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

CLASS: M.PHARM **SEMESTER : II**
BRANCH: PHARMACY **SESSION : SP/19**

SUBJECT: MQA203T AUDITS AND REGULATORY COMPLIANCE

TIME: 3.00 Hrs **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 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)	What do you mean by quality audit? Justify its role in pharmaceutical industry.	[7]
Q.4(b)	Explain the auditing process of a production department with special reference to Tablet manufacturing facilities with a suitable example.	[8]
Q.5(a)	Discuss the steps of Water audit.	[7]
Q.5(b)	What do you mean by Media fill and discuss its importance in audit of sterile unit?	[8]
Q.6(a)	Discuss physical & chemical process of Effluent treatment.	[7]
Q.6(b)	Explain the areas on which auditor of a microbiological lab should focus.	[8]
Q.7(a)	Discuss the parameters an auditor should check while auditing HVAC system.	[7]
Q.7(b)	Discuss the parameters an auditor should check while auditing an ETP.	[8]

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