

Question Paper

Exam Date & Time: 15-May-2024 (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 -S1]

Marks: 75

Duration: 180 mins.

SECTION - A

Answer all the questions.

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

- 1) What is Validation? Write the advantages of performing validation in pharmaceutical industry. (5)
 - a)
 - b) Discuss the types of validation performed in the pharmaceutical industry. (5)
- 2) Prepare a URS for HPLC equipment. (5)
 - a)
 - b) What are the steps involved in vendor qualification? Prepare a checklist for the same. (5)
- 3) Prepare a protocol for performing the installation qualification (IQ), operational qualification (OQ), and performance qualification (PQ) of a tablet hardness testing equipment. (10)
- 4) Explain the evaluation and verification of the upstream process involved in the validation of biopharmaceutical processes. (10)
- 5) Identify the challenges in cleaning the following equipment and suggest the methods to overcome the same. (10)





a) Fluid bed drier



b) Ribbon Blender

SECTION - B

Answer all the questions.

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

- 6) What are the objectives of calibration? Discuss briefly the calibration procedure of a pH meter. (5)
- 7) Prepare a protocol for installation qualification (IQ) of stability testing chamber. (5)
- 8) Explain the immediate actions and procedures implemented when a sterility test conducted as part of a media fill validation program yields a positive result. (5)
- 9) Explain the evaluation of equipment during the process validation of tablet dosage form. (5)
- 10) Match the following: (5)

Type of cleaning method	Example of Equipment

Clean in place	Turret of rotary compression machine
Clean out of place	Process tank for oral liquids
Ultra sonic washing	Rotating spray device
High pressure spraying	Hopper of filling machine
Manual cleaning	Filling needle/nozzle

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