

Question Paper

Exam Date & Time: 11-May-2023 (02:00 PM - 05:00 PM)



MANIPAL ACADEMY OF HIGHER EDUCATION

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

Scale-Up and Technology Transfer [PCE-MIP202T-S3]

Marks: 75

Duration: 180 mins.

SECTION - A

Answer all the questions.

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

- 1) Discuss on scale up stage for tablet dosage form. (10)
- 2) Discuss on causes and monitoring of electrical hazards in pharmaceutical industry. (10)
- 3) Discuss cleaning validation and deviations handling under Validation master plan for a new formulation facility. (10)
- 4) Discuss the importance of User Requirement Specifications (URS). Add a note on Factory Acceptance Testing (FAT) and Site Acceptance Testing (SAT). (10)
- 5) What is Material Safety Data Sheet? Briefly explain its components. (10)

SECTION - B

Answer all the questions.

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

- 6) Differentiate between laboratory batch, Laboratory pilot batch and Pilot production. (5)
- 7) . Mention different adverse conditions for testing, filling and sealing validation process. (5)
- 8) Discuss HVAC systems validation with respect to air flow pattern. (5)
- 9) What is Design Qualification? Give the list of documentation and certificates to be requested during DQ stage. (5)
- 10) Why vendor qualification is important in pharmaceuticals? Brief the procedure with a flow chart. (5)

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