

Question Paper

Exam Date & Time: 16-Jun-2023 (10:00 AM - 01:00 PM)



MANIPAL ACADEMY OF HIGHER EDUCATION

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

Audits and Regulatory Compliance [PQA-MQA203T -S2]

Marks: 75

Duration: 180 mins.

SECTION - A

Answer all the questions.

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

- 1) Discuss in detail about information gathering and its importance in regulatory and external audits, discuss the administration of the same. (10)
- 2) Discuss in detail about advantages and disadvantages of system based audit approach with suitable examples (10)
- 3) Prepare a detailed audit checklist for an excipient vendor as per cGMP requirement (10)
- 4) Write GMP audit checklist for sterile water for injection plant (10)
- 5) a. Explain the major areas of audit in the microbiology laboratory (8 Marks) (10)
b. Explain any 2 methods for monitoring the microbiological quality in the manufacturing unit (2 Marks)

SECTION - B

Answer all the questions.

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

- 6) How does an auditor gather information during an audit? Explain in detail How does an auditor gather information during an audit? Explain in detail (5)
- 7) What is an audit checklist and give its importance (5)
- 8) Discuss in detail about possible critical quality attributes (CQA'S) to be considered in tablet film coating (5)
- 9) Discuss the parameters to be checked in Effluent and its standards as per EPA. (5)
- 10) Explain the actions taken on an OOS in microbial testing of a primary packaging material used in commercial batch. (5)

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