Seat No.: _____ Enrolment No. _____

GUJARAT TECHNOLOGICAL UNIVERSITY

M. PHARMACY – SEMESTER – II • EXAMINATION – SUMMER - 2018

Subject Code: MCP203T **Date:18/05/2018**

Subject Name: Clinical Research and Drug Development

Time: 10:30 AM TO 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)	Explain the Phase 0 and Phase 5 of clinical trial.	06
	(b)	Explain NDA Vs ANDA review process.	05
	(c)	Write a short note on termination of clinical trial.	05
Q.2	(a)	Enlist ANDA certification clauses. Explain Para IV in brief.	06
	(b)	Explain the importance of "inform consent" form in clinical trial	05
	(c)	Explain the rights of subject in clinical trial.	05
Q.3	(a)	Explain the purpose of bioequivalence study.	06
	(b)	Write a note on drug safety reporting in clinical study.	05
	(c)	Explain IND filing process.	05
Q.4	(a)	Explain the IND process and interaction with FDA.	06
	(b)	Explain the role of principle investigator in clinical trial.	05
	(c)	Explain the importance of randomization techniques in clinical trial.	05
Q.5	(a)	Explain the inclusion and exclusion criteria of subject in clinical trial.	06
	(b)	When is a study exempt from an IND?	05
	(c)	Explain the compositions of IEC Explain their responsibilities.	05
Q. 6	(a)	Explain the role of drug safety monitoring board.	06
	(b)	Explain guideline for fixed dose combination (FDCs).	05
	(c)	Explain abbreviated new drug application filing review process.	05
Q.7	(a)	Enlist the clinical study design. Explain observational study.	06
	(b)	What is the role and rresponsibilities of stakeholders in audit process.	05
	(c)	Discuss ethical issues in biomedical research.	05

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