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MVE-004

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

Term-End Examination

June, 2022

MVE-004 : DRUG REGULATORY AFFAIRS

Time : 2 Hours

Maximum Marks : 50

Note : Answer any *five* questions.

1. (a) Write the full form of any *five* of the following : 5×1=5
- (i) IPA
 - (ii) TRIPS
 - (iii) GATT
 - (iv) IDMA
 - (v) OTC
 - (vi) DST
 - (vii) MTP

P. T. O.

- (b) What are the changes and reforms in Indian Pharmaceutical Industry after 1995 ? 5

2. Write short notes on any *two* of the following :

2×5=10

- (a) Preclinical Evaluation of Drugs
(b) Types of Toxicity Studies
(c) National Pharmaceutical Pricing Authority (NPPA)

3. (a) What are the differences between Pharmacokinetics and Pharmacodynamics ?

5

(b) Explain any *five* of the following terms in 2 sentences each :

5

- (i) Bulk drug
(ii) Schedule Y
(iii) Formulations
(iv) Drugs
(v) Cosmetics
(vi) Spurious drugs

4. Describe any **four** of the following terms :

$$4 \times 2 \frac{1}{2} = 10$$

- (a) Biotechnology
 - (b) Cell hybridisation
 - (c) Gene technology
 - (d) Genetic engineering
 - (e) Microorganism
5. (a) What are the different phases of clinical trials ? Explain any **one**. 5
- (b) Write the procedure of getting the permission to import new drug. 5

6. Write short notes on any **two** of the following :

$$2 \times 5 = 10$$

- (a) Shelf life
 - (b) Adulterated drugs
 - (c) Storage of medicines
7. (a) What are the factors affecting drug potency ? Explain in brief. 5

(b) Write the penalty imposed for the violation of : 5

(i) NDPS Act, 1985

(ii) The Drugs and Magic Remedies Act, 1954

(iii) Poison Act, 1919

8. Write short notes on the following : 2×5=10

(a) The Medical and Toilet Preparation Act, 1995

(b) MTP Act, 1971