Seat No.: _____ Enrolment No. _____

GUJARAT TECHNOLOGICAL UNIVERSITY

B.PHARM. - SEMESTER– VII • EXAMINATION – SUMMER-2016

Subject Code: 2270015 Date: 13/05/2016

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

Time: 2:30 PM to 5:30 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 the following terminology. 1) Quality by Design (QbD) 2) Process Analytical Technology (PAT) 3) Design Space	**06**
	(b)	Enlist and explain the elements of QbD.	**05**
	(c)	Write Classification of optimization techniques and explain any one.	**05**
Q.2	**(a)**	Enlist PAT tools and Explain process control tool.	**06**
	(b)	Draw a flow chart of quality risk management process.	**05**
	(c)	Explain the Control strategy approach for Quality Product.	**05**
Q.3	**(a)**	Enlist the different parts of CTD. Explain any one in detail.	**06**
	(b)	Enlist and explain in brief the elements of QbD.	**05**
	(c)	Explain in brief Risk Base Approach and Integrated System Approach.	**05**
Q.4	**(a)**	Explain the following 1) QTPP (Quality Target Product Profile), 2) CQA (Critical Quality Attributes) 3) CPP (Critical Process Parameter)	**06**
	(b)	Write about Current approaches to QbD.	**05**
	(c)	Draw a process map for Immediate Release Dosage Form by QbD.	**05**
Q.5	**(a)**	Compare the minimal requirements and enhanced approaches by QbD to pharmaceutical development.	**06**
	(b)	Explain the Failure Mode Effects Analysis (FMEA)	**05**
	(c)	Explain the following with Pharmaceutical examples	**05**
Q. 6	**(a)**	Write about Quality target product profile with respect to Modified release dosage form.	**06**
	(b)	Write about Scope and principles of PAT.	**05**
	(c)	Explain the Hazard Analysis and Critical Control Points (HACCP)	**05**
Q.7	**(a)**	Explain scope, principle and overview of Quality Risk Management.	**06**
	(b)	Explain Yate's method for optimization with example.	**05**
	(c)	Explain about the Real time release approach.	**05**

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