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MVE-004

POST GRADUATE DIPLOMA IN PHARMACEUTICAL SALES MANAGEMENT (PGDPSM)

Term-End Examination

December, 2020

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) Give the full form of any ***five*** of the following : 1 each

   (i) CSIR

   (ii) UNICEF

   (iii) DPCO

   (iv) COSCO

   (v) GCP

   (vi) DST

   (vii) IBSC

(b) Write the details about Dynamics of Indian Pharmaceutical Industry. 5

2. (a) Define NPPA and write any ***four*** functions of NPPA. 5

(b) What are the types of toxicity studies ? Explain any *one* type. 5

3. (a) List the phases of clinical trials and describe any ***one***. 5

(b) Describe the Informed Consent in the context of ethics committee. 5

4. (a) Explain any ***five*** of the following in one or two sentences each : 1 each

(i) Geriatrics

(ii) Haematology

(iii) Pathogens

(iv) Oxytocin

(v) London proof spirit

(vi) Mis-branded drugs

(b) What are the rules under government notification on approval and prohibition of novel diagnositic agents ? 5

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

(i) Drug Technical Adivisory Board (DTAB)

(ii) OTC drugs

(iii) Therapeutic confirmatory trials

(iv) Labelling and packaging of medicines

6. Discuss any ***two*** of the following : 5×2=10

(a) Factors affecting the potency of drug during storage

(b) Responsibilities of investigator of Ethics Committee

(c) Role of drugs enquiry committee

7. (a) What is the significance of "Chopra Committee" in the history of pharmaceutical legislation in India. 5

(b) Give any ***five*** powers of the state government for sale of poisons. 5

8. Describe the following : 5 each

(a) Drug prices control order

(b) Narcotic Drugs and Psychotropic Substances (NDPS) Act