Seat No.: _____ Enrolment No._____

GUJARAT TECHNOLOGICAL UNIVERSITY

M.PHARM- SEM-II–EXAMINATION – JULY 2012

Subject code: 2920206 Date: 09/07/2012

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)	Write on design protocol as per parallel versus cross over designs with suitable example.	**(6)**
	(b)	Explain data management in clinical research.	**(5)**
	(c)	Write the importance and essential content of investigator brochure.	**(5)**
Q.2	(a)	Explain basic ethical principles and ethical issues in clinical trials.	**(6)**
	(b)	What is IND? Enlist the cases in which the clinical hold can be imposed on IND prior to phase I investigation.	**(5)**
	(c)	Write a note on Abbreviated New Drug Application.	**(5)**
Q.3	(a)	Write in brief about the various stages of drug discovery to development. Write on Phase IV clinical study.	**(6)**
	(b)	Write a note on Institutional Review Board.	**(5)**
	(c)	Explain role of placebo in clinical study.	**(5)**
Q.4	(a)	Discuss clinical pharmacology section of NDA.	**(6)**
	(b)	Explain role and responsibility of sponsor as per GCP guideline.	**(5)**
	(c)	Give principle of sampling.	**(5)**
Q.5	(a)	Explain role and benefits of quality assurance in clinical research.	**(6)**
	(b)	Discuss contents of case report form.	**(5)**
	(c)	Explain process to Import Drugs-T licence.	**(5)**
Q. 6	(a)	Which data required to be submitted to import and manufacture a new drug already approved in the country as per schedule Y?	**(6)**
	(b)	Give outline of IND toxicolology study.	**(5)**
	(c)	Describe data submitted for chemistry requirements of NDA.	**(5)**
Q.7	(a)	Explain format and contents of NDA.	**(6)**
	(b)	Discuss regulatory requirements and methods of BE/BA studies.	**(5)**
	(c)	Explain essential documents in clinical trials.	**(5)**