# Gujarat Technological University

## M. Pharm.

Semester – III

**Paper code -930103**

# Clinical Research and Pharmacy Practice

## Subject of Specialization Paper- V (Pharmacology)

## Theory

**(Four hours per week, 7 credits)**

1. **Clinical development of drug**

   Introduction to clinical trials, various phases of clinical trials,
   IND applications, ANDA, NDA, Investigator Brochure
   Ethical guidelines in clinical research, Inform consent process,
   Composition, responsibility, procedures of IRB/IEC
   Role and responsibility of clinical trials personals as per ICH GCP guidelines.

2. **Clinical Pharmacy Practice**

   Concept of essential and Rational Drug use.
   General principles of clinical pharmacokinetics
   General principle of clinical toxicology
   Drug induced diseases, adverse drug reaction; their monitoring and reporting (Pharmacovigilance)
   Drug interaction- Prescription monitoring, documentation and other methods for minimizing clinically relevant drug interaction.
   Therapeutic drug monitoring and dosage adjustment in renal and hepatic disorders
   Drug treatment for special category of patients: pediatric and Geriatric consideration for drug treatment, drug treatment for pregnancy and lactation.
   Racial, ethnic and gender differences in response to drug (Pharmacogenetics)
   Principles of Pharmacoepidemilogy, and Pharmacoeconomics
   Interpretation of clinical laboratory test: Hematological, pathological and Biochemical investigations as markers of Disease/organ damage and their impact on drug therapy decision.
   Critical care: Critical care therapy and Transplantation

# Clinical Research and Pharmacy Practice

## Subject of Specialization Paper- V (Pharmacology)

## Practicals

### (Six hours per week, 8 credits)

Practical scenario on essentiality concept and skill for clinical pharmacy practice (2 cases each)
Rational drug use and essential drug concept
Medication adherence
Interpreting laboratory data –biochemistry and hematology
Interpreting laboratory data –infectious disease
Patient Counseling
Ward round participation
Therapeutic drug monitoring
Drug therapy review
Drug Interaction
Adverse drug reaction
Geriatric pharmacy practice
Pediatric pharmacy practice
Pharmacy practice for pregnant women

Evaluation of drug formulation (based on essentiality and rationality-50 formulations):
Illustrated Examples
Rational drug therapy for nutritional anemia
Rational drug therapy for Cough
Rational drug therapy for diarrhea
Prescription audit (10 )
Protocol preparation for submission to IRB

**Reference Books:**


1. Central Drugs Standard Control Organization. Good Clinical Practices-Guidelines for Clinical Trials on Pharmaceutical Products in India. New Delhi: Ministry of Health; 2001.
2. International Conference on Harmonization of Technical requirements for registration of Pharmaceuticals for human use. ICH Harmonized Tripartite Guideline. Guideline for Good Clinical Practice.E6; May 1996.
3. Ethical Guidelines for Biomedical Research on Human Subjects 2000. Indian Council of Medical Research, New Delhi.
4. Textbook of Clinical Trials edited by David Machin, Simon Day and Sylvan Green, March 2005, John Wiley and Sons.
5. Principles of Clinical Research edited by Giovanna di Ignazio, Di Giovanna and Haynes.
6. Clinical Pharmacy and Therapeutics Roger walker and Clive Edwards,Churchill Livingstone Edinburgh
7. Davidson's Principle and Practice of Medicine, EDs Christopher, Haslett, Edwin R.Chilvers.
8. Harrison's Principles of Internal medicine- Vol 1 and 2 Braunwald, Eugene & Others.
9. Textbook of Therapeutics Drug Disease Management- Eric T.Herfindal and Dick R.Gourley.
10. Comprehensive Pharmacy Review- Shargel Leon
11. Melmon and Morrells Clinical Pharmacology 4th Edition – S George Carrythers
12. A textbook of Clinical pharmacy practice- Parthasarthi G.