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MVE-004

POST GRADUATE DIPLOMA IN PHARMACEUTICAL SALES MANAGEMENT (PGDPSM)

Term-End Examination

June, 2015

MVE-004 : DRUGS REGULATORY AFFAIRS

Time : 2 hours *Maximum Marks : 50*

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

1.	(a)	Discuss the current status of pharmaceutical industry.	**5**
	(b)	What were the changes and reforms in pharma industry after 1995 ? Explain any one in brief.	**5**
2.	(a)	Write any five functions of National Pharmaceutical Pricing Authority.	**5**
	(b)	Give the procedure for fixing the pricing of formulations.	**5**
3.	(a)	Describe the 'sources of drug' step followed during the preclinical evaluation of drugs.	**6**
	(b)	What is meant by blindness in clinical trial ? Describe in brief its two types.	**4**
4.	(a)	Discuss the regulations applicable to the biologicals produced by rDNA technology.	**5**
	(b)	What are the rules that govern approval and prohibitions of novel diagnostic agents ?	**5**

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

   (i) NDA

   (ii) GEAC

   (iii) DLC

   (iv) SBCC

   (v) RDAC

   (b) Give an overview of new drug approval process. **6**

6. (a) What are the aims of Pharmacy Act 1948 ? **5**

   (b) Describe the 'Education Regulations' of Pharmacy Council of India. **5**

7. Write short notes on (**any two**) of the following : **10**

   (a) Storage of medicines in cold conditions

   (b) Shelf life

   (c) Modern trends in labelling of medicines

8. (a) Discuss the Medicinal and Toilet Preparations Act 1995. **5**

   (b) What is the Medical Termination of Pregnancy (MTP) Act ? Give any three reasons for MTP. **5**