

# Question Paper

Exam Date & Time: 28-Dec-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 - S3]**

**Marks: 75**

**Duration: 180 mins.**

### SECTION - A

**Answer all the questions.**

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

- 1) Discuss on solid state and solution phase stability studies during pre-formulation stage of formulation development. (10)
- 2) Explain the micellar solubilization process. (10)
- 3) . Compare and contrast dissolution tests as per Type I -IP and Type I- USP methods. Write a note on importance of IVIVC. (10)
- 4) Explain any two major categories of additives used in Tablets. Add a note on applications of DoE in product development. (10)
- 5) Briefly explain accelerated and intermediate stability study requirements. List the applications of stability studies. (10)

### SECTION - B

**Answer all the questions.**

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

- 6) Add a note on the crystallization process for the synthesis of different polymorphs of API. (5)
- 7) Briefly discuss on cyclodextrin complexes. (5)
- 8) Brief the dissolution theory through diffusion layer model. (5)
- 9) Write a note on stability study protocol and stability specification. (5)
- 10) What are the various experimental conditions to be monitored during dissolution study profiles? Give the importance of pH of media. (5)

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