Seat	No.: _	Enrolment No		
		GUJARAT TECHNOLOGICAL UNIVERSITY		
]	M. Pharm. – SEMESTER – III • EXAMINATION – SUMMER • 2015		
U				
•	Subject Name: Clinical Research and Pharmacy Practice			
		2:30 pm - 05:30 pm Total Marks: 80		
Instr				
	2.	Attempt any five questions. Make suitable assumptions wherever necessary. Figures to the right indicate full marks.		
Q.1	(a)	Explain drug discovery and development process. Discuss clinical phases of	06	
	(b)	drug development. Explain in brief about rationale for oral glucose tolerance test and glycated hemoglobin with clinical relevance.	05	
	(c)	Explain the concept of Essential drugs. Explain the properties and advantages of essential drugs.	05	
Q.2	(a)	Write a note on biomarkers used in clinical biochemistry. Enlist various biomarkers and Write in brief about any one biomarker for hepatic and renal dysfunction with clinical interpretation.	06	
	(b)	Write in brief about review process of NDA.	05	
	(c)	Write a note on therapeutic Drug monitoring with suitable example.	05	
Q.3	(a)	Describe the role of ICH in Pharmaceutical product quality. Mention the role and responsibilities of principal investigator and sponsor in the clinical studies.	06	
	(b)	Explain the role of cytochrome P450 superfamily enzymes in the biotransformation of various drugs.	05	
	(c)	Explain the effects of age on various pharmacokinetic parameters.	05	
Q.4	(a)	Explain various factors responsible for altered drug disposition in pediatric population.	06	
	(b)	Write a note on investigator brochure for IND.	05	
	(c)	Write a note on critical care therapy with suitable example. Prepare list of drugs to be used in critical therapy.	05	
Q.5	(a)	What is pharmacovigilance? How various phases of pharmacovigilance ensure safety throughout the lifecycle of a drug?	06	
	(b)	Write a note on periodic safety update reports (PSUR).	05	
	(c)	Describe the composition, role and responsibilities of IRB/IEC	05	
Q.6	(a)	Write a note on pharmacokinetic drug-drug interaction. Evaluate following drug-drug interactions for its type, mechanism responsible, possible clinical outcomes and suggest corrective measure.	06	

(b) Define the term "Pharmacoeconomics". Enlist different types and write a note on any one type of pharmacoeconomic evaluations.
(c) Write a note on pharmacoepidemiology with its merits/demerits over 05

Explain briefly about treatment of acute drug poisoning. Write a note on acute

Write a note on adverse drug reactions with special reference to its reporting.

ii) Rifampin + Cyclosporine

05

05

06

(c) Write a note on pharmacoepidemiology with its merits/demerits over 05 randomized controlled trials

i) Cholestyramine + Digoxin

barbiturate poisoning.

Q.7

(b) Write a note on clinical manifestations of drug induced diseases.