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MVE-004

POST GRADUATE DIPLOMA IN PHARMACEUTICAL SALES MANAGEMENT (PGDPSM)

Term-End Examination

December, 2021

MVE-004 : DRUGS REGULATORY AFFAIRS

Time : 2 Hours *Maximum Marks : 50*

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

(*ii*) *All questions carry equal marks.*

1. (a) Write full form of any ***five*** of the following : 1 each

   (i) IPI
   (ii) NDP
   (iii) CRAMS
   (iv) IPA
   (v) DPCO
   (vi) ICMR
   (vii) DBI

   (b) What is NPPA ? Write any *three* functions of NPPA. 2+3

2. (a) Name different types of toxicity studies and explain any *one*. 5

   (b) What is meant by clinical trial ? What are the responsibilities of sponsors for clinical trials ? 2+3

3. (a) Describe the Medical Termination of Pregnancy (MTP) Act, 1971. 5

   (b) Describe in brief the studies in special populations with respect to pediatrics. 5

4. Write short notes on any ***two*** of the following : 5 each

   (a) Historical evolution of Indian Pharmacy.

   (b) Change in the patent regime after 1995.

   (c) Department of Science and Technology.

5. (a) What is New Drug Application ? Write the significance of pharmacological and toxicological studies. 2+3

   (b) What is Investigational New Drug (IND) ? Write the different types of IND and explain any *two*. $2\frac{1}{2} + 2\frac{1}{2}$

6. (a) How is DTAB constituted and what are its functions ? 5

   (b) What are the salient features of adulterated drugs ? 5

7. Write short notes on any *two* of the following : 5 each

   (a) Narcotic Drugs and Psychotropic Substances (NDPS) Act, 1985.

   (b) The Drugs and Magic Remedies (Objectionable Advertisements) Act, 1954.

   (c) Poison Act, 1919.

8. (a) Describe the constitution of Pharmacy Council of India. 5

   (b) What is the difference between 'Cosmetic' and 'Drug' ? Give *one* example each. 3+2