GUJARAT TECHNOLOGICAL UNIVERSITY

B.Pharm

SEMESTER: VII

Subject Name: Quality by Design (QbD) and Process Analytical Technology (PAT)
Subject Code: 2270015

Teaching Scheme				Evaluation Scheme			
Theory	Tutorial	Practical	Total	Theory		Practical	
				External	Internal	External	Internal
3	0	0	3	80	20	0	0

.	Topic	Hours
1	**Introduction to QbD**: History, Current approch and its limitations. Why QbD is required, Advantages, Elements of QbD, Terminology: QTPP. CMA, CQA, CPP, RLD, Design space, Design of Experiments, Risk Assessment and mitigation/minimization.	2
2	**Pharmaceutical Development:** Introduction, Pharmaceutical Development, Submission of Pharmaceutical Development And Related Information In Common Technical Documents (CTD) Format, Design of experiments –Methods and applications Optimization techniques: Concept of optimization, optimization parameters, classical optimization. Statistical designs, Question Based Review (QbR).	10
3	**Quality Risk Management:**Introduction- What is quality? Relevence of quality with resepect to pharmaceuticals, Scope, Principles of Quality Risk Management ICH Q9, HACCP, FMEA, General Quality Risk Management Process.	3
4	**Pharmaceutical Quality Management**: Pharmaceutical Quality System, Management Responsibility, Continual Improvement of Process Performance And Product Quality, Continual Improvement of the Pharmaceutical Quality System.	5
5	**Detailed case study of QbD** for Immediate release dosage forms, Modified release dosage forms. Emphsis should be given to prototype QbD for various dosage forms considering manufacturing process variables, raw materials and desired attributes.	15
6	**Process Analytical Technology:** Introduction, Scope, Background, PAT Framework, PAT Tools, Risk-Based Approach, Integrated Systems Approach, Real Time Release, Strategy For Implementation, Regulatory Approach, Examples of PAT Implementation.	10

References:

1. ICH Guidelines
2. FDA Guidelines