

Question Paper

Exam Date & Time: 13-May-2023 (02:00 PM - 05:00 PM)



MANIPAL ACADEMY OF HIGHER EDUCATION

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

Pharmaceutical Validation [PQA-MQA202T -S3]

Marks: 75

Duration: 180 mins.

SECTION - A

Answer all the questions.

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

- 1) Explain FIVE key concepts of GAMP 5 guidelines. (10)
- 2) Prepare an Installation qualification (IQ) protocol for stability testing chamber. (10)
- 3) Prepare a protocol for validation of "Friability tester". (10)
- 4) Explain the process flow, critical quality parameters and in-process test involved in process validation of capsule formulation. (10)
- 5) What are the essential elements of an HVAC system? Prepare a validation checklist for an HVAC system (At least one checklist item under each category) (10)

SECTION - B

Answer all the questions.

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

- 6) Write a protocol for handling of defective instrument. (5)
- 7) Suggest relevant tests for performing OQ of a "Dissolution apparatus" along with their acceptance limits. (5)
- 8) List and explain the scope of 21 CFR electronic records and electronic signatures. (5)
- 9) Explain the procedure for qualifying a vendor media for media fill validation program. (5)
- 10) Explain the outline of a process validation program. (5)

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