Seat No.: _____ Enrolment No. _____

GUJARAT TECHNOLOGICAL UNIVERSITY

M.Pharm. – SEMESTER III– • EXAMINATION – WINTER-2016

Subject Code: 930103 **Date: 23/11/2016**

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)**	What is the role and responsibilities of principal investigator as per ICH GCP guideline?	**06**
	(b)	What is TDM? Explain the situations where TDM is useful.	**05**
	(c)	Describe the role of clinical pharmacist in the management of adverse drug reaction.	**05**
Q.2	**(a)**	Write short note on critical care therapy.	**06**
	(b)	Discuss the contra-indicated drugs during pregnancy and lactation with explanation.	**05**
	(c)	Define Pharmacoepidemiology. Explain case control and cohort studies.	**05**
Q.3	**(a)**	Write a note on adverse drug reaction detection and its reporting.	**06**
	(b)	Compare and contrast: cost benefit analysis and cost effectiveness analysis.	**05**
	(c)	Outline the role of pharmacist in rational drug use.	**05**
Q.4	**(a)**	Discuss various hematological parameters with their clinical significance.	**06**
	(b)	Enlist and explain the limitations of drug interaction information resources.	**05**
	(c)	What are the problems and key consideration in the drug therapy for elderly patients?	**05**
Q.5	**(a)**	Explain the flow of drug development process. Discuss Phase-I clinical trials in details.	**06**
	(b)	What are the problems in transplantation? How it is managed?	**05**
	(c)	Discuss the features of informed consent form	**05**
Q. 6	**(a)**	Explain primary and secondary pharmacokinetic parameters. Discuss the relevance of any one in determining dosage regimens.	**06**
	(b)	Write brief note on Pharmacogenetics.	**05**
	(c)	What is ANDA? Write in detail about Investigator Brochure	**05**
Q.7	**(a)**	Write a note on the general principles for management of poisoning.	**06**
	(b)	Describe in detail CMC data to be submitted in IND application.	**05**
	(c)	Write a short note on Pharmacovigilance.	**05**

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