Seat No.: _____ Enrolment No._____

GUJARAT TECHNOLOGICAL UNIVERSITY

M.PHARM – SEMESTER -1 - EXAMINATION –WINTER - 2018

Subject Code: MRA101T **Date: 01/01/2019**

Subject Name: Good Regulatory Practices

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)**	Discuss the following terms with respect to 21CFR 210- Fiber, Gang printed labelling, potency, acceptance criteria, actual yield and component.	**06**
	(b)	Write a note on Drug product containers and closures as per 21CFR 211.	**05**
	(c)	Enlist all the subparts of 21CFR 211.	**05**
Q.2	**(a)**	Write a note on site master file as per EC GMP.	**06**
	(b)	Describe Sampling and Testing as per EC GMP.	**05**
	(c)	Write a note on GAMP 5.	**05**
Q.3	**(a)**	Write a note on Manufacture of Pharmaceutical excipients as per WHO GMP.	**06**
	(b)	Describe the animal care facilities as per USFDA GLP for non-clinical laboratory studies.	**05**
	(c)	Write a note on Goals of Laboratory Quality audit.	**05**
Q.4	**(a)**	Describe the principles of GALP.	**06**
	(b)	Discuss Controls in 21CFR 11.	**05**
	(c)	What is GDP? Discuss Vehicles and Equipment as per GDP.	**05**
Q.5	**(a)**	Discuss GDP- supply chain integrity as per USP.	**06**
	(b)	Write a note on Six Sigma Concept.	**05**
	(c)	Discuss the term QbD and its applications.	**05**
Q. 6	**(a)**	Discuss ICH guidelines on Quality.	**06**
	(b)	What is OOS and Change control? Discuss with examples.	**05**
	(c)	Write a note on types of Validations and types of Qualifications.	**05**
Q.7	**(a)**	Discuss Stability testing principles as per GDP.	**06**
	(b)	Discuss the requirements for Medical device manufacturing as per Sch M III.	**05**
	(c)	Write a note on software evaluation as per ISO.	**05**

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