

**D.PHARM.  
SECOND YEAR  
PHARMACY LAW & ETHICS  
ER20-26T [SPECIAL REPEAT]  
[USE OMR FOR OBJECTIVE PART]**

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. 21 Sept 2009  
b. 31 Dec 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. 2002  
d. 2005
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. 1981  
c. 1980  
d. 1971
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 M
  - b. Schedule H1
  - c. Schedule S
  - d. Schedule Y
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. 1970
  - c. 1984
  - d. 1961
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 functions of CDSCO?
2. What are the requirements of a functional Blood bank?
3. What are the duties & functions of FSSAI?
4. What is CPCSEA? What are the principles of CPCSEA?
5. What is the constitution of a State Pharmacy Council?
6. What are the Penal provisions under Disaster Management Act?
7. What are (a) IND (b) NDA and (c) ANDA?
8. Define the following: (a) Consumer (b) Manufacturer and (c) Trader
9. What are the Penalties under Clinical Establishment Act?
10. What are the penalties under Poison's Act?
11. What are the objectives of Narcotic Drugs & Psychotropic Substances?

**[ 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?
2. What are the Essential principles & Objectives under IMRDA?
3. What are the classes of drugs that are prohibited to be imported?
4. Describe about Patents and Trademarks.
5. What are the applicable conditions for Pregnancy termination?
6. What are Patentable & Non Patentable Inventions?
7. What is BCS? What are the different classes of BCS?

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