No. of Printed Pages : 2 **MVE-004**

POST GRADUATE DIPLOMA IN PHARMACEUTICAL SALES MANAGEMENT (PGDPSM)

Term-End Examination

December, 2015

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** : **5**

(i) UNISEF
(ii) DPCO
(iii) TRIPS
(iv) GATT
(v) IPA
(vi) CRAMS
(vii) OTC

(b) What are the major sectors of Indian pharmaceutical industry ? **5**

2. (a) What do you understand by the Regulatory authorities ? **5**

(b) Discuss the different functions of National Pharmaceutical Pricing Authority (NPPA). **5**

3. (a) What is preclinical evaluation of drugs ? **5**

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

(ii) What is placebo ? **2.5**

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

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

(b) What are the composition of Institutional Bio-Safety Committee (IBSC) ?

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

(a) What is the mandatory information that is supposed to be provided when filing the Investigational New Drug Application ?

(b) Discuss the Requirement of permission to import and manufacture fixed dose combinations.

6. (a) Discuss the constitution of Pharmacy Council of India. **5**

(b) Discuss the Pharmacy Act. **5**

7. (a) What is Drug Technical Advisory Board (DTAB) ? Give its Constitution. **5**

(b) What are the powers of Drug Inspectors as per Drugs and Cosmetics Act ? **5**

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

(a) What are drugs and magic Remedies Act ?

(b) What are the Poison Act, 1919 ?

(c) What is medicinal and toilet preparation (Excise duty) act ?