

**M. PHARM. SEM-II (CHOICE BASED CREDIT & GRADE
SYSTEM) : SUMMER - 2019**
SUBJECT : ELECTIVE – II : B) IPR AND REGULATORY AFFAIRS

Day : Saturday
Date : 06/07/2019

Time : 10.00 A.M. TO 01.00 P.M.
Max. Marks : 60

S-2019-4492

N. B. :

- 1) Attempt **ANY THREE** questions from Section – I and attempt **ANY THREE** questions from Section – II.
- 2) Figures to the right indicate **FULL** marks.
- 3) Answers to both the sections should be written in **SEPARATE** answer books.

SECTION - I

- Q. 1** What is NOT patentable as per the Indian Patent Act, 1970? **(10)**
- Q. 2** What are the salient features of DPCO? **(10)**
- Q. 3** What are important aspects of the Narcotic Drugs and Psychotropic Substances Act of 1985? **(10)**
- Q. 4** Write short notes on **ANY TWO** of the following: **(10)**
- a) Trademark, Copyright and Design
 - b) Bonded and non –bonded premises as per Excise Duties Act
 - c) Objectionable Advertisements Act

SECTION - II

- Q. 5** Discuss various types of audits with special emphasis on Internal Audit. **(10)**
- Q. 6** Discuss sewage disposal and waste management provisions in detail. **(10)**
- Q. 7** Discuss the procedure for vendor approval in detail. **(10)**
- Q. 8** Write short notes on **ANY TWO** of the following: **(10)**
- a) Biostatistic Tool Techniques
 - b) Biomedical Waste Management
 - c) Contract Manufacturing

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