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MVE-004

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POST GRADUATE DIPLOMA IN PHARMACEUTICAL SALES MANAGEMENT (PGDPSM)

Term-End Examination

December, 2018

MVE-004 : DRUGS REGULATORY AFFAIRS

Time : 2 hours *Maximum Marks : 50*

Note : *Attempt **any five** questions.*

1. (a) Give an account on the reforms and institutional changes post 1995 period and write down the phases of evolution of Indian Pharma Industry. 5

   (b) Write short note on **any two** of the following : 5
   (i) OTC
   (ii) Indian Pharmaceutical Industry
   (iii) DST

2. (a) Describe the role and responsibilities of Indian Council of Medical Research (ICMR). 5

   (b) Discuss the functioning of CDSCO and its Zonal offices in India. 5

3. (a) What are the different types of toxicity studies and describe any one type of study in details. 5

   (b) What are the different phases of clinical trial ? Discuss their importance. 5

4. (a) What are the function of Reviews Committee on Genetic Manipulation (RCGM) ? 5

(b) Discuss the role of Genetic Engineering Approval Committee (GEAC). 5

5. (a) Discuss Rules of Drugs and Cosmetics Act. 5

(b) Write short note on **any one** of the following : 5

(i) Investigational new drug application (IND)

(ii) New Drug Application (NDA)

6. (a) Describe the role of Pharmacy Council of India in Pharmacy education. 5

(b) Discuss History of Pharmaceutical Legislation in India. 5

7. (a) Write the details that appear on the label of container of drugs. 5

(b) List any five conditions of Adulterated drugs as per the Drugs and Cosmetics Act. 5

8. (a) Describe in detail about Narcotics Drugs and Psychotropic Substance (NDPS) Act. 5

(b) Write short note on **any two** of the following : 5

(i) MTP

(ii) Drug Price Control Order

(iii) Poisons Act