Seat No.:			Enrolment No	
			GUJARAT TECHNOLOGICAL UNIVERSITY	
			I. Pharm. – SEMESTER – III • EXAMINATION – WINTER 2013	
Subject Code: 930103			e: 930103 Date: 11-12-2013	
Subje	ect I	Nam	e: Clinical Research and Pharmacy Practice	
Time	: 10	.30	am - 01.30 pm Total Marks: 80	
Instru				
1. Attempt any five questions.			*	
	 Make suitable assumptions wherever necessary. Figures to the right indicate full marks. 			
	3.	rigu	res to the right indicate full marks.	
Q.1		(a)	Enlist various stages of drug development process. Discuss important aspects of Phase I clinical trial.	0
		(b)	Describe various types of data to be submitted in an IND application.	0.
		(c)	Define ANDA? Explain how it is different from NDA?	0
Q.2		(a)	Describe the role and responsibilities of a clinical trial investigator.	0
		(b)	Write a note on functions of Institutional Review Board.	0
		(c)	What is an informed consent? Describe its content.	0.
Q.3		(a)	Define the term 'Clearance'. How it is determined? Why it is clinically important?	0
		(b)	Write a note on management of poisoning.	0
		(c)	Describe the role of pharmacist in rational drug use.	0
Q.4		(a)	Describe two major pharmacoepidemilogic models used to test the relationship between drug exposure and patient outcomes.	0
		(b)	Discuss the role of pharmacist in the management of adverse drug reaction	0
		(c)	Write a short note on pharmacogenetics.	0
Q.5		(a)	Enlist various factors that may affect serum drug concentration when interpreting TDM results.	0
		(b)	Write a note on ADR detection and its reporting.	0
		(c)	Enlist and explain the limitations of drug interaction information resources.	0
Q. 6		(a)	Discuss various physiological changes that occur in geriatric patients leading to altered drug disposition of drugs.	0

Q.7 Discuss various liver function tests with their clinical significance. **06** (a) Write a note on dosage and dosage form considerations in children. 05 (b) 05 (c)

Explain in detail cost- utility analysis.

situations where TDM is performed.

(b)

(c)

Write the principles and goals of critical care therapy. ******

What do you mean by 'Therapeutic Drug Monitoring (TDM)'? Enlist major

05

05