

GUJARAT TECHNOLOGICAL UNIVERSITY
M.PHARM - SEMESTER-2 EXAMINATION – SUMMER-2019

Subject Code: MPL204T**Date: 03/06/2019****Subject Name: Clinical Research and Pharmacovigilance****Time: 10:30 AM TO 01:30 PM****Total Marks: 80****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) | Write principles of ICH guidelines. | 06 |
| | (b) | Write the role and responsibilities of Institutional review board. | 05 |
| | (c) | Write the ethical aspects of informed consent process. | 05 |
| Q.2 | (a) | Enlist different types and design of experimental study. Write the advantages of RCT over Non-RCT. | 06 |
| | (b) | Explain in brief: Case control and Cross sectional study. | 05 |
| | (c) | Write the role and responsibilities of Sponsor. | 05 |
| Q.3 | (a) | Write a note on prospective and retrospective cohort study with giving suitable examples. | 06 |
| | (b) | Comment: Contract Research organization is demand of the current era. | 05 |
| | (c) | Enlist the protocol component. Write the importance of investigator brochure. | 05 |
| Q.4 | (a) | Define Adverse drug reactions. Write mechanism and different types of ADRs. | 06 |
| | (b) | Write the role of Pharmacist in management of Adverse drug reactions. | 05 |
| | (c) | Explain the following terms:
1. Pharmacovigilance 2. Adverse Event 3. Adverse Drug reaction
4. Dechallenge 5. Rechallenge | 05 |
| Q.5 | (a) | Explain the term: Causality and Causality assessment. Write in detail about WHO causality assessment criteria. | 06 |
| | (b) | What are the minimum criteria for a valid ADR report? | 05 |
| | (c) | Write the strategies to improve ADR reporting in India. | 05 |
| Q.6 | (a) | Write role of Pharmacist in Pharmacovigilance. | 06 |
| | (b) | Explain in brief about need of vaccine safety surveillance. | 05 |
| | (c) | Write a note on Spontaneous reporting system in India and Global level. | 05 |
| Q.7 | (a) | Define Pharmacoepidemiology. Enlist various methods of epidemiology studies. Write observational method in detail. | 06 |
| | (b) | Define Pharmacoeconomic. Write a note on cost effective analysis. | 05 |
| | (c) | Write basic principles of safety pharmacology. | 05 |
