Seat No.: _____ Enrolment No. _____

GUJARAT TECHNOLOGICAL UNIVERSITY

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

Subject Code: 2920104 **Date: 30/11/2016**

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)**	Write in brief the regulatory requirement of drug analysis as per ICH guidelines	**06**
	(b)	Write a short note on tryptic mapping.	**05**
	(c)	Discuss the effect of impurities on drug stability and its therapeutic action.	**05**
Q.2	**(a)**	Enlist the various analytical techniques used for preformulation analysis and discuss any one in detail.	**06**
	(b)	Define solubility and discuss any two methods for determination of solubility of solid in liquid.	**05**
	(c)	Discuss briefly sterility testing of parenteral products	**05**
Q.3	**(a)**	Write a note on compendial methods for evaluation of herbal formulations.	**06**
	(b)	Discuss the objectives and concepts behind automation in manufacturing of pharmaceuticals	**05**
	(c)	Describe role of near infrared (NIR) analysis in solid dosage form.	**05**
Q.4	**(a)**	Discuss in brief a compendial testing of active pharmaceutical ingredients.	**06**
	(b)	Explain briefly about regulatory guidelines for radiopharmaceuticals.	**05**
	(c)	How the hair care products and dental care products are evaluated?	**05**
Q.5	**(a)**	Give a brief account on isolation and identification of impurities.	**06**
	(b)	Write applications of ion exchange amino acid analysis technique for genetically engineered products.	**05**
	(c)	Write a short note on automated analysis.	**05**
Q. 6	**(a)**	Enlist various physicochemical characterization techniques for the analysis of solid oral dosage form and discuss any one in detail.	**06**
	(b)	Discuss quality control test parameters for parenteral products.	**05**
	(c)	Write a note on isoelectric focusing.	**05**
Q.7	**(a)**	Write a short note on classification and determination on residual solvents in API, in accordance to ICH guidelines.	**06**
	(b)	Discuss compendial methods for evaluation of crude drugs.	**05**
	(c)	What are radiopharmaceuticals? Briefly explain its QC tests.	**05**

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