Seat No.:	Enrolment No.

GUJARAT TECHNOLOGICAL UNIVERSITY M. Pharm. – SEMESTER – II • EXAMINATION – WINTER • 2015 Subject Code: 2920206 Date: 09-12-2015 **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 **06** per ICH-GCP. (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 05 responsibilities of sponsor in such a case? Q.2 (a) Elaborate the different methods for PMS. **06** (b) Explain the different methods for allocation and randomization of 05 participants in a clinical trial. (c) Explain the following with suitable examples: 1. single, double and triple 05 blind studies. 2. Observational and interventional studies. **Q.3** (a) Outline the components of an Informed Consent Form giving examples 06 wherever necessary. (b) Outline the composition of Human ethics committee, explaining the role 05 of each member. (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 05 regards to IB and ICF. **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 05 three). **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 05

05

06

05

05

study 2. ISV and power.

(c) Write a brief note on inclusion and exclusion criteria.

(c) Explain the importance of Data management in Clinical Trials.

Q.7 (a) What is ANDA? In what scenario is ANDA filed?

(b) Outline the main components of an IND.