of Non-exploitation

There should not be exploitation during the research work. Sufficient safeguards to protect participant groups should be ensured.

4. Principle of Social Responsibility

The research activities should be planned and conducted in such a way that it will not disturb social harmony in community relationships.

5. Principle of Ensuring Privacy and Confidentiality

The privacy and confidentiality of the potential participants must be protected and records should be handled by authorized persons only.

6. Principles of Risk Minimization

The care is to be taken by all stakeholders at all stages of the research to ensure that the risks are minimized and appropriate care and compensation is given if any harm occurs.

7. Principle of Professional Competence

The research is planned conducted, evaluated and monitored throughout by persons who are competent and have the appropriate and relevant qualification, experience, training, etc.

8. Principle of Maximization of Benefit

The care is to be taken to design and conduct research in such a way that it directly or indirectly maximizes the benefits to the research participants and the society.

9. Principle of Institutional Arrangements

The institutions must have policies for appropriate research governance and take the responsibility to facilitate research by providing required infrastructure, manpower, funds and training opportunities.

10. Principle of Transparency and Accountability

The research should be conducted fair, honest, impartial and transparent manner to guarantee accountability. Related records, data and notes should be retained for the required period for possible external scrutiny/audit.

11. Principle of Totality of Responsibility

All the stakeholders involved in research are responsible for their actions. The ethical guidelines and related regulations are binding to all stakeholders directly or indirectly.

12. Principle of Environmental Protection

The researchers are responsible for ensuring protection of the environment and resources at all stages of the research, in compliance with existing guidelines and regulations.

OBJECTIVE QUESTIONS WITH ANSWERS IN BOLD LETTERS

1. **Ethics** is the branch of knowledge that deals with moral principles.
2. **Bioethics** is the study of ethical issues emerging from advances in biology and medicines.
3. **Euthanasia** means painless killing of someone.
4. **ICMR** means Indian Council of medical Research.
5. EC stands for **ethics committee**.

Chapter

19

The Consumer Protection Act, 1986

Q.1. Give the objectives of Consumer Protection Act, 1986.

Objectives

The Consumer Protection Act, 1986 is passed with the following main objects.

1. The main objective of the act is to provide better protection to the interests of consumers.
2. To make provisions for the establishment of consumer councils and other authorities for the settlement of consumer's disputes and for matter connected therewith.

It extends to the whole of India except the State of Jammu and Kashmir and shall apply to all goods and services.

Q.2. Define the terms as per Consumer Protection Act, 1986.

1. **Appropriate laboratory:** It means a laboratory or an organization:
   - i. Recognized by the central government.
   - ii. Recognized by a state government subject to such guidelines as may be prescribed by the central government in this behalf; or
   - iii. Any such laboratory or organization established by or under any law for the time being in force which is maintained, financed or aided by the central government or a state government for carrying out analysis or test of any goods with a view to determining whether such goods suffer from any defect.

2. **Branch office**
   - i. Any establishment described as a branch by the opposite party or,
   - ii. Any establishment carrying on either the same or substantially the same activity as that carried on by the head office of the establishment.

3. **Complainant:** It includes:

i. A consumer; or

ii. Any voluntary consumer association registered under the Companies Act, 1956 (1 of 1956) or under any other law for the time being in force; or

iii. The central government or any state government who or which makes a complaint;

iv. One or more consumers where there are numerous consumers having the same interest.

4. **Complaint:** It means any allegation in writing made by a complaint that:

i. An unfair trade practice or a restrictive trade practice has been adopted by any trader;

ii. The goods bought by him or agreed to be bought by him suffer from one or more defect;

iii. The services hired or availed of or agreed to be hired or availed of by him suffer from deficiency in any respect;

iv. A trader has charged for the goods mentioned in the complaint a price in excess of the price fixed by or under any law for the time being in force or displayed on the goods or any package containing such goods;

v. Goods, which will be hazardous to life and safety when used, are being offered for sale to the public in contravention of the provisions of any law for the time being in force requiring traders to display information in regard to the contents manner and effect of use of such goods with a view to obtaining any relief provided by or under this Act.

5. **Consumer:** It means any person who:

i. Buys any goods for a consideration which has been paid or promised or partly paid and partly promised or under any system of deferred payment and includes any user of such goods other than the person who buys such good for consideration paid or promised or partly paid or partly promised or under any system of deferred payment when such use is made with the approval of such person but does not include a person who obtains such goods for resale or for any commercial purpose; or

ii. Hires or avails of any services for a consideration which has been paid or promised or partly paid and partly promised or under any system of deferred payment and includes any beneficiary of such services other than the person who hires or avails of the services for consideration paid

or promised or partly paid and partly promised or under any system of deferred payments when such services are availed of with the approval of the first-mentioned person.

[For the purposes of sub-clause—(i) commercial purpose does not include use by a consumer of goods bought and used by him exclusively for the purpose of earning his livelihood by means of self-employment].

6. **Consumer dispute:** It means a dispute where the person against whom a complaint has been made denies or disputes the allegations contained in the complaint.
7. **Defect:** Any fault, imperfection or shortcoming in the quality, quantity, potency, purity or standard which is required to be maintained by or under any law for any contract expressed or implied or as is claimed by the trader in any manner whatsoever in relation to any goods.
8. **Deficiency:** Any fault, imperfection, shortcoming or inadequacy in the quality nature and manner of performance which is required to be maintained by or under any law for the time being in force or has been undertaken to be performed by a person in pursuance of a contract or otherwise in relation to any service.
9. **Manufacturer:** It means a person who:
   a. Makes or manufactures any goods or parts thereof, or
   b. Does not make or manufacture any goods but assembles parts thereof made or manufactured by others and claims the end product to be goods manufactured by himself; or
   c. Puts or causes to be put his own mark on any goods made or manufactured by any other manufacturer and claims such goods to be goods made or manufactured by himself.
10. **Member:** It includes the President and a member of the National Commission or a State Commission or a District Forum as the case may be.
11. **National Commission:** It means the National Consumer Disputes Redressal Commission established under Clause (c) of Section 9.
12. **Notification:** It means a notification published in the official gazette.

Q.3. Enlist various "Consumer Protection Councils".

Consumer Protection Councils

There are following three Consumer Protection Councils:

1. The Central Consumer Protection Council.

2. The State Consumer Protection Councils.
3. District Forum.

Q.4. Give the objectives, members and procedure of meetings of the Central Consumer Protection Council (Central Council).

Objectives of the Central Council

The objects of the Central Council shall be to promote and protect the rights of the consumers such as:

i. The right to be protected against the marketing of goods and services, which are hazardous to life and property.
ii. The right to be informed about the quality, quantity, potency, purity, standard and price of goods, or services as the case may be so as to protect the consumer against unfair trade practices.
iii. The right to be assured wherever possible access to a variety of goods and services at competitive prices.
iv. The right to be heard and to be assured that consumers' interests will receive due consideration at appropriate forums.
v. The right to seek redressal against unfair trade practices or restrictive trade practices or unscrupulous exploitation of consumers.
vi. The right to consumer education.

Members of Central Consumer Protection Councils

a. The Minister in charge (of consumer affairs) in the central government who shall be its Chairman.
b. Such number of other official or non-official members representing such interests as may be prescribed.

Procedure for Meetings of the Central Council

a. The Central Council shall meet as and when necessary but at least one meeting of the council shall be held every year.
b. The Central Council shall meet at such time and place as the Chairman may think fit and shall observe such procedures in regard to the transaction of its business as may be prescribed.

Q.5. Give the objectives, members and procedure of meetings of the State Consumer Protection Councils (State Council).

Objectives of the State Consumer Protection Council

The objectives of the every State Council shall be to promote and protect the rights of the consumers such as:

i. The right to be protected against the marketing of goods and services, which are hazardous to life and property.
ii. The right to be informed about the quality, quantity, potency, purity, standard and price of goods, or services as the case may be so as to protect the consumer against unfair trade practices.
iii. The right to be assured wherever possible access to a variety of goods and services at competitive prices.
iv. The right to be heard and to be assured that consumers' interests will receive due consideration at appropriate forums.
v. The right to seek redressal against unfair trade practices or restrictive trade practices or unscrupulous exploitation of consumers.
vi. The right to consumer education.

Members of State Consumer Protection Council

The state council shall consist of the following members, namely:

a. The Minister in-charge of consumer affairs in the State Government who shall be its Chairman.
b. Such number of other official or non-official members representing such interests as may be prescribed by the State Government.

Procedure for Meetings of the State Council

a. The State Council shall meet as and when necessary but not less than two meetings shall be held every year.
b. The State Council shall meet as such time and place as the Chairman may think fit and shall observe such procedure in regard to the transaction of its business as may be prescribed by the state government.

Q.6. Who are the members of "District forum" as per Consumer Protection Act, 1986?

District Forum

Each district forum shall consist of:

a. A person who is or has been or is qualified to be a District Judge who shall be its President.
b. Two other members who shall be persons of ability, integrity and standing and have adequate knowledge or experience of or have shown capacity in dealing with problems relating to economics, law, commerce, accountancy, industry, public affairs or administration one of whom shall be a woman.

All the above appointments shall be made by the state government on the recommendation of a selection committee consisting of the following, namely:

i. The President of the State Commission: Chairman
ii. Secretary Law Department of the State: Member
iii. Secretary in-charge of the department dealing with consumer affairs in the State: Member.

Q.7. What are different Consumer Disputes Redressal Agencies?

Consumer Disputes Redressal Agencies

Following Consumer Disputes Redressal Agencies are established under the act:

a. A consumer disputes redressal forum to be known as the district forum established by the state government in each district of the state. The state government may, if it deems fit, establish more than one district forum in a district by notification.
b. A consumer disputes redressal commission to be known as the State Commission established by the state government in the state by notification.
c. A national consumer disputes redressal commission established by the central government by notification.

Q.8. Give the offences and penalties under the Consumer Protection Act, 1986.

Offences and Penalties

Where a trader or a person against whom a complaint is made or the complainant fails or omits to comply with any order made by the district forum, the state commission or the national commission as the case may be such trader or person or complainant shall be punishable with imprisonment for a term which shall not be less than one month, but which may extend to three years or with fine which shall not be less than two thousand rupees but which may extend to ten thousand rupees or with both.

Provided that the district forum the state commission or the national commission as the case may be may if it is satisfied that the circumstances of any case so require impose a sentence of imprisonment or fine or both for a term lesser than minimum term and the amount lesser than the minimum amount specified in this section.

OBJECTIVE QUESTIONS WITH ANSWERS IN BOLD LETTERS

1. The main objective of the Consumer Protection Act, 1986 is to provide **better protection to the interests of consumers.**
2. **National Commission** means the National Consumer Disputes Redressal Commission established under Clause (c) of Section 9.
3. Notification means a notification published in the **official gazette.**
4. The Consumer Protection Act was passed in **1986**.

Chapter

20

Introduction to Disaster Management Act

Q.1. What is disaster? Mention its types.

Disaster

A disaster can be defined as any occurrence that cause damage, ecological disruption, loss of human life, deterioration of health and health services on a scale, sufficient to warrant an extraordinary response from outside the affected community of area.
Disaster causes innumerable loss of human life and property.

Types of Disaster

A. Natural Disasters

1. Earthquake
2. Floods
3. Cyclones
4. Tsunami
5. Landslides
6. Fires

B. Man-made Disaster

1. Chemical disaster
2. Nuclear disaster
3. Biological disaster

Factors Affecting Disaster

a. Hosts Factors

- Age
- Immunization status
- Degree of mobility
- Emotional stability

b. Environmental Factors

- Physical factors
- Chemical factors
- Biological factors
- Social factors
- Psychological factors

Q.2. Write a note on Disaster Management Act.

The Disaster Management Act

- The Disaster Management Act, 2005 was enacted on 26th December 2005.
- This Act permits the States also to have their own legislation on disaster management.

Objectives of Disaster Management Act, 2005

- This Act provides for "The effective management of disasters and for matters connected therewith".
- This Act includes preparedness, prevention, mitigation and response to the situations occurred in disasters.

Various Authorities to Control Disasters

- National Authority
- State Disaster Management Authority (SDMA)
- District Disaster Management Authority (DDMA)
- National Disaster Management Authority (NDMA)

Disaster Management

Disaster management is defined as a continuous and integrated process of planning, organising, co-ordinating and implementing measures necessary to prevent the danger or threat of a disaster, mitigating or reducing the risk of a disaster or its consequences, capacity building, prompt responses to a disaster, rescue as relief and rehabilitation and reconstruction.

Principles of Disaster Management

- Disaster management is the responsibility of all spheres of government.
- Disaster management should use resources that exist for a day-to-day purpose.
- Organizations should function as an extension of their core business.

- Individuals are responsible for their own safety.
- Disaster management planning should focus on large-scale events.
- Disaster management should recognize the difference between incidents and disasters.
- Disaster management planning must take an account of type of physical environment and the structure of the population.
- Disaster management arrangements must recognize the involvement and potential role of non-government agencies.

Objective/Need /Purpose of Disaster Management

- To prevent/control disaster
- To undertake the rescue operations
- To provide relief measures
- To undertake the rehabilitation programs
- To reduce trauma and tension
- To control death rate
- To protect the environment
- To minimize losses.

Importance of Disaster Management (W. 23)

1. To reduce or avoid the potential losses from hazards.
2. To assure prompt and appropriate help to the victims of a disaster.
3. To achieve a rapid and effective recovery.
4. Disaster management groups that operate at local, district and state levels are responsible for the planning organisation, co-ordination and implementation of all measures to prevent, prepare, respond and recover from the disaster events.

Q.3. What are various phases of disaster management?

Phases of Disaster Management

1. Preparedness Phase

- National emergency
- Telecommunication and response plans
- Training and exercises
- Early warning
- Standard operating procedures

2. Response Phase

- Communication
- Coordination
- Saving lives

3. Recovery Phase

- Restoring
- Telecommunications
- Infrastructure building
- Improving lives
- Recovery and rehabilitation of other services

4. Mitigation Phase

- Public education
- Awareness
- Hazards and vulnerability awareness
- Improved infrastructure

OBJECTIVE QUESTIONS WITH ANSWERS IN BOLD LETTERS

1. **Disaster** cause innumerable loss of human life and property.
2. The Disaster Management Act was passed in **2005**.
3. SDMA means **State Disaster Management Authority**.
4. DDMA means **District Disaster Management Authority**.
5. NDMA means **National Disaster Management Authority**.
6. Public education comes under **Mitigation Phase** of the Disaster Management.
7. National emergency comes under **Preparedness Phase** of the Disaster Management.

Chapter

21

Medical Devices

Q.1. Define medical devices. Give the categorization/types/classification of medical devices as per Regulations. (S. 24)

Medical Device

A medical device is an instrument, apparatus, *in vitro* reagent, implant or other similar or related article, which is intended for use in the diagnosis of disease or other condition or disease or intended to affect the structure or any function of the body and which does not achieve any of its primary intended purposes through its chemical action within or on the body.

Classification/Types/Categorization of Medical Devices

Class A: Devices involving low risk levels

Class B: Devices involving low to medium risk

Class C: Devices involving moderate to high risk

Class D: Devices involving high risk.

Q.2. Who is the regulatory authority of medical devices in India?

1. In India, medical devices are governed by CDSCO (Central Drugs Standard Control Organization) which is regulated by Directorate General of Health Services, Ministry of Health and Family Welfare, Government of India.
2. CDSCO is the only government body which regulates the medical devices.
3. Many committees had been set up and given their opinion and recommendations, like the Mahelkar Committee–CDSCO.
4. All these committees are now being taken to form the Indian Medical Devices Regulation Act (IMDRA).

Q.3. What is IMDRA? Give composition, objectives/purpose, and principles and importance/role of IMDRA.

IMDRA

It means Indian Medical Devices Regulation Act, came into force on December 31, 2009.

Composition of IMDRA

The composition of IMDRA is represented by:

- Central government
- Eminent jurist
- Two eminent medical practitioners
- Two eminent medical technologists
- Secretary General Quality Council

Objectives/Purpose of IMDRA

- To protect public health and ensure safety and performance.
- To enforce uniformity and to address the development in device capability and technology.
- To provide risk-based classification of devices.
- To provide notification of essential principles.
- To notify standards and guidelines.
- To provide mechanism of conformity.
- To provide a post-market surveillance.

Essential Principles of IMDRA

1. It should not compromise health and safety.
2. The design and manufacture of devices must conform to safety principles.
3. The long-term safety should be ensured.
4. Medical devices should be useful for the intended purpose.
5. The medical device should not cause any side effect.

Importance/Role of IMDRA

IMDRA will issue/play an important role as:

1. Design and manufacturing requirements.
2. Performance evaluation.
3. Demonstration of device standards, testing and compliance.

4. Regulation of post-marketing follow-up.
5. Regulation of recalls.
6. Legislate and punishment for non-compliance of the regulation.
7. Principles of safety.

Q.4. Give/enlist the list of medical devices which are regulated under Drugs and Cosmetics Act, 1940.

The Drugs and Cosmetics Act, 1940 covers the Regulations for the following Medical Devices:

1. Covers the pharmaceuticals and cosmetics.
2. Added medical devices as early as 1992 (syringes, needles, etc.)
3. As per the latest list of regulated medical devices.
   - Disposable hypodermic needles
   - Disposable hypodermic syringes
   - Disposable hypodermic perfusion sets
   - *In vitro* diagnostic devices for HIV, etc.
   - Cardiac stents
   - Intra-ocular lenses
   - Drug eluting stents
   - IV cannulae
   - Bone cement
   - Heart valve
   - Scalp vein set
   - Orthopedic implants
   - Internal prosthetic replacement
4. Additionally following products are regulated as "Drugs" under Drugs and Cosmetics Act and Rules:
   - Blood group sera
   - Ligatures, sutures and staplers
   - Intrauterine devices
   - Condoms
   - Tubal rings
   - Surgical dressings
   - Umbilical cords
   - Blood and blood products

Q.5. Give the significance/applications of medical devices.

Significance/Applications of Medical Devices

1. Medical devices have extended the ability of physician to diagnose and treat diseases making great contribution to health and quality of life.
2. Like medicines and other health technologies they are essential for patient care, at the large specialized hospitals.
3. Medical devices are considered as a fundamental component of health system.
4. Medical devices are essential to prevent, diagnose, treat and rehabilitate illnesses and diseases in a safe and effective way.

Q.6. What do you mean by "medical device grouping"?

Medical Device Grouping

It means a set of devices having same or similar intended uses or commonality of technology allowing them to be classified in a group not reflecting specific characteristics.

Any person who intends to apply for grant of license in respect of medical devices for:

i. Import,
ii. Manufacture for sale or for distribution, and
iii. Sale, stock, exhibit or offer for sale may group all or any medical device in accordance with the guidance to be issued from time to time by the Ministry of Health and Family Welfare in the central government, by taking into consideration the technological changes or development in the field of medical devices and *in vitro* diagnostic medical devices.

Q.7. Write a note on "manufacture for sale or for distribution of Class A or Class B medical devices".

Manufacture for Sale or for Distribution of Class A or Class B Medical Devices

Application for manufacture for sale or for distribution of Class A or Class B medical devices:

1. Any person who intends to manufacture a Class A or Class B medical device including *in vitro* medical devices shall make an application for grant of license or loan license to manufacture for sale or for distribution to the State Licensing Authority.

2. The application under sub-rule (1) shall be made through an identified online portal of the Ministry of Health and Family Welfare in the Central Government in Form MD-3 for license or in Form MD-4 for license accompanied with a fee, as specified in the Second Schedule along with respective documents as specified in Part II of the Fourth Schedule.
3. The application made under sub-rule (1), shall, amongst others, be accompanied with an undertaking to the effect that the requirements of Quality Management System as specified in the Fifth Schedule have been complied with.
4. The State Licensing Authority shall, after scrutiny of documents and on being satisfied that the requirements of these rules have been complied with, grant a license to manufacture Class A medical devices in Form MD-5 or loan license in Form MD-6, as the case may be, or if not satisfied, reject the application for reasons to be recorded in writing, within forty-five days from the date, application is made under sub-rule (1).
5. Manufacturing site of applicant, in respect of Class B device, shall conform to the requirements of Quality Management System as specified under the Fifth Schedule and applicable standards as specified under these rules and such conformance shall be verified through and audit by a notified body as referred under Rule 13 before grant of license.
6. In case application for grant of license or loan license to manufacture for sale or distribution of Class B medical devices:
    i. The audit of manufacturing site shall be carried out within ninety days from the date of application by the registered notified body in the manner specified in the Third Schedule;
    ii. The notified body shall furnish its report to the State Licensing Authority within thirty days of the completion of audit;
    iii. The State Licensing Authority shall, after scrutiny of documents, audit reports as referred to in clause (ii) and on being satisfied that the requirement of these rules have been complied with, grant a license to manufacture Class B medical devices in Form MD-5 or loan license in Form MD-6, as the case may be, or if not satisfied, rejects the application for reasons to be recorded in writing, within a period of twenty days from the date of receipt of the report of audit by the notified body.
7. If the application for grant of license or loan license to manufacture for sale or distribution is rejected under sub-rule (4) or sub-rule (6), the aggrieved person may file an appeal before the state government within forty-five days from the date of receipt of such rejection, which may, after such

enquiry and after giving an opportunity of being heard to the appellant, be disposed of within a period of sixty days.

8. Where the Central Licensing Authority or the State Licensing Authority has reason to believe or it has been alleged or suspected that the medical devices does not conform to the standards of quality, or provisions of the Fifth Schedule are not complied with the State Licensing Authority, in case of Class A or B medical device, or the Central Licensing Authority, in case of any class of medical device, may direct a team of officers referred to in Rule 23 to cause inspection of licensed manufacturing site.

Q.8. Write a note on "manufacture for sale or for distribution of Class C or Class D medical devices".

Manufacture for Sale or for Distribution of Class C or Class D Medical Devices

Application for manufacture for sale or for distribution of Class C or Class D medical devices:

1. An application shall be made to the Central Licensing Authority through an identified online portal of the central government for license or loan license to manufacture for sale or distribution, as the case may be, of Class C or Class D medical device in Form MD-7 or Form MD-8, respectively.
2. The application in Form MD-7 or Form MD-8 referred to in sub-rule (1) relating to Class C or Class D medical device, as the case may be, shall be accompanied with a fee as specified in the Second Schedule along with documents as specified in clause (ii) of part II of the Fourth Schedule.
3. The central licensing Authority may, wherever required, in case of Class C or Class D medical devices, use the services of any expert in the relevant field for scrutiny of application and other technical documents.
4. The scrutiny referred to in sub-rule (3) shall be completed and in order, the Central Licensing Authority within a period of forty-five days from the date of online application.
5. In case, where the documents are found to be complete and in order, the Central Licensing Authority shall cause an inspection of the manufacturing site carried out under Rule 23 by a team of officers accompanied by such experts, as may be considered necessary.
6. The Central Licensing Authority may, where required, avail services of a Notified Body Referred to in sub-rule (4) of Rule 13 for inspecting the manufacturing site of Class C and Class D medical devices.
7. In case, where the documents furnished with the application referred to in sub-rule (1) are not found to be complete and in order, the Central

Licensing Authority shall reject the application and inform the applicant of the reasons for such rejection respectively.

Q.9. What are the labeling requirements of the medical devices as per the regulation?

Labeling Requirements of Medical Devices

The following particulars shall be printed in indelible ink on the label, on the shelf pack of the medical device or on the outer cover of the medical device and on every outer covering in which the medical device is packed, namely:

a. Name of medical device.
b. The details necessary for the user to identify the device and its use.
c. The name of manufacturer and address of manufacturing premises where the device has been manufactured.
d. The correct statement about the net quantity in terms of weight, measure, volume, number of units, as the case may be, and the number of the devices contained in the package expressed in metric system.
e. The month and year of manufacture and expiry.

OBJECTIVE QUESTIONS WITH ANSWERS IN BOLD LETTERS

1. **CDSCO** is the only government body which regulates the medical devices.
2. IMDRA means **Indian Medical Devices Regulation Act**, came into force on December 31, 2009.
3. **Medical Device Grouping** means a set of devices having same or similar intended uses or commonality of technology allowing them to be classified in a group not reflecting specific characteristics.
4. The medical devices involving **low risk levels** are categorized under **Class A**.
5. The medical devices involving **low to medium risk levels** are categorized under **Class B**.
6. The medical devices involving **moderate to high risk levels** are categorized under **Class C**.
7. The medical devices involving **high risk levels** are categorized under **Class D**.

Board Examination Papers

Summer Examination 2023 (Question Paper)
Second Year Diploma in Pharmacy
Subject: Pharmacy Law and Ethics (20226)

Time: 3 Hours **Max Marks: 80**

Q.1. Answer any SIX of the following: **30 Marks**

a. Give the procedure for preparing first register and what qualifications required for entry for first register as per Pharmacy Act, 1948?
b. Write the qualification for drug inspector and give the procedure of drug inspector in taking samples.
c. Define the term under D and C Act, 1940
   (i) Adulterated drugs
   (ii) Misbranded drugs
   Give the functions of CDL as per D and C Act, 1940.
d. State in detail provisions "Schedule N" of D and C Rules 1945.
e. Give the objectives of DPCO, 2013 and define the term under this Act:
   (i) Active pharmaceutical ingredients
   (ii) Formulation
   (iii) Maximum retail price
f. Give two points of difference in law and ethics. Explain the duties of a pharmacist in relation to his trade.
g. Explain the steps involved in new drug development.

Q.2. Answer any TEN of the following: **30 Marks**

a. Explain the general principles of law.
b. Define Drug and New Drug as per the D and C Act, 1940.
c. List licences (with form numbers) for sale of drugs under D and C Act, 1940.
d. Define repacking of drugs and state any six conditions for grant of repacking license.
e. Define Illicit traffic's under NDPS Act, 1985.
f. Give offences and penalties under Drugs and Magic Remedies (OA) Act, 1954.

g. Give provisions for sale and possession of poison under Poison Act, 1919.
h. Write the experience and training of Registered Medical Practitioner (RMP) required for termination of pregnancy as per MTP Act, 1971.
i. Explain the documentation, license and renewals in pharmaceutical manufacturing.
j. Write the difference between branded and generic drugs.
k. Explain the procedure for registration of the clinical establishment.

Q.3. Answer ALL questions of the following: 20 Marks

a. List of diseases and ailments which a drug may not claim to prevent or cure is covered under schedule _____.
b. As per D and C rules Schedule R prescribe _____.
c. Which of the following is prohibited to be imported?
   (i) Toilet preparations (ii) Ayurvedic drugs
   (iii) Misbranded drugs (iv) Schedule C, G drugs
d. CPCSEA stands for _____.
e. Define captive animal as per Prevention of Cruelty to Animal Act, 1960.
f. Out of 22 members of the food authority, the proportion of women is _____.
   (i) Half (ii) One-third
   (iii) One-fourth (iv) Two-third
g. Which act's prime objective is to make sure that the essential drugs are available to all at a reasonable price?
h. For calculation of price of bulk drugs a return of 12% is allowed on _____ costing.
   (i) Short-term marginal (ii) Long-term marginal
   (iii) Periodic (iv) Intermediate
i. Code of pharmaceutical ethics developed by _____.
j. Define the term minor.
k. The CDSCO is a _____ body.
l. Which authority issue the drug manufacturing license _____.
m. Minimum haemoglobin value required for a donor to donate blood is _____ gm/dl.
n. IMDRA stands for _____.

o. Head office of National Institute of Disaster Management (NIDM) is situated in which city?
p. Consumer Protection Act is significant to:
   (i) All goods and services
   (ii) Immovable goods
   (iii) Movable goods
   (iv) Selected goods and services
q. Define bioethics.
r. As per bioethics, enlist the principle of justice.
s. Moral rules to protect and defend the right of patient is mentioned under _____ principle of bioethics.
t. Animal anatomical waste are categorised under which category of biomedical waste.

Summer Examination 2023 (Specimen Answer Paper)
Second Year Diploma in Pharmacy
Subject: Pharmacy Law and Ethics (20226)

Time: 3 Hours **Max Marks: 80**

Q.1. Answer any SIX of the following: **30 Marks**

a. Give the procedure for preparing first register and what qualifications required for entry for first register as per Pharmacy Act, 1948?

Ans: Procedure for First Register Preparation

1. **Constitution of Registration Tribunal:** For the purpose of preparing the first register, State Government shall by notification in the Official Gazette constitute a Registration Tribunal consisting of three persons and shall appoint a registrar who shall act as Secretary of Registration Tribunal.
2. **Appointment of date for the application:** State Government shall by same or similar notification appoint a date on or before which the application for registration accompanied with the prescribed fees shall be made to the Registration Tribunal.
3. **Scrutiny:** Registration Tribunal shall examine each and every application received on or before the appointed date. If it is satisfied, the applicant is qualified and his name will be directly entered in the first register.
4. **Appeal:** First register so prepared shall be published in such manner as the State Government may direct and if any person who is aggrieved with the decisions of Registration Tribunal may appeal within 60 days of such publication to the authority appointed.
5. **Issue of a certificate of registration:** Registrar of State Council shall keep the register in accordance with the orders made by and shall thereupon, issue to every person a certificate of registration in the prescribed form.
6. Upon the constitution of State Council, the register shall be given into its custody and the registration fees shall be paid to the credit of State Pharmacy Council.

Qualifications for Entry for First Register as per Pharmacy Act, 1948

A person, who has attained his 18 years of age, resides or carries on his profession or business of pharmacy and has been paid the prescribed fees for the registration, shall be entitled to have his/her name to be entered on the first register and if he/she:

a. holds a degree or diploma in pharmacy or pharmaceutical chemistry or 'Chemists and Druggists' diploma of an Indian University or any other prescribed qualification granted by an authority outside India.
b. holds a degree other than degree in pharmacy or pharmaceutical chemistry of a recognized university with not less than three years' experience in compounding of drugs in a hospital or at any other place where drugs are dispensed on the prescription of Registered Medical Practitioner.
c. has passed an examination recognized as an adequate by State Government for the compounders and dispensers.
d. is engaged in compounding and dispensing of drugs for a total period of not less than five years in a hospital or dispensary where drugs are dispensed regularly on the prescription of Registered Medical Practitioner.

b. Write the qualification for drug inspector and give the procedure of drug inspector in taking samples.

Ans: Qualifications required for drug inspector: A person to be appointed as drug inspector should be graduate in pharmacy or pharmaceutical chemistry or medicine with specialization in Clinical Pharmacology or Microbiology from recognized university established in India.

Provided that:

1. a person who have not less than 18 months experience in the manufacture of at least one of the substances specified in Schedule C; or
2. who have not less than 18 months experience in testing of at least one of the substances specified in Schedule C; or
3. who have not less than 3 years experience in inspection of firms manufacturing at least one of the substances specified in Schedule C.

Procedure of Inspectors in taking Samples

1. Where an inspector takes the sample of drugs, he shall pay the fair price of it and may give written acknowledgment thereof.

2. Where a price is refused or where an inspector seizes the stock of drugs, he shall give receipt of it in Form 16.
3. Where an inspector takes the sample of drug for test or analysis he shall intimate such purpose in Form 17 in writing to a person from whom he takes it.
4. In presence of such person, unless he willfully absents himself, the drug inspector shall divide the sample into four portions, effectively seal and mark them and allow that person to add his own seal and mark.
5. Where an inspector takes the sample of drug or cosmetic from manufacturing premises sample should be divided into three portions only.
6. Where a drug or cosmetic is made up in small volume containers and if drug is likely to deteriorate or damage by exposure, drug inspector shall take three or more containers after suitably marking the same and sealing them.
7. Drug inspector shall give one portion of sample to a person from whom he takes it and divide the remaining four portions as follows:
   a. He shall give one portion of sample to a person from whom the sample is taken.
   b. He shall send second portion to the government analyst for test or analysis.
   c. He shall produce third portion in the court before which proceeding have been instituted.
   d. He shall send fourth portion to warrantor whose name, address and other particulars have been disclosed.
8. The portion of sample or container shall be sent by registered post or by hand.

   A copy of memorandum and specimen impression of seal used to seal the packets shall be sent separately by registered post.
9. Where an inspector seizes the register, records or other document and samples of drugs or cosmetics he shall inform Judicial Magistrate and take his order of custody.

c. Define the term under D and C Act, 1940

(i) Adulterated drugs

(ii) Misbranded drugs

Give the functions of CDL as per D and C Act, 1940.

Ans: (i) **Adulterated drug:** A drug shall be deemed to be adulterated if:

a. It contains in whole or in parts of filthy, putrid or decomposed substances; or
b. It is prepared, packed or stored under unsanitary conditions whereby it may have been contaminated with filth or which may render the contents injurious to the health, or
c. Its container is composed in whole or in parts of poisonous or deleterious substance which may render the contents injurious to the health; or
d. It contains or bears for the purpose of colouring only, a color other than those prescribed; or
e. It contains harmful or toxic substances which may render it injurious to health; or
f. Any substance has been mixed therewith so as to reduce its quality or strength.

(ii) **Misbranded drug:** A drug shall be deemed to be misbranded if:

a. It is so coloured, coated, powdered or polished that the damage is concealed or if it is made to appear of better or greater therapeutic value than it really is; or
b. It is not labelled in the prescribed manner; or
c. Its label or container or anything accompanying drug bears any statement, design or devices which makes any false claim for drug or which is false or misleading in any particular.

Functions of CDL

1. To analyze or test such samples of drugs as may be sent to it by the Custom Collectors or Courts.
2. To carry out such other duties as may be entrusted to it by the Central Government or, with the permission of the Central Government, by a State Government after consultation with the Drugs Technical Advisory Board.
3. In case of sera, vaccines, toxins, antigens, antisera, solution of serum proteins injections, sterilized ligature and suture and bacteriophages, the functions of CDL is carried out at the Central Research Institute, Kasauli and such functions are exercised by the Director of the said institute.

4. The functions regarding oral polio vaccine testing are exercised by the Deputy Director and Head of the Polio Vaccine Testing Laboratory of Central Research Institute, Kasauli.
5. In case of antisera, vaccines, diagnostic antigens and toxoids for veterinary use, the functions of CDL are carried out at the Indian Veterinary Research Institute, Izzatnagar or Mukteshwar and such functions are exercised by the Director of the said institution.
6. In case of condoms, the functions of CDL are carried out at Central Indian Pharmacopoeia Laboratory, Ghaziabad and such functions are exercised by Director of the said laboratory.
7. In case of VDRL (Venereal Disease Reference Laboratory) antigens the function of CDL is carried out at the Laboratory of Serologist and Chemical Examiner to Government of India and such functions are exercised by Serologist and Chemical Examiner of the said laboratory.
8. In case of IUCD (Intrauterine Contraceptive Devices) and felope rings, the functions of CDL are carried out at Department of Biochemical Engineering, Indian Institute of Technology, New Delhi and such functions are exercised by Head of said department.

d. State in detail provisions "Schedule N" of D and C Rules 1945.

Ans: Schedule N: It prescribes the list of minimum equipment, requirements of premises for the effective running of a pharmacy.

1. **Entrance:** The entrance of a pharmacy shall bear an inscription "Pharmacy" in front.
2. **Premises:** The premises of a pharmacy shall be separated from rooms for private use. The premises shall be well built, dry, well lit and ventilated and of sufficient dimensions to allow the goods in stock, especially medicaments and poisons to be kept in a clearly visible and appropriate manner. The areas of the section to be used as dispensing department shall be not less than 6 square meters for one pharmacist working therein with additional 2 square meters for each additional pharmacist. The height of the premises shall be at least 2.5 meters. The floor of the pharmacy shall be smooth and washable. The walls shall be plastered or tiled or oil painted so as to maintain smooth, durable and washable surface

devoid of holes, cracks and crevices. A pharmacy shall be provided with an ample supply of good quality water. The dispensing department shall be separated by a barrier to prevent the admission of the public.

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

   A pharmacy shall be provided with a cupboard with lock and key for the storage of poisons and shall be clearly marked with the word 'POISON' in red letters on a white background. Containers of all concentrated solutions shall bear special labels or marked with the words "To be diluted".

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

   Apparatus:

   Balance, dispensing, sensitivity 30 mg.
   Balance, counter, capacity 3 kg m, sensitivity 1 gm.
   Beakers, lipped, assorted sizes.
   Bottles, prescription, ungraduated assorted sizes.
   Corks assorted sizes and tapers.
   Cork, extracter.
   Evaporating dishes, porcelain.
   Filter paper.
   Funnels, glass.
   Litmus paper, blue and red. Measure glasses cylindrical 10 ml, 25 ml, 100 ml and 500 ml.
   Mortars and pestles, glass.

Mortars and pestles, wedgwood.
Ointment pots with bakelite or suitable caps.
Ointment slab, porcelain
Pipette graduated, 2 ml, 5 ml and 10 ml. Ring, stand (retort) iron, complete with rings.
Rubber stamps and pads, scissors.
Spatulas, rubber or vulcanite
Spatulas, stainless steel.
Spirit lamp
Glass stirring rods.
Thermometer, 0°C to 200°C.
Tripod stand.
Watch glasses.
Water bath.
Water distillation still in case eye drops and eye lotions are prepared.
Weights, metric, 1 mg to 100 gm.
Wire gauze.
Pill finisher, boxwood.
Pill machine.
Pill boxes.
Suppository mould.

Books:

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

4. **General provisions:** A pharmacy shall be conducted under the continuous personal supervision of a registered pharmacist whose name shall be displayed conspicuously in the premises. The pharmacist shall always put on clean white overalls. The premises and fittings of the pharmacy shall be properly kept and everything shall be in good order and clean. All records and registers shall be maintained in accordance with the laws in force. Any container taken from the poison cupboard shall be replaced therein immediately after use and

the cupboard locked. The keys of the poison cupboard shall be kept in the personal custody of the responsible person.

Medicaments when supplied shall have labels conforming to the provisions of laws in force.

e. Give the objectives of DPCO, 2013 and define the term under this Act:

(i) Active pharmaceutical ingredients

(ii) Formulation

(iii) Maximum retail price

Ans: Objectives of DPCO, 2013

The various objectives of DPCO, 2013 are:

1. Make the essential medicines available at reasonable prices.
2. To provide sufficient opportunity for innovation and competition to support the growth of industry.
3. To meet the goals of employment and shared economic growth of all.
4. To achieve adequate production.

(i) **Active pharmaceutical ingredients:** It means any pharmaceuticals, chemical, biological or plant product including its salts, esters, isomers, analogues and derivatives, conforming to pharmacopoeias or other standards specified in the Second Schedule to the Drugs and Cosmetics Act, 1940 (23 of 1940), and which is used as such or as an ingredient in any formulation.

(ii) **Formulation:** It means any medicine processed out of or containing one or more drug/drugs with or without use of any pharmaceutical aids, for internal or external use for or in the diagnosis, treatment, mitigation or prevention of disease but shall not include:

a. Any medicine included in any bonafide Ayurvedic (including Sidha) or Unani (Tibb) systems of medicines.
b. Any medicine included in the homeopathic system of medicine.
c. Any substance to which the provisions of the Drugs and Cosmetics Act, 1940 do not apply.

(iii) **Maximum retail price:** It 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.

f. Give two points of difference in law and ethics. Explain the duties of a pharmacist in relation to his trade.

Ans:

Law	*Ethics*
1. It is an authorative instrument that rules over the society.	1. It is a way of conducting life laid down by the society to help the individuals to decide what is right and wrong.
2. Laws are a set of rules and regulations enforced by the Government or authorities.	2. Ethics are morals and principles adapted by society from the environment.
3. Law can prevent the illegal practice of pharmacy.	3. It can prevent unethical practices of pharmacy that can cause grave risk or danger to the life of individual or patient.
4. Failure to follow laws can result in penalties and punishment.	4. Ethics do not attract penalties and punishment.
5. Laws are made by lawyers and legislature.	5. Ethics are made by religious leaders, philosophers and elders in the family.
6. Laws are compulsory and must to be followed.	6. Ethics are values to be considered to be a positive attitude to follow.
7. Laws are in a written document.	7. Ethics are not written.
8. Laws tend to be the same in a country.	8. Ethics tend to vary from one city to another.
9. Law can prevent the sale of substandard quality drugs but cannot prevent selling of drug at cheaper rate.	9. The sale of substandard quality drugs at cheaper rate is restricted by the code of ethics.

Duties of a Pharmacist in Relation to his Trade

a. **Pricing of drugs:** Pricing of drugs and pharmaceuticals should be fair. The overcharging of the products should be avoided. A suitable price structure should be adopted for pricing of drugs. He should calculate the retail price of his formulation according to the formula prescribed under Drugs and Price Control Order. While calculating the price he should consider the material cost, packaging charges, cost of packaging material, etc.

b. **Fair trade practice:** Pharmacist should not make any attempt to capture the business of fellow pharmacist by cutthroat competitions that is by offering gifts or reducing prices to the patient, etc. Trademarks, signs and symbols of another pharmacist should not be copied.

c. **Purchase of drugs:** Pharmacist should purchase drugs of standard quality only. He should not purchase substandard quality, adulterated drugs or misbranded drugs. He should purchase drugs under cash or credit memo from a duly licensed manufacturers and dealers.

d. **Hawking of drugs:** Hawking of drugs should be prohibited under the code of pharmaceutical ethics to prevent self-medication and mismedication.

e. **Advertising and display:** Advertisement and display of drug should also be prohibited under the code of pharmaceutical ethics to prevent self-medication and mismedication. Advertisements of drugs making a false claim or which gives misleading information about the drug should be prohibited.

g. Explain the steps involved in new drug development.

Ans: Steps involved in drug discovery and development process includes:

Step 1: Discovery and development: The identification of drug candidates, synthesis, characterization, screening, and tests for therapeutic efficacy are all parts of the drug development process. A compound will be subjected to the process of medication development after clinical trials when these investigations yield satisfactory results. Due to the high costs of research and development and clinical trials, developing new drugs is an expensive process. From the time, a new medication molecule is discovered until it is sold to patients, it takes about 12 to 15 years.

Step 2: Preclinical research: The two types of preclinical research are: *in vitro* and *in vivo*. Usually, preclinical studies are not very large. Preclinical trials of drug development are conducted on animals to collect the information on safety, efficacy. However, these studies must provide detailed information on dosing and toxicity levels. After preclinical testing, researchers review their findings and decide whether the drug should be tested in people.

Step 3: Clinical research: "Clinical research" refers to studies, or trials, that are done in people. As the developers design the clinical study, they will consider what they want to accomplish for each of the different clinical research phases. Clinical trials include Phase I, II, III, IV and begin the Investigational New Drug Process (IND), a process they must go through before clinical research begins.

Step 4: FDA drug review: If a drug developer has evidence from its early tests and preclinical and clinical research that a drug is safe and effective for its intended use, the company can file an application to market the drug. The FDA review team thoroughly examines all submitted data on the drug and makes a decision to approve or not to approve it.

Step 5: FDA post-market drug safety monitoring: Even though clinical trials provide important information on a drugs efficacy and safety, it is impossible to have complete information about the safety of a drug at the time of approval. Despite the rigorous steps in the process of drug development, limitations exist. FDA reviews reports of problems with prescription and over-the-counter drugs, and can decide to add cautions to the dosage or usage information, as well as other measures for more serious issues.

Committee of Safety of Medicine (CSM) receives the information of all studies and if it is satisfied the product license is issued. Medical practitioners report the efficacy and toxicity of product which is reviewed by the Committee of Review of Medicines. The committee may renew or cancel the licence of product.

Q.2. Answer any TEN of the following: 30 Marks

a. Explain the general principles of law.

Ans: **General principles of law:** The various general principles of law are:

1. **Supremacy of law:** Supremacy of law means that the law has authority over all people, including those who administer the law. Dicey believes that a man should only be punished for a specific violation of the law, and not for anything else. The person cannot be punished by the Government solely on its own authority, but only in accordance with established law.
2. **Equality before law:** It means all people must be treated equally under the law. It ensures that everyone is treated

equally before the law. It prohibits discrimination on various grounds, treats everyone as equal in public employment. Also, it abolishes untouchability and titles.

3. **Predominance of legal spirit:** The spirit of justice is referred to as the legal spirit. For the effective implementation of rules of laws, there should be impartial and independent judicial authority. According to Dicey, such authority will be court. This concept advocates the principle that law should be based on justice and interpreted without discriminations.
4. **Principle of justice:** The principle of justice obliges us to equitably distribute benefits, risks, costs, and resources. The following rules are supported by the principle of justice:
    1. To each person an equal share
    2. To each person according to need
    3. To each person according to effort
    4. To each person according to contribution
    5. To each person according to merit
5. **Principle of liberty:** According to John Stuart Mill, every person has right to exercise his power in the community and act as per his will to prevent harm to others. An earlier equivalent was stated in France's Declaration of the Rights of Man and of the Citizen.

b. Define Drug and New Drug as per the D and C Act, 1940.

Ans: (i) **Drug:**

a. All medicines for internal or external use of human beings or animals and all substances intended to be used for; or in the diagnosis, treatment, mitigation or prevention of any disease or disorder in human beings or animals, including preparations applied on human body for the purpose of repelling insects like mosquitoes.
b. Such substances other than food intended to affect the structure or any function of the human body or intended to be used for the destruction of vermin or insects which cause disease in human beings or animals.
c. All substances intended for use as components of a drug including empty gelatin capsules.
d. Such devices intended for internal or external use in the diagnosis, treatment, mitigation or prevention of disease or disorders in human beings or animals.

(ii) **New drug:**

a. A new substance of chemical, biological or biotechnological origin in bulk or prepared dosage form used for prevention, diagnosis or treatment of disease in man or animals, which except during local clinical trials has not been used in the country to any significant extent and which, except during local clinical trials has not been recognized in the country as effective and safe for the proposed claims.

b. A drug already approved by the licensing authority for certain claims, which is now proposed to be marketed with modified or new claims namely indications dosage, dosage form and route of administration.

c. A fixed dose combination of two or more drugs, individually approved earlier for certain claims which are now proposed to be combined for the first time in a ratio or if the ratio of ingredients in an already marketed combinations is proposed to be changed with certain claims viz. indications, dosage, dosage form (including sustained release dosage form) and route of administration.

c. List licences (with form numbers) for sale of drugs under D and C Act, 1940.

Ans: Issue of Licence

Licence issued	*Issue of licence (Form No.)*		
	Drugs other than Sch. C, C1& X	*Drugs in Sch. C & C1*	*Drugs specified in Sch. X*
Retail	20	21	20F
Wholesale	20B	21B	20G
Restricted	20A	21A	–
Wholesale or distribution from motor vehicle	20BB	21BB	–

d. Define repacking of drugs and state any six conditions for grant of repacking license.

Ans: Repacking of drugs: It is the process of breaking up any drug from a bulk container into small packages and the labelling of each such package with a view to its sale and distribution. But, it does not include the compounding, dispensing or the packing of any drug in the ordinary course of retail business.

Conditions of repacking: Persons licensed to repack drugs should observe the following conditions:

1. Adequate space and equipment for the repacking operations which must be carried out under hygienic conditions and under supervision of competent person.
2. License should maintain adequate arrangement for analysis and testing of each batch of raw material and repacked drugs or by testing approved institutions, maintain record for the period of 3 years from date manufacturing and in case of drugs with expiry date at least for 3 months from such date.
3. The drugs repacked should, in addition to other particulars, bears the no. of license preceded by the words 'Rpg. Lic. No.' on their label.
4. Application for the grant or renewal of such license shall be made in Form 24-B and the license shall be issued in Form 25-B.
5. License required for the repacking of drugs other than those specified in Schedule C and C1.
6. The factory premises should comply with requirement specified as per Schedule M, the licenses should make adequate arrangement for the storage of drugs.
7. Licensee shall allow inspector to inspect records and registers maintained under these rules. Also allow any inspector to enter with or without notice, in any premises, where packing of drugs is carried on and to inspect premises and to take samples of repacked drugs.
8. The licensee shall maintain an inspection book in Form 35 to enable inspector to record his impression and the defects noticed.
9. Any change in the competent staff named in the license should be forthwith notified to the licensing authority.
10. The license should comply with the provision of the Act and the Rules and with such further requirement of which he has been not less than 4 months' notice by the licensing authority.

e. Define Illicit traffic's under NDPS Act, 1985.

Ans: Illicit traffic: It includes:

(i) Cultivating any coca plant or gathering any portion of coca plant.

(ii) Cultivating the opium poppy or any cannabis plant.

(iii) Engaging in the production, manufacture, possession, sale, purchase, transportation, warehousing, concealment, use of consumption, interstate import, interstate export, import into India, export from India or transshipment, of narcotic drugs or psychotropic substances.

(iv) Dealing in narcotic drugs, psychotropic substances.

(v) Handling or letting any premises for use for any of the purposes referred in (i) to (iv).

(vi) Financing any activity by himself or through any other person in the furtherance or in support of doing any of the aforesaid acts.

(vii) Harbouring persons engaged in any of the activities specified in (i) to (vi).

(viii) Abetting or conspiring in the furtherance or in support of doing any of the aforesaid acts except to the extent permitted under the Narcotic Drugs and Psychotropic Substances Act, 1985, or any rule or order made, or any condition of any license, permit or authorisation issued, thereunder.

f. Give offences and penalties under Drugs and Magic Remedies (OA) Act, 1954.

Ans: Offences and Penalties under Drugs and Magic Remedies (OA) Act, 1954

1. Contravention of any of the provision of this Act or Rules thereunder shall be punishable with imprisonment six month or with fine or with both on first conviction. Punishable with imprisonment one year or with fine or with both on subsequent conviction.
2. In case of contravention of the provisions of the Act by a company, every person who at the time of the commission of the offence, was in-charge of and was responsible for the conduct of company business shall be deemed to be guilty and liable for the punishment.

   However, such person is not liable for the punishment if he proves that the offence was committed without his knowledge or he has taken all the precautions to prevent that the commission of such offence.

g. Give provisions for sale and possession of poison under Poison Act, 1919.

Ans: Possession and sale of specified poisons: The State Government may regulate the possession and sale of poison within the state. The sale may be wholesale or retail. The rules may be applicable for the whole or any part of the territories under the administration of the state. Such a rules may provide for:

(i) Grant of licenses for the possession of any specified poison for sale, either wholesale or retail.
(ii) Fixing of fees to be charged for such a licenses.
(iii) The classes of persons to whom the licenses for the possession and sale of poisons are to be granted.
(iv) The classes of persons to whom such poisons are to be sold.
(v) Maintenance of register for the sale of poisons and inspection of the same.
(vi) Safe custody of poisons and the labeling of the vessel, coverings or packages in which such poison is sold or stored for sale.
(vii) Inspection and examination of any such poison possessed for sale by any vendor.

Possession of any poison: State Government has power to make the rules regarding the possession of any specified poison in such local area where such poison may be used for murder or for poisoning cattle in such local area where such occurrences are very frequent.

h. Write the experience and training of Registered Medical Practitioner (RMP) required for termination of pregnancy as per MTP Act, 1971.

Ans: Experience and training of Registered Medical Practitioner (RMP) required for termination of pregnancy as per MTP Act, 1971: The Medical Termination of Pregnancy Rules, 1975 prescribes the experience or training in gynaecology and obstetrics that a registered medical practitioner should have to terminate any pregnancy.

a. A medical practitioner registered in a state medical register immediately before the commencement of the Act should have not less than three years experience in the practice of gynacecology and obstetrics.
b. A medical practitioner, registered in a state medical register on or after the date of the commencement, can terminate the pregnancy,

(i) If he has completed six months of house surgency in gynaecology and obstetrics, or

(ii) If he has experience at any hospital for a period of not less than one year in the practice of obstetrics and gynaecology, or

(iii) If he has assisted a registered medical practitioner in the performance of twenty-five cases of medical termination of pregnancy in a hospital established or maintained, or training institute approved by the Government, for this purpose.

c. In case of a registered medical practitioner who holds a post-graduate degree or diploma in gynaecology and obstetrics, the experience or training gained during the course of such degree or diploma is considered.

i. Explain the documentation, license and renewals in pharmaceutical manufacturing.

Ans: 1. **Documentation:** Manufacturer should maintain record as per Schedule U. He should obtain the required manufacturing licences from licensing authority. He should maintain the product master records, batch manufacturing records, material/components control record and personnel record. He should have adequate testing facility. Also, he should maintain equipment log books, cleaning log books. He should also maintain the records of distribution of each batch of products, records of returns/recall and customer contents. He should maintain the validation records.

2. **Licences:** For the manufacture of following classes of drugs he should obtain the licences in the following forms:
   a. Grant of a licence to manufacture drugs other than those specified in Schedule C, C1, and X-Form 25.
   b. Grant of a licence to manufacture drugs specified in Schedule C, C1, excluding those specified in Schedule X-Form 28.
   c. Grant of a licence to manufacture for sale drugs Specified in Schedule X-Form 25 F.

3. **Renewal of licences:** The granted licences are valid up to 5 years and should be renewed before expiry.

j. Write the difference between branded and generic drugs.

Ans:

Brand name	*Generic name*
1. Low-cost version of brand drugs.	1. Protected by a patent.
2. Generic drugs do not have any patent on their manufacturing and distribution.	2. Branded drugs have sole right (patent) to manufacturing and distribution for a period of time.
3. Produced by generic companies.	3. Supplied by single company.
4. No national price regulation for generic drugs.	4. Drug prices are decided by the pharmaceutical companies.
5. Generic drugs are cheaper than branded drugs.	5. Branded drugs are more costly than generic drugs.
6. Look different from relevant brand name drug.	6. Unique look as design during product development.
7. Example: Paracetamol.	7. Example: Tylenol, NAPA, Calpol, Dexamol, Dolex, Acamol, Febridol.

k. Explain the procedure for registration of the clinical establishment.

Ans: Registration procedure of the clinical establishment: Registration of clinical establishment is required as per the provisions of Clinical Establishment Act, 2010.

1. For registration and continuation, every clinical establishment shall fulfill the following conditions, namely:
   (i) Prescribed minimum standards of facilities and services.
   (ii) Prescribed minimum requirement of personnel.
   (iii) Prescribed provisions for maintenance of records and reports.
   (iv) Such other conditions as may be prescribed.
2. Medical examination facilities for staff
3. Maintenance of record

There are two types of registrations:

a. **Provisional registration:** In this, authority grants approval without inspection. Registration will get within 10 days from the date of application and valid up to 12 months. The provisional registration shall be renewed before 30 days of expiry.

b. **Permanent registration:** According to application format for permanent registration, applicant has to provide information such as details of establishment, types of services, system of medicines, etc. For the permanent registration of the establishment, the applicant has to apply with proof to comply with minimum standard. He shall display the standards for information to public. The registration is valid for 5 years from date of issue.

Application should be submitted to District Registering Authority in person or by post or online along with necessary fee.

Q.3. Answer ALL questions of the following: 20 Marks

a. List of diseases and ailments which a drug may not claim to prevent or cure is covered under Schedule J.

b. As per D and C rules Schedule R prescribe Standards for condoms made up of rubber latex intended for single use and other mechanical contraceptives.

c. Which of the following is prohibited to be imported?

(i) Toilet preparations (ii) Ayurvedic drugs
(iii) Misbranded drugs (iv) Schedule C, G drugs

Ans: (iii) Misbranded drugs

d. CPCSEA stands for Committee for the Purpose of Control and Supervision of Experimentation on Animals.

e. Define captive animal as per Prevention of Cruelty to Animal Act, 1960.

Ans: Captive animal means any animal (not being a domestic animal) which is in captivity 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.

f. Out of 22 members of the food authority, the proportion of women is _____.

(i) Half (ii) One-third
(iii) One-fourth (iv) Two-third

Ans: (ii) One-third

g. Which act's prime objective is to make sure that the essential drugs are available to all at a reasonable price?

Ans: Drugs Price Control Order (DPCO), 2013

h. For calculation of price of bulk drugs a return of 12% is allowed on _____ costing.

(i) Short-term marginal (ii) Long-term marginal
(iii) Periodic (iv) Intermediate

Ans: (ii) Long-term marginal

i. Code of pharmaceutical ethics developed by Pharmacy Council of India.

j. Define the term minor.

Ans: Means a person who, under the provisions of the Indian Majority Act, 1875 is to be deemed not to have attained his majority.

k. The CDSCO is a National Regulatory **body.**

l. Which authority issue the drug manufacturing license Central Drugs Standard Control Organization (CDSCO).

m. Minimum haemoglobin value required for a donor to donate blood is 12.5 **gm/dl.**

n. IMDRA stands for Indian Medical Devices Regulation Act.

o. Head office of National Institute of Disaster Management (NIDM) is situated in which city?

Ans: New Delhi

p. Consumer Protection Act is significant to:

(i) All goods and services (ii) Immovable goods
(iii) Movable goods (iv) Selected goods and services

Ans: (i) All goods and services

q. Define bioethics.

Ans: Bioethics is the study of ethical, social, and legal issues that arise in biomedicine and biological science.

r. As per bioethics, enlist the principle of justice.

Ans: Any one principle

1. Equal opportunity.
2. Eliminate discrimination in biological studies and healthcare.
3. No differentiation in research based on age, sex, races, religious beliefs.

s. Moral rules to protect and defend the right of patient is mentioned under Beneficence **principle of bioethics.**

t. Animal anatomical waste are categorised under which category of biomedical waste.

Ans: Yellow

Winter Examination 2023 (Question Paper)
Second Year Diploma in Pharmacy
Subject: Pharmacy Law and Ethics (20226)

Time: 3 Hours **Max Marks: 80**

Q.1. Answer any SIX of the following: **30 Marks**

a. Discuss the qualification and duties of drug inspector.
b. Discuss the constitution and functions of PCI.
c. What is clinical trial and explain various phases of clinical trial.
d. Discuss the various functions of CDL as per Drugs and Cosmetics Act, 1940.
e. What is the role of a pharmacist in relation to his job as per code of ethics?
f. Give constitution of DTAB.
g. Discuss the objectives of DPCO and the retail price of drug is calculated.

Q.2. Answer any TEN of the following: **30 Marks**

a. Define magic remedies and give exempted advertised under DMR Act, 1954.
b. Explain the BCS system of classification.
c. Give general principles of law.
d. What are the powers of drug inspector as per D&C Act, 1940?
e. Discuss certain operations controlled by the Central Govt. under NDPS Act, 1985.
f. Discuss the qualification of government analyst.
g. Discuss documentation, licenses and renewal procedure in hospital pharmacy.
h. Define 'Misbranded drug' as per D&C Act, 1940.
i. Discuss the rules prescribed by the State Government in relation to possession and possession for sale of poison.
j. What are the functions of National Council for Clinical Establishment?
k. Give bonafide reasons for termination of pregnancy under MTP, 1971.

Q.3. Attempt ALL questions of the following: 20 Marks

a. FSSAI stands for _____.
b. The HQ of CDSCO is located at _____.
   (i) Mumbai (ii) Delhi
   (iii) Chennai (iv) Kolkata
c. How often we donate blood?
   (i) After 24 hours (ii) After 3 hours
   (iii) After 3 months (iv) After 6 months
d. _____ is celebrated as World Consumer Day.
   (i) 10 April (ii) 15 March
   (iii) 28 Feb (iv) 1 Jan
e. The full form of IAEC is _____.
   (i) Institutional Animal Ethics Committee
   (ii) Institutional Animal Ethics Corporation
   (iii) Institutional Animal Education Committee
   (iv) None of the above
f. Give a function of CPCSEA.
g. Medical Device Class III stands for _____.
h. What does Schedule S prescribe under D&C Act, 1940?
i. MTP Act was passed in which year?
j. The provisions of DPCO are implemented and enforced by _____.
   (i) DPPA (ii) NPPA
   (iii) MAPE (iv) None of the above
k. The full form of NLEM is _____.
l. Give one function to the National Institute of Disaster Management.
m. Give functions of DTAB.
n. Pharmacist is liaison between _____ and _____.
o. Define bioethics.
p. For glass bottles, broken glass articles which bag is used as per Biomedical Waste Management Act?
q. State the long form of ICMR.
r. Enlist the principle of bioethics.
s. Indian Veterinary Research Institute is situated at _____.
t. What is good regulatory practice?

Winter Examination 2023 (Specimen Answer Paper)
Second Year Diploma in Pharmacy
Subject: Pharmacy Law and Ethics (20226)

Time: 3 Hours **Max Marks: 80**

Q.1 Answer any SIX of the following: **30 Marks**

a. Discuss the qualification and duties of drug inspector.

Ans: **Qualification of drug inspector:** A person who is appointed an inspector should possess the following qualifications:

Graduate in Pharmacy or Pharmaceutical Sciences or Medicine with specialization in Clinical Pharmacology or Microbiology from a recognized university.

Provided that for the purpose of inspection of manufacture of substances specified in Schedule C, a person appointed as a drug inspector should have:

1. Not less than 18 months experience in the manufacture of at least one of the substances specified in Schedule C, or
2. Not less than 18 months experience in testing of at least one of the substances in Schedule C in an approved laboratory, or
3. Not less than three years experience in the inspection of firms manufacturing any of the substances specified in Schedule C during the course of their services as drugs inspector.

Provided further that the first 4 years from the date on which Chapter IV of the Act takes effect in the States, person whose qualification, training and experience are considered adequate may be appointed as inspector and their appointments continued even after 4 years, if the State Govt. is satisfied.

Duties of drug inspectors in relation to sale of drugs and cosmetics:

1. To inspect at least twice a year all establishments licensed for sale of drugs in the area assigned to him and to check whether the conditions of the licenses are observed or not.
2. If he thinks necessary, to obtain and send the samples of imported drugs and cosmetics for test or analysis, which are being sold or stocked in contravention of the provisions of the Act.

3. To investigate any complaint in writing made to him.
4. To institute prosecutions in case of breach of the Act and Rules.
5. To maintain the records relating to all inspections and actions taken by him and to submit copies of such records to the controlling authority.
6. To make inquiries and inspections regarding the sale of drugs in contravention of the provisions of the Act.
7. To detain the imported packages, if he suspects to contain drugs, the import of which is prohibited.

Duties of drug inspector in relation to manufacture of D&C Act, 1940:

1. To inspect at least twice a year, all premises licenced for manufacturing of drugs within the area allotted to him and to satisfy whether the conditions of licence and provisions of the Act and Rules thereunder are being observed or not.
2. To inspect premises licenced for manufacture of drugs, specified in Schedule C & C(1) and to observe process of manufacturing, means employed for standardization and testing of drug and storage conditions and qualification of technical staff and employee and all other details of location, construction, administration of establishment, other things which may likely to affect potency and purity of the product.
3. To send after each inspection a detailed report of inspection to the controlling authority with which conditions of licence and provisions of the Act and the Rules thereunder being observed and which being not observed.
4. To take sample of drugs manufactured in the premises and sent them for test or analysis.
5. To check all the records and registers required to be maintained under the rules.
6. To institute prosecutions, in respect of breach of the act and rules.

b. Discuss the constitution and functions of PCI.

Ans: Constitution of PCI

a. **Elected members:**

(i) 6 members, among whom there shall be at least 1 teacher of each of subject Pharmaceutical Chemistry, Pharmacy,

Pharmacology and Pharmacognosy elected by UGC, from among persons on the teaching staff of an Indian University or a college affiliated which grants degree or diploma in pharmacy.

(ii) 1 member elected from amongst themselves by the members of Medical Council of India.

(iii) 1 member from each state elected by the members of the State Council amongst themselves who shall be a Registered Pharmacist.

b. **Nominated members:**

(i) 6 members nominated by the Central Government of whom at least 4 shall be possess degree or diploma in Pharmacy and Practicing Pharmacy or Pharmaceutical Chemistry.

(ii) 1 member from each state, nominated by State Government who shall be Registered Pharmacist.

c. **Ex-officio members:**

(i) Director-General of Health Services, who shall be Chairman

(ii) Drug Controller of India

(iii) Director of the Central Drug Laboratory (CDL)

Functions of PCI

1. To prescribe the minimum standard of education required for qualification as a pharmacist (This can be provided by making rules as Education Regulation which prescribes minimum qualification for admission, duration of course, details of syllabus, practical training, examination, minimum facilities required for the conduct of course, examination and practical training).
2. To regulate minimum educational standards. (For this purpose, council appoints inspectors to inspect the institutions providing the minimum standards in education in pharmacy and report on the facilities available and decides whether the institution should be recognized or not).
3. To recognize qualification 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 for Pharmacist containing names of all persons for the time being entered in the state register.

5. Any other functions that may be assigned to the Central Council in the furtherance of the objective of the Pharmacy Act, 1948.

c. What is clinical trial and explain various phases of clinical trial.

Ans: **Clinical trial:** Clinical trials are a type of research that studies new tests and treatments and evaluates their effects on human health outcomes.

Clinical trials are scientific investigations that examine and evaluate safety and efficacy of different therapies in human subjects.

Phases of Clinical Trials

Phase I trials: This phase is called as 'Human Pharmacology'. It usually tests new drugs for the first time in a small group of often healthy people (20 to 80) to judge its safety and side effects and to find the correct drug dosage.

Phase II trials: This phase is called as 'Therapeutic exploratory trial'. It is conducted on comparatively larger and homogeneous populations. It lasts for long period. The number of subjects involved is 100–300.

The primary objectives are:

(i) To evaluate the effectiveness of a drug for particular indications in patients with the condition to be treated, diagnosed or prevented.

(ii) To determine common short-term side effects and risk associated with the drug.

(iii) To determine dose and dosage regimen for Phase III trials.

Phase III trials: It is called as 'Therapeutic confirmatory trials'. Phase III trial gathers more information about safety and effectiveness, studying different populations and different dosages, using the drug in combination with other drugs. The number of subjects usually ranges from several hundred to about 3,000 people. These trials last for several years. It involves expanded controlled and uncontrolled trials after preliminary evidence suggesting effectiveness of the drug has been obtained and are intended to gather additional information to evaluate the benefit-risk relationship of the drug.

Phase IV trials: Phase IV trials are 'Post Marketing Trials'. It includes post marketing studies to describe additional information including drug's risks, benefits and optimal use. It is conducted in

large and diverse populations. It is conducted for long period for determination of drugs safety, efficacy and dose definition.

d. Discuss the various functions of CDL as per Drugs and Cosmetics Act, 1940.

Ans: Functions of CDL

1. To analyze or test the samples of drugs or cosmetics sent to it by custom collectors or any other authorized officers or courts.
2. To carry out such other duties as may be entrusted to it by Central or State Govt. after consultation with the DTAB.
3. In case of the various drugs or classes of drugs such as sera, solution of serum proteins intended for injection, vaccines, toxins, antigens, anti-toxins, sterilized surgical ligature and sterilized surgical suture and bacteriophages, functions of CDL is carried out at the Central Research Institute, Kasauli, and such functions are exercised by the Director of the said institute.
4. The functions regarding oral polio vaccine are exercised by the Deputy Director and Head of the Polio Vaccine Testing Laboratory in case of Central Research Institute, Kasauli.
5. In case of the various drugs or classes of drugs such as anti-sera, vaccines, toxoids, diagnostic antigens for veterinary use shall be carried out at the Indian Veterinary Research Institute, Izzatnagar or Mukteshwar, such functions are exercised by the Director of either of the said institutes.
6. In case of condoms, the functions of CDL are carried out at the Central Indian Pharmacopoeia Laboratory, Ghaziabad, and such functions are exercised by the Director of the said laboratory.
7. In case of VDRL Antigen (Venereal Disease Ref. Lab.) the functions of CDL are carried out at Laboratory of the Serologist and Chemical Examiner to the Government of India, Kolkata and the functions are exercised by Director of Serologist and Chemical Examiner of the said laboratory.
8. In respect of Intrauterine Devices and Felope Rings, the functions of laboratory shall be carried out at the Central Drug Testing Laboratory, Thane, Maharashtra and such functions shall be exercised by the Director of the said laboratory.

9. In respect of human blood and human blood products including components, to test for freedom of HIV antibodies, shall be carried out by the following institutes, hospitals and such functions are exercised by the head of the respective institutes:
   (i) National Institutes of Communicable Disease, Department of Microbiology, Delhi.
   (ii) National Institute of Virology, Pune
   (iii) Centre of Advanced Research in Virology, Christian Medical College, Vellore.
10. In respect of homoeopathic medicines, the function of CDL carried out at the Homoeopathic Pharmacopoeia Laboratory, Ghaziabad and such functions are exercised by the Director of the said laboratory.
11. In respect of blood grouping reagent and diagnostic kits for human immunodeficiency virus, hepatitis B surface antigen and hepatitis C virus, the function of CDL carried out at the National Institute of Biologicals, Noida and such functions are exercised by the Director of the said laboratory.

e. What is the role of a pharmacist in relation to his job as per code of ethics?

Ans: Role of a Pharmacist to his Job

1. **Pharmaceutical services:**
   (i) A pharmacist should provide efficient and reasonably comprehensive pharmaceutical services through the medical store or pharmacy.
   (ii) Such services should include supply of commonly required medicines without undue delay and furnishing the emergency supply at all times.
2. **Pharmacy/Drug store:**
   (i) In every pharmacy/drug store, there should be qualified pharmacist to have personal control the pharmacy.
   (ii) A pharmacy should be planned in such a way that there is no accidental contamination in the preparation, dispensing and supply of medicines.
   (iii) The appearance of the premises should reflect the professional character of pharmacy.
3. **Prescriptions:**
   (i) Prescriptions presented for dispensing should not be discussed with patients or others regarding the merits and demerits of their therapeutic efficiency.

(ii) A pharmacist should not show any expression on his face so that the patients will lose their faith in the physicians or prescribers after receiving the prescriptions.
(iii) No addition, omission or substitution of ingredients in a Rx should be made without the consent of prescriber whenever possible except in an emergency.
(iv) In case of any error in the prescription, it should be referred back to the prescriber for necessary correction or approval of the change suggested.
(v) If at all change in the prescription is necessary, it should not affect the reputation of physician.
(vi) A pharmacist should not recommend any particular prescriber unless he is specially asked to do so.

4. **Drugs/Ingredients:**
(i) While dispensing, the drugs or ingredients should be weighed or measured correctly.
(ii) Pharmacist should always use drugs and medicinal preparations of standard quality.
(iii) Drugs likely to cause addiction or abuse should not be supplied when there is reason to suppose that it is required for such purpose.

5. **Practical training:**
(i) While imparting practical training, the in-charge pharmacist should see that the trainees acquire sufficient technique and skill.
(ii) No certificate should be granted to the trainee pharmacist before completion of prescribed period of training or without undergoing practical training or unless the trainee acquires sufficient knowledge.

f. Give constitution of DTAB.

Ans: Constitution of DTAB: It is constituted by Central Government. It has the following members:

a. **Ex-officio members of DTAB:**
(i) The Director-General of Health Services, who is the chairman of the board.
(ii) The Drug Controller of India.
(iii) The Director of the Central Drug Laboratory, Kolkata.
(iv) The Director of the Central Research Institute, Kasauli.
(v) The Director of the Central Drug Research Institute, Lucknow.

(vi) The Director of the Indian Veterinary Research Institute, Izzatnagar.
(vii) The President, Pharmacy Council of India.
(viii) The President, Medical Council of India.

b. **Nominated members of DTAB:**
(i) Two persons from among persons who are in-charge of the drugs control in the states are to be nominated by Central Government.
(ii) One person from the pharmaceutical industry is to be nominated by Central Government.
(iii) Two government analysts are to be nominated by Central Government.

c. **Elected members of DTAB:**
(i) One teacher in Pharmacy, Pharmaceutical Chemistry or Pharmacognosy on the staff of an university or affiliated colleges is elected by the Executive Committee of Pharmacy Council of India.
(ii) One teacher in medicine or therapeutics on the staff of an university or affiliated colleges is elected by the Executive Committee of Medical Council of India.
(iii) One Pharmacologist is elected by the Governing Body of the Indian Council of Medical Research.
(iv) One person is elected by the Central Council of Indian Medical Association.
(v) One person is elected by the Council of the Indian Pharmaceutical Association.

g. Discuss the objectives of DPCO and the retail price of drug is calculated.

Ans: Objectives of DPCO: The various objectives of this order are:
1. To make the essential medicines available at reasonable prices.
2. To provide sufficient opportunity for innovation and competition to support the growth of industry.
3. To meet the goals of employment and shared economic growth of all.
4. To achieve adequate production.

Retail price calculation: By applying the following formula, the retail price of the formulation is calculated by the Government.

$$RP = (MC + CC + PM + PC) \times (1 + MAPE/100) + ED,$$

where,

RP: Means retail price.

MC: Means material cost which includes the cost of drugs and other pharmaceutical aids with overages, if any, plus process loss thereon in accordance with the norms specified from time-to-time by notification in the Official Gazette.

CC: Means conversion cost worked out in accordance with such norms as may be specified by the Government from time-to-time by notification in the Official Gazette.

PM: Means the cost of packing material including process loss thereon worked out in accordance with such norms as may be specified by the Government from time-to-time.

PC: Means packing charges worked out in accordance with such norms as may be specified by Government every year by notification in the Official Gazette.

MAPE: Maximum allowable post-manufacturing expenses. In means all the cost incurred by the manufacturer from the stage of ex-factory cost of retailing. It also includes trade margin and margin of manufacturer. MAPE shall not exceed 100% for indigenously scheduled formulations.

ED: Means excise duty.

Q.2. Answer any TEN of the following: 30 Marks

a. Define magic remedies and give exempted advertised under DMR Act, 1954. (Any four)

Ans: **Magic remedy:** It includes a Talisman, Mantra, Kavacha, and any other charm alleged to possess miraculous powers.

(i) For diagnosis, treatment and prevention of any disease in human beings or animals, or

(ii) For affecting or altering the structure or organic function of the body of human being or animal.

Classes of exempted advertisements:

1. Any advertisements relating to the drugs printed or published by the Government or any other person with prior permission of the Government.
2. Any advertisement relating to a drug which is sent confidentially in the prescribed manner to registered medical practitioner.
3. Advertisements including any book or treatise dealing with any matter relating to the diseases, disorders or conditions which are otherwise prohibited provided published from a bonafide scientific or social point of view.

4. Displayed signboards or notices by registered medical practitioners on his premises indicating that the treatment is undertaken for any disease, disorders or conditions specified in the schedule to this Act or in the rules made under this Act.
5. Advertisements relating to the drugs which comply with the required conditions as follows:
   a. Leaflets or literature along with packing of drugs; or advertisements of drugs in medicinal, pharmaceutical, scientific and technical journals.
   b. Therapeutic index or price list published by licensed manufacturer, importer or distributor of drugs or medical literature distributed by medical representatives. With conditions that:
      (i) The advertisement should contain only the information required for the guidance of registered medical practitioner regarding:
         a. Therapeutic indications;
         b. Route of administration;
         c. Dosage and side effects of such drug or drugs; and
         d. The precautions to be taken in treatment with the drug.
      (ii) The distribution of such literature should be given to registered medical practitioners, dispensaries, hospitals, medical and research institutions, chemists and druggists or pharmacies.

b. Explain the BCS system of classification.

Ans: The biopharmaceutical classification system is a system to differentiate the drugs on the basis of their solubility and permeability.

BCS Classes:

Class I—High permeability, high solubility

(i) Those compounds are well absorbed and their absorption rate is usually higher than excretion.

(ii) Example: Metoprolol, paracetamol.

Class II—High permeability, low solubility

(i) The bioavailability of those products is limited by their solvation rate. A correlation between the *in vivo* bioavailability and *in vitro* solvation can be found.

(ii) Example: Glibenclamide, bicalutamide, ezetimibe, aceclofenac.

Class III—Low permeability, high solubility

(i) The absorption is limited by the permeation rate but the drug is solvated very fast. If the formulation does not change the

permeability or gastrointestinal duration time, than class I criteria can be applied.

(ii) Example: Cimetidine

Class IV—Low permeability, low solubility

(i) Those compounds have a poor bioavailability. Usually, they are not well absorbed over the intestinal mucosa and a high variability is expected.

(ii) Example: Bifonazole.

c. Give general principles of law.

Ans: The various general principles of law are:

1. **Supremacy of law:** Supremacy of law means that the law has authority over all people, including those who administer the law. Dicey believes that a man should only be punished for a specific violation of the law, and not for anything else. The person cannot be punished by the Government solely on its own authority, but only in accordance with established law.
2. **Equality before law:** It means all people must be treated equally under the law. It ensures that everyone is treated equally before the law. It prohibits discrimination on various grounds, and treats everyone as equal in public employment. Also, it abolishes untouchability and titles.
3. **Predominance of legal spirit:** The spirit of justice is referred to as the legal spirit. For the effective implementation of rules of laws, there should be impartial and independent judicial authority. According to Dicey, such authority will be court. This concept advocates the principle that law should be based on justice and interpreted without discrimination.
4. **Principle of justice:** The principle of justice obliges us to equitably distribute benefits, risks, costs, and resources. The following rules are supported by the principle of justice:
   1. To each person an equal share
   2. To each person according to need
   3. To each person according to effort
   4. To each person according to contribution
   5. To each person according to merit
5. **Principle of liberty:** According to John Stuart Mill, every person has right to exercise his power in the community and act as per his will to prevent harm to others. An earlier equivalent was stated in France's Declaration of the Rights of Man and of the Citizen.

d. What are the powers of drug inspector as per D&C Act, 1940?

Ans: Powers of drug inspector: Within the local limits for which the inspector is appointed, he may,

(i) **Inspect:**
1. Any premises wherein any drug or cosmetic is being manufactured. And also he may inspect the means employed for standardizing and testing the drug or cosmetic.
2. Any premises wherein any drug or cosmetic is being sold or stocked or exhibited or offered for sale or distributed.

(ii) **Take samples of any drug or cosmetic:**
1. Which is being manufactured or being sold or is stocked or offered for sale or exhibited or being distributed.
2. From any person conveying, delivering or preparing to deliver any drug or cosmetic to a purchaser or a consignee.

(iii) Search any person in connection with the offence under this chapter at all reasonable times.

(iv) Enter and search at all reasonable times, any place or premises in which he has reason to believe that an offence is being committed or has been committed.

(v) Stop and search any vehicle or other conveyance which he has reason to believe used for carrying any drug or cosmetic in respect of which offence has been or is being committed.

(vi) Give order in writing to the person in possession of drug or cosmetic in respect of which offence has been committed or is being committed, not to dispose stock of such drug or cosmetic for a specified period not exceeding twenty days or unless the defect may be removed by the possessor of the drug or cosmetic, and may seize the stock of such drug or cosmetic or any substance or article used to carry drug.

(vii) Examine any record, register, document or any other material object found while exercising above powers and seize the same if he has reason to believe that it is evidence of the commission of an offence under the Act.

(viii) Exercise any other powers as may be necessary, for carrying out the purpose of this Act and the Rules thereunder.

e. Discuss certain operations controlled by the Central Govt. under NDPS Act, 1985.

Ans: (i) Government shall fix from time-to-time the limits within which licences may be given for the cultivation of opium poppy.

(ii) All opium, the product of land cultivated with the opium poppy shall be delivered by the cultivators to the officers authorized on behalf of the Central Government.

(iii) The Central Government may from time-to-time fix the price to be paid to the cultivators from the opium delivered.

(iv) The rules may prescribe the forms and conditions of licences or permits for the manufacture, possession, transport, import inter-state, export inter-state, sale, purchase, consumption or use of psychotropic substances. The rules may also prescribe the authorities granted and the fees that may be charged there for.

(v) The rules may prescribe the forms and conditions of licences for cultivation of the opium poppy and for the production and manufacture of opium. The rules may also prescribe the fees that may be charged therefore the authorities by which such licences may be granted, withheld, refused or cancelled and the authorities before which appeal against the orders of withholding, refusal or cancellation of licences shall lie.

(vi) The rules may prescribe that opium shall be weighed, examined and classified according to its quality and consistency by the officers authorized on this behalf by the Central Government in the presence of the cultivator at the time of delivery by the cultivator.

(vii) The rules may provide for the weighment, examination and classification according to the quality and consistency of the opium received at the factory and the deductions from or addition to the standard price to be made in accordance with the result of such examinations.

f. Discuss the qualification of government analyst.

Ans: Qualifications of government analyst: A person to be appointed as government analyst should possess the following qualifications:

(i) A graduate in medicine or science or pharmacy or pharmaceutical chemistry of a recognized university, with not less than 5 years postgraduate experience in the testing of drugs; or

(ii) A postgraduate degree in medicine or science or pharmacy or pharmaceutical chemistry of a recognized university with not less than 3 years postgraduate experience in the testing of drugs; or

(iii) Associateship Diploma of the Institution of Chemists with 'Analysis of Drugs & Pharmaceuticals' as one of the subjects with not less than 3 years experience in the testing of drugs in a laboratory under the control of:

1. A government analyst; or
2. Head of an institution; or
3. Testing laboratories approved for the purpose by appointing authority.

g. Discuss documentation, licenses and renewal procedure in hospital pharmacy.

Ans: Hospital Pharmacy

a. **Documentation:**

1. Statutory documents such as regulatory licenses, registrations, permissions, etc. for operating a pharmacy.
2. Operational documents, such as purchase invoices, sales invoices.
3. Other necessary documents such as:
   - (i) Protocols
   - (ii) Standard working procedures
   - (iii) Operation instructions
   - (iv) Quality manual
   - (v) Cleaning and maintenance records
   - (vi) Complaint records
   - (vii) Audit records (internal and external)
   - (viii) Policy documents
   - (ix) Personal documents (patients and health profile)
   - (x) Patients and medication records
   - (xi) Records of counselling follow-ups, etc.
4. Record of prescriptions: Prescription must contain-patients name, age, sex, address, and institution/hospital along with its strength (especially in pediatrics age group), its dose frequency, duration in days, and total quantity (number of tablets and capsules).
5. Laboratory investigation reports
6. Referral notes: Always keep the carbon copy of referral note especially in case of critically ill patient. Referral note should mention the date and time of writing the note. Also write the treatment given.

7. Discharge card: It shows the condition of the patient on the admission, investigation done, the treatment given and detail advice on discharge should be written on discharge card.
8. Copies of medical certificates issued as written evidence and accepted in court of if required.

b. **Licences:** For the manufacture of following classes of drugs he should obtain the licences in the following forms:
   1. Grant of a licence to manufacture drugs other than those specified in Schedule C, C1, and X-Form 20
   2. Grant of a licence to manufacture drugs specified in Schedule C, C1, excluding those specified in Schedule X-Form 21.
   3. Grant of a licence to manufacture for sale drugs specified in Schedule X-Form 20 F.

c. **Renewal of licences:**
   1. For pharmacy in hospital as per retail sale the granted licences are valid up to 5 years and should be renewed before expiry.
   2. The licensee should apply to the licensing authority in the prescribed form accompanied with the prescribed fees.
   3. If the licensee fails to pay license retention fee on or before the due date, he shall be liable to pay license retention fee along with a late fee, and in the event of non-payment of such fee, the license shall be deemed to have been cancelled.

h. Define 'Misbranded drug' as per D&C Act, 1940.

Ans: Misbranded drug: Drug shall be deemed to be misbranded if:

(i) It is so coloured, coated, powdered or polished that the damage is concealed or if it is made to appear of better or greater therapeutic value than it really is; or

(ii) It is not labelled in the prescribed manner; or

(iii) Its label or container or anything accompanying drug bears any statement, design or devices which makes any false claim for drug or which is false or misleading in any particular.

i. Discuss the rules prescribed by the State Government in relation to possession and possession for sale of poison.

Ans: Possession and sale of specified poisons: The State Govt. may regulate the possession and sale of poison within the state. The sale may be wholesale or retail. The rules may be applicable

for the whole or any part of the territories under the administration of the state. Such rules may provide for:

(i) Grant of licenses for the possession of any specified poison for sale, either wholesale or retail.
(ii) Fixing of fees to be charged for such licenses.
(iii) The classes of persons to whom the licenses for the possession and sale of poisons are to be granted.
(iv) The classes of persons to whom such poisons are to be sold.
(v) Maintenance of register for the sale of poisons and inspection of the same.
(vi) Safe custody of poisons and the labelling of the vessel, coverings or packages in which such poison is sold or stored for sale.
(vii) Inspection and examination of any such poison possessed for sale by any vendor.

Possession of any poison: State Government has power to make the rules regarding the possession of any specified poison in such local area where such poison may be used for murder or for poisoning cattle in such local area where such occurrences are very frequent.

j. What are the functions of National Council for Clinical Establishment?

Ans: Functions of National Council for Clinical Establishment

1. Compile and publish a national register of clinical establishments within two years from the date of the commencement of this Act.
2. Classify the clinical establishments into different categories.
3. Develop the minimum standards and their periodic review.
4. Determine within a period of two years from its establishment, the first set of standards for ensuring proper healthcare by the clinical establishments.
5. Collect the statistics in respect of clinical establishments.
6. Perform any other function determined by the Central Government from time-to-time.

k. Give bonafide reasons for termination of pregnancy under MTP, 1971.

Ans: Bonafide Reasons for Termination of Pregnancy under MTP, 1971

1. **Consent:** No pregnancy shall be terminated by a RMP without the consent of the pregnant women except:

(i) When the pregnant woman is less than 18 years of age; or
(ii) The pregnant woman is lunatic.

In case of pregnant woman who is minor or lunatic, the pregnancy may be terminated with a written consent of her guardian.

2. **Duration of pregnancies:**
   1. A pregnancy may be terminated if it is not more than 12 weeks old and a medical practitioner is of the opinion that continuation of such pregnancy
      (i) May involve a serious risk to the life of pregnant woman, and would result into serious injury to the physical or mental health of the pregnant woman.
      (ii) The child to be born would be seriously handicapped due to physical or mental abnormalities.
   2. A pregnancy may be terminated when the length of the pregnancy is more than 12 weeks old but not more than 20 weeks old and not less than 2 RMPs are of the same opinion as above.
   3. A pregnancy of any duration may be terminated by RMP when it is of the opinion that such termination is immediately necessary to save the life of pregnant women.
3. **Other cases:** The pregnancy caused due to rape or due to failure of contraceptive device used by any married woman or her husband for the purpose of family planning.

Q.3. Attempt ALL questions of the following: 20 Marks

a. FSSAI stands for Food Safety and Standards Authority of India.

b. The HQ of CDSCO is located at _____.

(i) Mumbai (ii) Delhi
(iii) Chennai (iv) Kolkata

Ans: (ii) Delhi

c. How often we donate blood?

(i) After 24 hours (ii) After 3 hours
(iii) After 3 months (iv) After 6 months

Ans: (iii) After 3 months

d. _____ is celebrated as World Consumer Day.

(i) 10 April (ii) 15 March
(iii) 28 Feb (iv) 1 Jan

Ans: (ii) 15 March

e. The full form of IAEC is _____.

(i) Institutional Animal Ethics Committee
(ii) Institutional Animal Ethics Corporation
(iii) Institutional Animal Education Committee
(iv) None of the above

Ans: (i) Institutional Animal Ethics Committee

f. Give a function of CPCSEA.

Ans: Functions of CPCSEA. (Any 1 function)

(i) To regulate experimentation on animals.
(ii) To regulate breeding and trade of animals for experimentation.
(iii) Registration of establishments engaged in breeding and trade of animals, for experimentation.
(iv) Registration of establishments conducting experiments on animals.
(v) Constitution of Institutional Animals Ethics Committees (IAEC) of register establishments.
(vi) Approval of animal house facilities.
(vii) To approve research projects using large animals.
(viii) To recommend on import of animals for experiments and breeding.
(ix) To take appropriate action against establishments for violation of legal norms/stipulation.
(x) To conduct and support a conference/workshop on animal ethics.

g. Medical Device Class III stands for Moderate high risk.

h. What does Schedule S prescribe under D&C Act, 1940?

Ans: Standards for Cosmetics

i. MTP Act was passed in the year 1971.

j. The provisions of DPCO are implemented and enforced by _____.

(i) DPPA (ii) NPPA
(iii) MAPE (iv) None of the above

Ans: (ii) NPPA

k. The full form of NLEM is National List of Essential Medicine (NLEM).

l. Give one function of the National Institute of Disaster Management.

Ans: (i) Planning and promoting training and research in the area of disaster management.

(ii) Documentation of a national level information base relating to disaster management policies, prevention mechanisms and mitigation measures.

(iii) In addition, the institute performs various important functions, as regards to disaster management, specified under the Act.

m. Give functions of DTAB.

Ans: (i) To advise the Central and State Governments on technical matters arising out during administration of the D&C Act.

(ii) To carry out the other function assigned to it under the D&C Act.

n. Pharmacist is liaison between Physician **and** Patient.

o. Define bioethics.

Ans: Bioethics is the study of ethical, social, and legal issues that arise in biomedicine and biological science.

p. For glass bottles, broken glass articles which bag is used as per Biomedical Waste Management Act?

Ans: Blue

q. The long form of ICMR is Indian Council of Medical Research.

r. Enlist the principle of bioethics.

Ans:
1. Principle of non-maleficence
2. Principle of respect for autonomy
3. Principle of beneficence
4. Principle of justice

s. Indian Veterinary Research Institute is situated at Izzatnagar or Mukteshwar.

t. What is good regulatory practice?

Ans: Good regulatory practices are recognized procedures, processes, systems and tools which improve quality and effective implementation of regulation. It provides sound, affordable and effective regulation of medical products and strengthens health care system.

Summer Examination 2024 (Question Paper)
Second Year Diploma in Pharmacy
Subject: Pharmacy Law and Ethics (20226)

Time: 3 Hours **Max Marks: 80**

Q.1. Attempt any SIX of the following: **30 Marks**

a. Define education regulation. Describe it in detail and define 'Central Register'.
b. Give the constitution and functions of Drugs Technical Advisory Board.
c. Discuss the ethics of pharmacists in relation to his job as per the code of pharmaceutical ethics.
d. Give the functions of Central Drug Laboratory (CDL).
e. Give the formula for calculation of retail price of drug formulation and explain the terms involved in it as per DPCO, 1995 and define 'Ceiling Price'.
f. What is clinical trial and explain various phases of clinical trials.
g. Define government analyst. State qualifications for appointment of government analyst as per D and C Act, 1940.

Q2. Attempt any TEN of the following: **30 Marks**

a. Write the classes of drugs and cosmetics prohibited for manufacture as per D and C Act and Rules.
b. Give any three bonafide reasons for termination of pregnancy under Medical Termination of Pregnancies Act, 1971.
c. Describe documentation, licenses and renewals of pharmaceutical manufacturing as per good regulators practices.
d. Write recommendation of 'Drug Enquiry Committee'.
e. State the classes of prohibited advertisements as per DMR Act, 1954. (Any three)
f. What are the labelling particulars required to appear on label of ophthalmic preparations?
g. Define poison as per Poison Act, 1919 and name any two poisons specified in list 'A' and list 'B' each.

h. Write penalties for punishment for contravention in relation to coca plant under NDPS Act and the rules.
i. Define repacking of drugs and state any four conditions for grant of repacking licence.
j. Differentiate brand name and generic name of drugs.
k. What are the functions of the National Council for Clinical Establishments?

Q.3. Attempt ALL questions of the following: 20 Marks

a. Define 'Chemist and Druggist'.
b. Clandestine arrangements as per code of pharmaceutical ethics means.
   (i) Secret agreements
   (ii) Pharmacist may render first aid to victim
   (iii) Link between medical profession and public
   (iv) All of the above
c. CPCSEA stands for _____.
d. What does schedule G to the rules prescribes?
e. Give function of food authority.
f. What is the objective of DPCO? (Any two)
g. Name of local body which allows experiments on small animals?
   (i) CPCSEA (ii) IAEC
   (iii) IACE (iv) IECC
h. Medical Termination of Pregnancy Act was passed in _____.
i. For production from basic stage post tax return of _____ considered on net worth is considered.
   (i) 10% (ii) 20%
   (iii) 8% (iv) 18%
j. Give two examples of schedule J.
k. State the principles of bioethics.
1. Mention different classes of medical devices.
m. GRP stands for _____.
n. National Institute of Disaster Management authority comes under _____.
   (i) Ministry of Home Affairs
   (ii) Ministry of Environment
   (iii) Ministry of Pollution
   (iv) Ministry of Foreign Affairs

o. Who is the head of the Central Authority's Investigation wing?
   (i) Police Inspector (ii) Director-General
   (iii) Magistrate (iv) Police Commissioner
p. ICMR stands for _____.
q. Who is the head of Central Drugs Standards Control Organization (CDSCO)?
r. Human anatomical waste is categorised in which colour bag as per Biomedical Waste Management Act.
s. Minimum haemoglobin require to donate blood is _____.
t. Define bioethics.

Summer Examination 2024 (Specimen Answer Paper)
Second Year Diploma in Pharmacy
Subject: Pharmacy Law and Ethics (20226)

Time: 3 Hours **Max Marks: 80**

Q.1. Attempt any SIX of the following: **30 Marks**

a. Define education regulation. Describe it in detail and define 'Central Register'.

Ans. Education regulations: PCI after approval of the Central Government under Section 10 of the Pharmacy Act, 1948 makes regulations prescribing the minimum standard of education required for qualification of pharmacist called education regulations.

Central Register of Pharmacists

Central register: Central council has to maintain a register of pharmacists to be known as central register under section 15A of the Pharmacy Act, 1948. This register contains the names of all persons whose names are entered in the register for a state.

Every state council has to supply five copies of a register for a state to the central council as soon as the 1st of April every year. Registrar of state council should also inform all additions and other amendments in the register for a state to the central council without delay.

Registrar of the central council has to keep the central register up to date in accordance with the orders made by the central council and publish it in the Gazette of India.

The central register is a public document within the meaning of the Indian Evidence Act, 1872.

Registration in central register: After receiving the report of a registration of a person in the register for a state, the registrar of the central council enters the name of such person in the central register.

b. Give the constitution and functions of Drugs Technical Advisory Board.

Ans. Constitution of DTAB: The board consists of the following members:

(i) **Elected members:**

a. A teacher in Pharmacy, Pharmaceutical Chemistry or Pharmacognosy on the staff of an university or affiliated college elected by the Executive Committee of the Pharmacy Council of India.
b. A teacher in medicine or therapeutics on the staff of an university or affiliated college elected by the Executive Committee of the Medical Council of India.
c. One Pharmacologist elected by the Governing Body of the Indian Council of Medical Research.
d. One person elected by the Central Council of Indian Medical Association.
e. One person elected by the Council of the Indian Pharmaceutical Association.

The nominated and elected members hold office for three years and are eligible for renomination and re-election. The Central Government appoints a secretary of board, and also provide clerical and other staff. The board also constitutes sub-committees.

There is a separate Ayurvedic and Unani DTAB constituted under Section 33-C of the Act.

(ii) **Nominated members:** The following members are nominated by Central Government:

a. The persons among the persons who are in charge of the drugs control in the state.
b. One person from the pharmaceutical industry.
c. Two government analyst.

(iii) **Ex-officio members:**

a. The Director-General of Health Services, who is the chairman of the board.
b. The Drugs Controller of India.
c. The Director of the Central Drugs Laboratory, Kolkata.
d. The Director of the Central Research Institute, Kasauli.
e. The Director of Indian Veterinary Research Institute, Izzatnagar.

f. Director, Central Drug Research Institute, Lucknow.
g. The President, Pharmacy Council of India.
h. The President, Medical Council of India.

Function of DTAB: Under the provisions (Section 5) of the Act, the Central Government appoints the Drugs Technical Advisory Board to advise the Central and State Governments on technical matters arising out of the administration of this Act and to carry out the other functions assigned to it by this Act.

c. Discuss the ethics of pharmacists in relation to his job as per the code of pharmaceutical ethics.

Ans: Pharmacist in Relation to his Job:

a. **Pharmaceutical services:**
   (i) Pharmacists should provide efficient and comprehensive pharmaceutical services through medical stores or pharmacies.
   (ii) Such services include a supply of commonly required medicines without undue delay and furnishing the emergency supply at all times.

b. **Pharmacy/Drug store:**
   (i) In every drug store/pharmacy, there should be a qualified-pharmacist to have personal control over the pharmacy.
   (ii) A pharmacy should be planned in such a way that there is no accidental contamination in the preparation, dispensing and supply of medicine.
   (iii) The appearance of the premises should reflect the professional characteristics of the pharmacy and indicate to the public that the practice of pharmacy is the main purpose of the establishment.

c. **Handling of prescription:**
   (i) Prescriptions presented for dispensing not be discussed with patients or others regarding the merits and demerits of their therapeutic efficiency.
   (ii) After receiving the prescriptions a pharmacist should not even show any expression on his face so that the patients will lose their faith in the physicians or prescriber.
   (iii) No addition, omission or substitution of ingredients in a prescription should be made without the consent of the prescriber or physician whenever possible except in an emergency.

(iv) In case of any obvious errors in the prescription, it should be referred back to the prescribers for necessary correction or approval of the change suggested.

(v) If all the changes in the prescription are necessary for the interest of the health of a patient, it should not affect the reputation of the physician or the prescriber.

(vi) A pharmacist should not recommend any particular prescriber, unless he is specially asked to do so.

d. **Handling of drugs/ingredients:**

(i) Pharmacists should always use drugs and medicinal preparations of standard quality.

(ii) The pharmacist should handle the drugs with utmost care while dispensing them.

(iii) Pharmacists should handle or dispense poisonous or habitual drugs carefully.

(iv) The drugs must be weighed or measured correctly.

(v) Drug or medicine likely to cause addiction or other forms of abuse should not be supplied when there is reason to suppose that it is required for such purpose.

Practical training/Apprentice pharmacist:

(i) While imparting practical training, the in-charge pharmacist should see that the trainees acquire sufficient technique and skill.

(ii) No certificate should be granted to the trainee before completion of a prescribed period of training or without undergoing practical training or unless the trainee acquires sufficient knowledge.

d. Give the functions of Central Drug Laboratory (CDL).

Ans: Functions of Central Drug Laboratory (CDL)

1. To analyze or test such samples of drugs as may be sent to it by the Custom Collectors or Courts.
2. To carry out such other duties as may be entrusted to it by the Central Government or, with the permission of the Central Government, by a State Government after consultation with the Drugs Technical Advisory Board.
3. In case of sera, vaccines, toxins, antigens, antisera, solution of serum proteins for injections, sterilized ligature and suture and bacteriophages, the functions of CDL is carried out at the Central Research Institute, Kasauli and such functions are exercised by the Director of the said institute.

4. The functions regarding oral polio vaccine testing are exercised by the Deputy Director and Head of the Polio Vaccine Testing Laboratory of Central Research Institute, Kasauli.
5. In case of antisera, vaccines, diagnostic antigens and toxoids for veterinary use, the functions of CDL are carried out at the Indian Veterinary Research Institute, Izzatnagar or Mukteshwar and such functions are exercised by the Director of the said institution.
6. In case of condoms, the functions of CDL are carried out at Central Indian Pharmacopoeia Laboratory, Ghaziabad and such functions are exercised by Director of the said laboratory.
7. In case of VDRL (Venereal Disease Reference Laboratory) antigens the function of CDL is carried out at the Laboratory of Serologist and Chemical Examiner to Government of India and such functions are exercised by Serologist and Chemical Examiner of the said laboratory.
8. In case of IUCD (Intrauterine Contraceptive Devices) and felope rings, the functions of CDL are carried out at Department of Biochemical Engineering, Indian Institute of Technology, New Delhi and such functions are exercised by Head of said department.

e. Give the formula for calculation of retail price of drug formulation and explain the terms involved in it as per DPCO, 1995 and define 'Ceilling Price'.

Ans. Calculation of retail price of drugs: Calculation of retail price of a new drug for existing manufacturers of scheduled formulations:

1. The retail price of the new drug available in the domestic market shall be calculated as provided in sub-paragraph (1) of paragraph 4.
2. The price to retailer of a new drug, not available in the 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 formed under paragraph 15.
3. The retail price of such a new drug shall be fixed by adding a sixteen percent margin to retailer on the price to retailer as fixed in item (i).

The formula for calculation of retail price of formulation: The retail price of a formulation is calculated by the Government by using the formula,

$$RP = (MC + CC + PM + PC) \times (1 + MAPE/100 + ED),$$

where,

RP = Retail price.
MC = Material cost which includes the cost of drugs and other pharmaceutical aids with averages.
CC = Conversion cost.
PM = Cost of packing material including process loss.
PC = Packing charges.
MAPE = Maximum allowable post-manufacturing expenses.
ED = Excise duty.

Maximum allowable post-manufacturing expenses means:

a. The cost of the manufacturer from the stage of ex-factory cost of retailing. It also includes trade margin and margin of the manufacturer.
b. MAPE shall not exceed 100% for indigenously manufactured scheduled formulation.

For imported formulations, the retail price may be fixed on the basis of landed costs and shall not exceed 50% of the landed cost.

f. What is clinical trial and explain various phases of clinical trials.

Ans. Clinical trials: Clinical trials are research studies performed on people that are aimed at evaluating a medical, surgical, or behavioural intervention. These are the primary way that researchers find out if a new treatment, like a new drug or diet or medical device (e.g. a pacemaker) is safe and effective in people.

Clinical trial—Various phases: Clinical trials are usually classified into four phases of development as phase I to phase IV, with each potentially tasting for many months to several years. Upon successful completion of each phase of the trial, necessary approvals are obtained from the appropriate regulatory authority or authorities. Recently, for speeding up the drug development process and to quickly identifies safety issues, phase 0 studies (human micro-dosing studies) have been introduced.

Phase 0: The official name of a phase 0 study is an Exploratory Investigational New Drug (IND) study. Its goal is to quickly establish whether a candidate drug will work as desired in humans. This study is based on *in vivo* safety, pharmacology and toxicological preclinical studies. At this phase of studies, a single sub-therapeutic dose of the Investigational New Drug (IND) is administered to a small number of healthy subjects (10 to 15), over a short duration of 7 days. The dose administered at this phase is too low to result in a therapeutic effect to ensure the absence of any toxic effects, preliminary pharmacokinetic (PK) and pharmacodynamic (PD) data are collected for evaluation to establish suitability.

(i) **Phase I trials:** The new/experimental drug or treatment is tried out on a small group (20–80) of healthy human subjects for the first time after it has been well tested in lab and animal studies. This initial phase of testing typically takes several months. The main purpose of this phase is to evaluate the safety, tolerability, pharmacokinetics, and pharmacodynamics of the new treatment or the new drug on humans and the side effects associated with increasing doses and also to determine what dosages patients can take without causing them harm.

(ii) **Phase II trial:** In this phase, the effectiveness and safety of the experimental study drug or treatment are evaluated by controlled studies. The study drug or experimental treatment is tested on a larger group of people (100–300) who have the disease or illness for which the new drug is being developed, to determine whether it is efficacious. This second phase of testing may last from several months to two years. Phase-II studies also help determine, the risks associated with the drug as well as short-term side effects.

(iii) **Phase III trials:** The purpose of a Phase III trial is to gain additional information regarding the effectiveness and safety that is required to evaluate the overall benefit-risk ratio of the new drug/treatment. It is usually performed in a larger group of individuals (1000–3000).

(iv) **Phase IV trials:** These are post-marketing studies to delineate additional information including the drug's risks, benefits, and optimal use. It also involves post-launch safety surveillance and ongoing technical support of a drug, helping detect long-term adverse effects in a larger population. Phase IV studies can be conducted either by regulatory authorities or by the

pharmaceutical company sponsoring the drug either for competitive or other reasons.

g. Define government analyst. State qualifications for appointment of government analyst as per D and C Act, 1940.

Ans: Government analyst: It means:

a. In relation to Ayurvedic, Siddha or Unani drugs, a person appointed under section 33-F; and

b. In relation to any other drugs or cosmetics, a person appointed under section 20 of Drugs and Cosmetics Act.

Qualifications of government analyst: A person to be appointed as government analyst should possess the following qualifications:

(i) A graduate in medicine or science or pharmacy or pharmaceutical chemistry of a recognized university, with not less than 5 years postgraduate experience in the testing of drugs; or

(ii) A postgraduate degree in medicine or science or pharmacy or pharmaceutical chemistry of a recognized university with not less than 3 years postgraduate experience in the testing of drugs; or

(iii) Associateship Diploma of the Institution of Chemists with 'Analysis of Drugs and Pharmaceuticals' as one of the subjects with not less than 3 years experience in the testing of drugs in a laboratory under the control of:

1. A government analyst; or
2. Head of an institution; or
3. Testing laboratories approved for the purpose by appointing authority.

Q2. Attempt any TEN of the following: 30 Marks

a. Write the classes of drugs and cosmetics prohibited for manufacture as per D and C Act and Rules.

Ans: Categories of drugs which need a license for manufacturing:

(i) Drugs other than those specified in Schedule C, C1 and X.

(ii) Drugs specified in Schedule C, C1 but not specified in Schedule X.

(iii) Drugs specified in Schedule C and C1.

(iv) Drugs specified in Schedule X but not in Schedule C and C1.

(v) Drugs for the purpose of examination, test or analysis.

(vi) Loan licenses.

(vii) Repacking licenses.

b. Give any three bonafide reasons for termination of pregnancy under Medical Termination of Pregnancies Act, 1971.

Ans: a. **Consent:** No pregnancy shall be terminated by a RMP without the consent of the pregnant women except:

(i) When the pregnant woman is less than 18 years of age; or

(ii) The pregnant woman is lunatic.

In case of pregnant woman who is minor or lunatic, the pregnancy may be terminated with a written consent of her guardian.

b. **Duration of pregnancies:**

1. A pregnancy may be terminated if it is not more than 12 weeks old and a medical practitioner is of the opinion that continuation of such pregnancy
   (i) May involve a serious risk to the life of pregnant woman, and would result into serious injury to the physical or mental health of the pregnant woman.
   (ii) The child to be born would be seriously handicapped due to physical or mental abnormalities.
2. A pregnancy may be terminated when the length of the pregnancy is more than 12 weeks old but not more than 20 weeks old and not less than 2 RMPs are of the same opinion as above.
3. A pregnancy of any duration may be terminated by RMP when it is of the opinion that such termination is immediately necessary to save the life of pregnant women.

c. **Other cases:** The pregnancy caused due to rape or due to failure of contraceptive device used by any married woman or her husband for the purpose of family planning.

c. Describe documentation, licenses and renewals of pharmaceutical manufacturing as per good regulators practices.

Ans: Pharma manufacturing: Pharmaceutical manufacturing is the industrial-level synthesis of pharmaceutical drugs and other products. It comes manufacturing of bulk drugs, extracts of plants formulations, etc.

Good regulatory practices is pharmaceutical manufacturing includes documentation, licenses, renewals and e-governance is explained here:

a. **Documentation:** As per the provisions of the Drugs and Cosmetic Act, and Schedule U and U (1) the following documents should be maintained.

Master records, Batch manufacturing records, Material component control records, Staff records, Adequate testing facility, Logbooks for equipment and cleaning, Distribution record of each batch, Records for return, recall, and complaints if any, Customer Validation records.

b. **Licences:**

(i) Manufacture for sale of drugs other than those specified in Schedule C, C1 and X-Form 25.

(ii) Manufacture for sale of drugs specified in Schedule X and not specified in Schedule C and C1-Form 25 F.

(iii) Manufacture of drugs specified in Schedule C, C1-Form 28 and Form 28 B for Schedule X.

c. **Renewals:** These licenses shall remain valid for a term before the expiry of a period of every succeding five years from the date of issue. If the licensee fails to do so he shall be liable to pay the licence retention fee. If there is non-payment, the licence has been cancelled.

d. Write recommendation of 'Drug Enquiry Committee'.

Ans: Drug Enquiry Committee (DEC)/Chopra Committee: Government of India appointed drug enquiry committee under the chairmanship of Col. RN Chopra in 1931. It is also known as Chopra Committee.

Recommendations of Chopra Committee

1. Central legislation to control drugs and pharmacy.
2. Setting up of testing laboratories in all the states so as to control quality of production of drugs and pharmaceuticals and also imported drugs.
3. To appoint an Advisory Board to advise the government in making rules.
4. Setting up of courses for training in pharmacy and prescribing minimum qualification as a pharmacist.
5. Registration of every patent and proprietary medicine.
6. Development of drug industries in India.
7. Steps should be taken to comply Indian pharmacopoeia.

e. State the classes of prohibited advertisements as per DMR Act, 1954. (Any three)

Ans: Classes of advertisements to which Act has been made applicable or classes of prohibited advertisements are as follows:

(i) **Advertisements of drug/drugs which may lead to its/their use for the treatment of certain diseases or disorders such as:**
   a. For the procurement of miscarriage or prevention of conception in women; or
   b. For the correction of menstrual disorders in women; or
   c. For the maintenance or improvement of the power of human beings for sexual pleasure; or
   d. For the diagnosis, cure, alleviation, treatment or prevention of any disease, disorder or condition specified in the schedule or rules made under this Act.

(ii) Advertisements of magic remedies for the treatment of certain diseases and disorders which claim to be efficacious for any of the purposes specified as above.

(iii) **Misleading advertisements relating to drugs:** The advertisements relating to drugs or drugs which:
   a. Directly or indirectly give a false impression regarding the true nature of the drug or drugs; or
   b. Make any false claims for such a drug or drugs.

(iv) **Prohibition of misleading advertisements relating to drugs:** The advertisements relating to drugs or drugs which:
   a. Directly or indirectly give a false impression regarding the true nature of the drug or drugs.
   b. Make any false claims for the drugs.
   c. It is otherwise false or misleading in any material is prohibited.

(v) **Prohibition of advertisements of magic remedies for treatment of certain diseases and disorders:** Prohibition of any advertisements related to any magic remedy which directly or indirectly claims to be efficacious for any of the purposes is prohibited.

(vi) **Prohibition of import into, and export from India of certain advertisements:** Import into and export from India of any document containing advertisements of the nature referred to in 3, 4, 5 above.

f. What are the labelling particulars required to appear on label of ophthalmic preparations?

Ans: Labelling of Ophthalmic Preparations (Schedule FF)

a. **Ophthalmic solutions and suspensions:** The following additional particulars shall be shown on the label of the container.
   (i) The statement 'use the solution within month after opening the container'.
   (ii) Name and concentration of preservative if used.
   (iii) The words 'NOT FOR INJECTION'.
   (iv) Special instructions regarding storage, wherever applicable.
   (v) A cautionary legend regarding as:
   Warning:
   a. If irritation persists or increases, discontinue the use and consult a physician.
   b. Do not touch the dropper tip or other dispensing tip on any surface since this may contaminate solutions.

b. **Ophthalmic ointments:** Special instructions regarding storage wherever is applicable.
   Warning: If irritation persists or increases, discontinue and consult the physician.

g. Define poison as per Poison Act, 1919 and name any two poisons specified in list 'A' and list 'B' each.

Ans: Poison: Poison means the substances which are notified as poisons under the Poisons Act, 1919.

For example, Aconite, Arsenic, Belladonna, Cantharides, Coca, Digitalis, Essential oils of almonds, Carbolic acid.

(i) **List A poisons:** Aconite, Aconine, Arsenic, Atropine, Belladonna, Cantharides, Chloral hydrate, Coca, Corrosive Sublimate, Potassium Cyanide, Diamorphine (Heroin), Diethyl barbituric acid, Digitalis, Ecognine, Ergot of Rye, Lead, Nux Vomica, Strychnine, Morphine, Pectrotoxine, Prussic acid, Savin and its oils, Stramonillan, Strophanthus, Stropanthin, Tartar Emetic, Tetraethyl Lead.

(ii) **List B poisons:** Essential oils of almonds (unless deprived of prussic acid), Antimonial wine, all salts of Barium except Barium sulphate, Tincture of cantharines, Carbolic acid, Chloroform, Mercuric sulphocyanide, Oxalic acid, poppies, All oxides of mercury, Sulphonal, Zinc chloride. Exemption from certain provisions of the Act is made for the poisonous substances in List B.

h. Write penalties for punishment for contravention in relation to coca plant under NDPS Act and the Rules.

Ans: Rigorous imprisonment for not less than 10 years which may extend to 20 years with a fine, not less than 1 lakh Rs. which may extend to 2 lakh Rs.

i. Define repacking of drugs and state any four conditions for grant of repacking licence.

Ans: **Repacking of drugs:** It is the process of breaking up any drug from a bulk container into small packages and the labelling of each package with a view to its sale and distribution. But it does not include the compounding, dispensing or packing of any drug in the ordinary course of retail business.

The drugs specified in Schedule C cannot be repacked.

Licences for repacking of drugs against application in Form 24-B shall be granted in Form 25-B.

Conditions for Repacking Licence

(i) The repacking operations shall be carried out under hygienic conditions and under the supervision of a competent person.

(ii) Factory premises shall comply with Schedule M requirements.

(iii) The applicant shall have a separate drug testing unit in his own premises.

(iv) The licensee shall make adequate arrangements for the storage of drugs.

(v) The licensee shall allow an inspector to enter any premises where repacking of drugs is carried out in respect to inspect the premises and to take samples.

(vi) The licensee shall test each batch or lot or raw material used by him for repacking and each batch of drug repacked and maintains records of the same as specified in Schedule U. The records should be kept for 5 years.

(vii) The licensee shall allow an inspector to inspect all registers, and records and shall supply necessary information as and when required.

(viii) The licensee shall maintain an inspection book, in Form 35.

(ix) The licensee shall maintain reference samples from each batch of the drug manufactured by him.

j. Differentiate brand name and generic name of drugs.

Ans:

Brand name	*Generic name*
1. Low-cost version of brand drugs.	1. Protected by a patent.
2. Generic drugs do not have any patent on their manufacturing and distribution.	2. Branded drugs have sole right (patent) to manufacturing and distribution for a period of time.
3. Produced by generic companies.	3. Supplied by single company.
4. No national price regulation for generic drugs.	4. Drug prices are decided by the pharmaceutical companies.
5. Generic drugs are cheaper than branded drugs.	5. Branded drugs are more costly than generic drugs.
6. Look different from relevant brand name drug.	6. Unique look as design during product development.
7. Example: Paracetamol.	7. Example: Tylenol, NAPA, Calpol, Dexamol, Dolex, Acamol, Febridol.

k. What are the functions of the National Council for Clinical Establishments?

Ans. Functions of National Council for Clinical Establishments

(i) Publishing the National Register of Clinical Institutions.
(ii) Sort clinic locations into distinct categories.
(iii) Improving lower standards and conducting periodic reviews.
(iv) Establishing the first set of standards for ensuring proper health care by clinical facilities within two years of its establishment.
(v) Collecting statistics at treatment centres.
(vi) Performing any other duties assigned by the Central Government.

Q.3. Attempt ALL questions of the following: 20 Marks

a. Define 'chemist and druggist'.

Ans: Chemist and druggist: It is a licensed premise for the sale of drug which requires services of "Qualified Person" but where drugs are not compounded against prescription.

b. Clandestine arrangements as per code of pharmaceutical ethics means _____

(i) Secret agreements
(ii) Pharmacist may render first aid to victim

(iii) Link between medical profession and public
(iv) All of the above

Ans: (i) Secret agreements

c. CPCSEA stands for Committee for the Purpose of Control and Supervision of Experiments on Animals.

d. What does Schedule G to the rules prescribe?

Ans: Schedule G prescribes list of drugs which are required to be taken only under the supervision of Registered Medical Practitioner.

OR

It is dangerous to take this preparation except under the supervision of medical practitioner.

e. Give the function of food authority.

Ans: Function of Food Authority

1. To laydown science based standards for food articles.
2. To regulate manufacture, storage, distribution, sale and import of food articles.
3. To ensure availability of safe and wholesome food for human consumption.

f. What is the objective of DPCO? (Any two)

Ans: Objective of DPCO

1. To ensure that necessary and life-saving medications are available at fair prices without compromising quality.
2. To promote rational use of medications.
3. To encourage cost-effective production of drugs.
4. To offer list of prices of controlled drugs.
5. To provide process of price fixation of scheduled and non-scheduled formulations.
6. To regulate equitable distribution of bulk drugs and to make the drugs available at fair prices from different manufacturers.
7. To fix the maximum retail price of the formulation.
8. To fix the maximum sale price of bulk drugs.

g. Name of local body which allows experiments on small animals?

(i) CPCSEA (ii) IAEC
(iii) IACE (iv) IECC

Ans: (ii) IAEC

h. Medical Termination of Pregnancy Act was passed in 1971.

i. For production from basic stage post tax return of _____ on net worth is considered.

(i) 10% (ii) 20%
(iii) 8% (iv) 18%

Ans: (iv) 18%

j. Give two examples of Schedule J.

Ans: Appendicitis, arteriosclerosis, blood poisoning, blindness, cancer, diabetes, optical system/nervous system/disorders, epilepsy, fever, glaucoma, goiter, leprosy, small pox, trachoma, typhoid fever, etc. or any other examples of diseases falling under Schedule J will be considered.

k. State the principles of bioethics.

Ans:
1. Principle of autonomy
2. Principle of beneficence
3. Principle of non-maleficence
4. Principle of justice

l. Mention different classes of medical devices.

Ans:
1. Class A (Low risk devices)
2. Class B (Low to moderate risk devices)
3. Class C (Moderate to high risk devices)
4. Class D (High risk devices)

m. GRP stands for Good Regulatory Practices.

n. National Institute of Disaster Management authority comes under _____.

(i) Ministry of Home Affairs
(ii) Ministry of Environment
(iii) Ministry of Pollution
(iv) Ministry of Foreign Affairs

Ans: (i) Ministry of Home Affairs

o. Who is the head of Central Authority's Investigation wing?

(i) Police Inspector (ii) Director-General
(iii) Magistrate (iv) Police Commissioner

Ans: (i) Director-General

p. ICMR stands for Indian Council of Medical Research.

q. Who is the head of Central Drugs Standard Control Organization (CDSCO)?

Ans: Directorate-General of Health Services, Ministry of Health and Family Welfare, Government of India.

r. Human anatomical waste is categorised in which colour bag as per Biomedical Waste Management Act?

Ans: Yellow coloured non-chlorinated plastic bags.

s. Minimum haemoglobin requires to donate blood is not less than 12.5 grams.

t. Define bioethics.

Ans: Bioethics is the study of the ethical, social and legal issues that arise in biomedicine and biological sciences.

OR

The discipline dealing with the ethical implications of biological research and applications especially in medicine.

Winter Examination 2024 (Question Paper)
Second Year Diploma in Pharmacy
Subject: Pharmacy Law and Ethics (20226)

Time: 3 Hours **Max Marks: 80**

Q.1. Attempt any SIX of the following: **30 Marks**

a. List ex-officio members and describe the functions of the Pharmacy Council of India.
b. Give objective of D&C Act, 1940 and give constitution of DTAB.
c. Define:
   (i) Misbranded drug and
   (ii) Adulterated drug as per D&C Act, 1940
d. What does following schedule contains as per Drugs and Cosmetic Act, 1940:
   (i) Schedule A (ii) Schedule G
   (iii) Schedule H (iv) Schedule N
   (v) Schedule R
e. Define 'bulk drug' as per DPCO and how the retail price of a formulation is calculated?
f. Explain the code of ethics by the PCI for the pharmacist in relation to his job.
g. Describe the phases of clinical trials.

Q.2. Attempt any TEN of the following: **30 Marks**

a. Describe the recommendations of the drug enquiry committee.
b. State the classes of drugs prohibited to import as per D&C Act, 1940.
c. Give functions of CDL as per D&C Act, 1940. (Any 6)
d. Write the qualification required to appoint a government analyst as per D&C Act, 1940.
e. Define opium. Addict and coca leaf as per NDPS Act, 1985.
f. Define magic remedies. State the objectives of Drugs and Magic Remedies Act, 1954.
g. State the various rules prescribed by State Government for possession, possession for sale and for sale of poisonous substances under Poison Act, 1919.

h. Write any three bonafied reasons for termination of pregnancy under MTP Act, 1971.
i. Discuss the documentation and license required for community pharmacy as per good regulatory practices.
j. Give difference between brand name drug and generic drug.
k. Explain the constitution of the national council for clinical establishments.

Q.3. Attempt ALL questions of the following: 20 Marks

a. DTAB has _____ ex-officio members.
b. Examples of schedule 'X' except:
   (i) Analgin
   (ii) Amobarbital
   (iii) Pentobarbital
   (iv) Cyclobarbital
c. Indian veterinary research institute is situated at _____.
d. CPCSEA stands for _____.
e. According to 'Prevention of Cruelty to Animal Act', 'Animal' means any living creature other than _____.
f. State any two important things should appear on the label of food supplements as per FSSAI.
g. What does schedule I prescribe as per DPCO?
h. State any two examples of drug added to the list of NLEM 2021.
i. Hawking of drugs is a part of ethics related to _____.
   (i) Pharmacist in relation to his job
   (ii) Pharmacist in relation to his trade
   (iii) Pharmacist in relation to medical profession
   (iv) Pharmacist in relation to his own profession
j. MTP Act was passed in year _____.
k. Role of CDSCO except _____.
   (i) Responsible for approval of new drug
   (ii) Conduct of clinical trials
   (iii) Amendments of D&C Act and Rules
   (iv) Publish Indian Pharmacopoeia
l. Write the full form of CDER with respect to pharmacy profession.
m. State the function of blood bank.
n. Human anatomical waste is discarded in which category as per biomedical waste management schedule.

o. What is the long form of ICMR?
p. What are the common bioethical issues?
   (i) Eugenics
   (ii) Euthanasia
   (iii) Organ donation
   (iv) All of these
q. State the name of bioethical principle.
r. The Consumer Protection Act was initiated in India in year _____.
s. National Institute of Disaster Management authority comes under:
   (i) Ministry of Home Affairs
   (ii) Ministry of Environment
   (iii) Ministry of Pollution
   (iv) Ministry of Foreign Affairs
t. Give two examples of medical device.

Winter Examination 2024 (Specimen Answer Paper)
Second Year Diploma in Pharmacy
Subject: Pharmacy Law and Ethics (20226)

Time: 3 Hours **Max Marks: 80**

Q.1. Attempt any SIX of the following: **30 Marks**

[*Refer Specimen Answer Papers of Summer 2023, winter 2023, Summer 2024 Examinations and Answers from this book for the Question 1 (a), (b), (c), (d), (e), (f), (g)]

Q.2. Attempt any TEN of the following: **30 Marks**

[*Refer Specimen Answers Paper of Summer 2023, Winter 2023, Summer 2024 Examinations and Answers from this book for the Question 2 (a), (b), (c), (d), (e), (f), (g), (h), (i), (j), (k)]

Q.3. Attempt ALL questions of the following: **20 Marks**

a. DTAB has Eight (8) **ex-officio members.**

b. Examples of schedule 'X' except:

(i) Analgin
(ii) Amobarbital
(iii) Pentobarbital
(iv) Cyclobarbital

Ans: (i) Analgin

c. Indian veterinary research institute is situated at Izzatnagar.

d. CPCSEA stands for Committee for the Purpose of Control and Supervision of Experiments on Animals.

e. According to 'Prevention of Cruelty to Animal Act', 'Animal' means any living creature other than Human Beings.

f. State any two important things should appear on the label of food supplements as per FSSAI.

Ans: 1. Nutritional content, Quantity of active ingredient.
2. FSSAI Logo.

g. What does schedule I prescribe as per DPCO?

Ans: Schedule I prescribes the list of bulk drugs required for the National Health Program such as National Tuberculosis Eradication Program, National Leprosy Eradication Program, National Malaria Eradication Program, etc.

h. State any two examples of drug added to the list of NLEM 2021.

Ans: **Antibiotics:** Amikacin, Cefuroxime, Meropenem
Anticancer: Azacitidine, Lenalidomide, Leuprolide acetate
Anti-TB: Badaquiline
Opioid Antagonists: Buprenorphine
Anticoagulant: Dabigatran
Anti-viral: Declatasvir
Endocrine disorders: Fludrocortisone, Ormeloxifene
Anti-diabetic: Insulin, Glargine
Anti-infectives: Ivermectin, Mupirocin

i. Hawking of drugs is a part of ethics related to _____.

(i) Pharmacist in relation to his job.
(ii) Pharmacist in relation to his trade.
(iii) Pharmacist in relation to medical profession.
(iv) Pharmacist in relation to his own profession.

Ans: (ii) Pharmacist in relation to his trade.

j. MTP Act was passed in year 1971.

k. Role of CDSCO except _____.

(i) Responsible for approval of new drug
(ii) Conduct of clinical trials
(iii) Amendments of D&C Act and Rules
(iv) Publish Indian Pharmacopoeia

Ans: (iv) Publish Indian Pharmacopoeia

l. Write the full form of CDER with respect to pharmacy profession.

Ans: Center for Drug Evaluation and Research

m. State the function of blood bank.

Ans: Blood collection and storage before its use for transfusion.

n. Human anatomical waste is discarded in which category as per biomedical waste management schedule.

Ans: Yellow waste

o. What is the long form of ICMR?

Ans: Indian Council of Medical Research.

p. What are the common bioethical issues?

(i) Eugenics (ii) Euthanasia
(iii) Organ donation (iv) All of these

Ans: (iv) All of these

q. State the name of bioethical principle.

Ans: Principle of autonomy
Principle of beneficence
Principle of non-maleficence
Principle of justice

r. The Consumer Protection Act was initiated in India in year 1986.

s. National Institute of Disaster Management authority comes under:

(i) Ministry of Home Affairs
(ii) Ministry of Environment
(iii) Ministry of Pollution
(iv) Ministry of Foreign Affairs

Ans: (i) Ministry of Home Affairs

t. Give two examples of medical device.

Ans: Electric toothbrush, tongue depressor, oxygen mask, reusable surgical scalpel, bandages, handheld surgical instruments, hospital beds, and nonelectric wheelchairs, catheters, blood pressure cuffs, pregnancy test kits, syringes, blood transfusion kits, contact lenses, surgical gloves, absorbable suture, breast implants, pacemakers, defibrillators, high-frequency ventilators, cochlear implants, fetal blood sampling monitors, implanted prosthetics, infusion pumps, surgical lasers, implantable pacemakers and breast implants, etc.

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Pharmacy Law and Ethics

for Second Year Diploma in Pharmacy

Course Code: ER20-26T

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