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MVE–004

POST GRADUATE DIPLOMA IN PHARMACEUTICAL SALES MANAGEMENT (PGDPSM)

Term-End Examination

December, 2023

MVE-004 : DRUGS REGULATORY AFFAIRS

Time : 2 Hours *Maximum Marks : 50*

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

(ii) All questions carry equal marks.

1. (a) Define any *five* of the following terms : 5×1=5

(i) Toxicity

(ii) LD-50

(iii) Shelf life

(iv) English Medicine

(v) Bulk drug

(vi) Cell hybridisation

(vii) Geriatrics

(b) Write a brief account on evolution of Indian Pharmaceutical Industry. 5

2. (a) State the role and responsibilities of Indian Council of Medical Research (ICMR). 5

(b) Explain the importance of post-marketing surveillance. 5

3. (a) Discuss any ***two*** of the following : 2×5=10

(i) Drug Price Control Order, 1995

(ii) Drugs and Cosmetics Act

(iii) MTP Act, 1971

4. (a) Differentiate between pre-clinical study and clinical trial. 5

(b) Write short notes on any ***two*** of the following : $2\times2\frac{1}{2}=5$

(i) Adulterated drugs

(ii) Carcinogenicity

(iii) Animal Ethical Guidelines

5. Discuss the significance of labelling and packaging of medicine. 10

6. Write the constitution of Pharmacy Council of India. Explain its role in regulation of pharmacy education. 10

7. Discuss the salient features of Narcotic Drugs and Psychotropic Substances Act. 10

8. Explain any ***two*** of the following : 2×5=10
   (i) Informed consent
   (ii) Storage of Medicine
   (iii) Types of Toxicity Studies