Seat No.: _____ Enrolment No._____

GUJARAT TECHNOLOGICAL UNIVERSITY

M. Pharm. – SEMESTER – III • EXAMINATION – SUMMER • 2014

Subject Code: 930103 **Date: 06-12-2014**

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.**

Q.1	**(a)**	Explain the flow of drug development process. Discuss phase II trial in detail.	**06**
	(b)	Describe in detail CMC data to be submitted in IND application.	**05**
	(c)	Define ANDA? Explain how it is different from NDA?	**05**
Q.2	**(a)**	What is TDM? Explain the situations where TDM is useful.	**06**
	(b)	Write composition & responsibilities of IRB.	**05**
	(c)	Outline the role of a pharmacist in rational drug use.	**05**
Q.3	**(a)**	Briefly describe terms 'renal clearance' and 'plasma clearance'.	**06**
	(b)	Describe role of clinical pharmacist to minimize drug interactions.	**05**
	(c)	Write brief note on pharmacogenetics.	**05**
Q.4	**(a)**	What is role and responsibilities of principal investigator as per ICH GCP guidelines.	**06**
	(b)	State the principles of data management in context of clinical research.	**05**
	(c)	How genetic polymorphism affects response of various drugs?	**05**
Q.5	**(a)**	Describe two major pharmacoepidemilogic models used to test the relationship between drug exposure and patient outcomes.	**06**
	(b)	Write a note on sources of drug information.	**05**
	(c)	What care should be taken in treating pediatric patients?	**05**
Q. 6	**(a)**	Describe the role of a clinical pharmacist in the management of adverse drug reactions.	**06**
	(b)	Discuss the tests associated with cardiac disorders.	**05**
	(c)	Write a note on Hepatic clearance.	**05**
Q.7	**(a)**	Explain calculations of loading and maintenance doses.	**06**
	(b)	How does patient counseling improve therapeutic outcome?	**05**
	(c)	Write objectives of Phase IV clinical trials.	**05**

****