Exam Date & Time: 14-Mar-2022 (10:00 AM - 01:00 PM)

MANIPAL ACADEMY OF HIGHER EDUCATION

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

Product Development and Technology Transfer [PQA-MQA104T - S2]

Marks: 75 **Duration: 180 mins.**

SECTION - A

Answer all the questions.

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

1) Analyze the importance of evaluation of "Rubber closures" for parenteral use. Explain the tests and acceptance criteria in detail. (10)

2) Discuss and differentiate between section III and section IV of SUPAC-MR guidelines (Modified Release Solid Oral Dosage Forms) under level 3 changes using a tabular column and highlight important and critical points as per your knowledge. (10)

3) How is the stability study data useful in pre-formulation studies? (10)

4) Discuss how the Hatch Waxman Act balanced the interests of customers, the generic drug industry, and the innovator company? Write the procedure for "Paragraph IV" filing and write the contents of ANDA. (10)

5) Explain the application of process maps, control charts, and the Ishikawa diagram in the risk management approach druing analytical transfer with an example. (10)

SECTION - B

Answer all the questions.

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

6) Write a note on FDA Adverse Event Reporting System. (5)

7) Discuss in detail about reporting categories and assessment of changes under BACPAC. (5)

8)	Explain the methods to improve the solubility of poorly water-soluble drugs in brief.	(5)
9)	Comment on the analytical methods useful for solubility studies in Pre-formulation studies.	(5)
10)	Explain the transfer of analytical procedure as per USP.	(5)

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