Seat No.: _____ Enrolment No._____

GUJARAT TECHNOLOGICAL UNIVERSITY

M. Pharm. – SEMESTER – II • EXAMINATION – WINTER 2013

Subject Code: 2920206 Date: 30-11-2013

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. Explain the various phases of clinical trials.	**06**
	(b)	Explain format and content of IND.	**05**
	(c)	Explain regulatory requirements for BA/BE studies.	**05**
Q.2	**(a)**	Explain Inform consent form. Write about inform consent process.	**06**
	(b)	Describe contents of clinical trial report.	**05**
	(c)	Discuss chemistry section of NDA.	**05**
Q.3	**(a)**	Write a note on ICMR guidelines for Biomedical research on human subject.	**06**
	(b)	Explain the drug development process.	**05**
	(c)	Explain the following in terms of Ethical Guidelines. (a) Justice (b) Principles of accountability and transparency	**05**
Q.4	**(a)**	Explain role of quality assurance in clinical trials.	**06**
	(b)	Write a note on Abbreviated New Drug Application.	**05**
	(c)	Write a note on 'Treatment use of IND'.	**05**
Q.5	**(a)**	Explain roles and responsibilities of Investigator and Monitor as per ICH GCP guidelines.	**06**
	(b)	Explain randomization and its importance in clinical trials.	**05**
	(c)	Write about Investigator Brochure.	**05**
Q. 6	**(a)**	Discuss in detail clinical section of NDA.	**06**
	(b)	Explain various methods of Post Marketing surveillance.	**05**
	(c)	Explain Inclusion and Exclusion criteria with a hypothetical case of clinical trial.	**05**
Q.7	**(a)**	Write a note on Institutional Ethics Committee.	**06**
	(b)	Write a note on NDA summery.	**05**
	(c)	Write about import and export of drug in India.	**05**

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