

M.PHARM. (REGULATORY AFFAIRS) SEM-I (CBCS-2019 COURSE) : MARCH - 2022
SUBJECT : REGULATIONS AND LEGISLATION FOR DRUGS AND COSMETICS,
MEDICAL DEVICES, BIOLOGICALS AND HERBALS AND FOOD AND
NUTRACEUTICALS IN INDIA AND INTELLECTUAL PROPERTY RIGHTS

Day : Monday
Date : 28.03.2022 M20744-2022

Time : 10.00 A.M. To 1.00 P.M.
Max. Marks : 75

N.B.

- 1) **Q.No. 1 and Q.No. 5** are **COMPULSORY**. Out of remaining questions answer **ANY TWO** from **each** section.
- 2) Answers to both sections should be written in **SEPARATE** answer books.
- 3) Figures to the **RIGHT** indicate **FULL** marks.

SECTION - I

- Q.1** Discuss the functions of PCI. (08)
- Q.2**
- a) Describe the rules, schedules and guidelines for approval of medical devices. (05)
 - b) Discuss regulatory requirements and approval procedures for herbals. (05)
 - c) Explain in detail Drug Price Control Order Act. (05)
- Q.3** Explain in detail the organization and responsibilities of CDSCO. (15)
- Q.4** Write notes on **ANY TWO** of the following : (15)
- a) Cruelty to Animals act
 - b) Medicinal and Toilet Preparations (Excise Duties) Act
 - c) Offenses and penalties in NDPS Act

SECTION - II

- Q.5** Add a note on patent and trade mark. (07)
- Q.6** Explain the guidelines for drug testing in animals. (15)
- Q.7** Elaborate on DBT guidelines for stem cell research. (15)
- Q.8** Write notes on **ANY TWO** of the following : (15)
- a) Bioavailability
 - b) BIS standards
 - c) BCS classification of drugs
