M. PHARM. SEM-I (CHOICE BASED CREDIT & GRADE SYSTEM) : WINTER - 2017

SUBJECT : ADVANCED DRUG RUGULATORY AFFAIRS – I

Day : **Monday**
Date : **08/01/2018**

W-2017-3863

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 books.
4) Draw neat and labelled diagram **WHEREVER** necessary.

SECTION - I

Q. 1 Discuss important provisions of GMP guidance generally accepted worldwide. **(10)**

Q. 2 Discuss ISO 9001:2008 structure briefly. **(10)**

Q. 3 How will you handle market complaints and product recalls? **(10)**

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

a) Drug approval process in Japan

b) Structure and composition of MCC

c) Quality by Design

SECTION - II

Q. 5 Enumerate Quality System elements. Discuss Quality Risk Management. **(10)**

Q. 6 Discuss various elements of CTD as per ICH. Add a note on e-filing (e CTD). **(10)**

Q. 7 Discuss important aspects pharmaceutical product development. **(10)**

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

a) Clinical trial management

b) Stability study - zones and protocols

c) Adverse drug reaction reporting

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