

Question Paper

Exam Date & Time: 13-May-2024 (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-S1]

Marks: 75

Duration: 180 mins.

SECTION - A

Answer all the questions.

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

- 1) Discuss about 'Personnel requirement' and 'Space requirement' in pilot plant. (10)
- 2) Discuss the importance of change controls and deviations in the validation master plan. (10)
- 3) Discuss the qualification of compressed air system in a formulation facility. (10)
- 4) Discuss on different types of process validations. (10)
- 5) Explain material safety data sheets (MSDS) and brief its contents. (10)

SECTION - B

Answer all the questions.

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

- 6) Briefly write about pilot plant scale up considerations for semi solid dosage forms. (5)
- 7) Briefly discuss about cleaning validation activity. (5)
- 8) What is HVAC? Briefly discuss the functions. (5)
- 9) Briefly explain heat penetration test in batch oven validation process. (5)
- 10) Mention any five causes for mechanical hazards in pharma industry. (5)

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