Exam Date & Time: 09-Sep-2021 (02:00 PM - 05:00 PM)

MANIPAL ACADEMY OF HIGHER EDUCATION

Manipal Academy of Higher Education, Manipal MPharm Theory End-Semester Examinations.

Pharmaceutical Validation [PQA-MQA202T]

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

SECTION - A

Answer all the questions.

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

1) Explain the requirements of analytical method validation for an HPLC method. (10)

2) Write a protocol for Qualification of pharmaceutical water system and pure steam (10)

3) Explain methods to determine accuracy of the analytical procedure for drug substance, drug product and impurities as per ICH guidelines. (5)

A)

B) Explain the media fill validation process in sterile pharmaceuticals. (5)

4) Enlist the key stages in the product & process development sequence.

A) (2.5)

1

2 Enlist the operational and procedural considerations for performing prospective process validation. (2.5)

B) Explain the process step, critical control variable, and quality control test for a granulated product. (5)

5) Explain the factors to be considered in setting the limits in cleaning validation. (5)

A)

B) Explain the reasons behind the selection of appropriate analytical methods for cleaning method validation in brief. (5)

SECTION - B

Answer all the questions.

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

6) Write the importance of Pharmaceutical validation and qualification. (5)

7) Analyse the importance of quality control charts in Performance Qualification. (5)

8)	Explain the scope and importance of qualification of friability apparatus and hardness test apparatus	(5)
9)	Discuss any five critical points in the qualification of HVAC	(5)
10)	Explain the elements of cleaning validation.	(5)

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