

Question Paper

Exam Date & Time: 29-Nov-2017 (02:00 PM - 05:00 PM)



MANIPAL ACADEMY OF HIGHER EDUCATION

MANIPAL COLLEGE OF PHARMACEUTICAL SCIENCES END SEMESTER THEORY EXAMINATIONS - NOVEMBER 2017

PROGRAM: MPHARM SEMESTER 1

DATE: 29/11/2017

TIME: 2:00PM - 5:00PM

Quality Management Systems [PQA-MQA102T]

Marks: 50

Duration: 180 mins.

Answer all the questions.

Answer the following (5 marks x 8 = 40 marks)

- 1) Write a note on stability testing of drug substance with special emphasis given to scope, selection of batches, testing frequency and storage conditions as per ICH Q1(A)R2. (5)
- 2) Write a note on statistical control charts based on variables. (5)
- 3) Write a note on risk assessment as per ICH Q9. (5)
- 4) Define the concept of regulatory compliance. Enlist the types and reasons for benchmarking in pharmaceutical industry. (5)
- 5) Discuss Total quality management system in detail. (5)
- 6) Write in detail about annual product review. (5)
- 7) Prepare a checklist for OOS investigation. (5)
- 8) Discuss CAPA in detail. (5)

Answer the following with specific answers (2 marks x 5 = 10 marks)

- 9) Differentiate between stress and accelerated stability testing. (2)
 - A)
 - B) Define the terms "Risk" and "Quality Risk Management" as per ICH Q9. (2)
 - C) Give the significance of statistical process control. (2)
 - D) (2)

Define Six sigma concept.

E)

Give any four importance of CFR-21 part 11.

(2)

-----End-----