Seat No.: _____ Enrolment No._____

GUJARAT TECHNOLOGICAL UNIVERSITY

M. Pharm. – SEMESTER – II • EXAMINATION – SUMMER • 2014

Subject Code: 2920206 **Date: 31-05-2014**

Subject Name: Clinical Research And Regulatory Affairs

Time: 02:30 pm - 05:30 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)**	Describe the drug discovery process with help of a diagram.	**06**
	(b)	Write a note on data management in clinical research.	**05**
	(c)	Write a note on randomization in clinical trials.	**05**
Q.2	**(a)**	Discuss the contents of Investigator's Brochure.	**06**
	(b)	Write a note on composition and responsibilities of IRB/IEC.	**05**
	(c)	Write a short note on clinical trial report.	**05**
Q.3	**(a)**	Describe how GCP guidelines historically evolved.	**06**
	(b)	Write a short note on safety monitoring in clinical trials.	**05**
	(c)	Explain the process of obtaining approval for clinical trial as per Schedule Y in India.	**05**
Q.4	**(a)**	Write a short note on ANDA.	**06**
	(b)	Describe the responsibility of auditors in a clinical trial.	**05**
	(c)	Write a short note on clinical trial protocol	**05**
Q.5	**(a)**	Briefly describe the content and format of NDA.	**06**
	(b)	Discuss the responsibilities of sponsor in a clinical trial.	**05**
	(c)	Write a short note on informed consent document.	**05**
Q. 6	**(a)**	Enlist the various essential documents required during the clinical trial and their location.	**06**
	(b)	Write a short note on phase 0 clinical trial.	**05**
	(c)	Discuss basic principles of ICH - GCP.	**05**
Q.7	**(a)**	Explain the design and conduct of BA/BE studies as per USFDA guidelines.	**06**
	(b)	Write a short note on quality assurance in clinical research.	**05**
	(c)	Write a short note on post marketing surveillance methods.	**05**

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