

Exam Date & Time: 13-Jul-2022 (10:00 AM - 01:00 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 on scale up study for tablet dosage form. (10)
- 2) Explain process validation for dry heat sterilization. (10)
- 3) What is validation master plan (VMP)? Discuss briefly on a) Key personnel requirements, and b) Change control system c) Deviations handling. (10)
- 4) What is Material Safety Data Sheets? Write a brief procedure adopted on usage of MSDS. Enlist the important contents of MSDS. (10)
- 5) What is Operational Qualification? Discuss in detail on the procedure adopted, enlist the acceptance criteria and important points to be considered at OQ stage. (10)

#### SECTION - B

**Answer all the questions.**

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

- 6) Write on different measures to be followed to prevent mechanical hazards in pharma industry. (5)
- 7) Write short note on effluent pre-treatment. (5)
- 8) Mention any five objectives of scale up study. (5)
- 9) Briefly discuss on different stages of validation for water process system. (5)
- 10) What is Factory acceptance testing (FAT)? Give the procedure adopted. Mention any two importance. (5)

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