Seat No.: _____ Enrolment No. _____

GUJARAT TECHNOLOGICAL UNIVERSITY

Pharm. D – 5th Year/Pharm.D(PB) - 2nd Year • EXAMINATION – WINTER - 2023

Subject Code: 858801/828901 **Date: 25/01/2024**

Subject Name: Clinical Research

Time: 10:30 AM to 1:30 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 roles & responsibilities of Investigator & Clinical research associate as per ICH – GCP	**06**
	(b)	Write a note on various phases of Clinical trials	**04**
	(c)	What is significance of Post marketing surveillance? Explain	**04**
Q.2	**(a)**	Discuss ICH – GCP guidelines of clinical trials	**06**
	(b)	Write a note on ADME profiling	**04**
	(c)	Explain the process of designing study protocol in clinical trial	**04**
Q.3	**(a)**	Explain the roles of DSMB	**06**
	(b)	Discuss various drug characterization techniques in Drug development process	**04**
	(c)	What is ANDA? Explain review process of ANDA	**04**
Q.4	**(a)**	Describe pharmaceutical regulations with regard to clinical trials in European union	**06**
	(b)	Explain double blind & randomization method	**04**
	(c)	Discuss composition and responsibilities of IEC	**04**
Q.5	**(a)**	Write a note on CDSCO guidelines for clinical research	**06**
	(b)	Define Ethics. Discuss ethical issues of clinical research involving children.	**04**
	(c)	Explain Informed Consent Process	**04**
Q. 6	**(a)**	Explain designing of CRF with suitable example	**06**
	(b)	Discuss the challenges in the implementation of guidelines	**04**
	(c)	Give an overview of regulatory environment in USA	**04**
Q.7	**(a)**	Describe the procedure of communicating ADR reports & Periodic Safety Update Reports (PSUR).	**06**
	(b)	Write a note on roles & responsibilities of sponsor in clinical trial	**04**
	(c)	What is Informed Consent Form? Which information must be given to each potential research subject before enrolling in clinical trial?	**04**

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