

GUJARAT TECHNOLOGICAL UNIVERSITY
M.PHARM – SEMESTER -1 - EXAMINATION –WINTER - 2018

Subject Code: MRA103T**Date: 05/01/2019****Subject Name: Clinical Research Regulations****Time :10:30 AM TO 01:30 PM****Total Marks: 80****Instructions:**

- 1. Attempt all questions.**
- 2. Make Suitable assumptions wherever necessary.**
- 3. Figures to the right indicate full marks.**

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| Q.1 | (a) | Write short note on Phase IV studies. | 06 |
| | (b) | Write the guidelines for clinical investigation and evaluation of medical devices. | 05 |
| | (c) | Discuss historical perspectives of Clinical research. | 05 |
| Q.2 | (a) | Discuss the key points of Schedule Y. | 06 |
| | (b) | Write the composition, roles and responsibilities of Ethics Committee. | 05 |
| | (c) | Discuss the ethical considerations involved in collecting patients consent. | 05 |
| Q.3 | (a) | Write a note on CRO and its management. | 06 |
| | (b) | Justify the use of placebos in clinical trials. | 05 |
| | (c) | Describe briefly biostatistics applied in clinical research. | 05 |
| Q.4 | (a) | Write a note on ANDA 505(j) application. | 06 |
| | (b) | Discuss the contents of Patient information sheet. | 05 |
| | (c) | Discuss vulnerable population in a clinical trial. | 05 |
| Q.5 | (a) | Compare and contrast Indian GCP and ICH GCP guidelines. | 06 |
| | (b) | Write a note on E7 guidelines. | 05 |
| | (c) | Describe various study designs adopted in clinical trials. | 05 |
| Q. 6 | (a) | Write a note on Good Pharmacovigilance practices. | 06 |
| | (b) | Provide the details about ISO 14155. | 05 |
| | (c) | What information is provided in EU Annual Safety Report? | 05 |
| Q.7 | (a) | Discuss Bioavailability and Bioequivalence requirements according to CFR 21Part 320. | 06 |
| | (b) | What are the responsibilities of sponsor and investigator in ethical conduct of clinical research? | 05 |
| | (c) | What are the regulatory requirements to market a pharmaceutical product in European countries? | 05 |
