

Seat No.: _____

Enrolment No. _____

GUJARAT TECHNOLOGICAL UNIVERSITY

M. Pharm. – SEMESTER – III • EXAMINATION – WINTER 2013

Subject Code: 930103

Date: 11-12-2013

Subject Name: Clinical Research and Pharmacy Practice

Time: 10.30 am - 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) | Enlist various stages of drug development process. Discuss important aspects of Phase I clinical trial. | 06 |
| | (b) | Describe various types of data to be submitted in an IND application. | 05 |
| | (c) | Define ANDA? Explain how it is different from NDA? | 05 |
| Q.2 | (a) | Describe the role and responsibilities of a clinical trial investigator. | 06 |
| | (b) | Write a note on functions of Institutional Review Board. | 05 |
| | (c) | What is an informed consent? Describe its content. | 05 |
| Q.3 | (a) | Define the term 'Clearance'. How it is determined? Why it is clinically important? | 06 |
| | (b) | Write a note on management of poisoning. | 05 |
| | (c) | Describe the role of pharmacist in rational drug use. | 05 |
| Q.4 | (a) | Describe two major pharmacoepidemiologic models used to test the relationship between drug exposure and patient outcomes. | 06 |
| | (b) | Discuss the role of pharmacist in the management of adverse drug reaction | 05 |
| | (c) | Write a short note on pharmacogenetics. | 05 |
| Q.5 | (a) | Enlist various factors that may affect serum drug concentration when interpreting TDM results. | 06 |
| | (b) | Write a note on ADR detection and its reporting. | 05 |
| | (c) | Enlist and explain the limitations of drug interaction information resources. | 05 |
| Q. 6 | (a) | Discuss various physiological changes that occur in geriatric patients leading to altered drug disposition of drugs. | 06 |
| | (b) | Explain in detail cost- utility analysis. | 05 |
| | (c) | What do you mean by 'Therapeutic Drug Monitoring (TDM)'? Enlist major situations where TDM is performed. | 05 |
| Q.7 | (a) | Discuss various liver function tests with their clinical significance. | 06 |
| | (b) | Write a note on dosage and dosage form considerations in children. | 05 |
| | (c) | Write the principles and goals of critical care therapy. | 05 |
