

Question Paper

Exam Date & Time: 05-May-2018 (02:00 PM - 05:00 PM)



MANIPAL ACADEMY OF HIGHER EDUCATION

MANIPAL COLLEGE OF PHARMACEUTICAL SCIENCES

END SEMESTER THEORY EXAMINATIONS- MAY 2018

PROGRAM: MPHARM SEMESTER 2

(PHARMACEUTICAL QUALITY ASSURANCE)

DATE: 05/05/2018

TIME: 2:00 PM - 5:00 PM

Pharmaceutical Validation [PQA-MQA202T]

Marks: 50

Duration: 180 mins.

a

Answer all the questions.

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

- 1) What are qualification and calibration? Differentiate the same. (5)
- 2) Explain operational qualification of FTIR. (5)
- 3) Explain the design qualification of dissolution test apparatus. (5)
- 4) Write a note on validation of pharmaceutical water system. (5)
- 5) What is analytical method validation? Explain accuracy as per ICH guideline. (5)
- 6) Write a note on process validation of aseptic filling. (5)
- 7) Define Electronic records and Electronic signatures. Discuss the requirements of Electronic records as per 21CFR part 11. (5)
- 8) Explain the primary process parameters in cleaning validation. (5)

b

Answer all the questions.

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

- 9) what is VMP? Enlist its scope. (2)
 - A)
 - B) Name the phases of validation. (2)
 - C) Name the parameters to be checked for system suitability test for HPLC with its tolerance limit. (2)

- D) Why the life cycle approach is essential for process validation? (2)
- E) What is CIP? (2)

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