Seat No.: _____ Enrolment No. _____

GUJARAT TECHNOLOGICAL UNIVERSITY

B. Pharm – SEMESTER VII • EXAMINATION – WINTER-2017

Subject Code: 2270015 Date: 16-11-2017

Subject Name: Quality by Design (QbD) and Process Analytical Technology (PAT)

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)**	Explain requirement of QbD. Discuss the various elements of QbD.	**06**
	(b)	Give the full name of the following terminology: 1.QTPP 2. CMA 3. CQA 4. CPP 5. RLD.	**05**
	(c)	Give significance of design of experiments and risk assessment in pharmaceutical product development.	**05**
Q.2	**(a)**	Enlist the optimization techniques and explain any one.	**06**
	(b)	Describe in detail Question Based Review (QbR).	**05**
	(c)	Explain in brief CTD.	**05**
Q.3	**(a)**	Explain what is quality? Write about relevance of quality with respect to pharmaceuticals.	**06**
	(b)	Describe in detail Principles and Scope of Quality Risk Management.	**05**
	(c)	Discuss in detail general qualities of risk management process.	**05**
Q.4	**(a)**	Describe in detail Management Responsibilities for Pharmaceutical Quality Management .	**06**
	(b)	Explain briefly Continual Improvement of Process Performance And Product Quality.	**05**
	(c)	Give the full name of HACCP and FMEA and explain briefly HACCP.	**05**
Q.5	**(a)**	Explain detail case study of QbD for any one immediate release dosage forms.	**06**
	(b)	Describe in detail QbD for vaginal dosage forms considering manufacturing process variables, raw materials and desired attributes.	**05**
	(c)	Explain about the Real time release approach.	**05**
Q. 6	**(a)**	Discuss in detail Introduction, Scope, Background of PAT.	**06**
	(b)	Write a note on Tools and Framework of PAT.	**05**
	(c)	Explain briefly Risk-Based Approach and Integrated Systems Approach for PAT.	**05**
Q.7	**(a)**	Explain in detail QbD for Topical dosage forms considering manufacturing process variables, raw materials and desired attributes.	**06**
	(b)	Discuss in details strategy for implementation of PAT.	**05**
	(c)	Write in detail case study of QbD for any one Modified release dosage forms.	**05**

****