Seat No.: _____ **Enrolment No._____**

GUJARAT TECHNOLOGICAL UNIVERSITY

M.Ph Semester–III Examination Dec. - 2011

Subject code: 930104 **Date: 10/12/2011**

Subject Name: Validation & 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)	Explain the term Calibration, Qualification & Verification and their interrelationship	**06**
	(b)	Explain different stages of facility & equipment qualification	**05**
	(c)	Write a note on vendor qualification with respect to procurement of materials	**05**
Q.2	(a)	Define the Validation Master Plan & explain its importance in setting up of a new manufacturing facility	**06**
	(b)	Describe the types of process validation and role of different technical personnel in executing the same	**05**
	(c)	Explain the terms Validation Protocol and Validation Report. Give Protocol for validation of tablet compression OR coating process	**05**
Q.3	(a)	Write a note on validation of Fluid Bed Dryer	**06**
	(b)	Write a note on validation of integrated lines by media fill test	**05**
	(c)	Write a note on qualification of Dissolution test apparatus	**05**
Q.4	(a)	Enumerate different parameters used for analytical method validation in Assay and Impurities testing	**06**
	(b)	Explain the terms Robustness and Reproducibility in method validation	**05**
	(c)	Briefly explain the terms System Suitability, Column Qualification & Method Transfer with respect to HPLC use	**05**
Q.5	(a)	How will you validate HVAC system installed in sterile product manufacturing facility?	**06**
	(b)	Explain different mechanisms to control cross contaminate in HVAC system	**05**
	(c)	Define the terms As-built, At – rest condition & operational condition with respect to facility design	**05**
Q. 6	(a)	Write a note on Performance Qualification of purified water system	**06**
	(b)	Write a note on validation of hardware & software	**05**
	(c)	Enumerate in process controls employed in manufacturing process design of ophthalmic & parenteral preparations	**05**
Q.7	(a)	What are SUPAC Guidelines? Explain different levels of changes with respect to Components & composition, Manufacturing equipment & process for immediate release solid oral dosage form	**06**
	(b)	Write a note on scaling up operation in pharmaceutical development	**05**
	(c)	What are current developments in GMP compliance giving reference to ICH guidelines	**05**

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