No. of Printed Pages : 3

MVE-004

POST GRADUATE DIPLOMA IN PHARMACEUTICAL SALES MANAGEMENT (PGDPSM)

00274

Term-End Examination

December, 2014

MVE-004 : DRUGS REGULATORY AFFAIRS

Time : 2 hours *Maximum Marks : 50*

Note : *Attempt any **five** questions.*

1. (a) What are the functions of the Review Committee on Genetic manipulation ? *6*

(b) Describe the evolution of Indian Pharmaceutical Industry. *4*

2. (a) Why is the task-force formulated for DOBT ? Name any three task-forces of DOBT. *4*

(b) Discuss the procedure for fixing the Pricing of Formulations by NPPA. *6*

3. (a) What do you mean by LD 50 ? Give the procedure for obtaining permission to start a clinical trial. *6*

(b) Write down the essential composition of an ethics committee. *4*

4. (a) Give the full form of any ***four*** of the following : *4*

(i) RDAC

(ii) ICMR

(iii) IBSC

(iv) GEAC

(v) DLC

(vi) SBCC

(vii) VRBPAC

(b) What is the process of approval of vaccines or other biologicals ? *6*

5. (a) Give an overview of drug approval process. *4*

(b) What is the mandatory information that is supposed to be provided when filing the New Drug Application ? *6*

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

(b) Discuss the Genesis of Drugs in 1940. *4*

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

(b) Discuss the labelling and packaging of medicines under Drugs and Cosmetics Acts and Rules. *5*

8. Write short notes on any ***two*** of the following : *2×5=10*

(a) Narcotic Drugs and Psychotropic Substances (NDPS) Act

(b) Drugs and Magic Remedies Act

(c) Drugs Prices Control Order