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MVE-004

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POST GRADUATE DIPLOMA IN PHARMACEUTICAL SALES MANAGEMENT (PGDPSM)

Term-End Examination

June, 2016

MVE-004 : DRUGS REGULATORY AFFAIRS

Time : 2 hours *Maximum Marks : 50*

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

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

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1. (a) Give the full forms of **any five** : **1x5=5**

(i) DGTD
(ii) IPI
(iii) NDP
(iv) OTC
(v) CRAMS
(vi) IPA
(vii) UNISEF

(b) What are Over the Counter Medicines ? **5**

2. (a) Give an overview of the governing body of the Indian Council of Medical Research (ICMR). **5**

(b) Discuss the role and responsibility of CDSCO. **5**

3. (a) What is carcinogenicity and teratogenicity ? **5**

(b) (i) What is acute toxicity study ? **2.5**

(ii) Define informed consent. **2.5**

4. Discuss **any two** in brief : **5x2=10**

(a) What is the process of approval of vaccines ?

(b) Discuss the role and constitution of State Biotechnology Co-ordination Committee (SBCC).

(c) Discuss the structure of IBSC committee.

5. Explain **any one** in detail : **10**

(a) What are the different phases of clinical trials and what is their importance ?

(b) Give the functions of National Pharmaceutical Pricing Authority.

6. (a) Discuss various drugs legislations during the British Rule. **5**

(b) Discuss the genesis of drugs act 1940. **5**

7. (a) Discuss the salient features of adulterated drugs. **5**

(b) Discuss the various storage conditions of medicines. **5**

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

(a) Narcotic Drugs and Psychotropic Substances (NDPS) Act.

(b) Medical Termination of Pregnancy (MTP) Act, 1971.

(c) Drug Price Control Order.