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MVE-004

POST GRADUATE DIPLOMA IN PHARMACEUTICAL SALES MANAGEMENT

(PGDPSM)

Term-End Examination, 2019

MVE-004 : DRUGS REGULATORY AFFAIRS

Time : 2 Hours] **[Maximum Marks : 50**

Note : Attempt **any five** questions.

1. (a) Discuss the constitution and function of Drug Technical Advisory Board (DTAB). [5]

   (b) What is clinical trial ? Discuss Phase-one of clinical trial. [5]

2. (a) Write short notes on **any two** : [5]

   (i) The Drugs and Magic Remedies Act.

   (ii) Narcotic Drugs and Psychotropic Substance Act.

   (iii) Drug and Price Control Order (DPCO)

(b) Briefly state the Medical Termination of Pregnancy (MTP) Act, 1971. [5]

3. (a) What is the process of approval of vaccines and other biologicals ? [5]

(b) What are the safety criterias to be complied for large scale experiments and manufacture ? [5]

4. Write short notes on **any two** : [5+5=10]

(a) Animal Toxicity Studies.

(b) Pharmacy Act, 1948.

(c) Drug Enquiry Committee.

5. (a) Discuss in detail the procedure for pricing of drug. [5]

(b) State the objective and functions of Central Drugs Standard Control Organisation. [5]

6. (a) Write notes on **any two** : [5]

(i) Spurious Drugs

(ii) Expiry Date of Drugs

(iii) New Drugs

(b) Give an overview of the governing body of ICMR.

7. (a) What are the functions of Recombinant DNA Advisor Committee (RDAC) ? [5]

(b) Discuss the different factors affecting the potency of drug during storage. [5]

8. (a) What are the functions of DTAB ? [5]

(b) Write short notes on **any two** : [5]

(i) Placebo

(ii) Blindness

(iii) Post marketing surveillance (PMS)

(iv) Informed consent

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