

Seat No.: _____

Enrolment No. _____

GUJARAT TECHNOLOGICAL UNIVERSITY
PHARM.D YEAR-5 / PHARM.D (PB) YEAR-2 EXAMINATION – WINTER - 2024

Subject Code: 858801/828901

Date: 02-12-2024

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.

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|------------|---|-----------|
| Q.1 | (a) Discuss pre-clinical drug discovery process | 06 |
| | (b) Briefly describe the various phases of clinical trials | 04 |
| | (c) Describe responsibilities of data and safety monitoring board | 04 |
| Q.2 | (a) Write roles and responsibilities of study investigator in clinical study team | 06 |
| | (b) Which type of preclinical information should be included in a IND application. | 04 |
| | (c) Write a brief note on Investigator's brochure. | 04 |
| Q.3 | (a) Write the safety issues on the investigational new drugs | 06 |
| | (b) Write important aspects of clinical study protocol preparation | 04 |
| | (c) Write a short note on clinical trial protocol | 04 |
| Q.4 | (a) What do you mean by NDA? Discuss its review process | 06 |
| | (b) Which events should be promptly informed by investigator to the ethics committee during clinical study. | 04 |
| | (c) Write a short note on regulatory setup in Europe | 04 |
| Q.5 | (a) Explain the importance of dosage form design in pre-clinical and clinical stages. | 06 |
| | (b) Describe essential elements of Informed Consent Form (ICF) | 04 |
| | (c) Explain the IEC review process of a clinical research proposal | 04 |
| Q.6 | (a) Classify randomization process and explain in detail any two methods with advantages and disadvantages. | 06 |
| | (b) Write differences between ICH-GCP and ICMR guidelines for conducting clinical research | 04 |
| | (c) Differentiate between Cohort study and case control sampling methods | 04 |
| Q.7 | (a) Describe procedure of communicating ADR reports & periodic safety update reports (PSUR) | 06 |
| | (b) Write significance of marketing surveillance | 04 |
| | (c) Discuss various methods of post marketing surveillance study. | 04 |
