Question Paper

Exam Date & Time: 28-Dec-2017 (09:30 AM - 12:30 PM)

MANIPAL ACADEMY OF HIGHER EDUCATION

Manipal University, Manipal MPharm Theory End-Semester Examinations.
MANIPAL COLLEGE OF PHARMACEUTICAL SCIENCES
END SEMESTER THEORY EXAMINATIONS- DECEMBER 2017 - JANUARY 2018
PROGRAM: MPHARM SEMESTER 1
DATE: 28/12/2017
TIME: 9:30AM - 12:30PM

Pharmaceutical Validation [PCH-MPA103T]

Marks: 50 **Duration: 180 mins.**

a

Answer all the questions.

Answer the following (5 marks x 8 = 40 marks)

1)	What is linearity, range and precision of an analytical method? Explain how linearity, range and precision studies are carried out for a chromatographic methods.	(5)
2)	What is CIP and discuss its importance? Explain the cleaning parameters that makeup cleaning process.	(5)
3)	What are non-patentable inventions under section 3 of Indian Patent Act 1970? Discuss on the different types of patent applications.	(5)
4)	4A. Discuss the V-model which illustrates the key lifecycle activities of computer system validation.(2 mark) 4B. What is system suitability testing? Explain how system suitability parameters are established for a chromatographic method. (3 mark)	(5)
5)	Discuss about Validation Master Plan including its advantage and the information that must be included in validation master plan	(5)
6)	Explain retrospective validation. List out the essential elements for Retrospective Validation.	(5)
7)	Name the parameters that must be checked during qualification of UV-Visible spectrophotometers	(5)
8)		(5)

Explain the regulatory requirements for receiving of samples and their storage.

b

Answer all the questions.

Answer the following with specific answers (2 marks x 5 = 10 marks)

9) What is robustness of an analytical method and how it is established? (2)

A) What are trademarks and copyrights and discuss their benefits? (2)

B) Write a note on cleaning validation master plan (2)

C) Explain Change control (2)

D) Name any four parameters that are checked during qualification of dissolution apparatus (2)

E)

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