Seat No.: _____ Enrolment No._____

GUJARAT TECHNOLOGICAL UNIVERSITY

M. Pharm. – SEMESTER – II • EXAMINATION – SUMMER • 2015

Subject Code: 2920206 Date: 16-05-2015

Subject Name: Clinical Research and Regulatory Affairs

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)**	Define clinical research and discuss briefly phase I and II of clinical trials.	**06**
	(b)	Explain what is Clinical Hold? Discuss the grounds for imposition of clinical hold under Investigational New Drug (IND) by FDA.	**05**
	(c)	Write a short note on Investigator's brochure.	**05**
Q.2	**(a)**	Explain briefly the drug development process.	**06**
	(b)	Give the elements of Informed Consent Form (ICF) and explain Informed Consent process.	**05**
	(c)	Write a short note on Abbreviated New Drug Application (ANDA)	**05**
Q.3	**(a)**	Define Bioequivalance. Discuss the parallel group and cross over design used in In-vivo Bioequivalance studies.	**06**
	(b)	What is Institutional Ethics Committee (IEC)? Give its composition and responsibilities.	**05**
	(c)	Discuss methods of Randomization in clinical trials.	**05**
Q.4	**(a)**	Discuss various methods adopted for Post Marketing Surveillance.	**06**
	(b)	Define Bioavailability and explain single dose and multiple dose Bioavailability studies.	**05**
	(c)	Explain when Protocol Amendment submitted to FDA? What should be its content and format?	**05**
Q.5	**(a)**	Explain the content and format of New Drug Application (NDA).	**06**
	(b)	Define Sponsor and Investigator. Explain their roles and responsibilities as per ICH-GCP guidelines.	**05**
	(c)	Write a short note on Treatment use of IND and Charging for IND.	**05**
Q. 6	**(a)**	Discuss Schedule Y of Clinical Research.	**06**
	(b)	Discuss methods of Randomization in clinical trials.	**05**
	(c)	Describe clinical section of NDA.	**05**
Q.7	**(a)**	Describe briefly ICMR guidelines for Biomedical research on human subjects.	**06**
	(b)	Define Case record Form (CRF), explain what it should include?	**05**
	(c)	Explain Pharmacokinetic methods for studying bioavailability.	**05**

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