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

Day: **Saturday** | **S-2018-4012** | Time: **10.00 AM to 01.00 PM**
Date: **07/07/2018** | 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 various documentation provision under Schedule M. **(10)**

Q.2 Discuss Generic Drug Filing under section 505 (j) in detail with special emphasis on Para IV filing. **(10)**

Q.3 What are the similarities and differences in NDA and 505 (b) (2)? Discus 505 (b) (2) filing in detail. **(10)**

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

a) GMP for topical products

b) Regulatory requirements for Cosmetics

c) Biowaivers

SECTION-II

Q.5 Discuss structure and functions of MCC. Add a note on stability study guideline of MCC. **(10)**

Q.6 Discuss various routes of obtaining marketing Authorization as per MHRA. **(10)**

Q.7 How do you define inventions under US patent Act? Explain types of US patent applications in detail. **(10)**

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

a) TGA – Australia

b) GATT and WTO

c) Section 3 and 4 exclusions under Indian patent Act 1970

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