Sample Paper

PHARMACY LAW AND ETHICS

D. PHARMA 2nd YEAR

TIME 03:00 HOURS **MAXIMUM MARKS: 80**

PART - A

I. Long Answers (Answer 6 out of 7) **6 x 5 = 30**

1. Narcotic Drugs and psychotropic substances Act 1985- Definition, objectives, authorities and officers, control and regulation, offences and penalties.
2. National Pharmaceutical Pricing Authority: Drugs Price Control Order (DPCO) - 2013. Objectives, Definitions, Sale prices of bulk drugs, Retail price of formulations and celling price.
3. Define the terminology (any five).
    A. Drugs Technical Advisory Board
    B. Central Drugs Laboratory.
    C. Drugs Consultative Committee
    D. Licensing authorities.
    E. Controlling authorities.
    F. Drug Inspectors.
4. Explain in detail about sale of drug (Definition, types, license criteria, illegal action). 1. Wholesale 2. Retail sale.
5. Explain the Code of Pharmaceutical Ethics: Definition, ethical principles regarding registration process of pharmacists and their relation to his job, trade, medical profession.
6. Explain the detail about the PCI (Pharmacy Council of India), its constitution, functions and different education regulation.
7. Write short notes on schedule C, C1, G, H, H1,K , M, N, X, Y with example.

II. Short Answers (Answer 10 out of 11) **10 x 3 = 30**

1. Explain the methods of testing, examination and analysis during drug manufacturing.
2. List out Drugs Prohibited for manufacture and sale in India.

3. Define the 'Import of the drugs' and specify the Classes of drugs and cosmetics prohibited from import and legal for import.
4. Medicinal and Toilet Preparations Act 1955: Objectives, Definitions, Licensing, Offences and Penalties.
5. Define the terminology (any three)
    a. Medical devices.
    b. Consumer protection Act (CPA)
    c. Bioethics.
    d. Blood bank.
6. Briefly explain about Biomedical Waste Management Rules 2016.
7. Why the laws are required in the Drugs and Pharmacy profession and enumerate it?
8. Give the information about Drugs and Magic Remedies and their Offences and Penalties.
9. Objectives of Drugs and Cosmetics Act 1940 and Rules 1945.
10. Salient features of Medical Termination of Pregnancy Act and Rules.
11. Define the terminology (any three).
    a. Central Drugs Standards Control Organization (CDSCO).
    b. Indian Pharmacopoeia Commission (IPC).
    c. Good regulatory practices (GRP).
    d. FSSAI (Food Safety and Standards Authority of India).

III. Objective type Answers (Answer all 20) **20 x 1 = 20**

1. Which of the following is not a condition for obtaining a retail drug license in India?
    a. The premises should be owned by the applicant
    b. The applicant should have a diploma in pharmacy
    c. The applicant should have adequate space for storage
    d. The applicant should have a qualified registered pharmacist
2. The Drugs and Cosmetics Act, 1940, requires that all drugs sold in India be labelled, which of the following?
    a. Batch number and expiry date
    b. Manufacturer's name and address
    c. Maximum retail price (MRP)
    d. All of the above
3. Which of the following is not a requirement for obtaining a wholesale drug license in India?
    a. Possession of a retail drug license

b. Approval of the premises for storage and distribution
c. Availability of qualified technical staff
d. Possession of a valid patent for the drugs sold

4. Which of the following is not a basic principle of medical ethics?
    a. Beneficence
    b. Non-maleficence
    c. Autonomy
    d. Loyalty
5. What is the name of the professional organization that represents pharmacists in the United States?
    a. American Medical Association (AMA)
    b. American Pharmacists Association (APhA)
    c. National Community Pharmacists Association (NCPA)
    d. American Society of Health-System Pharmacists (ASHP)
6. According to the Pharmacy Act 1948, which of the following is a requirement to practice as a pharmacist in India?
    a. A valid registration certificate issued by the PCI.
    b. A diploma in pharmacy from a recognized institution
    c. At least 18 years of age
    d. All of the above
7. Which of the following is a power of the State Pharmacy Councils under the Pharmacy Act 1948?
    a. To inspect pharmacy institutions
    b. To suspend or cancel a pharmacist's registration
    c. To recommend the minimum standards of pharmacy education
    d. All of the above
8. Which of the following is the main objective of the Pharmacy Council of India?
    a. To promote the education and training of pharmacists
    b. To regulate the practice of pharmacy in India
    c. To promote research and development in the pharmaceutical field
    d. All of the above
9. What is the term of office for the President of the Pharmacy Council of India?
    a. 1 year
    b. 2 years
    c. 3 years
    d. 4 years

10. What is the purpose of the Ethics Committee of the Pharmacy Council of India?
    a. To promote the ethical practice of pharmacy in India
    b. To regulate the prices of pharmaceuticals in India
    c. To conduct inspections of pharmaceutical manufacturing facilities in India
    d. None of the above
11. Which of the following is NOT a function of FSSAI?
    a. To set standards for food and supplements
    b. To regulate the manufacture, storage, sale, and labeling of food and supplements
    c. To conduct research on food and supplements
    d. To issue passports to food and supplement manufacturers

12. What is the main objective of NPPA?
    a. To ensure availability of essential medicines at affordable prices
    b. To regulate the import and export of pharmaceuticals
    c. To promote the use of traditional medicines
    d. None of the above
13. What is the retail price of a formulation?
    a. The price at which a bulk drug is sold to pharmacies
    b. The price at which a finished drug product is sold to patients
    c. The price at which a formulation is sold to hospitals and clinics
    d. The price at which a manufacturer sells its products to wholesale
14. What is the ceiling price of a scheduled formulation?
    a. The maximum price at which a formulation can be sold to patients
    b. The maximum price at which a bulk drug can be sold to pharmacies
    c. The price at which a formulation is sold to hospitals and clinics
    d. The price at which a manufacturer sells its products to wholesalers
15. Which agency is responsible for regulating the distribution of narcotic and psychotropic substances?
    a. The Drug Enforcement Administration (DEA)
    b. The Food and Drug Administration (FDA)
    c. The National Institute on Drug Abuse (NIDA)
    d. The Centres for Disease Control and Prevention (CDC)
16. What is an automated drug dispensing system (ADDS)?
    a. A machine that dispenses food
    b. A system that dispenses medications automatically
    c. A device that tracks patients' health status

d. A tool that monitors medication side effects

17. What is the purpose of licenses in Good Regulatory Practices?
    a. To ensure only qualified personnel are handling drugs and medical devices
    b. To increase the cost of drugs and medical devices
    c. To restrict the availability of drugs and medical devices
    d. To promote the use of generic drugs and medical devices
18. What is the difference between a brand name and a generic name for a drug?
    a. Brand names are longer and more complex than generic names
    b. Brand names are only used in the US, while generic names are used worldwide
    c. Brand names are given by the manufacturer, while generic names are standardized
    d. There is no difference, they refer to the same thing
19. What is the purpose of the BCS system?
    a. To classify drugs based on their therapeutic effect
    b. To classify drugs based on their chemical structure
    c. To predict the pharmacokinetic behaviour of drugs
    d. To regulate the marketing of drugs
20. Under the Poisons Act-1919, which of the following is considered an offence?
    a. Selling or supplying a poison without a license
    b. Possessing a poison without a license
    c. Importing a poison without a license
    d. All of the above

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