Seat No.: _____ Enrolment No. _____

GUJARAT TECHNOLOGICAL UNIVERSITY

Pharm D – 5th Year • EXAMINATION – WINTER - 2022

Subject Code: 858801 **Date: 24/01/2023**

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)**	Draw the flow chart of drug development process. Discuss the advantages and limitations of micro-dosing clinical trial.	**06**
	(b)	Discuss the roles and responsibilities of sponsors in clinical research.	**04**
	(c)	Define IND application and write contents of IND application.	**04**
Q.2	**(a)**	Define Bias. Discuss in detail about various sources of bias and methods to avoid Bias.	**06**
	(b)	What is Randomization? Brief about static and adaptive designs.	**04**
	(c)	Give an account on Abbreviated New drug Application.	**04**
Q.3	**(a)**	Discuss various methods of post marketing surveillance study.	**06**
	(b)	Describe the various pharmacological approaches to drug discovery.	**04**
	(c)	Compare and contrast of Phase-I and Phase-II clinical trial.	**04**
Q.4	**(a)**	Give a note on constitution and responsibilities of institutional review board.	**06**
	(b)	Write a short note on regulatory setup in Europe.	**04**
	(c)	Discuss the challenges in implementation of guidelines in clinical trials.	**04**
Q.5	**(a)**	Explain the components of clinical research protocol and the process of protocol preparation.	**06**
	(b)	Write the safety issues on the investigational new drugs.	**04**
	(c)	Discuss in detail about the role and responsibilities of clinical research associate in clinical research.	**04**
Q. 6	**(a)**	Describe the clinical trial data management process and its benefits.	**06**
	(b)	Briefly write about study site audits and its significance.	**04**
	(c)	Write a brief note on case record form.	**04**
Q.7	**(a)**	Describe in detail about regulatory setup that governs the clinical research process in India.	**06**
	(b)	Write a short note on informed consent process.	**04**
	(c)	Discuss Good Clinical Practice and its principles.	**04**

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