

**M. PHARM. SEM-I (CHOICE BASED CREDIT & GRADE  
SYSTEM) : WINTER - 2018**  
**SUBJECT : ADVANCED QUALITY ASSURANCE TECHNIQUES – I**

Day : Monday  
Date : 07/01/2019

**W-2018-4159**

Time : 10.00 A.M. TO 01.00 P.M.  
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 aspects related to Materials Management in Pharma Industry. (10)
- Q. 2** Discuss the requirements for buildings and facilities of a pharma manufacturing unit. (10)
- Q. 3** What are the responsibilities of heads of QC and production? Also add a note on their combined responsibilities. (10)
- Q. 4** Write short notes on **ANY TWO** of the following: (10)
- a) Personnel Training and Personnel Hygiene in pharmaceutical industry
  - b) Design and construction of process equipment
  - c) Factors in contractor selection for outsourcing of pharma operations

**SECTION - II**

- Q. 5** Discuss in detail manufacturing of Q. A. aspects of sterile pharmaceutical products. (10)
- Q. 6** Elaborate on recalled, returned rejected and recovered product. Add note on product complaint. (10)
- Q. 7** Discuss I.P.Q.C. activities in production and calculation of yields with its importance. (10)
- Q. 8** Write short notes on **ANY TWO** of the following: (10)
- a) WHO guidelines on inspection of Pharma MFG facilities
  - b) Concept of QA and QC
  - c) Release of finished products