

Question Paper

Exam Date & Time: 06-May-2019 (02:00 PM - 05:00 PM)



MANIPAL ACADEMY OF HIGHER EDUCATION

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

MPharm - Pharmaceutical Quality Assurance

MPharm Semester 2 - End-Semester Examination May 2019

Date : 06/05/2019

Audits and Regulatory Compliance [PQA-MQA203T]

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 management of audit, roles and responsibilities of an auditor and auditee (10)
- 2) Discuss in detail about role of quality systems and audits in pharmaceutical manufacturing environment. (10)
- 3) Prepare a detailed audit checklist for sterile dry production and packaging. (10)
- 4) Explain the importance of cleaning and sanitizing schedules and related documentation systems in microbiology laboratories (10)
- 5) a. Write about the treatment methods used in Effluent Treatment Plant. (10)
b. Write the audit checklist for Effluent Treatment Plant

SECTION - B

Answer all the questions.

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

- 6) Classify the deficiencies in an audit and explain the impact of major deficiencies on the regulatory inspection (5)
- 7) Discuss in detail about importance of cGMP regulations on controlling quality Systems (5)
- 8) Discuss in detail about points to be considered during preparation of a capsule production facility audit check list (5)
- 9) Discuss in detail about sample flow in microbiology lab as per the regulatory Requirement (5)
- 10) Give a comparative chart for HVAC parameters in sterile and non-sterile area. (5)

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