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

CLASS: MPHARM **SEMESTER : II**
BRANCH: PHARMACY **SESSION : SP/18**

SUBJECT: MPH2025 AUDITS & REGULATORY COMPLIANCE

TIME: 3.Hours **FULL MARKS: 60**

INSTRUCTIONS:
1. The question paper contains 7 questions each of 12 marks and total 84 marks.
2. Candidates may attempt any 5 questions maximum of 60 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 is audit? Write a note on significance of audit in pharmaceutical industry.	[6]
Q.1(b)	Discuss about SOP, classification and auditing procedures in pharmaceutical industry.	[6]
Q.2(a)	Discuss the significance of quality audit in pharmaceutical manufacturing process.	[6]
Q.2(b)	Write a note on management responsibilities and resources in quality system.	[6]
Q.3(a)	Describe about various aspects of manufacturing operations.	[6]
Q.3(b)	Justify the presence of audit checklist in pharmaceutical industries.	[6]
Q.4(a)	Discuss the various aspects of vendor qualification in manufacturing process.	[6]
Q.4(b)	Outline the reasons behind initiating an audit.	[6]
Q.5(a)	Describe the terms non-revenue loss and revenue loss in connection to water audit.	[6]
Q.5(b)	Outline water loss control program giving emphasis on the intervention phase and evaluation phase.	[6]
Q.6(a)	Explain the important aspects to be considered while auditing Engineering Department.	[6]
Q.6(b)	Why there is a requirement to audit HVAC system? Explain with suitable justifications.	[6]
Q.7(a)	What are the key parameters involved in auditing a microbiology and sterility testing quality laboratory? Explain.	[6]
Q.7(b)	Define: a) Bioburden b) Endotoxin c) Inoculum	[6]

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