Question Paper

Exam Date & Time: 13-May-2024 (10:00 AM - 01:00 PM)

MANIPAL ACADEMY OF HIGHER EDUCATION

PHARMACY LAW and ETHICS [PMA-ER20-26T-S1]

Marks: 80 **Duration: 180 mins.**

MCQs

Answer all the questions. Section Duration: 30 mins

20 Q x 1 mark = 20 marks

1) What is the primary objective of the Prevention of Cruelty to Animals Act-1960 in India? (1)

- To promote the use of animals for entertainment
- To protect animals from unnecessary suffering and cruelty
- To regulate the hunting of wild animals
- To encourage the use of animals in scientific experiment

2) Under the Poisons Act, 1919, what is the term used for substances that are subject to strict regulations due to their potential harm? (1)

- Controlled Drugs
- Hazardous Chemicals
- Toxic Pharmaceuticals
- Dangerous Substances

3) Which is least important to bioethics? (1)

- Ethical theory
- National laws
- Personal preference of healthcare Provider exclusive of Patient's
- Health Professional bodies regulations

4) Which of the following has the lowest chance of producing biomedical waste? (1)

- Hospitals
- Clinics
- Laboratories
- Agriculture lands

5) When was the Consumer Protection Act enacted in India? (1)

- 1986
- 1991
- 2000
- 2010

6) Which of the following is a mandatory requirement for blood banks in India? (1)

- Providing blood transfusion services round the

clock
Regular training of staff on blood safety protocols
Clean equipment when not in use
Maintaining blood categories

7) Which government agency is responsible for issuing the 'Certificate of Pharmaceutical Product (COPP)' for the export of pharmaceuticals from India? (1)

Bureau of Indian Standards (BIS)
National Pharmaceutical Pricing Authority (NPPA)
Directorate General of Foreign Trade (DGFT)
Central Drugs Standard Control Organization (CDSCO)

8) In the context of the Code of Pharmaceutical Ethics, what is the significance of transparency in relationships between pharmaceutical companies and healthcare professionals? (1)

Transparency is not important in these relationships
It helps build trust and credibility
It hinders effective collaboration
It allows for undisclosed financial transactions

9) Which of the following classes in the BCS is characterized by high solubility and high permeability, leading to rapid and complete absorption? (1)

Class I
Class II
Class III
Class IV

10) Which ethical committee is responsible for reviewing and approving the initiation of clinical trials at the trial site? (1)

Central Drugs Standard Control Organization (CDSCO)
Drug Controller General of India (DCGI)
Institutional Review Board (IRB)
Ethics Committee for Clinical Trials (ECCT)

11) The Code of Pharmaceutical Ethics in India is given by whom? (1)

ICI
DCI
MCI
PCI

12) Grant of license to manufacture a drug requires (1)

Form 25
Form 28
Form 30
Form 32

13) An Act regulates profession of Pharmacy (1)

Cosmetic Act
Patent Act
MTP Act
None of

these

14) Bengal Chemical and Pharmaceutical works, was started in Calcutta in 1901 by (1)

- Acharya Prafulla Chandra Ray
- Mr. Ghosh
- Mr. Chakrawarti
- Dr. Banarji

15) Schedule C is related to (1)

- List of Biological and Immunological Product
- List of Homeopathy Product
- List of Ayurvedic Product
- List of Allopathic Product

16) "Ampicillin Capsule should be used within 24 hours". This statement covers under (1)

- Schedule C
- Schedule R
- Schedule M
- Schedule P

17) Schedule X is related to (1)

- List of incurable diseases
- Guideline for clinical trials
- List of generic drugs
- None of the above

18) Mr. Raj is an Bpharm graduate who starts an industry of manufacturing drugs. His first project is for supply of Diclofenac Sodium tablets for marketing purposes. However, being the first time he forgot to include the Schedule H warning on his tablet label. As such his drug will be considered as..... (1)

- Misbranded
- Adulteraed
- Spurious
- Deceptive

19) Injection syringe and needles are covered under (1)

- Schedule P
- Schedule A
- Schedule B
- Schedule Q

20) Government Opium factory is situated at (1)

- Ghazipur
- Delhi
- Jamnagar
- Mumbai

Long Answers

Answer all the questions.

6 Q x 5 marks = 30 marks

1)	Define medical devices and classify as per Indian regulations	(5)
2)	Define "Registered Pharmacist" and "Displaced Person" Under Pharmacy Act 1948. Explain the functions of Pharmacy Council of India	(5)
3)	What are the salient features of FSS Act & Rules	(5)
4)	What is CDSCO? Enlist the functions of CDSCO	(5)
5)	Explain in detail schedule N as per D&C Act	(5)
6)	Explain the functions of central drug laboratory	(5)

Short Answers

Answer all the questions.

10 Q x 3 mark = 30 marks

1)	Define disaster as per Disaster Management Act 2005	(3)
2)	Enlist and explain the stages of clinical research	(3)
3)	Mention the offenses and penalties under imports of drugs	(3)
4)	Explain the objectives of "The Narcogics Drugs and Psychotrophic Substances Act".	(3)
5)	What are the objectives of Consumer Protection Act 1986.	(3)
6)	Explain the objectives of clinical establishment Act 2010.	(3)
7)	Enlist the essential components of informed consent	(3)
8)	Write the difference between bonded and non-bonded laboratory	(3)
9)	Explain any three offenses and penalties for contravening the Medicinal and Toilet Preparations Act 1955	(3)
10)	Explain the functions of Drug Consultative Committee	(3)

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