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

CLASS: M. PHARM. **SEMESTER : IInd**
BRANCH: PHARMACY **SESSION : SP/24**

SUBJECT: MQA203T AUDITS AND REGULATORY COMPLIANCE

TIME: 3.00 Hours **FULL MARKS: 75**

INSTRUCTIONS:
1. The question paper contains 7 questions each of 15 marks and total 105 marks.
2. Candidates may attempt any 5 questions maximum of 75 marks.
3. The missing data, if any, may be assumed suitably.
***4*. Before attempting the question paper, be sure that you have got the correct question paper.**
5. Tables/Data hand book/Graph paper etc. to be supplied to the candidates in the examination hall.

Q.1(a)	What do you mean by auditing? Discuss about objectives and importance of audit in pharmaceutical industry.	[7]
Q.1(b)	Write about components of audit and auditing procedure.	[8]
Q.2(a)	What are the major factors of quality system? Discuss the significance of management responsibilities in it.	[7]
Q.2(b)	Explain about cGMP and concept of modern quality system.	[8]
Q.3(a)	Discuss the importance of Vendor Audit in pharmaceutical industry.	[7]
Q.3(b)	Explain the role of manufacturing operations in robust quality system	[8]
Q.4(a)	"Audit can be an emotion experience." Comment.	[7]
Q.4(b)	Discuss the responsibilities of an auditor during an audit process.	[8]
Q.5(a)	Explain the difference between auditing sterile and non-sterile production sites.	[7]
Q.5(b)	Discuss the auditing parameters for Capsules production.	[8]
Q.6(a)	Discuss how auditing of microbiology lab is different form other facilities.	[7]
Q.6(b)	As an auditor what types of tactics you will use in order to get all information during an audit?	[8]
Q.7(a)	As an auditor, discuss the auditing of HVAC System taking care of critical and non-critical parameters.	[7]
Q.7(b)	Design an auditing process for Effluent Treatment Plant.	[8]

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