Seat No.: _____ Enrolment No. _____

GUJARAT TECHNOLOGICAL UNIVERSITY

M. PHARM- SEMESTER– II EXAMINATION – SUMMER 2016

Subject Code: 2920206 Date: 21/05/ 2016

Subject Name: Clinical Research and Regulatory Affairs

Time: 10:30 AM To 1:30 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 in brief drug discovery and development process.	**06**
	(b)	Explain the various phases of clinical trials.	**05**
	(c)	Explain roles and responsibilities of clinical trial monitor as per ICH GCP guidelines.	**05**
Q.2	**(a)**	Explain in detail clinical trial design.	**06**
	(b)	Enlist various documents in clinical study. Write a note on protocol design.	**05**
	(c)	Write a note on allocation and randomization of participants in a clinical trial.	**05**
Q.3	**(a)**	Explain Inclusion and Exclusion criteria with a hypothetical case of clinical trial.	**06**
	(b)	Describe contents of clinical trial report.	**05**
	(c)	Write a note on case record form design with a hypothetical case of clinical trial.	**05**
Q.4	**(a)**	Explain in brief the basic principles of informed consent process. Explain all the essential steps for conducting informed consent process.	**06**
	(b)	Write a short note on post marketing surveillance methods.	**05**
	(c)	Write the importance and essential content of investigator brochure.	**05**
Q.5	**(a)**	Explain the clinical data management process in brief.	**06**
	(b)	Discuss in detail clinical section of NDA.	**05**
	(c)	Explain regulatory requirements for BA/BE studies.	**05**
Q. 6	**(a)**	Write a note on ethics committee as per ICH guidelines.	**06**
	(b)	Explain role of quality assurance in clinical trials.	**05**
	(c)	Write a note on latest amendment in schedule Y.	**05**
Q.7	**(a)**	What is ICH-GCP? What are the main principles of ICH guidelines.	**06**
	(b)	Explain format and content of Investigational new drug application.	**05**
	(c)	Explain the role and responsibilities of auditors in audits and inspections in clinical trials.	**05**

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