Seat No.: _____ *Enrolment No._____*

GUJARAT TECHNOLOGICAL UNIVERSITY

M. Pharm. Semester – IIND Examination –June/July- 2011

Subject code: 920206

Subject Name: Clinical Research and Regulatory Affairs

Date:04/07/2011 **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)**	Explain objectives of various phases of clinical trial	**06**
	(b)	Illustrate flow of discovery process with diagram	**05**
	(c)	Pre-clinical testing in drug discovery process is vital - Justify	**05**
Q.2	**(a)**	What is randomization? Enumerate different methods to achieve randomization. Explain Restricted randomization	**06**
	(b)	Write components of Clinical Trial Protocol.	**05**
	(c)	Explain Inclusion and exclusion criteria using a hypothetical case of a clinical trial.	**05**
Q.3	**(a)**	Lay out essential elements of an ideal Informed Consent Document. Explain inform consent process in brief.	**06**
	(b)	Write a note on Audits and Inspections	**05**
	(c)	Explain various essential documents after completion of clinical trial	**05**
Q.4	**(a)**	Describe Data Management in clinical Research	**06**
	(b)	Write in brief about Abbreviated New Drug Application (ANDA)	**05**
	(c)	Discuss the responsibilities of Sponsor	**05**
Q.5	**(a)**	Write basic principles of ICH-GCP	**06**
	(b)	Enumerate different codes and guidelines pertaining to ethical issues in Clinical Research. Explain fundamental ethical principles underlying the conduct of research.	**05**
	(c)	Detail the process of obtaining approval for clinical trial as per Schedule Y in India.	**05**
Q. 6	**(a)**	Discuss responsibilities of investigator with special reference to record keeping and data handling as per GCP.	**06**
	(b)	Discuss how termination of multicenter clinical study should be communicated and documented?	**05**
	(c)	Explain the responsibilities of Institutional Review Board	**05**
Q.7	**(a)**	Discuss blood Sampling in BA/BE studies	**06**
	(b)	Explain the following i) Pharmaceutical alternatives and ii) Pharmaceutical equivalents	**05**
	(c)	Explain various oral dosage forms along with regulatory requirements for their bioequivalence studies	**05**

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