



MODEL PAPER
2nd Year Examination, June-2025

Program: D.Pharm
Year: 2nd Year
Course: Pharmacy Law & Ethics
Course Code: ER20-26T

SECTION-II

Short Answer Type Question

(3 marks each)

UNIT-I

1. Explain the classes of drugs & cosmetics, which prohibited from import.
2. Elaborate the function of the Pharmacy Council of India (PCI).
3. Elaborate about the “Hathi Committee”.
4. Describe the recommendation of the Bhore committee.
5. Write a short note on labelling and packing of cosmetics.

UNIT -II

6. What do you mean by illicit traffic, in relation to Narcotic Drugs and Psychotropic Substances?
7. What are the objectives of Drugs and Magic Remedies (Objectionable Advertisements) Act, 1954?
8. Describe the objective of “The Prevention of Cruelty to Animals Act, 1960”.
9. Write note on Penalties under “Poisons Act, 1919”.
10. What are the Objectives of DPCO 2013?
11. What do you understand by Ceiling price, Market price, Maximum retail price & Wholesaler?

UNIT-III

12. Write the Procedure for Grant of a Patent in India.
13. Elaborate the “Pharmacist in relation to his profession”.
14. Write note on termination of pregnancy by Registered Medical Practitioners (RMPs).
15. Discuss the vision and mission of IPC.
16. What do you understand by CDSCO? Where is the zonal and sub zonal offices of CDSCO located?
17. Elaborate the phases of Clinical trials.
18. What are the objectives of Clinical trials?
19. What are the functions of blood banks?

UNIT-IV

20. What are the primary objectives of the “Clinical Establishments (Registration and Regulation) Act, 2010”?
21. What are the treatment and disposal methods for biomedical waste?
22. Elaborate the principle of Bioethics.
23. When was the Consumer Protection Act implemented? How can you define “consumer”?
24. When was the Disaster Management Act implemented? How can you define “disaster”?
25. Discuss about the medical devices.

SECTION-III

Long Answer Type Questions

(5 marks each)

UNIT-I

1. How would you identify the qualification, powers and duties of a Drug inspector? Also explain the procedure of Inspection.
2. Determine the Main recommendations of the Drug Enquiry Committee.
3. Elaborate the functions and composition of the State Pharmacy Councils and Joint Pharmacy Council.
4. How can you express the composition of PCI? How can you outline the offences and penalties in the Pharmacy act?
5. What is your analysis on pharmaceutical legislation in India?
6. Elaborate about the following Schedules as per Drugs and Cosmetic Act 1948:
 - (a) Schedule A
 - (b) Schedule L1
 - (c) Schedule T
 - (d) Schedule D
 - (e) Schedule K
 - (f) Schedule H
 - (g) Schedule C & C(1)
 - (h) Schedule N

UNIT-II

7. How can you outline the Offences and Penalties under Narcotics Drugs and Psychotropic substances Act, 1985?
8. Elaborate about Magic remedy. How can you express the Offences & Penalty related to Drugs & Magic Remedies Act?
9. What is the main idea about the function of the Animal Welfare Board?

10. How can you express Power of the State Government to regulate possession for sale and sale of any poison?

11. How would you demonstrate the Rules and Regulations under FSSAI act?

UNIT-III

12. How would you describe the termination of pregnancy by Registered Medical Practitioners (RMP)?

13. How can you express the offence and penalties in Medical Termination of Pregnancy (MTP) Act?

14. Elaborate a detailed note on Indian Pharmacopoeia Commission (IPC).

15. Elaborate the objective of GRP. Write importance of Good Regulatory Practices (GRP) in Pharmacy.

16. Illustrate the steps involved in the drug development process.

UNIT-IV

17. Elaborate the ICMR's national ethical guidelines for biomedical and health research involving human participants.

18. What is your analysis on "bio-medical waste"? Elaborate the duties of the occupier.

19. What are the objectives of The Consumer Protection Act, 1986? Explain about the Consumer Disputes Redressal Commission.

20. Elaborate the salient features & benefits of the CEA 2010.

21. Elaborate the Governing bodies established by DMA 2005.

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Disclaimer: - This is a Model Paper. The Question in End semester examination will differ from the Model Paper. This Model paper is meant for practice only.