Seat No.: _____ Enrolment No. _____

GUJARAT TECHNOLOGICAL UNIVERSITY

M.PHARM - SEMESTER–2 EXAMINATION – SUMMER-2019

Subject Code: MPA202T **Date: 29/05/2019**

Subject Name: Modern Bio-Analytical Techniques

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)**	Give an account on need for extraction of drugs and metabolites from biological matrices.	**06**
	(b)	Enlist various methods for extraction of drugs from biological samples. Explain novel sample preparation approach.	**05**
	(c)	Discuss EMEA guideline for bio-analytical method validation.	**05**
Q.2	**(a)**	Describe cytochrome P450-based drug interactions.	**06**
	(b)	Short notes: protein binding interactions and drug interactions linked to transporters.	**05**
	(c)	Discuss evaluation and importance of Toxicokinetics in preclinical studies.	**05**
Q.3	**(a)**	Discuss biopharmaceutical factors affecting drug bioavailability.	**06**
	(b)	Explain in-vitro method for testing of drug's bioavailability.	**05**
	(c)	What is biopharmaceutical classification system? Explain experimental methods for drug solubility.	**05**
Q.4	**(a)**	Write a note on bio-analytical method validation according to USFDA guideline.	**06**
	(b)	Give details of in-vitro, in-situ and in-vivo methods for drug permeability.	**05**
	(c)	Explain role of LC-MS in bioactivity screening and proteomics.	**05**
Q.5	**(a)**	Define: Bioavailability and Bioequivalence. Discuss purpose for BA-BE studies.	**06**
	(b)	Write methods for assessing bioavailability and bioequivalence studies.	**05**
	(c)	Explain clinical significance of bioequivalence studies.	**05**
Q. 6	**(a)**	Short note: principles and applications of flow cytometry.	**06**
	(b)	Discuss regulatory perspectives in microsomal approaches for metabolite identification.	**05**
	(c)	Describe in-vitro assay of drug metabolites and drug metabolizing enzymes.	**05**
Q.7	**(a)**	Give brief account on various types of cell cultures, general procedures for cell cultures and isolation of cells.	**06**
	(b)	What is cryopreservation? Explain characterization of cells and their applications.	**05**
	(c)	Discuss principles and applications of cell viability assays.	**05**

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