

Seat No.: _____

Enrolment No. _____

GUJARAT TECHNOLOGICAL UNIVERSITY
M.Ph. - SEMESTER-II • EXAMINATION – SUMMER -2018**Subject Code: MPA202T****Date: 16/05/2018****Subject Name: MODERN BIO-ANALYTICAL TECHNIQUES****Time: 10:30AM TO 01:30PM****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)	Why it is essential to extract drugs and metabolites from biological matrices?	06
	(b)	Discuss in detail about Protein precipitation method.	05
	(c)	Discuss in detail about Liquid-Liquid extraction.	05
Q.2	(a)	Discuss in detail significance and limitation of Solid phase extraction.	06
	(b)	Explain system suitability parameters in Bio-analytical method validation.	05
	(c)	Explain significantly the novel sample preparation approach in Bio-analytical method.	05
Q.3	(a)	How to validate bio- analytical methods according to USFDA guidelines.	06
	(b)	Explain LLOQ, carry-over and matrix effect in bio-analytical method validation according to EMEA guidelines.	05
	(c)	Discuss in detail about Factors affecting Drug Bioavailability.	05
Q.4	(a)	Discuss Dissolution and Drug Release Testing.	06
	(b)	Explain Alternative Methods of Dissolution Testing.	05
	(c)	Discuss in detail In-vitro, in-situ and In-vivo methods.	05
Q.5	(a)	Explain drug interaction in Pharmacokinetics and Toxicokinetics.	06
	(b)	Explain the effect of protein-binding and tissue-binding interactions.	05
	(c)	Explain Cytochrome P450-based drug interactions.	05
Q. 6	(a)	Explain Cell culture media and various types of cell culture.	06
	(b)	Discuss in detail about general procedure for cell cultures and isolation of cells.	05
	(c)	Explain Principles and applications of cell viability assays.	05
Q.7	(a)	In-vitro and in-vivo approaches for metabolite identification.	06
	(b)	Design and Evaluation of Bioequivalence Studies.	05
	(c)	Clinical Significance of Bioequivalence Studies.	05
