

**M. PHARM. SEM-II (CHOICE BASED CREDIT & GRADE SYSTEM)
: SUMMER - 2018**

SUBJECT: ELECTIVE – II: IPR & REGULATORY AFFAIRS

Day: **Saturday**
Date: **07/07/2018**

S-2018-4013

Time: **10.00 AM to 01.00 PM**
Max. Marks: 60

N.B.:

- 1) Attempt any **THREE** questions from Section –I and 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 book.

SECTION-I

- Q.1** Write about the salient features of Narcotic Drugs and Psychotropic substances Act 1985. (10)
- Q.2** Discuss the steps in process of patenting an invention as per Indian patent Act 1970. (10)
- Q.3** Write about Labour Laws in India as applicable to Pharma Industry. (10)
- Q.4** Write short notes on any **TWO** of the following: (10)
- a) DPCO
 - b) GATT and TRIPS
 - c) Bonded and non-bonded premises as per Excise Duties Act

SECTION-II

- Q.5** Discuss the process of inspection of a manufacturing plant as per WHO guidelines. (10)
- Q.6** Discuss contract manufacturing in relation to pharma Industry. (10)
- Q.7** Write about self-inspection and its importance in Pharma Industry. (10)
- Q.8** Write short notes on any **TWO** of the following: (10)
- a) Biomedical waste (Management and Handling) Rules 1998
 - b) Biostatistics tools and techniques
 - c) Vendor Selection process

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