

Seat No.: \_\_\_\_\_

Enrolment No. \_\_\_\_\_

**GUJARAT TECHNOLOGICAL UNIVERSITY**  
**M.Ph Semester–III Examination Dec. - 2011**

**Subject code: 930103**

**Date: 10/12/2011**

**Subject Name: Clinical Research & 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.**

- Q.1**
- (a) Describe in detail CMC data to be submitted in IND application **06**
  - (b) Define the concept of essential and rational drug use. Explain the properties and advantages of essential drugs. **05**
  - (c) Write a note on various phases of clinical trials. **05**
- Q.2**
- (a) “The Investigator’s Brochure is important and constantly evolving document.” Justify this statement. **06**
  - (b) Describe the general measures taken in an event of clinical drug toxicity. **05**
  - (c) Classify adverse drug reaction. Describe commonly used causality assessment terms for establishing a cause effect relationship between drug and an adverse drug reaction. **05**
- Q.3**
- (a) What is TDM? Explain the situations where TDM is useful. **06**
  - (b) Write brief note on pharmacogenetics. **05**
  - (c) What is role and responsibilities of principal investigator as per ICH GCP guidelines. **05**
- Q.4**
- (a) Enlist various technical data sections of form NDA 356h and explain in brief non clinical pharmacology and toxicology section. **06**
  - (b) Write a note on Institutional Review Board. **05**
  - (c) Explain the effect of age on biotransformation of drugs in elderly patients. **05**
- Q.5**
- (a) What information to be submitted to FDA under the title of the adverse experience section of integrated summary of safety for new drug application. **06**
  - (b) Write in brief about Critical Care Therapy, and also the DNR ethical issues associated with it. **05**
  - (c) Enlist and explain all the drug interaction information resources and their limitations. **05**

- Q. 6** (a) Enlist and explain the significance of common liver and kidney function test. **06**
- (b) Write a note on IND safety reports. **05**
- (c) What are the precautions and treatment for the following conditions in pregnant women **05**
- i. Nausea and Vomiting
  - ii. Epilepsy
  - iii. Hypertension
- Q.7** (a) Classify pharmacoeconomic evaluation studies and explain any two of them with suitable examples. **06**
- (b) What is Hatch Waxman amendment with reference to ANDA submission? What are the benefits of this amendment to innovator and generic companies? **05**
- (c) Explain the pharmacokinetic and pharmacodynamic factors that are responsible for major changes in disposition of drugs in pediatric population as compared to adults. **05**

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