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MVE-004

POST GRADUATE DIPLOMA IN PHARMACEUTICAL SALES MANAGEMENT PGDPSM

00995

Term-End Examination

June, 2012

MVE-004 : DRUGS REGULATORY AFFAIRS

Time : 2 hours *Maximum Marks : 50*

Note : *(i) Answer **any five** questions.*
*(ii) All carry **equal (10 each)** marks.*

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1. (a) List any five conditions of Adulterated drugs as per the Drugs and Cosmetics Act. **5x2=10**

(b) What are the details that should appear on the label of container of drugs ?

2. What are the different phases of clinical trials ? Discuss any one in detail. **10**

3. Write short notes on ***any two*** **5x2=10**

(a) The Drugs and Magic Remedis Act

(b) Narcotic Drugs and Psychotropic Substances Act

(c) Drugs Price Control Order (DPCO)

4. (a) What is the process of approval of vaccines and other biologicals ? **5x2=10**

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

5. Discuss the functioning of CDSCO and its zonal offices in India. **10**

6. Write short notes on ***any two*** : **5x2=10**
   (a) Animal toxicity studies
   (b) Aims of Pharmacy Act 1948
   (c) Drugs Enquiry Committee.

7. Discuss the role of following government organization in clinical research **10**
   (a) ICMR
   (b) DBT
   (c) DST.

8. Write short notes on ***any four*** : **2.5x4=10**
   (a) New Drug Approval (NDA)
   (b) Spurious Drugs
   (c) Informed Consent
   (d) Investigational New Drug (IND)
   (e) Drug Technical Advisory Board (DTAB).