Seat No.: _____ Enrolment No. _____

GUJARAT TECHNOLOGICAL UNIVERSITY

M. Pharm- SEMESTER– II EXAMINATION – SUMMER 2017

Subject Code: 2920206 **Date: 31/05/2017**
Subject Name: Clinical Research and Regulatory Affairs
Time: 10:30 AM to 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)**	Discuss concept of Para I to IV in ANDA.	**06**
	(b)	Describe in brief the various principles of GCP	**05**
	(c)	Write a short note on clinical trial protocol	**05**
Q.2	**(a)**	Classify NDA. Discuss regulatory requirements for NDA.	**06**
	(b)	Discuss the responsibilities of investigator in a clinical trial.	**05**
	(c)	Write a short note on informed consent process.	**05**
Q.3	**(a)**	Discuss the contents of Investigator's Brochure.	**06**
	(b)	Write a note on composition of IRB/IEC.	**05**
	(c)	Discuss the contents of clinical trial report.	**05**
Q.4	**(a)**	Discuss various phases of clinical trials.	**06**
	(b)	Enlist the various essential documents required before the clinical trial is initiated and their location.	**05**
	(c)	Write a short note on review procedure of IEC.	**05**
Q.5	**(a)**	Discuss in brief about the drug discovery process.	**06**
	(b)	Write a note on data management in clinical research.	**05**
	(c)	Write a note on sampling in clinical trials.	**05**
Q. 6	**(a)**	Write a short note on CRF.	**06**
	(b)	Write a short note on quality assurance in clinical research.	**05**
	(c)	Explain different methods for post marketing surveillance.	**05**
Q.7	**(a)**	Discuss study conduct methodology of BE study.	**06**
	(b)	Discuss historical evolution of GCP guidelines.	**05**
	(c)	Explain the process of obtaining approval for clinical trial as per Schedule Y in India.	**05**

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