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GUJARAT TECHNOLOGICAL UNIVERSITY

M. Ph.- SEMESTER–II • EXAMINATION – SUMMER -2018

Subject Code:MPT204T **Date: 21/05/2018**

Subject Name: Regulatory Requirements for Pharmaceutical Manufacturing

Time: 10:30 AM TO 01:30 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)**	Describe principles of QbD as per ICH.	**06**
	(b)	Write advantages, limitations and key elements of QbD in detail.	**05**
	(c)	Explain QTPP and CQA as per ICH.	**05**
Q.2	**(a)**	Write objectives of Pharmaceutical development and discuss components of the drug products.	**06**
	(b)	Discuss in detail about submission of Pharmaceutical development and related information as per CTD format.	**05**
	(c)	Write an overview on "Optimization techniques in Pharmaceutical formulation and processing".	**05**
Q.3	**(a)**	Discuss in general about Quality Risk Management process.	**06**
	(b)	What is Quality with respect to Pharmaceuticals? Write scope and principles of Quality Risk Management.	**05**
	(c)	Explain HACCP and FMEA in detail.	**05**
Q.4	**(a)**	Write scope, objectives and Continual Improvements of the Pharmaceutical Quality Management System as per ICH Q10.	**06**
	(b)	Discuss QbD approach as per ICH.	**05**
	(c)	Explain in detail about Components and purpose of Experimental Design.	**05**
Q.5	**(a)**	Discuss QbD control strategy for Immediate Release and Modified Release dosage forms.	**06**
	(b)	Explain Risk Assessment of Drug Product manufacturing process for modified release dosage forms.	**05**
	(c)	Discuss Management responsibilities in PQM.	**05**
Q. 6	**(a)**	Write details on (i) PAT Framework ; (ii) PAT Tools	**06**
	(b)	Discuss examples of PAT implementation in detail.	**05**
	(c)	Explain Risk Assessment of the Tablet compression process variables for Immediate release dosage forms.	**05**
Q.7	**(a)**	Write a short note on "QbD Implementation – An FDA Perspective"	**06**
	(b)	Highlight brief review on QRM tools.	**05**
	(c)	Explain Implications & Benefits of ICH in the Drug Development Cycle.	**05**

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