POST GRADUATE DIPLOMA IN PHARMACEUTICAL SALES MANAGEMENT (PGDPSM)

Term-End Examination

December, 2022

MVE-004 : DRUGS REGULATORY AFFAIRS

Time : 2 hours *Maximum Marks : 50*

Note : *Attempt any* ***five*** *questions. All questions carry equal marks.*

1. (a) Write a brief note on "Over-The-Counter-Medicines". *3*

(b) Give the full form of the following : *7*

(i) IPA

(ii) DPCO

(iii) TRIPS

(iv) IDMA

(v) GATT

(vi) DCGI

(vii) NPPA

2. Describe the steps involved in fixation/revision of bulk drug prices. *10*

3. (a) Explain the points to be considered while designing toxicity experiments. *5*

(b) Differentiate between acute toxicity and chronic toxicity studies. *5*

4. (a) Mention the composition and responsibilities of the Ethics Committee. *8*

(b) Define the term New Drug. *2*

5. (a) List the committees engaged in the approval of special products and explain the functions of any one. 5

(b) List the various storage conditions for medicines. Explain any one. *5*

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

(a) Pharmacy Council of India

(b) Expiry Date of Medicines

(c) Shelf Life

7. Explain any ***four*** of the following : $4 \times 2\frac{1}{2} = 10$

(a) Adulterated Drugs

(b) Spurious Drugs

(c) Cosmetics

(d) Counterfeit Medicines

(e) Misbranded Drugs

8. (a) Explain the basic features of the Narcotic Drugs and Psychotropic Substances Act, 1985. *5*

(b) Write a short note on "The Drugs and Magic Remedies (Objectionable Advertisement) Act". *5*