Question Paper

Exam Date & Time: 01-Dec-2017 (02:00 PM - 05:00 PM)

MANIPAL ACADEMY OF HIGHER EDUCATION

MANIPAL COLLEGE OF PHARMACEUTICAL SCIENCES
END SEMESTER THEORY EXAMINATIONS - NOVEMBER 2017
PROGRAM : MPHARM SEMESTER I
DATE :01-12-2017
TIME : 2:00PM - 5:00PM

Pharmaceutical Validation [PCH-MPA103T]

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

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

1)	What is specificity and accuracy of an analytical method? How specificity and accuracy studies are carried out for a chromatographic method.	(5)
2)	What are the different computerized operations associated with a pharmaceutical industry? Write a note on fundamental task and supporting procedures involved in the validation of computer systems?	(5)
3)	What is a complete specification? Explain the contents and format of a complete specification	(5)
4)	What is Patent Cooperation Treaty? Discuss the objectives and benefits of PCT and explain the PCT filing system	(5)
5)	List out the advantages of validation.	(5)
6)	Discuss in detail about Prospective validation.	(5)
7)	Name the parameters that must be checked during qualification of IR spectrophotometers	(5)
8)	Write about level 3 and level 4 qualification of pH meters.	(5)

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

9)	What is peak purity? How it is established for a chromatographic	(2)

A)	method?	
B)	What are the various mechanisms (source) of contamination in pharmaceutical operations and enlist the factors to be considered for setting acceptable limits for cleaning process.	(2)
C)	Under what circumstances revalidation is required? Explain	(2)
D)	Explain Design qualification	(2)
E)	Explain the difference between validation and qualification.	(2)

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