M. PHARM. SEM-I (CHOICE BASED CREDIT & GRADE SYSTEM) : WINTER - 2018

SUBJECT : ADVANCED DRUG RUGULATORY AFFAIRS – I

Day : Monday **W-2018-4160** Time : 10.00 A.M. TO 01.00 P.M.
Date : 07/01/2019 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 books.
4) Draw neat and labelled diagram **WHEREVER** necessary.

SECTION - I

Q. 1 Discuss the basic principles of Material Management. **(10)**

Q. 2 Discuss the WHO good practices in production and quality control. **(10)**

Q. 3 Discuss in details, fundamentals of Quality Management System as per ISO. **(10)**

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

a) ANVISA guidelines for GMP

b) Market complaints and product recall

c) Documentation Control

SECTION - II

Q. 5 Discuss various steps involved in pharmaceutical development. **(10)**

Q. 6 Discuss Quality Risk Management in detail. **(10)**

Q. 7 Discuss roles and responsibilities of various stakeholders in conducting a clinical trial. **(10)**

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

a) Accuracy, precision and robustness of analytical method

b) Reporting of ADR in clinical trial

c) Components of a CTD dossier

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