Seat No.: _____ Enrolment No. _____

GUJARAT TECHNOLOGICAL UNIVERSITY

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

Subject Code: 2270015 Date: 10/05/2017

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

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 by Design. Explain the need of QbD for Pharma sector.	**06**
	(b)	Explain the QTPP (quality target product profile) parameter with example.	**05**
	(c)	Draw a flow chart of quality risk management process.	**05**
Q.2	**(a)**	Explain the following terminology: a) CQA (Critical Quality Attributes) b) CPP (Critical Process Parameter)	**06**
	(b)	Discuss advantage and limitation of QbD.	**05**
	(c)	Discuss Scope and principles of PAT.	**05**
Q.3	**(a)**	Classify the Optimization techniques.	**06**
	(b)	Compare the Traditional and QbD approach for Pharmaceutical product supply.	**05**
	(c)	Explain the Clinical Study Reports of CTD.	**05**
Q.4	**(a)**	Explain the elements of QbD.	**06**
	(b)	Explain the need of optimization for Pharmaceutical development.	**05**
	(c)	Discuss challenges for implementation of QbD.	**05**
Q.5	**(a)**	Define: a) Design Space b) Level c) Factor	**06**
	(b)	Explain scope and principle of Quality Risk Management.	**05**
	(c)	Explain: Failure Mode Effects Analysis (FMEA).	**05**
Q. 6	**(a)**	Explain Yate's method for optimization with example.	**06**
	(b)	Explain process control tool for PAT.	**05**
	(c)	Enlist the different parts of CTD.	**05**
Q.7	**(a)**	Discuss Quality target product profile with respect to Modified release dosage form.	**06**
	(b)	Discuss Scope and principles of PAT.	**05**
	(c)	Discuss management responsibility for Pharmaceutical Quality Management.	**05**

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