

Exam Date & Time: 31-Mar-2021 (01:30 PM - 04:30 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) Discuss in detail about SNDA. (10)
 - 2) Represent diagrammatically the organization of CTD and discuss the description requirements of "drug substance" and "drug product" in a new drug application. (10)
 - 3) Explain the importance of Pre-formulation studies. (10)
 - 4) Explain the procedure and acceptance criteria for "systemic injection test" and "intra-cutaneous test" for plastic containers for injectable preparations. (10)
 - 5) List the components of analytical transfer protocol. (2)
- A)
- B) Explain the method familiarization stage in technology transfer process. (8)

SECTION - B

Answer all the questions.

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

- 6) Write a note on PAS and CBE-30. (5)
- 7) Write a note on post marketing surveillance. (5)
- 8) Explain the need for the polymorphism study. (5)
- 9) Explain the methods of stability testing in brief. (5)
- 10) Explain the cases for transfer waiver. (5)

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