Day: Friday   Time: 10:00AM TO 1:00 P.M.
Date: 04-07-2014   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   Explain the concept of continuous improvement for quality improvement and   **(10)**
cost reduction.

Q.2   Discuss various measurements of quality control with suitable example.   **(10)**

Q.3   Discuss Quality project management in detail.   **(10)**

Q.4   Write short notes on any **TWO** of the following: **(10)**
    a)   Six Sigma
    b)   Six step quality control
    c)   Role of middle management and workforce in quality

SECTION-II

Q.5   Discuss manufacturing planning in detail.   **(10)**

Q.6   What is statistical process control (SPC)? What are the advantages of SPC?   **(10)**

Q.7   Discuss importance of quality audit? Discuss components of quality audit   **(10)**
with a suitable example.

Q.8   Write short notes on any **TWO** of the following: **(10)**
    a)   McGragor's theory of motivation
    b)   Reporting audit results
    c)   Statistical control charts

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SIYANA - II (CBCS) (2012 COURSE) : JULY- 2014
SUBJECT : ADVANCE CORE SUBJECT - II : ADVANCED QUALITY
ASSURANCE TECHNIQUES - II

Day : Wednesday   Time : 10:00AM. TO 1:00 PM.
Date : 02-07-2014   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 a complete process of validation of a tablet compression machine.   (10)

Q.2   Describe in detail the process validation plan for injectable formulation.   (10)

Q.3   Describe analytical method validation.   (10)

Q.4   Write short note on any **TWO**:   (10)
   a) Quality Assurance
   b) cGMP
   c) Validation of contract manufacturing

SECTION - II

Q.5   Describe the organization of process validation.   (10)

Q.6   Explain computer system validation.   (10)

Q.7   Validation of existing equipment.   (10)

Q.8   Write short note on any **TWO**:   (10)
   a) Validation of pure steam generator
   b) Cleaning validation
   c) Harmonization

*   *   *