M. PHARM. SEM-II (CHOICE BASED CREDIT & GRADE SYSTEM)
: SUMMER - 2018
SUBJECT: ADVANCE CORE SUBJECT- II: ADVANCED DRUG REGULATORY AFFAIRS -II

Day: **Tuesday** | **S-2018-4004** | Time: **10.00 AM to 01.00 PM**
Date: **03/07/2018** | 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 Discuss the requirements for obtaining Biowaivers as per 21 CFR320. **(10)**

Q.2 US FDA cGMP requirements for personnel, facilities and equipment. **(10)**

Q.3 Discuss various type of 'para' filings in the US. **(10)**

Q.4 Write short notes on any **TWO** of the following: **(10)**

a) IND filing with US FDA
b) Salient features of the Hatch Waxman Act
c) EU cGMP requirements for Documentation

SECTION-II

Q.5 Discuss various routes of marketing Authorization in Europe. **(10)**

Q.6 Write in detail about SUPAC documentation required for non- sterile semi-solid dosage forms. **(10)**

Q.7 Describe various approaches suggested by US guidance for setting dissolution specification for New chemical Entity. **(10)**

Q.8 Write short notes on any **TWO** of the following: **(10)**

a) IV- IV correlation
b) European Drug master file
c) Post approval changes

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