M. PHARM. SEM-II (CHOICE BASED CREDIT & GRADE SYSTEM) : SUMMER - 2019

SUBJECT: ELECTIVE – II: DRUG REGULATORY AFFAIRS

Day: Saturday
Date: 06/07/2019

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

S-2019-4491

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 What is biowaiver? Discuss USFDA provisions for getting a biowaiver. **(10)**

Q.2 Discuss generic drug filing as per 505 (j) in detail. What are the exclusivities given for Para IV filing? **(10)**

Q.3 Discuss GMP requirements for parenteral products with emphasis on Air handling system. **(10)**

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

a) Schedule L-1 Good Laboratory Practices

b) Premises for Cosmetics

c) Schedule T

SECTION-II

Q.5 Discuss WHO- GMP guidelines with specific requirements for documentation and Quality management system. **(10)**

Q.6 Discuss Japanese drug product approval process in detail. **(10)**

Q.7 Discuss effect of GATT and WTO on Indian pharmaceutical Industry. **(10)**

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

a) Copyright and trademarks

b) MCC South Africa

c) Patent Term extension

* * * *