Exam Date & Time: 16-Dec-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 - S2]

Marks: 75 **Duration: 180 mins.**

SECTION - A

Answer all the questions.

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

1) What is calibration? Explain the correction factors required for the calibration of volumetric apparatus (5)

A)

B) Explain the calibration of UV visible spectrophotometer (5)

2) Discuss the relevance of "21 CFR part 11" in the current era of computers (5)

A)

B) Explain five categories of GAMP (5)

3) Under what circumstances revalidation is required? (5)

A)

B) What is retrospective validation and what are the essential elements of retrospective validation (5)

4) What is specificity and accuracy of an analytical method? How specificity including peak purity and accuracy studies are carried out for a chromatographic method? (7)

A)

B) What are the different types of analytical procedures? Discuss on the components of data quality (3)

5) What is a complete specification? Explain the contents and format of a complete specification (6)

A)

B) What are non-patentable inventions under section 3 of Indian Patent Act 1970 (4)

SECTION - B

Answer all the questions.

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

6)	Explain the potential items for a cleaning validation masterplan	(5)
7)	Write a note on levels of cleaning in cleaning validation	(5)
8)	Write in detail about quality standards for pure steam	(5)
9)	What information is part of a user requirement specification document?	(5)
10)	Write a note on qualification of chromatographic columns	(5)

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