Seat No.: _____ Enrolment No. _____

GUJARAT TECHNOLOGICAL UNIVERSITY

M.PHARM - SEMESTER–2 EXAMINATION – SUMMER-2019

Subject Code: MPT204T Date: 03/06/2019

Subject Name: Regulatory Requirements for Pharmaceutical Manufacturing

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)**	What is QTPP, CQA and CPP with respect to Quality by Design.	**06**
	(b)	Discuss concept of optimization and any one classical optimization technique.	**05**
	(c)	Deliberate on the scope of ICH Q9 guidelines.	**05**
Q.2	**(a)**	Discuss what is quality in Quality Risk Management as per ICH guidelines.	**06**
	(b)	What is Design Space as per ICH Q8? Discuss briefly the advantages of Design of Experiments over one factor at a time approach.	**05**
	(c)	Discuss in brief Module 2 of Common Technical Document.	**05**
Q.3	**(a)**	Describe in detail failure modes and effect analysis with respect to ICH.	**06**
	(b)	Briefly discuss seven steps of Hazard Analysis and Critical Control Points.	**05**
	(c)	Introduce Pharmaceutical Quality System as a facilitator between pharmaceutical development and manufacturing activities.	**05**
Q.4	**(a)**	Discuss the overview of a typical quality risk management process.	**06**
	(b)	Discuss Continual Improvement of Process Performance and Product Quality as per ICH Q10.	**05**
	(c)	Discuss Management of Outsourced Activities and Purchased Materials.	**05**
Q.5	**(a)**	Describe QbD for Immediate release dosage forms with example.	**08**
	(b)	Design a prototype QbD protocol for drug nanoparticles formulation.	**08**
Q. 6	**(a)**	Write details on PAT Framework as per USFDA guidelines.	**06**
	(b)	Write a note on process analyzers as a PAT tool.	**05**
	(c)	Discuss implementation of PAT with the help of example.	**05**
Q.7	**(a)**	Enumerate PQS elements. Discuss any one in detail.	**06**
	(b)	Discuss ICH Q10 objectives.	**05**
	(c)	Discuss risk ranking as a QRM tool.	**05**

****