Seat No.: _____ Enrolment No. _____

GUJARAT TECHNOLOGICAL UNIVERSITY

M. Ph. - SEMESTER– I EXAMINATION – SUMMER 2018

Subject Code: MRA103T **Date: 07/05/2018**

Subject Name: Clinical Research Regulations

Time: 02:30PM TO 05:30PM **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)	What are IVDs? Discuss the clinical evaluation of IVDs.	06
	(b)	Define RCT. Compare RCT with non-RCT.	05
	(c)	Explain the importance of ethics in clinical research using the Talhalidomide study as an example.	05
Q.2	(a)	Enumerate the various phases of Clinical Trials. Write a note on Phase 0.	06
	(b)	Discuss phase III of clinical trials in detail.	05
	(c)	Write in brief about the following: 1. Placebo 2. PSUR	05
Q.3	(a)	Write a brief note on Pharmacovigilance.	06
	(b)	Write in brief about the EMEA guidelines for medicinal products containing GMOs.	05
	(c)	Highlight the requirements of safety reports for pharmacokinetic studies as per US FDA.	05
Q.4	(a)	Discuss the applicability of following in the healthcare industry: 1. ISO 14155:2011. 2. Eudralex Vol. 9A	06
	(b)	Discuss the policies for compensation to participants in clinical studies.	05
	(c)	Outline the process for review and approval of clinical studies by IRB?	05
Q.5	(a)	What is an Independent ethics committee? Discuss its role in the Indian context.	06
	(b)	List out the essential components of an Informed Consent Form.	05
	(c)	Discuss the purpose, scope and recordkeeping in context of CFR 21 part 54.	05
Q. 6	(a)	What is ANDA? Describe the main components of ANDA 505(j) of FD&C act?	06
	(b)	Outline the main components of an IND application.	05
	(c)	Discuss the application of ISO 14155:2011 in the healthcare industry.	05
Q.7	(a)	Give the salient features of ICH guidelines on clinical investigations in pediatric population.	06
	(b)	What is the role of a Sponsor in a Clinical Trial?	05
	(c)	Write a note on Data safety monitoring boards.	05

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