Seat No.: _____ Enrolment No._____

GUJARAT TECHNOLOGICAL UNIVERSITY

M. Pharmacy Sem-II Examination July 2010
Subject code: 920206
Subject Name: Clinical Research And Regulatory Affairs

Date: 07 /07 /2010 **Time: 11.00 am – 02.00 pm**
Instructions: **Total Marks: 80**

1. **Attempt any five questions.**
2. **Make suitable assumptions wherever necessary.**
3. **Figures to the right indicate full marks.**

Q.1	(a)	Discuss in detail the roles and responsibilities of the following clinical trial personnel as per ICH GCP guidelines- (i) Investigator (ii) Sponsor	**06**
	(b)	Explain patient inclusion and exclusion criteria in relation to clinical research protocol.	**05**
	(c)	Write a short note on- Termination of Investigational New Drug Application (IND)	**05**
Q.2	(a)	Describe design, conduct and outcome of Phase I and Phase II of clinical trials.	**06**
	(b)	Describe in brief physical and chemical characterstics of a drug substance to be included in New Drug Application (NDA).	**05**
	(c)	Write a short note on- Abbreviated New Drug Applications (ANDA).	**05**
Q.3	(a)	Explain the phases of Drug discovery and Drug development.	**06**
	(b)	Define randomization and explain different methods of randomization.	**05**
	(c)	Writa a note on following documents in a clinical study- (i) Investigator's brochure (IB) (ii) Case report form (CRF)	**05**
Q.4	(a)	Discuss principles of ICH- GCP guidelines.	**06**
	(b)	What is clinical hold? Describe grounds for imposition of clinical hold under IND.	**05**
	(c)	Write a short note on various methods of Post Marketing surveillance.	**05**
Q.5	(a)	Describe briefly the content and format of NDA.	**06**
	(b)	What in Institution Ethics Committee (IEC)? Give its composition and responsibilities.	**05**
	(c)	Write a short note on Schedule Y of clinical research.	**05**
Q. 6	(a)	Write a short note on regulatory requirements and methodology of BA/BE studies.	**06**
	(b)	Explain the following terms- (i) Waivers (ii) Orphan drugs	**05**
	(c)	Write a short note on- IND safety reports	**05**
Q.7	(a)	Discuss the principles of sampling in clinical trials.	**06**
	(b)	Give the importance of Informed Consent (IC) in clinical trials and explain the process of obtaining informed consent.	**05**
	(c)	Write a note on ICMR guidelines for Biomedical Research on human subjects.	**05**

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