

Exam Date & Time: 29-Mar-2021 (01:30 PM - 04:30 PM)



MANIPAL ACADEMY OF HIGHER EDUCATION

Manipal Academy of Higher Education, Manipal MPharm Semester I Theory End-Semester Examinations. March 2021

MPharm - Pharmaceutical Analysis Specialization
Pharmaceutical Validation [PCH-MPA103T - S3]

Marks: 75

Duration: 180 mins.

SECTION - A

Answer all the questions.

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

- 1) a) Discuss on the different stages of filing a patent application.(5 Marks)
 b) What is PCT? What are the objectives of PCT and advantages of PCT? (5 Marks) (10)
- 2) a) What is specificity and accuracy of an analytical method? How specificity and accuracy studies are carried out for a chromatographic method?. (6 Marks)
 b) What are the analytical method validation parameters as per ICH and USP? Write a note on types of analytical methods to be validated. (4 Marks) (10)
- 3) a) Describe the steps involved in calibration of pipette. (7Marks)
 b) Differentiate qualification and calibration. (3 Marks) (10)
- 4) a) Explain the factors that need to be evaluated during installation qualification of pure water system. (5 Marks)
 b) Explain the qualification of HPLC column. (5 Marks) (10)
- 5) a) What are the advantages offered by Validation process? (5 Marks)
 b) What aspects are covered during prospective validation? Explain. (5 Marks) (10)

SECTION - B

Answer all the questions.

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

- 6) What are patents? Explain the conditions to be satisfied by an invention to be patentable. (5)
- 7) Write a note on mechanism of contamination and types of cleaning situations (5)
- 8) Explain the objectives of different types of Qualification. (5)
- 9) Explain the performance qualification of UV visible spectrophotometer (5)
- 10) Explain the importance and necessity for performing calibration of instruments. (5)

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