No. of Printed Pages : 3

MVE-004

POST GRADUATE DIPLOMA IN PHARMACEUTICAL SALES MANAGEMENT (PGDPSM)

Term-End Examination

June, 2023

MVE-004 : DRUGS REGULATORY AFFAIRS

Time : 2 Hours *Maximum Marks : 50*

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

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

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1. Write short notes on any ***two*** of the following : 2×5=10

   (a) ICMR

   (b) DBT

   (c) DST

2. (a) Explain the *two* steps involved in the preclinical evaluation of a new drug. 5

   (b) List the steps involved in fixation/revision of bulk drug prices. 5

3. (a) List the types of toxicity studies. Explain any *one* in detail. 5

   (b) Describe briefly the approval process of vaccine. 5

4. (a) Describe the dynamics of Indian Pharmaceutical Industry. 5

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

5. Explain any ***four*** of the following : 4×2.5=10

   (i) Bulk drug

   (ii) Pharmacological studies

   (iii) Toxicological studies

   (iv) Schedule Y

   (v) Formulation

6. Describe the process of new drug approval using a flow chart. 10

7. (a) Explain the factors affecting the drug potency during storage. 5

   (b) List the details to be mentioned on the label of a medicine. 5

8. (a) Describe the various powers of the State Government under the Poisons Act, 1919. 5

   (b) Briefly describe the basic features of Medical Termination of Pregnancy Act, 1971. 5