

GUJARAT TECHNOLOGICAL UNIVERSITY**M. Pharmacy Sem-III Regular Examination January 2011****Subject code: 930103****Subject Name: Clinical Research and Pharmacy Practice****Date: 06 /01 /2011****Time: 10.30 am – 01.30 pm****Instructions:****Total Marks: 80**

- 1. Attempt any five questions.**
- 2. Make suitable assumptions wherever necessary.**
- 3. Figures to the right indicate full marks.**

- | | | | |
|-------------|-----|--|-----------|
| Q.1 | (a) | Explain rational drug therapy. Describe the role of pharmacist in overcoming irrational prescribing of drugs | 06 |
| | (b) | Define pharmacogenetics. Discuss its applications | 05 |
| | (c) | Write on clinical applications of therapeutic drug monitoring | 05 |
| Q.2 | (a) | Explain comparative bioavailability for different routes of drug administration. Describe factors affecting bioavailability in brief | 06 |
| | (b) | Define ANDA. Discuss AND Application for generic drugs | 05 |
| | (c) | What is the scope of pharmacoepidemiology? Justify its need. | 05 |
| Q.3 | (a) | What is pharmacovigilance? Discuss its status in India. How it can be improved? | 06 |
| | (b) | What is Clinical hold? Describe grounds for imposition of clinical hold under an IND | 05 |
| | (c) | Write on Haematological markers of infectious diseases | 05 |
| Q.4 | (a) | Justify clinical investigation of a new drug. Describe phase-I study of clinical trials | 06 |
| | (b) | What is the significance of enzymes in Body tissues as an important diagnostic tool in some diseases? Describe. | 05 |
| | (c) | How major organ failure is managed in an ICU? | 05 |
| Q.5 | (a) | Write about dose adjustment in renal failure. Give measures to enhance clearance | 06 |
| | (b) | Discuss in brief important aspects of NDA regulations | 05 |
| | (c) | Discuss pharmacokinetic factors for therapy in paediatrics | 05 |
| Q. 6 | (a) | Write general principles for management of poisoning | 06 |
| | (b) | Write principles and goals of critical care therapy | 05 |
| | (c) | Write on informed consent | 05 |
| Q.7 | (a) | Describe principles and goals of geriatric therapy | 06 |
| | (b) | How diabetes mellitus and AIDS can be treated when they are associated with pregnancy? | 05 |
| | (c) | Write on food-drug interactions with some appropriate examples | 05 |
