

SIYANA - II (CBCS) SUMMER - 2015  
SUBJECT : ADVANCE CORE SUBJECT - II : ADVANCED QUALITY  
ASSURANCE TECHNIQUES - II

Day : *Thursday*  
Date : *02-07-2015*

Time : *10:00AM TO 1:00 PM.*  
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 Define process validation and give its importance. (10)
- Q.2 Highlight the salient features of cleaning validation. (10)
- Q.3 Discuss the salient features of analytical method validation. (10)
- Q.4 Write short note on any **TWO**: (10)
- a) Scope of Pharmaceutical Validation
  - b) cGMP
  - c) Validation in contract manufacturing

**SECTION - II**

- Q.5 Describe in detail the content validation Master Plan. (10)
- Q.6 Describe computer system validation. (10)
- Q.7 Explain the validation of water systems. (10)
- Q.8 Write short note on any **TWO**: (10)
- a) Process validation
  - b) Harmonization
  - c) Quality Assurance

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**SIYANA- II (CBCS): SUMMER - 2015**  
**SUBJECT: QUALITY ASSURANCE TECHNIQUES - III**

Day: **Saturday**  
Date: **04-07-2015**

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

**N.B.:**

- 1) Attempt any **THREE** questions from Section –I and any **THREE** questions from Section –II.
- 2) Figures to the right indicate **FULL** marks.
- 3) Answers to both the sections should be written in **SEPARATE** answer book.
- 4) Assume suitable data if necessary.

**SECTION-I**

- Q.1** Explain sporadic and chronic quality problems with help of suitable example. (10)  
Draw suitable diagram.
- Q.2** Explain Pareto principle with suitable example. Add a note on concept of (10)  
continuous improvement.
- Q.3** What is quality? Give different definitions of quality? Add a note on history of (10)  
quality movement world wide.
- Q.4** Write short notes on: ( Any **TWO**) (10)
- a) Self control
  - b) Role of upper management and quality director
  - c) Role of middle management and workforce

**SECTION-II**

- Q.5** Which are different types of control charts? Write in detail common control (10)  
charts for attribute and variable data.
- Q.6** Which are different types of sampling plans? Give characteristics of good (10)  
acceptance plan.
- Q.7** How will you classify seriousness? Add a note on inspection planning. (10)
- Q.8** Write short notes on: (Any **TWO**) (10)
- a) Process capability and capability index
  - b) Estimating inherent or potential capability from a control chart analysis
  - c) Concept of pre-control

