

Seat No.: _____

Enrolment No. _____

GUJARAT TECHNOLOGICAL UNIVERSITY
DIPLOMA PHARMACY YEAR- 2 • EXAMINATION – WINTER - 2023

Subject Code: DP206TT

Date: 16/12/2023

Subject Name: Pharmacy Law and Ethics

Time: 10:30 AM TO 01:30 PM

Total Marks: 80

Instructions:

1. Question -1 is compulsory to attempt.
2. Attempt any 04 questions from Question 2 to 7.
3. Make suitable assumptions wherever necessary.
4. Figures to the right indicate full marks.

- Q.1** Answer the following questions. (Attempt Any 16) (1 mark each) **16**
- 1) Define Drug
 - 2) Mention the contents of schedule X with one example
 - 3) Define Cosmetics
 - 4) Mention the contents of schedule J with one example
 - 5) Define Spurious drugs
 - 6) Give two examples of copyright
 - 7) Give two examples of Trade Marks
 - 8) Write Full Form of CDL
 - 9) Give the full form of DTAB
 - 10) Where central drug laboratory is situated in India?
 - 11) What do you mean by BMW in reference to Blood Bank?
 - 12) Give two examples of Geographical indication
 - 13) Write Full Form of IND
 - 14) Write full form of FSSAI
 - 15) Write full form of IPC
 - 16) Define Disaster
 - 17) Define Addict
 - 18) Write full form of CPCSEA
 - 19) What do you mean by BCS Class II drug?
 - 20) Write full form of CDSCO
- Q.2** (a) Write Constitution of Central Pharmacy Council **06**
(b) Describe History of pharmaceutical legislation in detail. **05**
(c) Write a detailed note on General labelling requirements for drugs **05**
- Q.3** (a) Describe at length Powers and Procedure for Drug Inspector. **06**
(b) Write note on Retail sale of schedule X and H drugs **05**
(c) Discuss Subsequent registration of pharmacists in detail **05**
- Q.4** (a) Discuss various phases of Clinical Trials in detail **06**
(b) Write a note on Provisions of Medical Termination of Pregnancy Act **05**
(c) Write Short note on Abbreviated New Drug Application (ANDA) **05**

- Q.5** (a) Write in brief about Institutional Animal Ethics Committee (IAEC) **06**
(b) Discuss provisions of Drugs and Magic Remedies act' 1954 **05**
(c) Define Code of Pharmaceutical Ethics. Discuss it in relation to pharmacist's Job. **05**
- Q. 6** (a) Write short note on Patent and Copyright **06**
(b) Write a note about Emergency Use Authorization (EUA) **05**
(c) Write a note on Documentation required for Community pharmacy (Retail sale) **05**
- Q.7** (a) Write about Consumer protection Act OR Education Regulation **06**
(b) Documentation required for Export of drugs and medical devices **05**
(c) Write a note on Good Manufacturing Practice OR Requirements of Blood Bank **05**

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