

Question Paper

Exam Date & Time: 27-Nov-2023 (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 - S2]

Marks: 75

Duration: 180 mins.

SECTION - A

Answer all the questions.

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

- 1) What are the computerized operations in pharmaceutical industry? Explain software validation in computer system validation (10)
- 2) What is calibration? Explain the calibration of micropipette and volumetric apparatus (10)
- 3) Under what circumstances revalidation is necessary? Explain. (5)
 - A)
 - B) Write a note on qualification of HVAC (5)
- 4) What is system suitability testing? Explain how system suitability parameters are established for a chromatographic method (5)
 - A)
 - B) What are the different types of analytical procedures? Discuss on the components of data quality (5)
- 5) What are patents? Explain the conditions to be satisfied by an invention to be patentable (5)
 - A)
 - B) What is Patent Cooperation Treaty? Explain the PCT filing system (5)

SECTION - B

Answer all the questions.

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

- 6) What is CIP and different ways of performing CIP? (5)
- 7) Explain the elements of cleaning validation protocol (5)
- 8) Discuss in detail about Site acceptance test (5)
- 9) Write in detail about validation of pure steam (5)
- 10) Discuss in detail about User Requirement specification (5)

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