

SIYANA-I (CBCS): WINTER - 2016
SUBJECT: ADVANCED QUALITY ASSURANCE TECHNIQUES-I
(QUALITY ASSURANCE TECHNIQUES)

Day: **Friday**
Date: **06-01-2017**

Time: **10:00 AM TO 1:00 PM.**
Max Marks: 60

N.B:

- 1) Attempt any **THREE** questions from each section.
 - 2) Figures to the right indicate **FULL** marks.
 - 3) Answer each section on **SEPARATE** answer sheets.
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SECTION-I

- Q.1** Discuss QA aspects of Raw and Packaging material management. (10)
- Q.2** Discuss Quality Agreement in detail. (10)
- Q.3** Discuss building and facility details of a pharmaceutical manufacturing plant. (10)
- Q.4** Write short notes on any **TWO** of the following: (10)
- a) Pharmaceutical Purchasing
 - b) Key Persons and their responsibilities
 - c) Equipment design and location

SECTION-II

- Q.5** Discuss in detail concept of QA and QC. (10)
- Q.6** Elaborate on manufacturing aspects of sterile pharmaceutical products. (10)
- Q.7** Discuss I.P.Q.C activities in production and its importance. (10)
- Q.8** Write short notes on any **TWO** of the following: (10)
- a) WHO guidelines on inspection of Pharma manufacturing facilities
 - b) Recovered Products
 - c) Charge in of components

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