Pharma Unit

Pharmacy Law & Ethics

Top 25 Most Important Questions with Answers

According to New Syllabus ER 2020-21

2nd Year D. Pharmacy

1) What is Pharmacy Council of India? Explain its functions and constitution?

Ans.

Pharmacy Council of India: 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 Pharmacy Council of India (PCI): The council comprises individuals elected, nominated, and ex-officio positions.

A. Elected Members:
- Six individuals elected by the University Grants Commission (UGC) from the teaching staff of universities or affiliated colleges granting degrees or diplomas in pharmacy. This includes one representative each from the fields of pharmacy, pharmaceutical chemistry, pharmacognosy, and pharmacology.
- Additionally, one person is elected by the Medical Council of India from its membership.
- Each state pharmacy council elects one registered pharmacist from its members.

B. Nominated Members:
- Six individuals nominated by the central government, with a mandate for at least four to possess a degree or diploma in pharmacy or be actively engaged in the practice of pharmacy or pharmaceutical chemistry.
- Each state government nominates one registered pharmacist.
- Representation from the University Grants Commission (UGC) and All India Council for Technical Education (AICTE) includes one nominee.

C. Ex-officio Members:
- The Director General of Health Services.
- The Drugs Controller of India.
- The Director of Central Drug Laboratory.

Functions of PCI/Central Council:
- Establishing minimum education standards for pharmacist qualification.
- Designing the curriculum for pharmacy education.
- Regulating minimum educational benchmarks.
- Maintaining a central register of pharmacists.
- Defining roles and responsibilities of council members, including the president, vice-president, and secretary.

- Determining remuneration rates and allowances for council members.
- Drafting education regulations.
- Conducting institution inspections through appointed inspectors.
- Granting approval to institutions offering pharmacy courses.
- Undertaking any additional functions delegated by the central government.

2) Explain in detail about education regulation?

Ans.

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:

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

3) Write a note on drug technical advisory board?

Ans.

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

- The Director General of Health Services (Chairman).
- The Drugs Controller of India.
- The Director, Central Drug Laboratory (Kolkata).
- The Director, Central Research Institute, Kasauli.
- The Director, Central Drug Research Institute, Lucknow.
- The Director, Indian Veterinary Research Institute, Izatnagar.
- The President, Pharmacy Council of India.
- The President, Medical Council of India.

Functions of DTAB

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

4) Write a note on drug inspector?

Ans.

Definition:

- In relation to Ayurvedic, Siddha or Unani drugs, an inspector appointed by central or state government under Section 33 G of the Act.
- In relation to other drugs and cosmetics, an inspector appointed by central or state government under Section 21 of the Act.

Qualifications:

1. Must hold a graduate degree in pharmacy, pharmaceutical sciences, or medicine with specialization in clinical pharmacology or microbiology from a recognized university.
2. For inspecting premises licensed for Schedule 'C' drugs:

- Minimum 18 months experience in manufacturing Schedule 'C' substances.
- Minimum 18 months experience in testing Schedule 'C' substances in an approved laboratory.
- Minimum 3 years experience in inspecting firms licensed for manufacturing Schedule 'C' drugs.

Powers of Drug Inspector:

- Inspection: Check the premises licensed for drug sale. Check the premises licensed for drug manufacture.
- Sampling: Can take samples of manufactured, sold, exhibited, or distributed drugs or cosmetics.
- Search: Can search any person related to an offense at reasonable times.
- Entry and Search: Can enter and search premises where offenses are suspected.
- Stop and Search: Can stop and search vehicles suspected of carrying illegal drugs or cosmetics.
- Issuing Orders: Can order the possession holder of offending drugs or cosmetics not to dispose of stock for up to 20 days.
- Examination: Can examine registers, records, or documents mandated by the Act.

Duties of Drug Inspector:

A. Duties Related to Sale of Drugs:

a) Inspection: Inspect drug sale premises at least twice a year.
b) Sampling: Take samples of drugs or cosmetics for testing.
c) Investigation: Investigate written complaints.
d) Documentation: Examine required registers and records.
e) Prosecution: Institute prosecution for Act and rule breaches.
f) Reporting: Submit detailed inspection reports and actions to the controlling authority.

B. Duties Related to Manufacture of Drugs and Cosmetics:

a) Inspection: Inspect manufacturing premises at least twice a year.
b) Observation: Observe manufacturing processes, standardization means, testing, storage, technical staff qualifications, and facility conditions affecting product potency.
c) Sampling: Take samples of drugs or cosmetics for testing.
d) Investigation: Investigate written complaints.
e) Documentation: Examine required registers and records.
f) Prosecution: Institute prosecution for Act and rule breaches.
g) Reporting: Submit detailed inspection reports and actions to the controlling authority.

5) Write a note on state pharmacy council?

Ans.

Definition: 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:

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

Constitution:

a) Six members, elected from amongst themselves by registered pharmacists of the State.
b) Five members, of whom at least three shall be persons possessing a prescribed degree or diploma in pharmacy or pharmaceutical chemistry or registered pharmacists.
c) One member elected from amongst themselves by the members of each Medical Council or the Council of Medical Registration of the State.
d) Ex-officio members
   - The chief administrative medical officer of the State.
   - The officer-in-charge of drugs control organization of the State.
   - The Government Analyst.

6) Write a note on central drug laboratory?

Ans.

Definition: The Central Drugs Laboratory, Kolkata is the nation statutory laboratory of the Government of India for Quality control of Drugs and Cosmetics and is established under the Indian Drugs & Cosmetic Act, 1940. It is the oldest quality control laboratory of the Drugs Controls Authorities in India.

Functions:

- To analyse or test the samples of drugs or cosmetics sent to it by the court or custom collectors or any other authorized officer.
- To carry out such other functions as may be entrusted to it by the central government or state government after consultation with DTAB.
- 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.
- 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.
- 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.

7) Write a note on FSSAI?

Ans.

Definition: FSSAI is 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: 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

- Laying down procedures and guidelines for accreditation of laboratories and notification of the accredited laboratories.
- 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.
- Collect and analyse the data regarding food consumption, incidence and prevalence of biological risk, contaminants in food and food products.
- 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. Provide training programs for persons who are involved or intended to get involved in food businesses.
- Contribute to the development of international technical standards for food, sanitary standards.
- Promote general awareness about food safety and food standards.

8) Explain prevention of cruelty to animal act 1960?

Ans.

Introduction: 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 like 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.

Objectives:

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

Functions

- 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.
- To suggest the government any improvement in the design of the vehicle to lessen the burden on draught animals.
- 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.
- To take the steps for the amelioration of animals by providing facilities like shades, water, troughs, etc. along with veterinary assistance.
- To encourage the animals welfare associations by providing financial assistance or forming rescue homes, shelter to the old animals and birds.
- To advise the government on medical care and attention to be provided in animal hospitals.
- To cooperate with the various associations established to prevent the infliction of unnecessary pains or sufferings to the animals.
- To impart the education relating to the handling of animals by human beings by means of lectures, books, posters, etc.
- To advise the government on any other such matters relating to animal welfare.

9) Write a note on pharmacist oath?

Ans.

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 in violated, 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.

10) What is code of pharmaceutical ethics? Describe the code of ethics for pharmacist in relation to his profession?

Ans.

Definition: The code of pharmaceutical ethics is formulated by PCI for the guidance of Indian pharmacist. The code of pharmaceutical ethics helps to guide the pharmacist as to how he should conduct himself in relation to His job, His trade, His fellow pharmacist, His physician, With medical profession, With his profession (pharmacy), With public.

Code of ethics for pharmacist in relation to his profession:

- 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.

11) What is medical termination of pregnancy act and rule? What are the provisions under which RMP may terminate the pregnancies of women?

Ans.

Definition: 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.

Objectives:

- 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.

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

- Those who are 18 years of age or more with their written consent.
- Those who are less than 18 years of age or more than 18 years but are lunatic, with the written consent of their guardians.
- 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.
- 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.
- If pregnancy is caused because of rape can be terminated by RMP as per provisions.
- 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.
- The pregnancy of any duration may be terminated by RMP, if it is immediately necessary to save the life of a pregnant woman.

12) Discuss the significance of clinical trials in drug development and describe various phase of clinical trials?

Ans.

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

Importance or Significance of Clinical Trials:

- Important for discovering new treatments for diseases.
- Important for new ways to detect, diagnose and reduce the chance of developing the disease.
- Clinical trials benefit the participants as well as the investigators, the sponsors, and the medical community.
- Clinical trials provide a scientific basis for advising and treating patients.
- Clinical trials help to determine the most effective dosages, and best method delivery.
- Clinical trial is a research study that tests a new medical treatment or a new way of using an existing treatment.

Phases of Clinical Trials:

a) 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.
b) 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.
c) 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 labelling.
d) 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.

13) What is CDSCO? Write its objective and function?

Ans.

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

Objectives:

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

Functions:

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

14) Write offences and penalties under Drug and cosmetics act 1940?

Ans.

Penalty for the use of government analyst report for advertising: Anyone 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.

Penalty for nondisclosure of the name of manufacturer: Anyone 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.

Offences and penalty for manufacture for sale or for distribution of stocks or exhibits for sale or offers for sale or distribution of cosmetics:

- Any spurious cosmetics shall be punishable with imprisonment up to 3 years and with fine.
- 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.

15) Describe offences and penalties under pharmacy act 1948?

Ans.

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. 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.

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.

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.

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/-.

16) Define magic remedy? write objectives, and prohibition of certain advertisement as per magic and remedies act 1954?

Ans.

Definition: 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.

Objectives

- This Act is passed to control and prohibit the advertisements related to drugs and magic remedies which make false claim and mislead the public.
- This Act covers all the advertisements which are objectionable and unethical, and which are used to promote self-medication and self-treatment.

Classes of advertisements are prohibited under the Act:

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

B. Advertisements relating to drug,
   1. Which directly or indirectly give false impression regarding true character of the drug.
   2. Make false claim for it.
   3. Are otherwise false and deceptive.

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

17) Write objectives, offences and penalties of narcotic drugs and psychotropic substance act 1985?

Ans.

Objectives:

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

Offences & Penalties:

A. Offences:

- Operations relating to poppy straw.
- Cultivating coca plant and gathering its portion.
- Operations relating to prepared opium.
- Operations relating to opium poppy and opium.
- Operation relating to cannabis plant except Ganja.

Penalties

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

B. Offences:

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

Penalties

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

C. 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:

- Imprisonment up to 1 year or fine or both where narcotic drugs or psychotropic substances consumed is— cocaine, morphine, heroin, etc.
- Imprisonment up to 6 months or fine or both where narcotic drugs or psychotropic substances consumed is other than above.

18) Discuss in detail good drug regulatory practice?

Ans.

Definition: 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:

- Government frames regulatory requirements for health and safety of goods and services, including imports.
- Regulations stipulated through various Acts/Rules by different ministries.
- Enactment considers relevant WTO Agreements.

Key Considerations of Regulatory Requirements:

- Minimum required regulatory measures.
- Minimum compliance cost.
- Benefit society.
- Compliance with national laws.
- Transparent making and enforcement.
- Fair treatment for all.
- Clear and simple language in drafting.
- Flexible for amendments/revisions.

Principles of Good Regulatory Practices (GRPs):

- Legality: Regulations must have a sound legal basis.
- Consistency: Consistent with government policies and legislation.
- Independence: Institutions implementing regulations should be independent.
- Proportionality: Regulation proportional to risk and capacity to enforce.
- Flexibility: Responsive to changing circumstances, especially in emergencies.
- Clarity: Requirements should be assessable and understood.
- Efficiency: Goals achieved within required time and reasonable effort.
- Transparency: System and decisions should be transparent.
- Impartiality: All regulated parties treated equitably and fairly.

19) Write a note on IPC?

Ans.

Definition: 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.

Aims and Objectives of IPC:

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

Functions of IPC:

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

20) Write in detail about biomedical waste management?

Ans.

Definition: 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.

Benefits:

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

Methods of Disposal of Biomedical Wastes:

a) Incineration: Waste is burned at high temperatures to turn it into inert material and gases. Incinerators can be powered by oil, fire, electricity, or a combination.
b) Non-Incineration: Utilizes thermal, chemical, irradiative, or biological processes to decontaminate waste and destroy pathogens.
c) Autoclaving: Waste is sterilized using steam at high temperatures, suitable for microbiology and biotechnology waste, sharps, and solid waste.
d) Microwave Irradiation: High-frequency waves generate heat within waste, killing pathogens.
e) Chemical Disinfection: Utilizes a 1% hypochlorite solution for disinfection.
f) Plasma Pyrolysis: Advanced technology that converts organic waste into useful byproducts through intense heat generated by plasma, ensuring safe disposal of medical waste.

21) Write a note on medical devices?

Ans.

Definition: 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 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.

Applications of Medical Devices:

- Medical devices have extended the ability of physician to diagnose and treat diseases making great contribution to health and quality of life.
- Like medicines and other health technologies they are essential for patient care, at the large, specialized hospitals.
- Medical devices are considered as a fundamental component of health system.
- Medical devices are essential to prevent, diagnose, treat and rehabilitate illnesses and diseases in a safe and effective way.

22) Explain intellectual property right?

Ans.

Definition: 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:

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

Importance of IPR:

- To provide exclusive rights and to protect the interest of the creator and encourage investment in research and information creation.
- It is a right which gives monopoly of any intellectual creation of mind.
- It is a combination of science and technology both.
- It is given for new creation such as composition of music, writing a book, invention.
- It has a significant influence on economic progress.
- It gives recognition to the efforts employed by the person, firms, or organization.
- It promotes further inventions and research activities.

23) What is blood bank? Give its objectives, and function?

Ans.

Definition: A blood bank stores blood or its components from donations for later transfusions. Charles Richard Drew pioneered blood banking.

Objectives:

1) Collect, process, and store blood for medical use.
2) Ensure donated blood is safe for transfusions.
3) Save lives by providing blood.
4) Separate blood components for specific patient needs.
5) Identify patients and blood products during transfusions.
6) Connect blood banks, volunteers, donors, and patients.

Functions:

1) Collect, process, and store blood for medical purposes.
2) Provide quick service for urgent blood requests.
3) Check pre-transfusion samples and requests.
4) Ensure compatibility between donors and patients.
5) Choose suitable blood components for each condition.
6) Match blood groups.
7) Safely handle blood components.
8) Provide blood components for transfusion.
9) Integral part of hospitals, managing donor registration to storage.

24) Write about requirement to set up a blood bank?

Ans.

General Requirements for Blood Banks:

1) Blood banks must have their own rules defining management roles.
2) They need a qualified physician overseeing medical, technical, and administrative aspects.
3) Licensed by State Drug Controller and approved by Drugs Controller General (India).
4) Must adhere to Drugs and Cosmetics Rules for donor recruitment, collection, processing, and distribution.
5) Maintain a quality policy and manual.
6) Keep detailed standard operating procedures and records.
7) Staffing must meet regulatory standards.
8) Ensure adequate space, environment, and equipment for safety.
9) Maintain equipment calibration and validation records.
10) Use sterile, pyrogen-free, disposable materials stored in a controlled environment.
11) Containers and preservatives must meet regulatory and quality standards.
12) Implement and maintain a quality assurance system.

25) Explain poison act 1919?

Ans.

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

Possession and Sale of Poison: The rule made by state government.

- Granting licenses for wholesale or retail possession of specified poisons.
- Setting license fees.
- Defining who can get licenses.
- Specifying who poisons can be sold to.
- Limiting the quantity sold to one person.
- Mandating sales register maintenance and inspections.
- Ensuring safe storage and labelling of poisons.
- Inspection by government-appointed inspectors.

Offences & Penalties:

- 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.
- 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.
- 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.

Notes:

1) Please Read All the Topics & All the Chapters of Pharmacy Law & Ethics Very Carefully.
2) This Pdf Notes/Questions & Answers Are Only for Reference Purpose.