Seat No.: _____ Enrolment No. _____

GUJARAT TECHNOLOGICAL UNIVERSITY

M. PHARM SEMESTER–II EXAMINATION – SUMMER-2017

Subject Code: 2920104 **Date: 29/05/2017**
Subject Name: Modern Pharmaceutical Analysis
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)**	What are the analytical methods used for biotechnology derived products? Discuss amino acid sequencing and isoelectric focusing techniques.	**08**
	(b)	Describe role of near-infrared analysis in solid dosage form analysis	**08**
Q.2	**(a)**	Give a detailed account on Isolation and identification of impurities	**08**
	(b)	Write a note on evaluation of hair products	**08**
Q.3	**(a)**	Enlist WHO guideline for QC standards of medicinal plant materials. Describe any two	**08**
	(b)	How do impurities affect quality of drug formulation? Discuss stability study requirements for new Drug substance and Drug products as per ICH guideline.	**08**
Q.4	**(a)**	Enlist the characteristics of parenteral dosage forms. Explain the properties to be evaluated during preformulation stage	**08**
	(b)	Enlist quality control standards for radiopharmaceuticals. Compare ELISA and RIA	**08**
Q.5	**(a)**	Enlist the properties associated with the molecular level, particulate level and the bulk level as regards “Solid state analysis” of drug substances. Explain in detail the properties associated with the particulate level.	**08**
	(b)	What is Automated analysis? State its advantages and briefly explain the concept.	**08**
Q. 6	**(a)**	Describe in detail Bacterial endotoxin testing in parenteral products.	**08**
	(b)	Explain various pharmacopoeia tests for analysis of API	**08**
Q.7	**(a)**	Explain the importance of pre-formulation studies . Describe the analytical techniques for pre-formulation studies.	**08**
	(b)	Describe the US-FDA guidelines in pharmaceutical analysis	**08**

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