Seat No.: _____ *Enrolment No._____*

GUJARAT TECHNOLOGICAL UNIVERSITY

M. Pharm. Sem-III - Examination –June- 2011

Subject code: 930103

Subject Name: Clinical Research and Pharmacy Practice

Date:07/06/2011 **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 flow of drug development process. Discuss phase I trial in detail.	**06**
	(b)	What are the problems in transplantation? How it is managed?	**05**
	(c)	Describe various procedures for elimination enhancement in poisoning.	**05**
Q.2	**(a)**	Write composition & responsibilities of IRB.	**06**
	(b)	Describe the procedure for adverse drug reaction reporting.	**05**
	(c)	Discuss various Hematological parameters with their clinical significance.	**05**
Q.3	**(a)**	Discuss role & responsibility of Investigator as per ICH GCP guideline.	**06**
	(b)	Outline the role of a pharmacist in rational drug use.	**05**
	(c)	Discuss fundamentals of NDA submissions.	**05**
Q.4	**(a)**	What is inform consent? Write in brief about inform consent process.	**06**
	(b)	Describe role of clinical pharmacist to minimize drug interactions.	**05**
	(c)	Enlist contraindicated drugs during pregnancy and lactation with explanation.	**05**
Q.5	**(a)**	Explain the clinical pharmacokinetic parameters and illustrate their significance in patient care.	**06**
	(b)	Compare and contrast - cost benefit analysis and cost effectiveness analysis.	**05**
	(c)	How genetic polymorphism affects response of various drugs?	**05**
Q. 6	**(a)**	Write coagulation tests and explain their role in therapeutic management.	**06**
	(b)	Explain one compartment pharmacokinetic model.	**05**
	(c)	Define therapeutic drug monitoring. When it should be performed?	**05**
Q.7	**(a)**	Describe the role of a clinical pharmacist in the management of adverse drug reactions.	**06**
	(b)	Give advantages and disadvantages of cohort and case control study.	**05**
	(c)	What care should be taken in treating geriatric patients?	**05**

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