

Pre. Ph.D. Course Work (2017 Course) : SUMMER - 2018 (Quality Assurance Techniques)

SUBJECT: PAPER-II – QUALITY ASSURANCE TECHNIQUES

Day : **Tuesday**
Date : **26/06/2018**

S-2018-4781

Time : **10.00 AM TO 01.00 PM**
Max. Marks: 100.

N.B.:

- 1) Attempt any **FIVE** questions from Section-I and any **FIVE** questions from Section-II.
- 2) Both the sections should be written in **SEPARATE** answer books.
- 3) Figures to the **RIGHT** indicate full marks.
- 4) Draw neat and labeled diagrams **WHEREVER** necessary.

SECTION-I

- Q.1** Discuss in detail principle areas of a manufacturing facility with man and material flow. **(10)**
- Q.2** Describe personnel requirements as per Schedule M. **(10)**
- Q.3** Discuss Quality Management System as per cGMP. **(10)**
- Q.4** Discuss product recall, reprocessing and reject handling procedure. **(10)**
- Q.5** Discuss Quality functions with reference to Juran's trilogy. **(10)**
- Q.6** Discuss "Internal Audit" in detail. **(10)**

SECTION-II

- Q.7** Describe various aspects of cleaning validation of any one equipment used in tablet processing. **(10)**
- Q.8** Describe in details analytical method validation. **(10)**
- Q.9** Describe process validations types and describe in brief, tablet granulation and compression process validation. **(10)**
- Q.10** Describe various aspects of computer system validation. **(10)**
- Q.11** Discuss initial planning for quality in a manufacturing facility. **(10)**
- Q.12** Discuss principles and operations of HPLC. **(10)**

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