

Exam Date & Time: 11-Mar-2022 (10:00 AM - 01:00 PM)



MANIPAL ACADEMY OF HIGHER EDUCATION

Manipal Academy of Higher Education, Manipal MPharm Theory End-Semester Examinations. March 2022

Subject: Quality Control and Quality Assurance [PQA-MQA103T]

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Marks: 75

Duration: 180 mins.

SECTION - A

Answer all the questions.

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

- 1) Explain the methods to establish stability of a selected subset of the total number of possible samples for all factor combinations tested at a specified time point for a new drug product. (10)
- 2) a. Discuss the best way to minimize cross contamination and mix-up in manufacturing operation and control (5 Marks) (10)
b. Explain the guidelines for sanitation of manufacturing premises (5 Marks)
- 3) Enlist and explain the Finished Product QC tests for Parenterals according to US Pharmacopoeia (10)
- 4) a. Explain the importance and benefits of intellectual property rights (5 Marks) (10)
b. Write a note on change control (5 Marks)
- 5) a. Define Quality Audit. Write about the Quality Audit Plan (5 Marks) (10)
b. Discuss the Three-tier documentation procedure in Pharmaceutical industry (5 Marks)

SECTION - B

Answer all the questions.

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

- 6) What are the things to be considered to maintain Good Warehouse in pharmaceutical industry (5)
- 7) Enlist the difference between CTD and eCTD. (5)

- 8) In the manufacturing a batch of nicotine transdermal patch enlist the contents of Batch Production Controlled Record (5)
- 9) Discuss about purchase specifications and maintenance of stores for raw materials. (5)
- 10) Explain requirements for training and Hygiene in GMP (5)

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