Pharmacy Law and Ethics Important Questions

D.Pharma 2nd year

Syllabus & Questions

Pharmacy Law and Ethics D.Pharma 2nd Year Important Questions Chapter wise

Chapter-1

General Principals of Law, History and various Acts related to Drugs and Pharmacy profession

Questions:

- Define the term law and ethics.
- Which place chemist shop open first time.
- What are the acts related to pharmacy in India?

Chapter-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.

Questions:

- What are the objectives and functions of Pharmacy Act 1948?
- What is the Pharmacy Council of India with its function and constitution?
- Define any four
    a) Registered Pharmacist
    b) Central council

c) Executive committee
d) Medicinal practitioner
e) Repatriates

- Give the Constitution of Joint state pharmacy council.
- Write the details note on Pharmacy Council of India.
- Write a details note on registration of Pharmacist.
- What is the education regulation of pharmacist?

Chapter-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 – 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. 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, X and Y.
- 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.

Questions:

- What are the objectives of drug and cosmetic Act 1940 and Rules 1945?
- Define loan license?
- What is repacking license?
- What is the study of Schedule C and C1?
- What is schedule K?
- What is schedule H drug used?
- Write a note on Drugs Technical Advisory Board (DTAB) Drug Consultative Committee (DCC) Central Drug Laboratory.
- Write the details note on Drugs Inspector.

Chapter-4

Medicinal and Toilet Preparations Act 1955: Objectives, Definitions, Licensing, Offences and Penalties

Questions:

- What are medicinal preparations?
- What is the objective of the medicinal and toilet preparations act 1955?
- What are the Offences and penalties of medicinal and Toilet Preparation Act?

Chapter-5

Narcotic Drugs and psychotropic substances Act 1985 and Rules Objectives, Definitions, Authorities and Officers, Prohibition, Control and Regulation, Offences and Penalties.

Questions:

- What are the objectives of Narcotic Drugs and Psychotropic Substances Act, 1985 and rules?
- What is the Authority and Officers under Narcotic Drugs and Psychotropic Substance Act 1985?
- Describe the Prohibition, Control and Regulation of NDPS
- Give the Offences and Penalties under NDPS Act 1985.

Chapter-6

Drugs and Magic Remedies (Objectionable Advertisements) Act 1954 Objectives, Definitions, Prohibition of certain advertisements, Classes of Exempted advertisements, Offences and Penalties.

Question:

- What are the objectives of drug and Magic Remedies Act 1954?
- What is a drug and remedy?
- Define advertisements and magic remedies.
- Give the Classes of advertisements which are prohibited under the Drugs and Magical Remedies Act 1954.
- Give the Offences and Penalties under Drugs and Magical Remedies Act 1954.

Chapter-7

Prevention of cruelty to Animals Act-1960:

Objectives, Definitions, CPCSEA – brief overview, Institutional Animal Ethics Committee, Breeding and Stocking of Animals, Performance of Experiments, Transfer

and Acquisition of animals for experiment, Records, Power to suspend or revoke registration, Offences and Penalties.

Questions:

- What are the rules of PETA?
- What are the main objectives of the Prevention of Cruelty to Animals Act-1960?
- What are the offences and penalties of Prevention of Cruelty to Animals Act-1960?
- Define Experiment.
- What is the main object of Institutional Animals Ethics (IAE) committee.
- What is Breeding and Stocking of Animals.

Chapter-8

Poisons Act-1919:

Poisons Act-1919: Introduction, objective, definition, possession, possession for sales and sale of any poison, import of poisons

Questions:

- What are the objectives of Poisons Act 1919?
- What is the poison Sales Act?
- Define Poison.
- What is the process of Possession for sale.

Chapter-9

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.

Questions:

- What is the brief overview of the Food Safety and Standards Authority of India (FSSAI) Act?
- What are the labelling requirements under the FSSAI Act for Food Supplements?

Chapter-10

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)

Questions:

- What are the objectives of the DPCO Act 2013?
- What is National Pharmaceutical Pricing Authority DPCO 2013?
- How does the DPCO define key terms like "bulk drugs," "formulations," "scheduled formulations," and "maximum retail price (MRP)"?
- What is the difference between the retail price and the ceiling price of scheduled formulations.
- What is the National List of Essential Medicines (NLEM) and what is its purpose.

Chapter-11

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.

Questions:

- What is the code and ethics of pharmacist?
- What is the oath of a pharmacist?
- What is the process for pharmaceutical registration?
- What are the ethical guidelines for a pharmacist in relation to the medical profession?

Chapter-12

Medical Termination of Pregnancy Act and Rules – basic understanding/salient features

Questions:

- What is the objective of the Medical Termination of Pregnancy Act?
- What are the responsibilities of healthcare providers under the MTP Act?

Chapter-13

Role of all the government pharma regulator bodies – Central Drugs Standards Control Organization (CDSCO), Indian Pharmacopoeia Commission (IPC)

Questions:

- What is the role of the CDSCO?
- What is the role of Indian Pharmacopoeia Commission?
- Define Pharmacopoeia.

Chapter-14

Good Regulatory practices:

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

Questions:

- What is good regulatory practices?
- Define Community Pharmacy.
- What are the best practices for maintaining electronic records to ensure traceability and compliance with e-governance regulations?
- What are the different types of licenses needed for community pharmacies, hospital pharmacies, pharmaceutical manufacturing, and wholesale businesses?
- What are the procedures for regulatory inspections of pharmacies, manufacturing facilities, and wholesale businesses?

Chapter-15

Introduction to BCS system of classification:

Introduction to BCS system of classification, Basic concepts of Clinical Trials, ANDA, NDA, New Drug development, Schedule Y. Brand v/s Generic, Trade name concept, Introduction to Patent Law and Intellectual Property Rights, Emergency Use Authorization.

Questions:

- What is the BCS system of classification?
- Write the short note on New drug Applications.
- What is different between Brand v/s Generic?
- What is schedule Y?
- Define Intellectual property rights.

Chapter-16

Blood bank – basic requirements and functions

Question:

- **Write the details note on Blood bank.**

Chapter-17

Clinical Establishment Act and Rules – Aspects related to Pharmacy

Questions:

- What is the Clinical Establishment Act and rule?

Chapter-18

Biomedical Waste Management Rules 2016 – Basic aspects, and aspects related to pharma manufacture to disposal of pharma / medical waste at homes, pharmacies, and hospitals

Questions:

- What are the new bio medical waste management rules 2016?
- Write the waste management process in medical waste at homes, pharmacies, and hospitals.

Chapter-19

Bioethics – Basic concepts, history and principles. Brief overview of ICMR's National Ethical Guidelines for Biomedical and Health Research involving human participants

Questions:

- What are the ICMR guidelines for bioethics?
- What is Bioethics and write there principle?

Chapter-20

Introduction to the Consumer Protection Act

Question:

- Write the details note on consumer protection act.

Chapter-21

IMedical Devices – Categorization, basic aspects related to manufacture and sale

Questions:

- What is iMedical devices?
- Write the short note on IMedical Devices.