

Exam Date & Time: 15-Jul-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 [PQA-MQA202T]

Marks: 75

Duration: 180 mins.

SECTION - A

Answer all the questions.

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

- 1) Comment critically on the clean in place cleaning cycle. (10)
- 2) Explain the process step, critical control variable and quality control test for aerosols. (10)
- 3) Write the procedure and acceptance criteria for analytical method validation of an HPLC method. (10)
- 4) Discuss in detail about validation of pharmaceutical utility systems. (10)
- 5) Design a operational qualification document for following modules of an HPLC
a) Column oven (room temperature to 85°C)
b) Photo diode array detector (200 to 800 nm with ± 1 nm accuracy)
c) Autosampler with 100 vials capacity (10)

SECTION - B

Answer all the questions.

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

- 6) Explain the reason for failure in media fill validation process. (5)
- 7) Prepare a "User requirement specification" for an HPLC equipment. (5)
- 8) Write the importance of Pharmaceutical validation. (5)
- 9) Explain a master plan for a process validation program. (5)
- 10) Which factors are considered for setting a limit for a residue analysis in cleaning validation? (5)

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