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MVE-004

POST GRADUATE DIPLOMA IN PHARMACEUTICAL SALES MANAGEMENT (PGDPSM)

Term-End Examination

June, 2024

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

(i) IND
(ii) FDA
(iii) NDA
(iv) DBT
(v) NPPA
(vi) DGTD
(vii) IDMA
(viii) IBSC

(b) Discuss briefly the composition and responsibility of an Ethics Committee. 5

2. (a) Give a brief account on dynamics of Indian Pharmaceutical Industry. 5

(b) Explain the experimental design for a clinical study. 5

3. (a) Define the term new drugs. Explain the objectives of developing new drugs. 5

(b) Discuss the meaning and composition of Institutional Biosafety Committee. 5

4. Write the procedure for approval of vaccine. 10

5. Discuss briefly different phases of clinical trials. 10

6. Discuss the salient features of Medical and Toilet Preparation Act, 1995. 10

7. (a) What are the details that should appear on the label of a medicine. 5

(b) Define any *five* of the following : 5×1=5

(i) Drug
(ii) Special Products
(iii) Misbranded Drugs
(iv) Drug Inspectors
(v) Expired Drugs
(vi) Cool Place
(vii) Cosmetics

8. (a) Discuss the functioning of CDSCO and its zonal offices. 5

(b) Enlist the major responsibilities of DST. 5