## **GUJARAT TECHNOLOGICAL UNIVERSITY** M. Pharm. – SEMESTER – III • EXAMINATION – SUMMER • 2014

Subject Code: 930103Date: 22-05-2014Subject Name: Clinical Research and Pharmacy PracticeTime: 02:30 pm - 05:30 pmInstructions:

- 1. Attempt any five questions.
- 2. Make suitable assumptions wherever necessary.
- 3. Figures to the right indicate full marks.

Q.1	(a) (b) (c)	Write a note on the general principles for management of poisoning. Explain the role of pharmacist in minimizing drug interaction. Explain the significance of Rational drug use with the help of examples.	06 05 05
Q.2	(a)	Explain primary and secondary pharmacokinetic parameters. Discuss the relevance of any one in determining dosage regimens.	06
		Explain in brief the stepwise management of hypertension in pregnancy. What are essential drugs? Enlist the drugs included in essential drug list according to different categories.	05 05
Q.3	(a) (b)	Discuss the criteria for and significance of Therapeutic Drug Monitoring. Explain with examples drug induced diseases and role of pharmacist in preventing them.	06 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) (c)	Discuss the use of Naranjo and WHO scales in ADR monitoring. What is Pharmacoepidemiology? Explain case control and cohort studies.	05 05
Q.5	<b>(a)</b>	Explain with example (atleast three) the impact of Pharmacogenetic differences on drug effects.	06
	(b) (c)	Discuss the features of an Informed consent form. Explain the role of Monitor in a clinical trial as per ICH guidelines.	05 05
Q. 6	(a) (b) (c)	Give the salient features of different phases of clinical trials. Discuss in detail phase 0. When is an ANDA filed? Describe in brief the contents of ANDA. Explain the role of IRB regarding adverse event in a clinical trial.	06 05 05
Q.7	(a) (b) (c)	Explain the differential diagnosis of nutritional anemia using hematological tests. Explain the effect of advanced age on biotransformation of drugs. Write in brief about care of transplantation patients.	06 05 05

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