

Exam Date & Time: 27-Mar-2021 (01:30 PM - 04:30 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 pre-formulation studies with respect to (i) Solubility study (ii) Stability study (10)
- 2) Define solubility and discuss on micellar solubility of drugs. (10)
- 3) Explain 'Diffusion layer model' theory of dissolution. (10)
- 4) Explain the precautions, importance of careful selection of preservatives and buffers in sterile preparations. (10)
- 5) Explain the various zone as per ICH guidelines. Discuss about design of stability specification and compilation of final reports. (10)

### SECTION - B

**Answer all the questions.**

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

- 6) Differentiate between crystalline and amorphous substances. (5)
- 7) Briefly write about Kinetic solubility analysis. (5)
- 8) Discuss the various experimental conditions to be monitored during dissolution profile studies as per IP. (5)
- 9) Briefly discuss accelerated stability studies as per ICH guidelines. State the regulatory advantage of performing study at this condition. (5)
- 10) What is matrixing in stability study? List the important advantages. (5)

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