No. of Printed Pages : 2

MVE-004

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POST GRADUATE DIPLOMA IN PHARMACEUTICAL SALES MANAGEMENT (PGDPSM)

Term-End Examination

December, 2012

MVE-004 : DRUGS REGULATORY AFFAIRS

Time : 2 hours *Maximum Marks : 50*

Note : *(i) Answer **any five** questions.*
*(ii) All carry **equal** marks **(10** each).*

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1. (a) Give the composition and function of Ethics committee. **6**

(b) Discuss the out look of Indian Pharmaceutical Industry. **4**

2. (a) Describe Pre - clinical evaluation of drugs. **6**

(b) Discuss the role of Drugs Consultative Committee (DCC). **4**

3. (a) State the various activities of Dept. of Science & Technology (DST) **6**

(b) Give the organisational set up and functions of Indian Council of Medical Research (ICMR) **4**

4. (a) Discuss the role of Placebo in clinical trial. **6**

(b) Discuss shelf - life of drug **4**

5. (a) Discuss the genesis of Drug Act, 1940 7

(b) Discuss the functions of NPPA. 3

6. (a) Discuss the objectives and function of Review Committee on Genetic Manipulation (RCGM) 5

(b) Discuss Drug & Magic Remedies Act. 5

7. Write a short notes on *(any Four)* **2.5x4=10**

(a) Poison Act

(b) MTP Act

(c) DPCO

(d) Toilet Preparations

(e) Post Marketing Surveillance (PMS)

(f) Placebo

8. Discuss in detail current status of Pharmaceutical Industry in India. **10**