Seat N	lo.: _	Enrolment No		
		GUJARAT TECHNOLOGICAL UNIVERSITY		
]	B.PF	IARM – SEMESTER – VII • EXAMINATION – WINTER – 2015		
Subject Code: 2270015 Date: 16/12/20				
•	Subject Name: Quality by Design (QbD) and Process Analytical Technology (PAT)			
Time: 10.30 AM to 1.30 PM Instructions: Total Marks: 80				
				1.
2.	Ma	ke suitable assumptions wherever necessary.		
3.	Fig	ures to the right indicate full marks.		
Q.1	(a)	Explain the following terms:	06	
	(b)	1) QTPP 2) CQA 3) FMEA 4) Design Space 5) RLD 6) CMA Write a note on approach and limitation of QbD.	05	
	(c)	Give importance of DoE and risk assessment in formulation development.	05	
Q.2	(a)	Define Quality. Write a note on relevance of quality with respect to pharmaceuticals.	06	
	(b)	Write a note on scope and Principle of Risk Management	05	
	(c)	Explain HACCP and FMEA in detail	05	
Q.3	(a)	Write a note on pharmaceutical development and explain CTD (Common Technical Document)	06	
	(b)	Explain Concept of Optimization and Optimization Parameters required for development of sustained and controlled release formulation.	05	
	(c)	What is design of experiment? Give method and application of optimization of parameters in formulation with example.	05	
Q.4	(a)	Write a note on management responsibility for Pharmaceutical Quality System.	06	
	(b)	How one can improve the quality of product in manufacturing area.	05	
	(c)	Give your inputs to develop zero defect formulation based on quality point of view.	05	
Q.5	(a)	How will you determine and minimize the risk assessed in formulation.	06	
	(b)	Give general quality risk management process.	05	
	(c)	Give the difference between Classical optimization and statistical design	05	
Q. 6	(a)	What is PAT? Give its scope and framework.	06	
	(b)	Write a note on risk based approach and integrated system approach.	05	
	(c)	How PAT is implemented, explain with example.	05	
Q.7	(a)	Give QbD of immediate release formulation with example.	06	
	(b)	Write a short note on question based review (QbR).	05	
	(c)	Give brief review on ICH Q9.	05	
