

Question Paper

Exam Date & Time: 16-May-2023 (02:00 PM - 05:00 PM)



MANIPAL ACADEMY OF HIGHER EDUCATION

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

Audits and Regulatory Compliance [PQA-MQA203T -S1]

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 inspections, discuss the administration of the same. (10)
- 2) Discuss in detail about role of quality systems and audits in pharmaceutical manufacturing environment. (10)
- 3) Prepare a detailed audit checklist for warehouse and weighing of pharmaceutical facility (10)
- 4) Write the audit checklist for HVAC system, highlight any 10 critical points (10)
- 5) Explain the requirements and procedure for sterility testing activity in a microbiological laboratory. (10)

SECTION - B

Answer all the questions.

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

- 6) Explain the role and responsibility of management in a regulatory audit (5)
- 7) What is an audit checklist and give its importance (5)
- 8) Discuss in detail about points to be considered during preparation of soft gelatine capsule production facility audit check list (5)
- 9) a. Write the requirements for water distribution system pipework in Sterile pharmaceutical industry. (3 Marks) (5)
b. Discuss about the types of water used in pharmaceutical industry. (2 Marks)
- 10) a. Explain the handling of raw materials and reference standards in a microbiological laboratory (4 Marks) (5)
b. Prepare a label for water sample collection for microbiological testing (1 Mark)

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