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

CLASS: M. PHARM. **SEMESTER: II**
BRANCH: PHARMACY **SESSION: SP/2023**

SUBJECT: MQA203T AUDITS & 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.	Explain the detail procedure for auditing an Effluent Treatment Plant (ETP).	[7]
1b.	Explain the detail procedure for auditing a Heating, Ventilation and Air-Conditioning (HVAC) system.	[8]
2a.	Describe the general guidelines for Auditing of a Microbiological laboratory.	[7]
2b.	Discuss the skill required by an Auditor to successfully complete an audit procedure.	[8]
3a.	Discuss the importance of Audit Checklist for drug industries with suitable examples.	[7]
3b.	Discuss the role of quality systems and audits in pharmaceutical manufacturing environment with reference to cGMP regulations/guidelines.	[8]
4a.	Discuss documentation and other regulatory compliance in audit.	[7]
4b.	Explain how vendor audit is related to QbD involving understanding of product variability.	[8]
5a.	Discuss in short: (i) Internal Audit (ii) External Audit	[7]
5b.	Elaborate on quality management system in auditing.	[8]
6a.	Discuss components of packaging with respect to vendor auditing.	[7]
6b.	Elaborate preapproval auditing of any solid dosage form.	[8]
7a.	Briefly discuss the documentation involved in auditing.	[7]
7b.	Discuss on checklist for non-sterile preparations.	[8]

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