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MVE-004

00486

POST GRADUATE DIPLOMA IN PHARMACEUTICAL SALES MANAGEMENT (PGDPSM)

Term-End Examination

June, 2013

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).*

1. (a) Discuss the constitution and function of Drug Technical Advisory Board (DTAB). 6

   (b) Discuss phase - one of clinical - trial. 4

2. (a) Describe the role and responsibilities of Indian Council of Medical Research. 6

   (b) Briefly describe Drug Price Control Order (DPCO) 1995. 4

3. (a) State the objective and function of Central Drugs Standard Control Organisation. 6

   (b) Discuss the importance of Informed consent in clinical trial. 4

4. (a) Discuss the approval procedure of Investigational New Drugs (IND). 7

   (b) Describe shelf life of drugs. 3

5. Discuss the responsibilities of sponsor, regulator, investigator and ethics committee before initiation of clinical trials. 10

6. (a) Briefly state the Medical Termination of Pregnancy (MTP) Act 1971. 5

(b) Discuss the role of Genetic Engineering Approval Committee (GEAC). 5

7. Write short notes on (*any four*) : 2.5x4=10

(a) Placebo

(b) Blindness

(c) Pharmacy Council of India

(d) Informed consent

(e) OTC drugs

(f) Post Marketing Surveillance (PMS)

8. Discuss in detail, the procedure for pricing of drugs. 10