Seat No.: _____ Enrolment No. _____

GUJARAT TECHNOLOGICAL UNIVERSITY

B.Ph. - SEMESTER– VII • EXAMINATION – WINTER-2018

Subject Code: 2270015 **Date: 28/11/2018**

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

Time: 10:30AM TO 01:30PM **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)**	Discuss the Process performance and product quality monitoring system as an element of ICH Q10 Pharmaceutical Quality System.	**06**
	(b)	Draw the CTD triangle and Explain the Module 5 Clinical study reports.	**05**
	(c)	Write a note on HACCP (Hazard Analysis and Critical Control Points).	**05**
Q.2	**(a)**	Define QbD. Discuss the elements of QbD.	**06**
	(b)	Write two primary principles of QRM and Draw the flow chart of typical Quality Risk Management Process.	**05**
	(c)	Write a note on PAT tools.	**05**
Q.3	**(a)**	Explain the Ishikawa Diagram that used as a Risk Assessment Tool.	**06**
	(b)	Define PAT. Discuss scope and principle of PAT.	**05**
	(c)	Explain Yate's method for optimization with example.	**05**
Q.4	**(a)**	Explain the terminology QTPP and CPP with suitable example with respect to QbD.	**06**
	(b)	What is Risk Priority Number? Explain with any Risk Assessment Example.	**05**
	(c)	Write the total number of experiments and treatment combination and interaction chart for 3^2 Factorial design.	**05**
Q.5	**(a)**	Compare the Traditional and QbD approach for Pharmaceutical product supply.	**06**
	(b)	Explain with example 1) CQA 2) CMA	**05**
	(c)	Write about need of QbD for Pharma sector.	**05**
Q. 6	**(a)**	Discuss challenges for implementation of QbD.	**06**
	(b)	Explain the Real Time Release Study of PAT.	**05**
	(c)	Explain the mapping of CMA and CPP to CQAs with example.	**05**
Q.7	**(a)**	Explain the CTD module 3 Quality in detail.	**06**
	(b)	Explain the Design Space.	**05**
	(c)	Explain the control strategy approach for Quality product.	**05**

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