

M. PHARM. SEM-II (CHOICE BASED CREDIT & GRADE SYSTEM)

: SUMMER - 2018

**SUBJECT : ADVANCE CORE SUBJECT – II : ADVANCED QUALITY ASSURANCE
TECHNIQUES - II**

Day : **Tuesday**
Date : **03/07/2018**

S-2018-4003

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

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 various features of ICH guidelines pertaining to Process Validation.
- Q.2** Elaborate on Organizing for Validation.
- Q.3** Explain with the help of Mathematical equations the validation of sterilization process.
- Q.4** Write short notes on **ANY TWO** of the following.
- a) Analytical methods Validation
 - b) Cleaning Validation
 - c) Computer Systems Validation
 - d) Calibration Master Plan

SECTION – II

- Q.5** Discuss on prospective, retrospective, concurrent and revalidation.
- Q.6** Elaborate on salient features of validation of HVAC system.
- Q.7** Discuss on importance of validation of water system.
- Q.8** Write short notes on **ANY TWO** of the following.
- a) Process validation and quality assurance
 - b) Validation in contract manufacturing
 - c) Harmonization, cGMP and validation
 - d) Validation of filtration system

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