

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
