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MVE–004

POST GRADUATE DIPLOMA IN PHARMACEUTICAL SALES MANAGEMENT (PGDPSM)

Term-End Examination

June, 2025

MVE-004 : DRUG REGULATORY AFFAIRS

Time : 2 Hours *Maximum Marks : 50*

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

1. (a) Define the following : 1×5=5

   (i) Drug formulation

   (ii) Clinical trials

   (iii) Schedule Y

   (iv) Bulk drug

   (v) Gene technology

(b) Discuss the types of toxicity studies for pre-clinical evaluation of drugs. 5

2. (a) What are the approval and prohibitions of novel diagnostic agents in Govt. notifications ? 5

(b) Explain the process of application for getting the permission to import new drugs. 5

3. (a) Who is a Drug Inspector ? How is a drug inspected ? 5

(b) Write the salient features of adulterated drug. 5

4. Write short notes on the following :

2.5×4=10

(a) Task force of DBT

(b) Shelf life

(c) Poisons Act

(d) Expiry date of drug

5. Differentiate between the following : 5+5

   (a) Phase I and Phase II Clinical Trials

   (b) Institutional Biosafety Committee and District Level Committee

6. Describe Narcotic Drugs and Psychotropic Substances (NDPS) Act, 1985. 10

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

   (a) Dynamics of Indian Pharmaceutical Industry

   (b) Procedure for pricing of formulation

   (c) Factors affecting the potency of drug during storage

   (d) Drugs Enquiry Committee

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