Seat No.: _____ Enrolment No. _____

GUJARAT TECHNOLOGICAL UNIVERSITY

M. Pharm - SEMESTER–I • EXAMINATION – SUMMER-2018

Subject Code: MQA103T **Date: 07/05/2018**

Subject Name: QUALITY CONTROL AND QUALITY ASSURANCE

Time: 02:30PM TO 05:30PM **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)**	Describe concepts of QA, GMP and GLP in brief	**06**
	(b)	What is GLP? Describe the responsibilities of the Quality assurance unit of a non-clinical testing laboratory.	**05**
	(c)	Enumerate different guidelines of GMP	**05**
Q.2	**(a)**	cGMP guideline as per the USFDA	**06**
	(b)	Write note on QSEM guideline	**05**
	(c)	cGMP guideline as per Schedule M	**05**
Q.3	**(a)**	In process quality control of tablet as per IP	**06**
	(b)	In process quality control of parental as per USP	**05**
	(c)	Analysis of raw material in purchase specification and maintenance of store	**05**
Q.4	**(a)**	Define SOP, write objective of SOPs	**06**
	(b)	Short note on Batch Manufacturing Record	**05**
	(c)	Note on CTD and eCTD	**05**
Q.5	**(a)**	How to minimize mix up and cross contamination in manufacturing operation and controls.	**06**
	(b)	Write note on sanitization of manufacturing unit.	**05**
	(c)	Short note on drug product inspection in manufacturing operation and control	**05**
Q. 6	**(a)**	CPCSEA guideline	**06**
	(b)	IPQC of semisolid dosage form	**05**
	(c)	Handling of waste and scrap disposal in manufacturing operation.	**05**
Q.7	**(a)**	Scope and importance of IPR	**06**
	(b)	Short note on Quality audit	**05**
	(c)	Write note on GLP	**05**

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