No. of Printed Pages : 2

MVE-004

00528

POST GRADUATE DIPLOMA IN PHARMACEUTICAL SALES MANAGEMENT (PGDPSM)

Term-End Examination

June, 2018

MVE-004 : DRUGS REGULATORY AFFAIRS

Time : 2 hours *Maximum Marks : 50*

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

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

---

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

(i) NPPA (ii) DGTD

(iii) BRCPC (iv) ICMR

(v) IPI (vi) RDAC

(vii) CDSCO

(b) Give a brief summary on evoluation of Indian pharmaceutical industry. 5

2. (a) What are the functions of review Committee on genetic manipulation ? 5

(b) What is the process of approval of vaccines and other biologicals ? 5

3. (a) Give an overview on new drug approval process. 5

(b) Describe Shelf life of drugs. 5

4. (a) Discuss the history of pharmaceutical legislation in India. 5

(b) Describe the role of drugs enquiry Committee. 5

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

(a) Carcinogenicity

(b) Drug Technical Advisory Board (DTAB)

(c) Therapeutic Confirmatory trials

(d) Acute Toxicity Study

(e) Mis-branded drugs

(f) OTC drugs

6. Discuss **any two** : 5x2=10

(a) Narcotic Drugs and Psychotropic Substance (NDPS) Act.

(b) Drug Price Control Order, 1995.

(c) The Medical Termination of Pregnancy (MTP) Act, 1971.

7. (a) What is Pharmacy Council of India. Give its functions ? 5

(b) State the responsibilities of Department of Science and Technology (DST). 5

8. (a) What are salient features of adulterated drug and spurious drugs ? 5

(b) Discuss the various storage condition prescribed by Indian pharmaceutical manufacturers. 5