

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 pharmacoepidemiologic 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
