Seat No.: _____ Enrolment No._____

GUJARAT TECHNOLOGICAL UNIVERSITY

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

Subject Code: 2920206 Date: 26-12-2014

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)	Explain the responsibilities of Principal Investigator in a clinical trial as per ICH-GCP.	**06**
	(b)	What is the significance of a Monitor in a Clinical Trial?	**05**
	(c)	Which circumstances may lead to termination of trial? What are the responsibilities of sponsor in such a case?	**05**
Q.2	(a)	Elaborate the different methods for PMS.	**06**
	(b)	Explain the different methods for allocation and randomization of participants in a clinical trial.	**05**
	(c)	Explain the following with suitable examples : 1. single, double and triple blind studies. 2. observational and interventional studies.	**05**
Q.3	(a)	Outline the components of an Informed Consent Form giving examples wherever necessary.	**06**
	(b)	Outline the composition of Human ethics committee, explaining the role of each member.	**05**
	(c)	What are the chief contents of a clinical trial report?	**05**
Q.4	(a)	What is ICH-GCP? What are the main principles of ICH guidelines?	**06**
	(b)	Explain the components of a CRF and its significance in a trial.	**05**
	(c)	Explain the role and responsibility of various clinical trial personnel with regards to IB and ICF.	**05**
Q.5	(a)	Enumerate the various phases of Clinical Trials. Explain Phase 0.	**06**
	(b)	Write in detail about phase III.	**05**
	(c)	Explain in brief significance of phase IV with suitable examples (atleast three).	**05**
Q. 6	(a)	What are BA/BE studies? Explain in brief how they are conducted.	**06**
	(b)	Explain, with significance, in the context of BA/BE: 1. fasting and fed study 2. ISV and power.	**05**
	(c)	Write a brief note on inclusion and exclusion criteria.	**05**
Q.7	(a)	What is ANDA? In what scenario is ANDA filed?	**06**
	(b)	Outline the main components of an IND.	**05**
	(c)	Explain the importance of Data management in Clinical Trials.	**05**

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