BIRLA INSTITUTE OF TECHNOLOGY, MESRA, RANCHI
(END SEMESTER EXAMINATION)

CLASS: M.PHARM **SEMESTER: II**
BRANCH: PHARMACY **SESSION: SP/25**

SUBJECT: MQA203T AUDITS AND REGULATORY COMPLIANCE

TIME: 3.00 Hours **FULL MARK: 75**

INSTRUCTIONS:

1. The missing data, if any, may be assumed suitably.
2. Before attempting the question paper, be sure that you have got the correct question paper.
3. Tables/Data hand book/Graph paper etc. to be supplied to the candidates in the examination hall.
5. Answer any five questions.

1a.	What do you mean by compliance classification in auditing? Write the SOP & significance of auditing in pharmaceutical industry.	[7]
1b.	What is the purpose of FDA audit? Explain the auditing procedure with suitable flow chart.	[8]
2a.	What are reasons for FDA's CGMP guidance? Discuss the significance of manufacturing in quality system.	[7]
2b.	Why quality audit is necessary? Write about auditors' tools, audit observations, audit report & checklist.	[8]
3a.	Explain about CGMP and the different concepts of modern quality systems	[7]
3b.	Discuss about 21 CFR CGMP regulations related to management responsibilities	[8]
4a.	Write a note on dry production: capsules vendor audit.	[7]
4b.	Describe the process of auditing in sterile production	[8]
5a.	Justify the role of auditing in bulk pharmaceutical chemicals and vendors.	[7]
5b.	Mention the audit checklist for the drug industry	[8]
6a.	Discuss the steps of Water audit.	[7]
6b.	What do you mean by Media fill and discuss its importance in audit of sterile unit?	[8]
7a.	Discuss the parameters an auditor should check while auditing HVAC system.	[7]
7b.	Discuss the parameters an auditor should check while auditing an ETP.	[8]

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