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**MVE-004**

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# POST GRADUATE DIPLOMA IN PHARMACEUTICAL SALES MANAGEMENT (PGDPSM)

## Term-End Examination

## December, 2017

## MVE-004 : DRUGS REGULATORY AFFAIRS

*Time : 2 hours* *Maximum Marks : 50*

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

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

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

   (i) DPCO **(ii)** TRIPS

   (iii) IPA **(iv)** FDA

   (v) ICAR **(vi)** DST

   (vii) RDAC

   (b) Describe the phase wise evolution of Indian Pharmaceutical Industry. **5**

2. (a) Write the constitution and function of Genetic Engineering Approval Committee (GEAC). **5**

   (b) What are the FDA requirements for manufacturing of vaccines ? **5**

3. (a) What are the different types of toxicity studies ? Describe any one type. **5**

   (b) Name the four phases of Clinical trials. Briefly describe any one phase. **5**

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

(a) Drugs Consultative Committee

(b) Shelf life of drugs

(c) Misbranded drugs

5. Discuss in detail 'Drug and Cosmetic Act '1940. **10**

6. Write short notes on **any four** : **2.5x4=10**

(a) Informed Consent

(b) Teratogenicity

(c) Post-marketing Surveillance

(d) Adulterated drugs

(e) Cell hybridization

7. (a) What are the factors affecting the potency of drugs during storage ? Describe briefly. **5**

(b) Describe the responsibilities of Ethics Committee. **5**

8. (a) What is Poison Act, 1919 ? Write the power of State government for Sale of Poisons. **5**

(b) Give the functions of National Pharamaceutical Pricing Authority (NPPA). **5**