Seat No.: _____ Enrolment No._____

GUJARAT TECHNOLOGICAL UNIVERSITY

M. Pharm. – SEMESTER – II • EXAMINATION – SUMMER • 2014

Subject Code: 2920104 **Date: 29-05-2014**

Subject Name: Modern Pharmaceutical Analysis

Time: 02:30 pm - 05:30 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)**	What are quality standards for parenteral preparation? Describe sterility testing of antibiotics, packing material and thermo labile drug product.	**10**
	(b)	Discuss Bio-burden testing of parenteral products.	**06**
Q.2	**(a)**	Explain dissolution standards and general method for dissolution test of enteric coated oral dosage form.	**06**
	(b)	What are objectives and concepts of automation adopted in manufacturing of pharmaceuticals.	**05**
	(c)	As per ICH guideline outline validation of assay method of impurities in API.	**05**
Q.3	**(a)**	Discuss principle and application of Isoelectric focusing technique of electrophoresis.	**06**
	(b)	As per IP outline method of validation of UV spectrophotometer.	**05**
	(c)	What is effect of impurity in API? Write note on degradation study.	**05**
Q.4	**(a)**	Explain Radio immune-assay of Insulin.	**08**
	(b)	What are cosmetics? How are they evaluated?	**08**
Q.5	**(a)**	Describe application of DSC, NMR and Near-infrared in physicochemical characterization of solid dosage forms.	**10**
	(b)	Discuss quality control of radiopharmaceuticals.	**06**
Q. 6	**(a)**	How will you determine solubility, dissociation constant, and partition coefficient of a new drug substance?	**10**
	(b)	What are classes of residual solvents in API? Describe GC method of its determination.	**06**
Q.7	**(a)**	Discuss Purposes and methodology of peptide mapping?	**08**
	(b)	Quality control methods for medicinal plant materials as per WHO.	**08**

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