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MVE–004

POST GRADUATE DIPLOMA IN PHARMACEUTICAL SALES MANAGEMENT (PGDPSM)

Term-End Examination

June, 2026

MVE-004 : DRUG REGULATORY AFFAIRS

Time : 2 Hours *Maximum Marks : 50*

Note : *(i) Answer any* ***five*** *questions.*

(ii) All questions carry equal marks.

1. (a) Enlist any *five* functions of NPPA. 5

   (b) Describe any *five* major responsibilities of DST. 5

2. Give a detailed account on phase-I of clinical trials. 10

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

   (i) Vaccine Approval

(ii) Institutional biosafety committee

(iii) Rules for approval and promotions of novel diagnostic agents.

4. (a) What is Investigational New Drug (IND) ? Elaborate the three categories. 5

(b) Write a short note on 'New Drugs.' 5

5. (a) Discuss the genesis of modern medicine and pharmacy in India. 5

(b) What is Pharmacy Act ? Describe the aims of Pharmacy Act, 1948. 5

6. (a) List any ten medicine storage conditions prescribed by the Indian pharmaceutical manufactures. 5

(b) Explain the following terms with relevant examples : 5

(i) Shelf life

(ii) Expiry dates

7. Give a detailed account on Medical Termination of Pregnancy Act, 1971. 10

8. (a) Expand the following acronyms : 5×1=5

(i) CRAMS

(ii) DST

(iii) WHO

(iv) UNICEF

(v) NCF

(b) Discuss evolution of Indian Pharmacy Industry. 5

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