

**M. PHARM. SEM-I (CHOICE BASED CREDIT &  
GRADE SYSTEM) : WINTER - 2017**  
**SUBJECT : ADVANCED QUALITY ASSURANCE TECHNIQUES – I**

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

Time : **10.00 AM to 01.00 PM**  
Max. Marks : **60**

**W-2017-3862**

**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** Describe the important aspects related to building and facilities of pharmaceutical manufacturing units. **(10)**
- Q. 2** What is Outsourcing? What are the advantages and disadvantages of outsourcing pharmaceutical operations? Discuss 'due diligence' while contractor selection. **(10)**
- Q. 3** Write about Materials Management in Pharma Industry. **(10)**
- Q. 4** Write short notes on **ANY TWO** of the following: **(10)**
- a) Combined responsibilities of Heads of Production and QC
  - b) Equipment maintenance and cleaning
  - c) Personnel qualification, experience and training in pharma industry

**SECTION - II**

- Q. 5** Define Mix-ups and Cross contamination. Elaborate on avoiding it in pharmaceutical production. **(10)**
- Q. 6** Explain I. P. Q. C activities in production and its importance. **(10)**
- Q. 7** Discuss in detail key activities in quality management function as per cGMP guidelines. **(10)**
- Q. 8** Write short notes on **ANY TWO** of the following: **(10)**
- a) Q. A. aspects of biological products
  - b) Process Deviations
  - c) Recalled, Returned and Recovered Products

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