

**D.PHARM.
SECOND YEAR
PHARMACY LAW & ETHICS
ER20-26T**

Duration : 3 hrs.

Full Marks : 80

(PART-A : Objective)

Choose the correct answer from the following:

1×20=20

1. IMRDA came into effect from:
 - a. 31 Dec 2009
 - b. 21 Sept 2009
 - c. 17 Aug 2010
 - d. 12 October 2010
2. Poison's Act was passed in:
 - a. 1990
 - b. 1919
 - c. 1920
 - d. 1980
3. Consumer Protection Act was amended in:
 - a. 1986
 - b. 1980
 - c. 2000
 - d. 2002
4. WTO stands for:
 - a. World Technology Organization
 - b. World Treatment Organization
 - c. World Trade Organization
 - d. World Therapy Organization
5. MTP Act was passed in:
 - a. 1960
 - b. 1971
 - c. 1980
 - d. 1981
6. Import of poisons is controlled by:
 - a. Central Government
 - b. State Government
 - c. Both (a) and (b)
 - d. None of the above
7. NDPS Acts & Rules was passed in:
 - a. 1980
 - b. 1960
 - c. 1965
 - d. 1985
8. Administrative Ministry of FSSAI is:
 - a. Indian Council of Medical Research
 - b. National health Mission
 - c. Ministry of health & family Welfare
 - d. Medical Council of India
9. Patentable Inventions should meet which criteria:
 - a. Novelty
 - b. Invention
 - c. Industrial application
 - d. All of the above
10. Prevention of cruelty to Animal's Act is excluded from which state?
 - a. Mizoram+
 - b. Telengana
 - c. Jammu & Kashmir
 - d. Rajasthan

11. Patent Act came into force from:
 - a. 1972
 - b. 1960
 - c. 1990
 - d. 1980
12. As per IP, title of the Monograph is approved by:
 - a. World Trade organization
 - b. Medical Council of India
 - c. World Health organization
 - d. Pharmacy Council of India
13. Which Schedule of Drugs grant permission for conducting Clinical trials:
 - a. Schedule Y
 - b. Schedule H
 - c. Schedule X
 - d. Schedule C
14. The DCGI is advised by:
 - a. Drug Technical Advisory Board
 - b. Drug Consultative Committee
 - c. Both (a) & (b)
 - d. None of the above+
15. Blood Group known as Universal Donor is:
 - a. AB+
 - b. AB -
 - c. O -
 - d. O+
16. National Disaster Management Authority is chaired by
 - a. Chief minister
 - b. Prime Minister
 - c. President
 - d. Finance Minister
17. Hatch-Waxman Act was passed in:
 - a. 1978
 - b. 1989
 - c. 1972
 - d. 1984
18. Drugs & Cosmetics Act was passed in:
 - a. 1940
 - b. 1935
 - c. 1950
 - d. 1945
19. Head-office of CDSCO is located in:
 - a. Mumbai
 - b. New-Delhi
 - c. Hyderabad
 - d. Gujarat
20. DTAB stands for:
 - a. Drug Therapeutic Administration Board
 - b. Dose Treatment Agency Board
 - c. Dose technology Absorption Board
 - d. Drug Technical Advisory Board

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(PART-B : Short Answers)

[Answer any ten (10) from the following]

[3x10=30]

1. What are the objectives of Narcotic Drugs & Psychotropic Substances? 3
2. What are the requirements of a functional Blood bank? 3
3. What are the Penalties under Clinical Establishment Act? 3
4. What is CPCSEA? What are the principles of CPCSEA? 3
5. Define the following: (a) Consumer (b) Manufacturer and (c) Trader 3
6. What are the Penal provisions under Disaster Management Act? 3
7. What are the classes of prohibited advertisements? 3
8. What is the constitution of a State Pharmacy Council? 3
9. What are the duties & functions of FSSAI? 3
10. What are the penalties under Poison's Act? 3
11. What are the functions of CDSCO? 3

(PART-C : Long Answers)

[Answer any six (6) from the following]

[5x6=30]

1. What are Clinical Trials? What are the different Phases of Clinical Trials? 5
2. What are the Essential principles & Objectives under IMRDA? 5
3. What are the classes of drugs that are prohibited to be imported? 5
4. Describe about Patents and Copyrights. 5
5. What are the applicable conditions for Pregnancy termination? 5
6. What is the role of Pharmacist in relation to his profession? 5
7. What is BCS? What are the different classes of BCS? 5

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