Seat No.: _____ Enrolment No._____

GUJARAT TECHNOLOGICAL UNIVERSITY

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

Subject Code: 930103 **Date: 22-05-2014**

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)**	Write a note on the general principles for management of poisoning.	**06**
	(b)	Explain the role of pharmacist in minimizing drug interaction.	**05**
	(c)	Explain the significance of Rational drug use with the help of examples.	**05**
Q.2	**(a)**	Explain primary and secondary pharmacokinetic parameters. Discuss the relevance of any one in determining dosage regimens.	**06**
	(b)	Explain in brief the stepwise management of hypertension in pregnancy.	**05**
	(c)	What are essential drugs? Enlist the drugs included in essential drug list according to different categories.	**05**
Q.3	**(a)**	Discuss the criteria for and significance of Therapeutic Drug Monitoring.	**06**
	(b)	Explain with examples drug induced diseases and role of pharmacist in preventing them.	**05**
	(c)	Enlist various markers for cardiac disease. Discuss the significance of any two.	**05**
Q.4	**(a)**	Enumerate various indicators used in Pharmacoeconomics. Explain with examples direct and indirect cost	**06**
	(b)	Discuss the use of Naranjo and WHO scales in ADR monitoring.	**05**
	(c)	What is Pharmacoepidemiology? Explain case control and cohort studies.	**05**
Q.5	**(a)**	Explain with example (atleast three) the impact of Pharmacogenetic differences on drug effects.	**06**
	(b)	Discuss the features of an Informed consent form.	**05**
	(c)	Explain the role of Monitor in a clinical trial as per ICH guidelines.	**05**
Q. 6	**(a)**	Give the salient features of different phases of clinical trials. Discuss in detail phase 0.	**06**
	(b)	When is an ANDA filed? Describe in brief the contents of ANDA.	**05**
	(c)	Explain the role of IRB regarding adverse event in a clinical trial.	**05**
Q.7	**(a)**	Explain the differential diagnosis of nutritional anemia using hematological tests.	**06**
	(b)	Explain the effect of advanced age on biotransformation of drugs.	**05**
	(c)	Write in brief about care of transplantation patients.	**05**

****