Seat No.: _____ Enrolment No. _____

GUJARAT TECHNOLOGICAL UNIVERSITY

M.PHARM - SEMESTER–1 EXAMINATION – SUMMER-2019

Subject Code: MQA103T Date: 01/06/2019

Subject Name: Quality Control and Quality Assurance

Time: 02:30 PM TO 05:30 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 Quality Control and Quality Assurance. Write scope of QA and QC in Pharmaceutical Company.	**06**
	(b)	Enlist the ICH Q series Guidelines and Discuss ICH guideline Q3B (R2) Impurities in New Drug Products.	**05**
	(c)	Discuss the case study of Change Control procedure.	**05**
Q.2	**(a)**	Draw the flow chart for Establishing Acceptance Criterion For a Degradation Product in a New Drug Product as per ICH Q6 A guidelines.	**06**
	(b)	Discuss the Out of Specification Case study.	**05**
	(c)	Write in brief Batch Manufacturing Record.	**05**
Q.3	**(a)**	Draw triangle of CTD and discuss Module 5 Clinical Study Reports.	**06**
	(b)	Enlist and explain the Finished Product QC test for Parenteral.	**05**
	(c)	Write about release of finished products.	**05**
Q.4	**(a)**	Enlist and explain in brief IPQC tests of Ophthalmic dosage form.	**06**
	(b)	Discuss the importance of Documentation in Quality Control Department.	**05**
	(c)	Discuss the three tier documentation procedure in Pharmaceutical industry.	**05**
Q.5	**(a)**	Discuss the need for protection of Intellectual properties.	**06**
	(b)	Discuss the control on animal house as per GLP guidelines.	**05**
	(c)	Define and explain Copyright.	**05**
Q. 6	**(a)**	Discuss the scope of GLP guidelines.	**06**
	(b)	Discuss the way to control mix ups and cross contamination at manufacturing site.	**05**
	(c)	Define Quality Audit. Write about the Quality Audit Plan.	**05**
Q.7	**(a)**	Explain the layout of SOP with suitable example.	**06**
	(b)	Discuss the organization and personnel responsibilities as per cGMP.	**05**
	(c)	Write the protocol to conduct non clinical testing.	**05**

****