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MVE–004

POST GRADUATE DIPLOMA IN PHARMACEUTICAL SALES MANAGEMENT (PGDPSM)

Term-End Examination

December, 2025

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) Expand the following acronyms : 5×1=5
   - (i) IPA
   - (ii) UNICEF
   - (iii) NDP
   - (iv) IPI
   - (v) DPCO

   (b) Define the following terms with *one* suitable example : 2×2.5=5
   - (i) Over-The-Counter Medicine
   - (ii) Drug

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

   (i) CDSCO

   (ii) NPPA

   (iii) DST

3. Give a detailed account on Pre-clinical Evaluation of Drug. 10

4. (a) What are special products ? Give *three* examples. 5

   (b) What is Genetic Engineering Approval Committee (GEAC) ? Give its composition. 5

5. (a) Explain new drug approval process using a flowchart. 5

   (b) Write the important applications of investigational new drug. 5

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

   (b) Discuss the genesis of Drugs Act in 1940. 5

7. List different storage conditions. Explain any *two* of them. 10

8. (a) Discuss the salient features of Poisons Act, 1919. 5

   (b) Write a short note on the Drugs and Magic Remedies Act, 1954. 5

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