Seat No.: _____ Enrolment No. _____

GUJARAT TECHNOLOGICAL UNIVERSITY

Pharm. D. – 5th Year/ Pharm . D. (PB) - 2nd Year • EXAMINATION – SUMMER - 2022

Subject Code: 858801/828901 Date: 31/05/2022

Subject Name: Clinical Research

Time: 02:30pm to 05:30pm 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)**	Write a note on Various phases of clinical trial.	**06**
	(b)	Give a brief note on investigator's brochure.	**04**
	(c)	What is Data Safety Monitoring Board (DSMB)?	**04**
Q.2	**(a)**	Write in detail about Data storage and security in CDM.	**06**
	(b)	Explain the regulatory environment for conduct of clinical trials in USA.	**04**
	(c)	Write a note on ICH guidelines in clinical trials.	**04**
Q.3	**(a)**	Discuss in detail about CDSCO guidelines.	**06**
	(b)	What is the role of ICMR in regulation of clinical trials?	**04**
	(c)	Write a note on Informed consent process.	**04**
Q.4	**(a)**	What is NDA? Mention the data which is submitted with the application and its review process.	**06**
	(b)	Write Significance of post marketing surveillance.	**04**
	(c)	Write Roles and responsibilities of Investigations.	**04**
Q.5	**(a)**	What is regulatory authority? Write the general roles and responsibilities of regulatory authority.	**06**
	(b)	Describe the procedure of communicating ADR reports & Periodic Safety Update Reports (PSUR).	**04**
	(c)	What is drug discovery? What are the steps involved in the process?	**04**
Q. 6	**(a)**	Write in detail various components of clinical trial "protocol". Add notes on protocol amendments.	**06**
	(b)	Discuss various animal pharmacology testing required for discovery of new drugs.	**04**
	(c)	Elaborate the role and responsibilities of sponsor in clinical trials as per ICH GCP.	**04**
Q.7	**(a)**	Explain the IEC review procedure of a research proposal and the methods of review process adopted by IEC.	**06**
	(b)	Give an overview of regulatory environment in Europe.	**04**
	(c)	Explain the importance of dosage form design in pre-clinical and clinical stages.	**04**

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