Seat No.: _____ Enrolment No._____

GUJARAT TECHNOLOGICAL UNIVERSITY

M.PHARM- SEM-III–EXAMINATION – MAY 2012

Subject code: 930103 Date: 18/05/2012

Subject Name: Clinical Research and Pharmacy Practice

Time: 10:30 am – 01:30 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)**	Enlist major clinical disorders in neonates and explain any one of them detailing its pathophysiology, causes and treatment.	**06**
	(b)	Write a brief account on Audit certificate.	**05**
	(c)	Describe the interrelationship of primary pharmacokinetic parameters and their relevance in determining dosage regimens.	**05**
Q.2	**(a)**	Describe various detection methods of ADR.	**06**
	(b)	Describe the roles and responsibilities of Principle investigator and sponsorer as per ICH GCP guideline.	**05**
	(c)	Write short note on Critical Care Therapy	**05**
Q.3	**(a)**	Describe the role of various agencies in implementing the rational drug use.	**06**
	(b)	Write on informed consent and examples of IRB violations.	**05**
	(c)	Explain the pharmacokinetic and pharmacodynamic factors that are responsible for major changes in disposition of drugs in geriatric population as compared to adults.	**05**
Q.4	**(a)**	Describe the technical data section of NDA submission.	**06**
	(b)	Explain the risk factors and consequences of drug interactions and the methods to evaluate the clinical relevance of drug interactions.	**05**
	(c)	Discuss various Hematological parameters with their clinical significance.	**05**
Q.5	**(a)**	Describe the algorithm for assessment and treatment of a poison exposure. Also give suitable examples of two toxidromes.	**06**
	(b)	Enlist contraindicated drugs during pregnancy and lactation with explanation.	**05**
	(c)	Write short note on Investigator Brochure.	**05**
Q.6	**(a)**	Describe the Types of cost and outcomes used in Pharmacoeconomic evaluation; also explain cost benefit analysis, giving suitable example.	**06**
	(b)	Which type of information can be submitted under section 312.30in protocol amendments with suitable examples?	**05**
	(c)	Describe the factors affecting drug response in different racial, ethnic and sex groups.	**05**
Q.7	**(a)**	Describe various stages of TDM and the situations where TDM is useful.	**06**
	(b)	Describe various phases of clinical trials.	**05**
	(c)	Describe the properties of essential drugs and the general rules of updating and reviewing the essential drug list.	**05**

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