

Question Paper

Exam Date & Time: 14-Jun-2023 (10:00 AM - 01:00 PM)



MANIPAL ACADEMY OF HIGHER EDUCATION

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

Pharmaceutical Validation [PQA-MQA202T -S1]

Marks: 75

Duration: 180 mins.

SECTION - A

Answer all the questions.

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

- 1) Explain the parameters evaluated in a process simulation of sterile preparation. (10)
- 2) Prepare a Design Qualification protocol for "stability testing chamber". (10)
- 3) Prepare a protocol for validation of "Hardness tester". (10)
- 4) Write the procedure and acceptance criteria for calibration of the following equipment (any four parameters) (10)
 - a. UV-Visible Spectrophotometer
 - b. HPLC
- 5) A compression machine was used to manufacture gliclazide 160mg tablets and cleaned with methylene chloride followed by water. You were asked to check its suitability for the next product which is paracetamol 500 mg tablets. How will you carry out this responsibility? Explain in detail with assumptions if any. (10)

SECTION - B

Answer all the questions.

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

- 6) Explain the evaluation of precision parameter with specifications for Assay, Blend uniformity, and dissolution test as per US FDA guidelines. (5)
- 7) Prepare a process validation protocol format for granules. (5)
- 8) Write the importance of validation in pharmaceutical industry. (5)
- 9) Suggest relevant tests to perform Operational Qualification of a UV-Visible Spectrophotometer along with their acceptance limits. (5)
- 10) FDA's "General principle of software validation" is applicable to which of following category/ies of softwares? (5)
 1. Software used as a component, part, or accessory of a medical device.
 2. Software that is itself a medical device.
 3. Software used to maintain the personnel qualification and records of employees.
 4. Software used in the production of a device.
 5. Software used in implementation of the device manufacturer's quality system.

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