Seat No.: _____ Enrolment No._____

GUJARAT TECHNOLOGICAL UNIVERSITY

M. Pharm. – SEMESTER – II • EXAMINATION – WINTER 2013

Subject Code: 2920104 Date: 28-11-2013

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)**	Enlist analytical methods for biotechnological products. Discuss isoelectric focusing.	**06**
	(b)	Give a brief account on "tryptic mapping".	**05**
	(c)	What is Automated analysis? State its advantages and briefly explain the concept.	**05**
Q.2	**(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**
Q.3	**(a)**	State the importance of solid-state analysis. Explain in detail about the properties associated with particulate level.	**06**
	(b)	Write a note on Drug substance degradation study.	**05**
	(c)	Elaborate upon compendial testing for API and its formulated products.	**05**
Q.4	**(a)**	Describe sampling of medicinal plant materials. State the importance of macroscopic and microscopic examination.	**08**
	(b)	Explain how the following parameters would be determined in medicinal plant materials-(1) Pesticide residue (2) Bitterness value (3) Swelling index	**08**
Q.5	**(a)**	Describe methods of analysis of ANY ONE of the cosmetic formulations.	**06**
	(b)	Define the term 'Cosmetic'. Give a brief account on ingredients used in manufacturing cosmetic formulations.	**05**
	(c)	Explain the concept of automation with respect to solid dosage form analysis.	**05**
Q. 6	**(a)**	How the parenteral dosage forms are evaluated for sterility tesing?	**08**
	(b)	Describe in detail Bacterial endotoxin testing in parenteral products.	**08**
Q.7	**(a)**	What do you mean by radiopharmaceuticals? Give a brief account on QC tests for radiopharmaceuticals.	**08**
	(b)	Describe regulatory guidelines for radiopharmaceuticals.	**08**

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