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MVE-004

POST GRADUATE DIPLOMA IN PHARMACEUTICAL SALES MANAGEMENT (PGDPSM)

Term-End Examination

December, 2016

MVE-004 : DRUGS REGULATORY AFFAIRS

Time : 2 hours *Maximum Marks : 50*

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

1. (a) What do you mean by generic and OTC product ? Describe in brief. 5

(b) Write the different phases involved in evolution of Indian pharmaceutical Industries, indicate in tabular form. 5

2. (a) Describe the different tasks performed by CDSCO. Enlist the major responsibilities of Dept. of Science and Technology (DST). 5

(b) What does MAPE stands for ? How are the retail prices of formulations calculated ? 5

3. (a) What are the different phases in clinical evaluation of a drug in human beings ? Describe phase III clinical trial in brief. 5

(b) Define **any two** : 5

(i) Informed consent

(ii) Placebo

(iii) Ethics committee

4. (a) What are the processes of approval of vaccines and other biologicals ? 6

(b) Write the full forms and functions of following committee. **(Any two)** : 4

(i) GEAC

(ii) RDAC

(iii) IBSC

(iv) CBER

5. (a) What are functions of DTAB and DCC ? 5

(b) Define misbranded, adulterated and spurious drugs. 5

6. (a) What do you understand by expiry date of a Drug ? 5

(b) Define the terms "Drug" and "cosmetics". 5

7. (a) What are the details to be shown on the label of a medicine ? 5

(b) Discuss the different factors affecting the potency of drug during storage. 5

8. Write short note on **any two** of the followings : **2x5=10**

(a) Medical Termination of Pregnancy Act.

(b) Drugs and Magic Remedies Act.

(c) Drug prices control order.

(d) Paison Act.
