

Exam Date & Time: 07-Sep-2021 (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]

Marks: 75

Duration: 180 mins.

SECTION - A

Answer all the questions.

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

- 1) Define pilot plant. Discuss on space and processing equipment requirement for a newly setup pilot plant laboratory. (10)
- 2) Discuss in detail on filling and sealing process validation of parenterals. (10)
- 3) Explain the causes and prevention of mechanical hazards in pharmaceutical industry. (10)
- 4) Why approved vendor is important in pharmaceuticals? Discuss the various GMP systems adopted, documentation required. Add a brief note on procedure for approving alternate vendor. (10)
- 5) What is URS? Discuss the user requirement specifications (URS) for a new order Fluid bed dryer (FBD). (10)

SECTION - B

Answer all the questions.

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

- 6) Mention the objectives of scale up studies. (5)
- 7) What is validation master plan? Discuss any four components. (5)
- 8) Define Qualification. Mention any four importance of FAT and SAT as per FDA standards. (5)
- 9) Discuss brief procedure on usage of material safety data sheets (MSDS). (5)
- 10) Write a note on eye protection measures adopted in pharma companies while handling dangerous chemicals. (5)

-----End-----