

Question Paper

Exam Date & Time: 24-Nov-2023 (10:00 AM - 01:00 PM)



MANIPAL ACADEMY OF HIGHER EDUCATION

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

Pharmaceutical Formulation Development [PCE-MIP102T - S2]

Marks: 75

Duration: 180 mins.

SECTION - A

Answer all the questions.

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

- 1) Discuss on importance of particle size, shape during pre-formulation stage of formulation development. (10)
- 2) Describe the process of percentage purity determination for the drug by phase solubility process with a neat labelled diagram. (10)
- 3) Explain the need for dissolution studies and enlist various experimental conditions to be monitored during the dissolution studies. Discuss USP Type I apparatus. (10)
- 4) What is an additive? Explain various excipients used in sterile preparations with an example. Add a note on Tonicity adjusters used in sterile preparations with examples. (10)
- 5) Enlist the various zones and explain various conditions adopted for stability studies as per ICH guidelines. (10)

SECTION - B

Answer all the questions.

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

- 6) Write a short note on test for organoleptic properties during pre-formulation study phase. (5)
- 7) Discuss on salt former selection in solubility enhancement process. (5)
- 8) Briefly discuss on Hixson-Crowell model of drug dissolution. (5)
- 9) Write a note on concept of Bracketing approach during stability studies with examples. List the advantages. (5)
- 10) Define dissolution. List any four applications of dissolution studies. (5)

-----End-----