Seat No.: _____ Enrolment No. _____

GUJARAT TECHNOLOGICAL UNIVERSITY

B.Pharm – SEMESTER VII • EXAMINATION – WINTER-2016

Subject Code: 2270015 Date: 29/11/2016

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 in detail CTD.	**06**
	(b)	Write history, current approach and limitations of QbD.	**05**
	(c)	Why QbD is required? Write advantages and elements of QbD.	**05**
Q.2	**(a)**	Discuss General Quality Risk Management Process.	**06**
	(b)	Write full forms of Terminology: QTPP, CMA, CQA, CPP and RLD.	**05**
	(c)	Write in brief about Design space and design of experiments.	**05**
Q.3	**(a)**	Discuss classical optimization and optimization parameters.	**06**
	(b)	Explain in detail Question Based Review (QbR).	**05**
	(c)	Explain the concept of optimization and application of optimization techniques.	**05**
Q.4	**(a)**	Short note on Statistical designs.	**06**
	(b)	What is quality? Explain relevance of quality with respect to pharmaceuticals.	**05**
	(c)	Write scope and principles of Quality Risk Management.	**05**
Q.5	**(a)**	Give detailed case study of QbD for any one Immediate release dosage forms.	**06**
	(b)	QbD for vaginal dosage forms considering manufacturing process variables, raw materials and desired attributes.	**05**
	(c)	Write a note on Total Quality Management (TQM).	**05**
Q. 6	**(a)**	Give detailed case study of QbD for any one Modified release dosage forms.	**06**
	(b)	Write on Continual Improvement of Process Performance And Product Quality.	**05**
	(c)	Introduction, Scope and background of Process Analytical Technology.	**05**
Q.7	**(a)**	QbD for Topical dosage forms considering manufacturing process variables, raw materials and desired attributes.	**06**
	(b)	Write on Process Analytical Technology Framework and Tools.	**05**
	(c)	Discuss Process Analytical Technology(PAT) in pharmaceutical development and its application.	**05**

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