Seat No.: _____ Enrolment No. _____

GUJARAT TECHNOLOGICAL UNIVERSITY

M.PHARM - SEMESTER–2 EXAMINATION – SUMMER-2019

Subject Code: MCP203T **Date: 31/05/2019**

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)**	Describe constitution and responsibilities of Independent Ethics Committee.	**06**
	(b)	Explain the role and responsibilities of principal investigator of a clinical trial.	**05**
	(c)	Discuss salient features of a clinical trial protocol.	**05**
Q.2	**(a)**	Explain IND process and discuss regulatory issues associated with it.	**06**
	(b)	Explain in brief various randomization techniques.	**05**
	(c)	Discuss NDA Vs ANDA review process.	**05**
Q.3	**(a)**	Describe the importance and salient features of "Informed Consent Form".	**06**
	(b)	Why is it important to have inclusion and exclusion criteria in clinical trials?	**05**
	(c)	Explain the responsibilities of stakeholders in audit process in clinical trials.	**05**
Q.4	**(a)**	Describe regulatory requirements to be met for approval of BA/ BE centres.	**06**
	(b)	Discuss various reasons for termination of a clinical trial.	**05**
	(c)	What are various ethical issues involved in clinical research?	**05**
Q.5	**(a)**	Enlist ANDA certification clauses. Explain Para IV in brief.	**06**
	(b)	Explain the role of drug safety monitoring board.	**05**
	(c)	Write a note on Helsinki Declaration and its importance.	**05**
Q. 6	**(a)**	Describe various sampling methods in clinical research.	**06**
	(b)	Describe various types of audits in clinical trials.	**05**
	(c)	Describe role and responsibilities of Sponsor in clinical trials.	**05**
Q.7	**(a)**	Enlist various clinical study design methods. Explain observational study design.	**06**
	(b)	What are different phases of clinical trials?	**05**
	(c)	What do you mean by "Case Report Form"? What is its importance?	**05**

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