Seat No.:	Enrolment No.

**GUJARAT TECHNOLOGICAL UNIVERSITY** M. Pharm. - SEMESTER - III • EXAMINATION - WINTER • 2015 Subject Code: 930103 Date: 08-12-2015 **Subject Name: Clinical Research and Pharmacy Practice** 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. 0.1 Describe the process of therapeutic drug monitoring (TDM) stepwise, in detail. 06 (a) (b) Enumerate some common clinical applications of TDM with specific examples. 05 State the limitations of TDM in an Indian scenario. 05 (c) **Q.2** Elaborate various phases of clinical trials. **06** (a) Differentiate between IND and NDA and Write about investigator's brochures. (b) 05 Discuss the importance of clinical trials. (c) 05 **Q.3** Describe examples of variations in drug response due to genetic polymorphism. **06** (a) Differentiate between pharmacogenetics and pharmacogenomics. (b) 05 Enumerate clinical the applications of pharmacogenetics. (c) 05 **Q.4** Classify various adverse drug reactions (ADRs) as per their mechanisms of 06 (a) actions with respective examples. Discuss various ADR reporting methods. (b) 05 Explain the term pharmacovigilance along with its importance. 05 0.5 Discuss the types of drug interactions and classify various drug-drug 06 (a) interactions based on their mechanisms of actions with respective examples. Compare the drug treatment and prescribing practice in pediatrics vs. geriatrics. 05 (b) Write comprehensive notes on liver function tests and renal function tests. (c) 05 **O.** 6 Define volume of drug distribution and clearance, how each of these parameters 06 (a) are determined and give its clinical significance. Write a note on dose adjustment for patients with hepatic and renal failure. 05 (b) Write a brief note on critical care therapy and transplantation. 05 (c)

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State the principles of pharmacoeconomics and its importance in clinical

Explain in brief, the concept of essential and rational drug use.

Explain three important 'C's of patient counseling process.

06

05

05

**Q.7** 

(a)

(b)

pharmacy.