

**Pre. Ph.D. Course Work (2017 Course) : ( Quality Assurance  
Techniques ) : SUMMER - 2019**  
**SUBJECT: PAPER – II: RECENT ADVANCES IN QUALITY ASSURANCE  
TECHNIQUES**

Day: Wednesday  
Date: 24/04/2019

Time: 10.00 AM TO 1.00 PM  
Max. Marks: 100

**S-2019-5357**

**N.B.:**

- 1) Attempt any **FIVE** questions from each section.
- 2) Figures to the right indicate **FULL** marks.
- 3) Answers to both the sections should be written in **SEPARATE** answer book.
- 4) Draw neat diagrams **WHEREVER** necessary.

**SECTION-I**

- Q.1** Discuss basic principles in QbD. (10)
- Q.2** What is GLP? Discuss schedule L-I in brief. (10)
- Q.3** Discuss various steps in equipment validation ( qualification) (10)
- Q.4** Discuss computer system validation in detail. (10)
- Q.5** Discuss basic concepts of Quality with specific reference to Juran's Trilogy. (10)
- Q.6** Discuss Lean manufacturing in detail. (10)

**SECTION-II**

- Q.7** What is Quality Audit? Explain the principle of Quality Audit. (10)
- Q.8** Give principle and applications of LC- MS. (10)
- Q.9** Write importance of documentation. Elaborate on plant level department wise documentation. (10)
- Q.10** Write a note on HPTLC. (10)
- Q.11** Discuss the principle of GC- MS. (10)
- Q.12** Discuss Theory and principle of NMR. (10)

\* \* \* \*