

**POST GRADUATE DIPLOMA IN
PHARMACEUTICAL SALES
MANAGEMENT (PGDPSM)**

Term-End Examination

December, 2024

MVE-004 : DRUG REGULATORY AFFAIRS

Time : 2 Hours

Maximum Marks : 50

Note : (i) Answer any **five** questions.

(ii) All questions carry equal marks.

1. (a) Define the following : 1×5=5
- (i) Drug
 - (ii) Informed consent
 - (iii) Hematology
 - (iv) Cell hybridization
 - (v) Shelf life
- (b) Write the full form of the following : 1×5=5
- (i) DTAB

- (ii) DCC
 - (iii) LD₅₀
 - (iv) GCP
 - (v) PMS
2. (a) Explain the different steps involved in the price fixation of bulk drug. 5
- (b) Discuss the responsibilities of Ethics Committee. 2+3=5
3. (a) Enlist any *four* regulatory authorities. Write the role of any *one* of them. 2+3=5
- (b) Describe the role of special population in clinical trial studies. 5
4. (a) Discuss the phases of approval of vaccine. 5
- (b) Give an overview on New drugs. 5
5. Differentiate between the following : 5+5=10
- (a) Adulterated drugs and Spurious drugs
- (b) Subacute toxicity and Chronic toxicity
6. (a) Describe the Medicine and Toilet Preparation Act, 1995. 5
- (b) How are medicines labelled and packaged ? 5

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7. Write notes on any *two* of the following : 5+5=10

- (a) Current status of the Indian Pharmaceutical Industry
- (b) Department of Biotechnology
- (c) Factors affecting potency of drug during storage

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