Seat No.: _____ Enrolment No._____

GUJARAT TECHNOLOGICAL UNIVERSITY

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

Subject Code: MPA103T **Date: 05/01/2019**

Subject Name: Pharmaceutical Validation

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)**	Enlist different HVAC system parameters used in qualification of pharmaceutical facility.	**06**
	(b)	Discuss significance of 21CFR part 11.	**05**
	(c)	Describe works and rights protected by copyrights.	**05**
Q.2	**(a)**	Describe the significance and key elements of Validation Master Plan.	**06**
	(b)	Explain Qualification protocol vs Qualification report.	**05**
	(c)	Explain pilot scale up operation.	**05**
Q.3	**(a)**	What do you mean by Analytical Method Validation? Discuss characteristics for validation of assay and impurity testing.	**06**
	(b)	What do you mean by patent? Discuss patent protection.	**05**
	(c)	Describe acceptance criteria used in cleaning validation.	**05**
Q.4	**(a)**	Explain qualification of Different glasswares used in laboratory.	**06**
	(b)	Explain the phases of pharmaceutical water system validation.	**05**
	(c)	Discuss the factors affecting on choice of IP.	**05**
Q.5	**(a)**	Explain the relationship between Action Limit and Alert Limit, Requalification and Change Control.	**06**
	(b)	Write a protocol for qualification of HPLC.	**05**
	(c)	Enumerate Validation parameters as per ICH and USP. Discuss any two in detail.	**05**
Q. 6	**(a)**	What is the significance of system suitability? What are the parameters used for system suitability of HPLC test method?	**06**
	(b)	Discuss procedure for filing of patent application.	**05**
	(c)	Write a note on different types of pharmaceutical waters. Draw a diagram of purified water generation, storage and distribution system.	**05**
Q.7	**(a)**	Define Patent Infringement. Give its scope. Discuss rights and responsibilities of Patentee.	**06**
	(b)	Describe the advantages of validation and discuss its regulatory importance of validation.	**05**
	(c)	Discuss the computer system validation with respect to hardware and software.	**05**

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