

ec-2018 (02:00 PM - 05:00 PM)



## MANIPAL ACADEMY OF HIGHER EDUCATION

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

Specialization: Pharmaceutical Quality Assurance

Date: 03-12-2018

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) Explain in detail about Total Quality Management. (10)
- 2) Discuss in detail about Quality risk management (10)
- 3) Discuss in detail about Bench marking (10)
- 4) Explain the process of long-term stability studies for zone III countries with the help of a stability study protocol for semisolids (10)
- 5) Write in short about the packaging and labelling system (10)

### SECTION - B

Answer all the questions.

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

- 6) Explain the evolution of quality and its impact on the pharma industry (5)
- 7) Explain in detail about ISO 9001:2008 (5)
- 8) Explain P chart with suitable examples (5)
- 9) Explain in detail about evaluation of the complaints. (5)
- 10) Write the evaluation activities involved in quality system control (5)

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