

SIYANA-II
(CBCS) (2012 COURSE): SUMMER-2016
SUBJECT: ADVANCED QUALITY ASSURANCE TECHNIQUES-III

Day: **Tuesday**
Date: **05-07-2016**

Time: **10:00AM-TO 1:00 P.M.**
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** answer books.

SECTION-I

- Q.1 Discuss Quality functions in detail. (10)
- Q.2 Discuss 7 step approaches for Quality Control. (10)
- Q.3 Discuss Six Sigma approach for improvement in Quality. (10)
- Q.4 Write short notes on (ANY TWO): (10)
- a) Role of upper management and Quality Director
 - b) Feedback Loop
 - c) Little 'Q' and Big 'Q'

SECTION-II

- Q.5 How do we set Quality Goals? Discuss various measures of setting and deploying quality goals for an organization. (10)
- Q.6 Discuss Lean manufacturing. Explain error proofing. (10)
- Q.7 Discuss various Statistical Control charts in detail explaining the applications of each in pharmaceutical operations. (10)
- Q.8 Write short notes on (ANY TWO): (10)
- a) Inspection planning
 - b) Quality Culture
 - c) Internal Audits

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SIYANA-II (CBCS 2012 COURSE): SUMMER -2016
SUBJECT: ADVANCED QUALITY ASSURANCE TECHNIQUES-II

Day: Saturday
Date: 02-07-2016

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

N.B:

- 1) Attempt any **THREE** questions from each section.
 - 2) All questions carry **EQUAL** marks.
 - 3) Write each section on different answer sheets.
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SECTION-I

- Q.1** Discuss FDA guidelines governing process validation in detail. (10)
- Q.2** Discuss the critical factors in validation of solid dosage forms. (10)
- Q.3** What is the importance of cleaning efficiency in a pharmaceutical manufacturing operation? Discuss cleaning validation in detail. (10)
- Q.4** Write short notes on any (**TWO**) of the following: (10)
- a) Calibration Master Plan
 - b) Vendor certification
 - c) Computer system validation

SECTION-II

- Q.5** Elaborate on various steps in Analytical method Validation. (10)
- Q.6** Explain process Validation & role of quality Assurance. (10)
- Q.7** Describe important steps in validation of water systems in Pharma Plant. (10)
- Q.8** Write short notes on any (**TWO**) of the following: (10)
- a) Validation of HEPA filters
 - b) Vendor certification
 - c) D, Z, F values

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