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MVE-004

00535

POST GRADUATE DIPLOMA IN PHARMACEUTICAL SALES MANAGEMENT PGDPSM

Term-End Examination

June, 2011

MVE-004 : DRUGS REGULATORY AFFAIRS

Time : 2 hours *Maximum Marks : 50*

Note : *Answer **any five** questions. All questions **carry equal** marks.*

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1. (a) Describe the role of pharmacy council India in pharmacy education. **5**

(b) Write a short note on Indian Pharmaceutical Industry. **5**

2. (a) What are different types of toxicity studies and describe any one type of study in details ? **6**

(b) State the limitation of toxicity studies. **4**

3. (a) What are different phases of clinical trial and their importance ? **6**

(b) What is safety criteria for large scale experiments and manufacturing adopted by Genetic engineering approval committee ? **4**

4. (a) Outline the procedure for pricing of formulation by NPPA ? **6**

(b) What are the functions of Reviews Committee on Genetic Manipulation (RCGM) ? 4

5. (a) Give an outline of clinical studies in paediatric special population with reference to clinical trials. 6

(b) Give the full form of the following (**any four**): 4

(i)	BRCPC	(ii)	ICMR
(iii)	NDA	(iv)	RCGM
(v)	IND	(vi)	CDSCO
(vii)	IDMA		

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

(a) The Drugs and Magic Remedies act

(b) Drug Consultative Committee

(c) Spurious drugs

7. Write short notes on (**any two**) : **5x2=10**

(a) Drugs Technical Advisory Board

(b) Expiry date of Drugs

(c) Single and double blind studies

(d) New Drugs

8. (a) Outline the requirement of labelling of Medicine. 6

(b) Describe different types of Investigational new drugs. 4