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MVE-004

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POST GRADUATE DIPLOMA IN PHARMACEUTICAL SALES MANAGEMENT (PGDPSM)

Term-End Examination

December, 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).*

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1. (a) What is the full form of ***any five*** of the following ? **5**

(i) CRAMS

(ii) UNICEF

(iii) DPCO

(iv) NDP

(v) IPA

(vi) IPI

(vii) WHO

(viii) GATT

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

2. (a) How the retail prices of formulations are calculated ? **5**

(b) List the task performed by Central Drug Standard Control Organization. **5**

3. (a) What are the Phase III Clinical trial ? 5

(b) What is Placebo ? 5

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

(a) Preclinical evaluation of Drugs.

(b) Informed consent.

(c) Post Marketing Surveilence Study.

5. (a) What are special products ? 5

(b) What is the process of approval of Vaccines and biologicals ? 5

6. Explain *any two* in brief : 5x2=10

(a) Investigational New Drugs.

(b) New Drug Approval Process.

(c) Rules of Drugs & Cosmetics Act.

(d) Bulk Drug.

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

(a) Pharmacy Act 1948.

(b) Spurious drugs.

(c) Drug Consultative Committee (DCC).

8. (a) Discuss the requirement of Labelling and Packaging of Medicines in Drugs and Cosmetics Act. 5

(b) What is 'Narcotic Drugs and Psychotropic Substances' Act (NDPS) ? 5