Seat No.: _____ Enrolment No._____

GUJARAT TECHNOLOGICAL UNIVERSITY

M. Pharm. – SEMESTER – III • EXAMINATION – WINTER • 2014

Subject Code: 930104 Date: 06-12-2014

Subject Name: Validation and Product Development

Time: 10:30 am - 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)**	Define validation. Discuss types and advantages of Validation.	**06**
	(b)	Discuss design and installation qualification in process validation.	**05**
	(c)	Describe calibration of pH meter.	**05**
Q.2	**(a)**	Enumerate in process controls employed in manufacturing process design of ophthalmic & parenteral preparations.	**06**
	(b)	What are limitations of sterility test? Explain techniques of rapid or real time sterility test.	**05**
	(c)	Write note on packing material for parenteral product.	**05**
Q.3	**(a)**	Discuss the validation process for fluid bed and tray dryer.	**06**
	(b)	What are the objectives of cleaning validation? Describe the methods of cleaning validation.	**05**
	(c)	Describe validation of water system for pharmaceuticals.	**05**
Q.4	**(a)**	Explain the terms Validation Protocol and Validation Report. Give Protocol for validation of tablet compression.	**08**
	(b)	What is Validation Master Plan? Explain its importance in setting up of a new manufacturing facility.	**08**
Q.5	**(a)**	Define D-value and F-value. Describe OQ and PQ steps involved in the validation of autoclave.	**08**
	(b)	Describe validation of HVAC system in sterile product manufacturing area.	**08**
Q. 6	**(a)**	Discuss the requirements of scale-up and post-approval changes in immediate release dosage form (SUPAC-IR).	**08**
	(b)	Write a note on validation of integrated lines by media fill test.	**08**
Q.7	**(a)**	Tabulate USP validation requirements for each of four categories of analytical procedures. Why and how is robustness and Reproducibility of assay method determined?	**08**
	(b)	Describe validation of UV-VIS spectrophotometer.	**08**

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