

**M. PHARM. SEM-II (CHOICE BASED CREDIT & GRADE
SYSTEM) : SUMMER - 2019**
**SUBJECT : ELECTIVE – III : PHARMACEUTICAL PLANT DESIGN AND
OPERATIONS**

Day : Tuesday
Date : 09/07/2019

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

S-2019-4495

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.

SECTION – I

- Q.1** Elaborate on cGMP requirements for Pharmaceutical facility for Regulated markets.
- Q.2** Explain with examples the role of Project Manager in Fast Track Project Management.
- Q.3** Draw with details the route charts for Tablet manufacturing and Packaging facility (Large Scale) **OR** Sterile (Lyophilized Products) Products facility (Large Scale) for advanced markets.
- Q.4** Write short notes on **ANY TWO** of the following.
- a) Maharashtra Factories Act and rules
 - b) QC lab and Pilot Plant
 - c) Hard Gelatin Capsules Manufacturing route chart
 - d) Pharmaceutical Ware house

SECTION – II

- Q.5** Discuss on various important features of effluent treatment plant.
- Q.6** Elaborate on operation of production department.
- Q.7** Discuss on importance of Engineering department.
- Q.8** Write short notes on **ANY TWO** of the following.
- a) Pharma ware house
 - b) Records room for QA
 - c) Reject area in stores
 - d) Importance of house keeping

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