Seat No.: _____ Enrolment No._____

GUJARAT TECHNOLOGICAL UNIVERSITY

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

Subject Code: 2920104 Date: 24-12-2014

Subject Name: Modern Pharmaceutical Analysis

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)**	State the importance of solid-state analysis. Explain in detail about the properties associated with particulate level.	**06**
	(b)	Explain various pharmacopoeia tests for analysis of API	**05**
	(c)	Explain briefly techniques of physicochemical characterization of solid oral dosage form.	**05**
Q.2	**(a)**	Describe the US-FDA guidelines in pharmaceutical analysis.	**06**
	(b)	Which are the tests for quality control of parenteral preparation? Describe bioburden test.	**05**
	(c)	What are the concepts of solubility? Outline two methods for determination of solubility of solid in liquid.	**05**
Q.3	**(a)**	What is the effect of impurities on drug stability and its therapeutic action?	**06**
	(b)	Describe regulatory guidelines for radiopharmaceuticals.	**05**
	(c)	What is Automated analysis? State its advantages and briefly explain the concept.	**05**
Q.4	**(a)**	Enlist analytical methods for biotechnological products. Discuss isoelectric focusing.	**06**
	(b)	Elaborate upon Sterility testing of Parenteral dosage forms.	**05**
	(c)	Enlist various compendial parameters of standardization of herbal drugs and formulations and discuss any two of them in detail.	**05**
Q.5	**(a)**	Explain the importance of pre-formulation studies. Describe the analytical techniques for pre-formulation studies.	**06**
	(b)	Define the term “cosmetic”. Explain in brief various methods of analysis of cosmetic formulations.	**05**
	(c)	Enlist WHO guideline for QC standards of medicinal plant materials. Describe any two.	**05**
Q. 6	**(a)**	How do impurities affect quality of drug formulation? Discuss stability requirements for new drug substance and drug products as per ICH guideline.	**06**
	(b)	Write brief account on Ion exchange amino acid analysis.	**05**
	(c)	Quality control of radiopharmaceuticals.	**05**
Q.7	**(a)**	Give a brief account on “tryptic mapping”.	**06**
	(b)	Give a brief account on regulatory requirements of cosmetic formulations.	**05**
	(c)	Evaluation of hair products.	**05**

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