

SIYANA - I (C B C S) (2012 COURSE): **JULY-2014**
SUBJECT: QUALITY ASSURANCE TECHNIQUES-I

Day: **Thursday**
Date: **03-07-2014**

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

N.B.:

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

SECTION-I

- Q.1** Define key-personnel in pharma industry and discuss the role of Head of Q. A. (10)
- Q.2** Discuss cGMP related requirements of "Warehousing Area in pharma -plant". (10)
- Q.3** Discuss cGMP related requirements of equipment related to design, size, (10)
location and construction.
- Q.4** Write short notes on (Any TWO) (10)
- a) Planned Preventive Maintenance Programme
 - b) Management of Returned Goods
 - c) Use of laboratory Animals

SECTION-II

- Q.5** Briefly discuss the process of IPQC in production and explain its importance. (10)
- Q.6** Define "Site Master File" and discuss its key-contents. (10)
- Q.7** Discuss in detail the environmental control factors for sterile -products (10)
manufacturing.
- Q.8** Write short notes on (Any TWO) (10)
- a) Specification for water for injection
 - b) Media fill Tests
 - c) Product recall

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