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MVE–004

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) LD_{50}

(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

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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