Seat No.: _____ Enrolment No. _____

GUJARAT TECHNOLOGICAL UNIVERSITY

M. Pharm - SEMESTER– II • EXAMINATION – SUMMER-2016

Subject Code:2920104 **Date: 19/05/2016**

Subject Name: Modern Pharmaceutical Analysis

Time: 10:30 AM to 1:30 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)**	Write in brief the regulatory requirement of drug analysis as per ICH guidelines	**06**
	(b)	Write the usefulness of ion exchange chromatography.	**05**
	(c)	Write a note on isoelectric focusing.	**05**
Q.2	**(a)**	Give the importance of performing preformulation study.	**06**
	(b)	List various preformulation studies. Explain any two technique.	**05**
	(c)	Give a brief account on tryptic mapping.	**05**
Q.3	**(a)**	Enlist the different properties associated with molecular level in the solid state analysis and explain any two.	**06**
	(b)	Why impurity analysis is required? Discuss drug substance degradation studies.	**05**
	(c)	Explain the sterility testing of parenteral products.	**05**
Q.4	**(a)**	Enlist various compendial methods for evaluation of crude drugs and explain any two methods.	**06**
	(b)	Explain briefly the different instruments used in the analysis of radiopharmaceuticals.	**05**
	(c)	Describe the various quality control test performed in the nail care preparation and dental care products.	**05**
Q.5	**(a)**	What is automation? What is the need of automation? Write the advantages and disadvantages of automated analysis.	**06**
	(b)	Classify the automated analysis suitably. Explain continuous flow analysis	**05**
	(c)	Explain the compendial testing of API and formulated products	**05**
Q. 6	**(a)**	Enlist the analytical performed for injectable dosage form. Discuss the bacterial endotoxin test.	**06**
	(b)	What is the concept of solubility? Outline any two methods for the determination of solubility of solid in liquid.	**05**
	(c)	Outline IP method for validation of UV spectrophotometer.	**05**
Q.7	**(a)**	Give brief account on regulatory requirements of cosmetic formulation.	**06**
	(b)	Describe the evaluation of hair products.	**05**
	(c)	Describe role of near infrared analysis in solid dosage form.	**05**

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