

**GUJARAT TECHNOLOGICAL UNIVERSITY**  
**M.Pharm – SEMESTER III –EXAMINATION – SUMMER 2017**

**Subject Code: 930103****Date: 29/04/2017****Subject Name: Clinical Research and Pharmacy Practice****Time: 02:30 PM to 05:30 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 a note on Investigator Brochure. **06**  
(b) Classify adverse drug reactions. Describe the procedure for adverse drug reaction reporting. **05**  
(c) Describe the process of Therapeutic Drug Monitoring (TDM). State the limitations of TDM in Indian scenario. **05**
- Q.2** (a) What is the role and responsibilities of principal investigator and sponsor as per ICH GCP guidelines? **06**  
(b) Describe examples of variations in CVS drugs response due to genetic polymorphism. **05**  
(c) Discuss various parameters used to establish types of anemia with clinical significance. **05**
- Q.3** (a) Define the term “pharmacoeconomics”. State its types and write any one in detail. **06**  
(b) Discuss factors affecting drug dosage adjustments in pediatric patients. **05**  
(c) Write short note on informed consent. **05**
- Q.4** (a) Explain essential drug. Describe properties and advantages of essential drugs. **06**  
(b) Explain one compartment pharmacokinetic model. **05**  
(c) Write short note on Transplantation. **05**
- Q.5** (a) What is pharmacoepidemiology? Discuss the advantages and disadvantages of randomized controlled trials. **06**  
(b) Discuss general measures for management of heavy metals and barbiturate poisoning. **05**  
(c) Explain the clinical pharmacokinetic parameters and illustrate their significance in patient care. **05**
- Q. 6** (a) Enlist the drugs frequently used in ICU. Write short note on role of pharmacists in critical care therapy. **06**  
(b) Discuss various markers for cardiac disorders with clinical interpretation. **05**  
(c) Write a note on IRB/IEC. **05**
- Q.7** (a) What precautions are required while administering drugs to pregnant and lactating woman? **06**  
(b) Write a note on pharmacodynamic drug-drug interactions with examples. **05**  
(c) Enlist the laboratory tests done for infectious diseases along with their significance. **05**