

PHB Education
Sample Paper-1
Session: 2024–25
Course: D. Pharm IInd Year
Subject: Pharmacy Law & Ethics
Exam: 3rd Sessional Question Paper-1

Attempt all the questions:

(Section: A)

Q. A Multiple Choice Questions: **[5]**

1. Metformin drug comes under which of the following Schedule?

- | | |
|----------------------|---------------|
| a) Schedule C and C, | b) Schedule G |
| c) Schedule H | d) Schedule K |

2. Recommend temperature for storing the product at one place is:

- | | |
|--------------|---------------|
| a) 4°C -8°C | b) 8°C-15°C |
| c) 15°C-25°C | d) Above 25°C |

3. Schedule M describes which of the following?

- | | |
|-------------------------------------|---------------------------------|
| a) Standards for surgical dressings | b) Good Manufacturing Practices |
| c) Life Period of drugs | d) None of the above |

4. Which of the following is the full form of FSSAI?

- a) Food safety & sample Authority of India
- b) Fire Safety & Standards Authority of India
- c) Fire safety & sanitisation Authority of India
- d) Food safety & standards Authority of India

5. The optimum dose of therapy is determined in which of the following phases of clinical trials?

- | | |
|--------------|-------------|
| a) Phase I | b) Phase II |
| c) Phase III | d) Phase IV |

Q.B Fill in the blanks: **[5]**

1. Central Drug Laboratory is situated at.....
2. A person which is dependent on narcotic drug or psychotropic's drug is known as.....
3. Advertisement of drug claiming cure of cancer is.....
4. Pharmacy Act was implemented in the year.....
5. The blood donor hemoglobin should be not less than

(Section: B)

Q. C Short Answer Type Questions: (Attempt any five)

[5 × 3 = 15]

1. Explain the role of Central Drugs Standards Control Organization (CDSCO).
2. Define the "advertisement" or "magic remedies" as per objectionable advertisement Act 1954.
3. Write the functions of drugs inspector.
4. What are the objectives of CPCSEA?
5. Write a short note on Poison Act 1919.
6. Write in brief about schedule C and C1.

(Section: C)

Q. D Long Answer Type Questions: (Attempt any three)

[5 × 3 = 15]

1. Define and classify sale of drugs as per Drugs and Cosmetics Act 1940. Write about retail sale of drugs.
2. What are the objectives of Patent Act 1970? Write in short about procedure to get the patent.
3. Write a short note on any one of the following:
 - a) Education Regulations
 - b) Brand V's Generic medicines
4. Give the bonafied reasons for termination of pregnancy under medical termination of pregnancy Act 1970.

PHB Education
Sample Paper-2
Session: 2024–25
Course: D. Pharm IInd Year
Subject: Pharmacy Law & Ethics
Exam: 3rd Sessional Question Paper-2

Attempt all the questions:

(Section: A)

Q. A Very short answer type questions: **[5]**

1. Which of the following is the drug regulatory body in India?

- a) Central Drugs Standard Control Organisation
- b) Food Safety & Standards Authority of India.
- c) Pharmacy council of India
- d) Food and Drug Administration.

2. Among the elected members of PCI six members are elected by which of the following?

- a) UGC
- b) MCI
- c) AICTE
- d) None of these

3. Which of the following is the drug regulatory body in India?

- a) CDSCO
- b) FSSAI
- c) PCI
- d) FDA

4. In which year FSSAI came?

- a) 1998
- b) 2006
- c) 2011
- d) 1997

5. Medicinal and Toilet preparation act come in India.

- a) 1955
- b) 1959
- c) 1998
- d) 1999

Q. B Fill in the blanks: **[5]**

1. CDSCO stands for
2. National Pharmaceutical Pricing authority was established in
3. Full form of PCI
4. DTAB stands for

5.approves medical devices in India.

(Section: B)

Q. C Short Answer Type Questions: (Attempt any five)

[5 × 3 = 15]

1. Write short note on clinical trials.
2. What is repacking license?
3. Give qualifications required for Government Analyst.
4. What are the objectives of consumer protection Act 2010?
5. What are the salient features of clinical establishment Act 2010?
6. Write the offences and penalties according to Poison act 1919.

(Section: C)

Q. D Long Answer Type Questions: (Attempt any three)

[5 × 3 = 15]

1. What do you understand by code of Pharmaceutical ethics? Write in brief about ethics for pharmacist in relation to his job.
2. Write the objectives of Drugs Price control under 2013. How will you calculate the ceiling price of scheduled formulation?
3. Write the constitution of pharmacy council of India.
4. Explain food safety & standard authority of India (2006).