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MVE-004

00285

POST GRADUATE DIPLOMA IN PHARMACEUTICAL SALES MANAGEMENT PGDPSM

Term-End Examination

December, 2010

MVE-004 : DRUGS REGULATORY AFFAIRS

Time : 2 hours *Maximum Marks : 50*

Note : *(i) Answer **any five** questions.*

*(ii) All questions **carry equal marks (10 each).***

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1. (a) Define "Drug" and "New Drug" as per the Drugs and Cosmetic Act and rules 1940 ? **4**

(b) Describe the powers of a Drug Inspector ? **4**

(c) Define the mis branded drugs. **2**

2. (a) Define the special products. **2**

(b) Give the full forms of ***any four.*** **4**

(i) DTAB (ii) DST

(iii) IBSC (iv) IND

(v) IDMA (vi) GATT

(vii) RCGM

(c) Write a short note on. Genetic Engineering Approval Committee (GEAC). **4**

3. (a) Write any five function of National Pharmaceutical pricing authority. **5**

(b) Enlist any five activities of Department of Biotechnology. **5**

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

(a) Pharmacy Council of India

(b) Sale of Medicine

(c) Placebo

(d) Phases of clinical trial

5. (a) What is medicinal and toilet preparation Act ? **5x2=10**

(b) State various offences and penalties under this Act.

6. (a) Give the organisational set up of Central Drugs Standard Control Organisation. **5x2=10**

(b) Write a short note on Indian Pharmaceutical Industry.

7. (a) What is pre-clinical evaluation of Drugs ?

(b) State the configuration of an ethics committee. **5x2=10**

8. Discuss *any two* : **5x2=10**

(a) Novel diagnostic agents

(b) Post Marketing surveillence.

(c) Investigational new drugs.
