

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.

Pharmaceutical Validation [PCH-MPA103T]

Marks: 75

Duration: 180 mins.

SECTION - A

Answer all the questions.

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

- 1) What is validation and qualification? Explain the types of validation and phases of qualification. (10)
- 2) What is linearity, range and precision of an analytical method? Explain how linearity, range and precision studies are carried out for a chromatographic method. (7)
 - A)
 - B) Write a note on types of analytical methods to be validated (3)
- 3) What is cleaning in place and its importance? Discuss the parameters that make up the cleaning process (5)
 - A)
 - B) Explain the elements of cleaning validation protocol (5)
- 4) Write a note on different system qualification parameters in computer system validation (5)
 - A)
 - B) What are the objectives of computer system validation master plan? Explain V-Life cycle model in computer system validation (5)

- 5) What is calibration? Describe the steps involved in calibration of volumetric apparatus with suitable example (10)

SECTION - B

Answer all the questions.

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

- 6) Explain the steps involved in grant of a patent through PCT route (5)
- 7) What is intellectual property rights and how it is classified? Explain the criteria for patentability as per Indian patent law (5)
- 8) Explain Qualification of UV visible spectrophotometer (5)
- 9) Write a note on qualification of chromatographic columns (5)
- 10) What is validation master plan? Explain its benefits (5)

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