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MVE-004

00543

POST GRADUATE DIPLOMA IN PHARMACEUTICAL SALES MANAGEMENT PGDPSM

Term-End Examination

December, 2011

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. What is pre-clinical evaluation of drugs ? Describe the steps involved. **10**

2. List the two main functions of National Pharmaceutical Pricing Authority (NPPA) and describe the methodology of price fixation of bulk drugs by NPPA. **10**

3. (a) Give the full forms of any five. **5x2=10**

(i) DPCO
(ii) GATT
(iii) AIDS
(iv) CDSCO
(v) GEAC
(vi) DBT
(vii) GCP

(b) Discuss the role of ICMR in biomedical research.

4. Discuss on following in brief *(any two)* : 5x2=10
   (a) Phase II of clinical trial
   (b) Post marketing survellience
   (c) Ethics committee

5. Explain *any four* in brief : 2.5x4=10
   (a) Over the Counter Medicine
   (b) Drugs Technical Advisory Board
   (c) Investigational New Drugs
   (d) New Drug Application
   (e) Special Products

6. Discuss in detail the various techniques adopted for storage of drugs. 10

7. Write short notes on *any two* : 5x2=10
   (a) Poison Act
   (b) Generic drugs
   (c) Informed Consent

8. Write short notes on *any two* : 5x2=10
   (a) Drug consultative committee
   (b) MTP (Medical Termination of Pregnancy)
   (c) Drug price control order