Seat No.: _____ Enrolment No. _____

GUJARAT TECHNOLOGICAL UNIVERSITY

PHARM.D YEAR-5/PHARM.D(PB) YEAR-2 EXAMINATION – SUMMER-2023

Subject Code: 858801/828901 Date: 23\06\2023

Subject Name: Clinical Research

Time:10:30 AM TO 01:30 PM Total Marks: 70

Instructions:

1. **Attempt any five questions.**
2. **Make suitable assumptions wherever necessary.**
3. **Figures to the right indicate full marks.**

Q.1	**(a)**	Discuss the role of pharmacological studies in drug development process.	**06**
	(b)	Compare and contrast of Phase-1 & Phase-2 clinical trials.	**04**
	(c)	Explain the role and responsibilities of clinical research associates in clinical trial studies.	**04**
Q.2	**(a)**	Discuss in detail about CDSCO guidelines.	**06**
	(b)	What is drug discovery? What are the steps involved in the process?	**04**
	(c)	Enlist various methods of PMS study. Discuss the any two methods of PMS study.	**04**
Q.3	**(a)**	Explain the role and responsibilities of investigator in clinical trial studies.	**06**
	(b)	Explain investigator brochure.	**04**
	(c)	Write in detail various components of protocol in clinical trial. Describe the protocol amendments.	**04**
Q.4	**(a)**	Write a note on ANDA requirements.	**06**
	(b)	Write a note on micro dosing clinical trial study.	**04**
	(c)	Explain Data Safety Monitoring Board.	**04**
Q.5	**(a)**	Explain composition and role and responsibilities of IRB/IEC.	**06**
	(b)	Describe the procedure of communicating ADR reports & Periodic Safety Update Reports (PSUR).	**04**
	(c)	Discuss the role of dosage form studies in drug development process.	**04**
Q. 6	**(a)**	Discuss the purpose of IND, NDA and ANDA.	**06**
	(b)	Write a note on Informed Consent Process.	**04**
	(c)	Give an overview of regulatory environment in USA.	**04**
Q.7	**(a)**	Write in detail about Data storage and security in CDM.	**06**
	(b)	Write a note on compensation for clinical trial subjects as per ethical guideline.	**04**
	(c)	Describe the essential criteria of ICH-GCP guideline for conducting clinical trials.	**04**

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