Seat No.: _____ Enrolment No._____

GUJARAT TECHNOLOGICAL UNIVERSITY

M. Pharm. – SEMESTER – III • EXAMINATION – SUMMER • 2015

Subject Code: 930103 Date: 13-05-2015

Subject Name: Clinical Research and Pharmacy Practice

Time: 02:30 pm - 05:30 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 drug discovery and development process. Discuss clinical phases of drug development.	**06**
	(b)	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. i) Cholestyramine + Digoxin ii) Rifampin + Cyclosporine	**06**
	(b)	Write a note on clinical manifestations of drug induced diseases.	**05**
	(c)	Write a note on adverse drug reactions with special reference to its reporting.	**05**
Q.7	(a)	Explain briefly about treatment of acute drug poisoning. Write a note on acute barbiturate poisoning.	**06**
	(b)	Define the term "Pharmacoeconomics". Enlist different types and write a note on any one type of pharmacoeconomic evaluations.	**05**
	(c)	Write a note on pharmacoepidemiology with its merits/demerits over randomized controlled trials	**05**

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