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MVE-004

POST GRADUATE DIPLOMA IN PHARMACEUTICAL SALES MANAGEMENT (PGDPSM)

Term-End Examination

December, 2019

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) Describe briefly "Over-The-Counter Medicines". 5
   (b) Explain briefly the Historical background of Indian Pharmaceutical Industry. 5

2. (a) Write the functions of National Pharmaceutical Pricing Authority (NPPA). 5
   (b) What are different phases of clinical trial ? Describe any one of them briefly. 5

3. (a) What is the process of approval of vaccines and other biologicals ? 5
   (b) What is the essential composition of an ethics committee ? 5

4. Explain **any four** of the following : 4x2.5=10
   (a) Formulation
   (b) Bulk Drug
   (c) New Drug
   (d) Investigational New Drug
   (e) Vaccines

5. (a) Give the Process of New Drug approval ? 5
   (b) Describe acute and chronic toxicity studies. 5

6. (a) Discuss the Constitution of Pharmacy Council of India. 5
   (b) Write the genesis of Drug Act, 1940. 5

7. Write short notes on **any two** : 2x5=10
   (a) Adulterated Drugs
   (b) Drugs Technical Advisory Board
   (c) Poison Act

8. (a) Write Investigative Procedures of NDPS. 5
   (b) Discuss the term of Ceiling and Non-Ceiling prices. 5