

SIYANA - II (CBCS) (2012 COURSE) : JULY - 2013
SUBJECT : ADVANCE CORE SUBJECT - II : ADVANCED QUALITY
ASSURANCE TECHNIQUES - II

Day : Wednesday
Date : 03/07/2013

Time : 10:00 A.M. TO 1:00 P.M.
Max. Marks : 60

N.B.

- 1) Answer any **THREE** questions from Section - I and any **THREE** questions from Section - II.
- 2) Figures to the right indicate **FULL** marks.
- 3) Answers to Section - I and Section - II should be written in **SEPARATE** answer books.

SECTION - I

- Q.1** Describe F.D.A. guidelines for Pharmaceutical validation. (10)
- Q.2** Write an exhaustive note on validation of sterilization process. (10)
- Q.3** Highlight the validation of HVAC. (10)
- Q.4** Write short note on any **TWO**: (10)
- a) Harmonization
 - b) cGMP
 - c) Quality Assurance

SECTION - II

- Q.5** Discuss the scale up of process validation. (10)
- Q.6** Write a note on Vendor Certification. (10)
- Q.7** Describe analytical method validation. (10)
- Q.8** Write short note on any **TWO**: (10)
- a) Process validation
 - b) Validation of dissolution test apparatus
 - c) Importance of facility for cleaning validation

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SIYANA-II(C.B.C.S.) (2012 COURSE): JULY – 2013
SUBJECT: ADVANCE CORE SUBJECT-III: ADVANCED QUALITY ASSURANCE
TECHNIQUES-III

Day: Friday
Date: 05/07/2013

Time: 10:00 A.M. TO 1:00 P.M.
Max. Marks: 60

N.B.:

- 1) Attempt any **THREE** questions each from Section-I and Section-II.
- 2) Figures to the **RIGHT** indicate full marks.

SECTION-I

- Q.1** Define Quality. Write in detail 'Managing Quality'. (10)
- Q.2** What is 'product by product' approach to quality improvement and cost reduction? (10)
- Q.3** Explain concept of continuous improvement with suitable examples. (10)
- Q.4** Write short notes on any **TWO** of the following: (10)
- a) Six Sigma Improvement
 - b) Role of upper management and Quality Director.
 - c) Self control

SECTION-II

- Q.5** Explain Maslow's theory of motivation. How does it help in developing quality culture in a pharmaceutical organization? (10)
- Q.6** Explain the important quality features of an automated manufacturing process. (10)
- Q.7** What is statistical process control (SPC)? What are the advantages of SPC? (10)
- Q.8** Write short notes on any **TWO** of the following: (10)
- a) Human relation in auditing
 - b) Manufacturing planning
 - c) Quality goals