

Exam Date & Time: 19-Dec-2022 (10:00 AM - 01:00 PM)



MANIPAL ACADEMY OF HIGHER EDUCATION

Manipal College of Pharmaceutical Sciences, Manipal Academy of Higher Education, Manipal
MPharm Theory End-Semester Examinations. December-2022
Sub title: Product Development & Technology Transfer
Sub code: PQA-MQA104T

Product Development and Technology Transfer [PQA-MQA104T - S3]

Marks: 75

Duration: 180 mins.

SECTION - A

Answer all the questions.

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

- 1) What are the contents of the "clinical data section" of NDA? Critically analyse the "review and approval process" of NDA. (10)
- 2) Explain the principle in the various methods to determine the particle size of an API. (10)
- 3) Describe the procedure and acceptance criteria for the following tests. Critically analyse the relevance of these tests with respect to the safety and efficacy:
a) Hydrolytic resistance test for glass containers. (10)
b) Test for metal particles in metal containers for eye ointments.
- 4) Explain the content of analytical transfer package using suitable examples. (10)
- 5) a) Mention the factors affecting Post-marketing safety Reporting systems according to USFDA. (5 Marks)
b) Describe the process to register an establishment and list a drug with FDA. (5 Marks) (10)

SECTION - B

Answer all the questions.

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

- 6) Analyse the relevance of CTD format for submission of a new drug application. (5)
- 7) Explain SUPAC guidelines to the Industry for Immediate Release Solid Oral Dosage Forms with respect to changes in Specifications (5)
- 8) Comment on the relation between Carr's Index and type of flow (5)
- 9) How polymorphs are differentiated? (5)
- 10) a) Which type of validation is performed when both the transferring and receiving laboratories generate data on a selected lot of material within a reasonably short time period, dictated by the stability of the sample? (1 mark) (5)
b) Explain responsibilities of receiving and sending laboratories during analytical

technology transfer. (4 marks)

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