

**M. PHARM. SEM-II (CHOICE BASED CREDIT & GRADE  
SYSTEM) : SUMMER - 2019**  
**SUBJECT : ADVANCE CORE SUBJECT – II : ADVANCED QUALITY ASSURANCE  
TECHNIQUES - II**

Day : Tuesday  
Date : 02/07/2019

**S-2019-4482**

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

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N.B.

- 1) Attempt **ANY THREE** questions from each section.
  - 2) All questions carry **EQUAL** marks.
  - 3) Answers to both the sections should be written in the **SEPARATE** answerbooks.
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**SECTION – I**

- Q.1** Discuss on FDA guidelines for validations.
- Q.2** Explain with examples importance of cleaning validation **OR** vendor certification.
- Q.3** Explain with the help of mathematical equations the validation of steam sterilization process.
- Q.4** Write short notes on **ANY TWO** of the following.
- a) F, Z and D values
  - b) CIP / SIP
  - c) Computer systems validation
  - d) Calibration Master Plan

**SECTION – II**

- Q.5** Elaborate on analytical method valuation.
- Q.6** Discuss on importance on HVAC validation.
- Q.7** Discuss on validation of water system for plants for regulated market.
- Q.8** Write short notes on **ANY TWO** of the following.
- a) Contract manufacturing
  - b) Role of QA in validation
  - c) Different stages of validation
  - d) cGMP and process validation

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