

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.**

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|------------|---|-----------|
| 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**
