

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 toxicology 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)