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MVE-004

00864

POST GRADUATE DIPLOMA IN PHARMACEUTICAL SALES MANAGEMENT PGDPSM

Term-End Examination

June, 2010

MVE-004 : DRUGS REGULATORY AFFAIRS

Time : 2 hours *Maximum Marks : 50*

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

1. (a) Discuss the process of filing for Investigational New Drug (IND). **5x2=10**

(b) Define NDA (New Drug Application) documentary requirement for submission in regulatory authorities.

2. Discuss the constitution and functioning of Central Drugs Standard Control Organization (CDSCO). **10**

3. Explain the following (***any two***) : **5x2=10**

(a) Phase IV clinical trial

(b) Informed consent process

(c) Ethics committee

4. (a) Discuss in detail the animal toxicity studies.

(b) Explain the various development phases of clinical trials. **5x2=10**

5. (a) What do you understand by OTC medicine ? 3

(b) Explain the term Generic drugs. 3

(c) Write down the short note on special products (special drugs). 4

6. (a) What are labelling requirement of medical devices ? 5x2=10

(b) What do you understand by blindness in clinical trial ?

7. (a) Discuss the brief of Chopra Committee regarding the pharmaceutical legislature in India. 4

(b) Define ***any three*** : 6

(i) CDSCO (ii) DTAB

(iii) GEAC (iv) RCGM

(v) ICMR

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

(a) Spurious Drugs

(b) Shelf Life

(c) Poison Act