INDIRA UNIVERSITY, PUNE

SCHOOL OF PHARMACY- MPHARM (Pharmaceutical Quality Assurance)

Term End Examination (2025 Pattern) April- May – 2026- Semester – II

Course Name: Audits and Regulatory Compliance **Max. Marks: 75**
Course Code: MQA203T **Time: 3:00 Hrs.**

Instructions

- All Questions are Compulsory. Write two sections on separate answersheets.
- Neat diagram must be drawn wherever necessary.
- Figures to the right indicate full marks.

Section : I

Q.1 **Solve any ONE from the following** **15 Marks**

a. Give a detail account on types of audit. Explain the various steps involved in the audit process. Discuss the planning stage and methods of information gathering during an audit

b. Describe the structure of cGMP regulations as per USFDA guidelines, including its main parts and subparts.

Q.2 **Solve any FOUR from the following** **20 Marks**

a. Classify and discuss the deficiencies found during Audits

b. Differentiate between internal and external audits in pharmaceutical quality systems.

c. Describe management responsibilities under cGMP regulations.

d. Discuss checklist for production department

e. Discuss the essential attributes and qualifications required for an auditor.

f. Elaborate the duties of Quality control unit under cGMP regulations.

Section : II

Q.3 **Solve any ONE from the following** **15 Marks**

a. Explain in detail the auditing of tableting and coating processes in pharmaceutical manufacturing, including key checks, controls, and GMP compliance requirements.

b. Explain in detail the quality assurance audit of different types of water systems in pharmaceutical manufacturing facilities.

Q.4 **Solve any TWO from the following** **15 Marks**

a. Compare and contrast process audit and product audit

b. Write note on auditing personnel practices and sample handling procedures in a microbiology laboratory.

c. Explain OOT and OOS with suitable examples and their role in quality management.

d. Write a detailed note on audit report.

Q.5 **Solve any TWO from the following** **10 Marks**

a. Discuss API audit checklist in detail.

b. Elaborate HVAC audit report.

c. Discuss primary packaging material audit

d. Describe GMP-compliant cleaning and disinfection practices in a microbiology laboratory.

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