MVE-004

POST GRADUATE DIPLOMA IN PHARMACEUTICAL SALES MANAGEMENT (PGDPSM)

Term-End Examination

June, 2021

MVE-004 : DRUGS REGULATORY AFFAIRS

Time : 2 hours *Maximum Marks : 50*

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

1. (a) Give the full form of any ***five*** of the following : *5×1=5*

(i) ICMR

(ii) DLC

(iii) NPPA

(iv) DST

(v) DTAB

(vi) RDAC

(vii) NDPS

(viii) WTO

(b) Write the key liberalisation measures post 1995 period of Indian Pharmaceutical Industries. *5*

2. (a) List any five functions of the Department of Biotechnology (DBT). *5*

(b) Differentiate between subacute and chronic toxicity. *5*

3. (a) Describe the ways to study controlled clinical trials. *5*

(b) Explain expiry dates and expiration dating. *5*

4. (a) What is the process of approval of vaccines and other biologicals ? *5*

(b) What is meant by Investigational New Drugs (IND) ? Discuss its different types. *5*

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

(a) The Drugs and Magic Remedies Act (1954)

(b) The Poisons Act (1919)

(c) The Medical Termination of Pregnancy (MTP) Act, (1971)

6. (a) List the different phases of clinical trials and describe any one.

(b) What are the functions of Pharmacy Council of India ? *5+5=10*

7. Explain any ***five*** of the following terms in one or two sentences each : *5×2=10*

(a) Cosmetics

(b) Teratogenicity

(c) Schedule Y

(d) Biologics

(e) Pharmacodynamics

(f) LD 50

8. (a) What is the mandatory information that is supposed to be provided when filing the New Drug Application ? *5*

(b) Discuss the process of getting the permission to import new drugs. *5*