

Exam Date & Time: 09-Mar-2022 (10:00 AM - 01:00 PM)



## MANIPAL ACADEMY OF HIGHER EDUCATION

Manipal Academy of Higher Education, Manipal MPharm Theory End-Semester Examinations.

Quality Management Systems, PQA\_MQA\_102T

**Quality Management Systems [PQA-MQA102T]**

**Marks: 75**

**Duration: 180 mins.**

### SECTION - A

**Answer all the questions.**

Answer the following (10 marks x 5 = 50 marks)

- 1) Discuss in detail about strategic quality management (10)
- 2) Describe the process of NABL accreditation (10)
- 3) Discuss the concept of statistical quality control in pharmaceutical industries (10)
- 4) Explain the process of intermediate stability studies for zone III countries with the help of a stability study protocol for a film coated tablets adopting bracketing strategies (10)
- 5)
  - a. Explain the exclusion of vendor from approved vendor list. (5 M)
  - b. Explain the criteria for vendor re-qualification. (5 M) (10)

### SECTION - B

**Answer all the questions.**

Answer the following (5 marks x 5 = 25 marks)

- 6) Explain in detail about key elements of TQM (5)
- 7) Write a note on Deming/s Philosophy (5)

- 8) Write a note on quality by design and its importance in pharmaceutical industry (5)
- 9) Explain the requirements for sampling and testing of In-process materials & drug products (5)
- 10) Market Complaint was received in pharmacy from a patient for shortage of capsules in a bottle (Venlafaxine capsules 50's count) with 5 capsules less. (5)
- a. Classify this complaint. (1 M)
  - b. Explain how this complaint can be handled and investigated using a flow chart. (4 M)

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