Seat No.: _____ Enrolment No. _____

GUJARAT TECHNOLOGICAL UNIVERSITY
M. Pharm. - SEMESTER– III. EXAMINATION – SUMMER 2013

Subject Code: 930103 **Date: 27/05/2016**
Subject Name: Clinical Research and Pharmacy Practice
Time: 2:30 PM to 5:30 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 the importance and procedure of Phase IV clinical trial in brief.	**6**
	(b)	Write general principles of Clinical Pharmacokinetics.	**5**
	(c)	Write in brief about biochemical markers of Diabetes mellitus	**5**
Q.2	**(a)**	What precautions are required while administering drugs to children?	**6**
	(b)	Explain in brief Therapeutic Drugs Monitoring.	**5**
	(c)	Write in brief about pharmacokinetic drug-drug interactions.	**5**
Q.3	**(a)**	Write a note on Adverse Drug Events monitoring.	**6**
	(b)	Briefly explain iatrogenic disorders.	**5**
	(c)	Write about general principles of clinical toxicology.	**5**
Q.4	**(a)**	Explain the dose adjustment of drugs in renal disorder.	**6**
	(b)	Write a note on ethical guidelines in clinical research.	**5**
	(c)	Write briefly on components of Informed Consent Form.	**5**
Q.5	**(a)**	What is impact of drug therapy in hepatic disorders?	**6**
	(b)	Write important components of IND application.	**5**
	(c)	Write in brief about pharmacoepidemiology.	**5**
Q.6	**(a)**	Write about biochemical markers of renal damage.	**6**
	(b)	Write in brief on pharmacoeconomics.	**5**
	(c)	Briefly dwell upon Phase III clinical trials.	**5**
Q.7	**(a)**	Write about constitution and duties of Independent Ethics Committee.	**6**
	(b)	Explain precautions to be taken in drug therapy during pregnancy and lactation.	**5**
	(c)	Write a note on Investigation Brochure.	**5**

****

Q. 1	(a) Explain the importance and procedure of Phase IV clinical trial in brief.	(6)
	(b) Write general principles of Clinical Pharmacokinetics.	(5)
	(c) Write in brief about biochemical markers of Diabetes mellitus.	(5)
Q. 2	(a) What precautions are required while administering drugs to children?	(6)
	(b) Explain in brief Therapeutic Drugs Monitoring.	(5)
	(c) Write in brief about pharmacokinetic drug-drug interactions.	(5)
Q. 3	(a) Write a note on Adverse Drug Events monitoring.	(6)
	(b) Briefly explain iatrogenic disorders.	(5)
	(c) Write about general principles of clinical toxicology.	(5)
Q. 4	(a) Explain the dose adjustment of drugs in renal disorder.	(6)
	(b) Write a note on ethical guidelines in clinical research.	(5)
	(c) Write briefly on components of Informed Consent Form.	(5)
Q. 5	(a) What is impact of drug therapy in hepatic disorders?	(6)
	(b) Write important components of IND application.	(5)
	(c) Write in brief about pharmacoepidemiology.	(5)
Q. 6	(a) Write about biochemical markers of renal damage.	(6)
	(b) Write in brief on pharmacoeconomics.	(5)
	(c) Briefly dwell upon Phase III clinical trials.	(5)

Q. 7. (a) Write about constitution and duties of Independent Ethics Committee. (6)

(b) Explain precautions to be taken in drug therapy during pregnancy and lactation. (5)

(c) Write a note on Investigation Brochure. (5)