

**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 : $5 \times 1 = 5$
- (i) IPA
 - (ii) UNICEF
 - (iii) NDP
 - (iv) IPI
 - (v) DPCO
- (b) Define the following terms with *one* suitable example : $2 \times 2.5 = 5$
- (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

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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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