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MVE-004

POST GRADUATE DIPLOMA IN PHARMACEUTICAL SALES MANAGEMENT(PGDPSM)

Term-End Examination

MVE-004 : DRUGS REGULATORY AFFAIRS

Time : 2 Hours] *[Maximum Marks : 50*

Note: Answer any five questions.

All questions carry equal marks

1. (a) Write the Historical Evolution of Indian Pharma Industry. 5
   (b) Discuss the confirmatory clinical trial phase III. 5
2. (a) Give the major responsibilities of department of Science and Technology (DST). 5
   (b) Write the main function of Department of Biotechnology (DBT). 5
3. (a) Explain the special population studies on Pediatrics. 5
   (b) Discuss the Responsibilities of the Ethics committee. 5
4. (a) Give the full form of any five of following: 1x5=5

i	DLC	ii	RCGM
iii	IBSC	iv	SBCC

v GEAC vi RDAC

vii ICMR

(b) What is the composition of the committee of Genetic Engineering Approval Committee (GEAC)? 5

5. Explain any four of the following: 2.5x4=10

(a) Misbranded drugs

(b) Schedule y

(c) Bulk Drug

(d) Formulation

(e) Bulk drug

6. (a Discuss the aims of Pharmacy act 1948. 5

(b) Give the Genesis of modern medicine and pharmacy. 5

7. (a) What are directions given under Drugs and Cosmetics act for labeling packaging requirement? 5

(b) What are the factors affecting the portending and storage condition of the drugs? 5

8. Write short notes on any two of the following:5x2=10

(a) Narcotic Drugs and Psychotropic Substances act (NDPS).

(b) (MTP) Medical Termination of Pregnancy Act 1971.

(c) "The drugs and magic remedies act."

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