

GUJARAT TECHNOLOGICAL UNIVERSITY
M.PHARM - SEMESTER-2 EXAMINATION – SUMMER-2019

Subject Code: MQA203T**Date: 31/05/2019****Subject Name: Audits and Regulatory Compliance****Time: 10:30 AM TO 01:30 PM****Total Marks: 80****Instructions:**

1. Attempt any five questions.
2. Make suitable assumptions wherever necessary.
3. Figures to the right indicate full marks.

Q.1	(a)	Define an audit and explain why audits are carried out.	06
	(b)	Discuss types and levels of audits.	05
	(c)	Describe types of deficiencies observed in an audit.	05
Q.2	(a)	Discuss designing and Implementation for internal audit system.	06
	(b)	Describe component and management of an audit.	05
	(c)	Write a note on Internal audit.	05
Q.3	(a)	Explain in brief about planning process for an audit.	06
	(b)	Discuss the process and method of information gathering by auditor.	05
	(c)	Write note on quality management system.	05
Q.4	(a)	Discuss role of quality assurance in Pharmaceutical manufacturing.	06
	(b)	Describe audit checklist for drug industries.	05
	(c)	Explain auditing of Tablet manufacturing department.	05
Q.5	(a)	Describe process for auditing of vendors of bulk pharmaceutical chemicals.	06
	(b)	Write a note on auditing of packing material vendor.	05
	(c)	Discuss general standards of building raw materials for Microbiology laboratory.	05
Q. 6	(a)	Explain standards and evaluation parameters for water for injection.	06
	(b)	Discuss steps for auditing of capsule department.	05
	(c)	Explain in brief about auditing of HVAC system.	05
Q.7	(a)	Explain general cGMP regulation for pharmaceutical industries.	06
	(b)	Write a note on auditing of pharmaceutical Effluent treatment plant.	05
	(c)	Discuss importance of role of quality system approach in pharmaceutical industries.	05
