

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
