

# Gujarat Technological University

## M. Pharm. Semester – II

Structure for Second Semester of Master of Pharmacy Course

Sr. No.	Subject	Teaching scheme		
		Theory	Practical	Credits
1	Research Methodology	6	--	06
2	Subject of Specialisation Paper – III	6	6	12
3	Subject of Specialisation Paper – IV	6	--	6
	<b>Total</b>	<b>18</b>	<b>6</b>	<b>24</b>

# Gujarat Technological University

## Master of Pharmacy

### Semester – II

## Research Methodology

(Common to all discipline)

### Theory

(Four hours per week, 6 credits)

- 1 Research-Meaning, purpose, Types, (Educational, Clinical, Experimental, historical descriptive, Basic applied and Patent oriented Research) objective of research
- 2 Literature survey-Use of Library, books and journals-Medlines-Internet, Patent Search, and reprints of articles as a source for Literature survey.
- 3 Selecting a problem and preparing Research proposals
- 4 Methods and tools use in research –
  - A. Qualities studies, quantitative studies
  - B. Simple data organization descriptive data analysis,
  - C. Limitation & sources of Error
  - D. Inquiries in form of Questionnaire, etc.
- 5 Documentation-
  - “How” of documentation
  - Techniques of documentation
  - Importance of documentation
  - Use of computer packages in documentation.
- 6 The Research Report Paper writing/ thesis writing
  - Different parts of the Research paper
    1. Title –Title of project with authors name
    2. Abstract- Statement of the problem, Background list in brief and purpose and scope.
    3. Key Words.
    4. Methodology-subject, apparatus, instrumentation & procedure.
    5. Results- tables, graphs, figures & statistical presentation
    6. Discussion support or non support of hypothesis, practical & theoretical Implications
    7. Conclusion
    8. Acknowledgements.
    9. References
    10. Errata
    11. Importance of Spell check for entire project
    12. Uses of footnotes
- 7 **Presentation** (especially for oral presentation)
  - Importance, types different skills, contained, format of model, introduction, Poster, Gestures, eye contact, facial, expressions, stage, fright, volume- pitch, speed, pause & language, Visual aids & seating, Questionnaire
- 8 Cost analysis of the project – cost incurred on raw materials- Procedure, instrumentations and clinical trials.

- 9 Sources for procurement research grants – international agencies, Government and private bodies.
- 10 Industrial-institution interaction- Industrial projects, their, feasibility reports. Interaction with industries .

**References Books:**

1. Research In Education- John V. Best, John V. Kahn 7<sup>th</sup> edition
2. Presentation skills - Michael Hallon- Indian Society for Institute education
2. Practical Introduction o copyright.- Gavin Mcfarlane
3. Thesis projects in Science & Engineering – Richard M. Davis.
4. Scientist in legal Systems- Ann labor science
5. Thesis & Assignment – Jonathan Anderson
6. Writing a technical paper- Donald Menzel
7. Effective Business Report Writing –Leland Brown
8. Protection of industrial Property rights- P. Das & Gokul Das
9. Spelling for the millions- Edna Furness
10. Preparation for publication – King Edward Hospital Fund for London
11. Information Technology – The Hindu speaks
12. Documentation – Genesis & Development 3792.
13. Manual for evaluation of industrial projects-United Nations
14. Manual for the preparation of industrial feasibility studies

# Gujarat Technological University

## Master of Pharmacy

### Semester – II

#### Specialization paper - III

#### Novel Drug Delivery System Part-I

#### Theory

(Four hours per week, 6 credits)

1. Recent Innovations in Conventional Dosage Forms – including *site specific* and *time release modulation*.

e.g. : Tablets : Osmotic, Colon target, Gastro-retentive, Buccal, Sublingual.

Capsules : Modified release,

Semi-solids :

Parenterals :

Powders : Particle coating, Taste-masking,

Liquids :

2. Packaging components and its evaluation: factors affecting selection, Types and classification, Primary and secondary and regulatory aspects. Contribution in stability of the dosage forms.

#### Subject of Specialization paper - III

#### Novel Drug Delivery System Part-I

#### Practical

(Four hours per week, 6 credits)

Laboratory examination including oral and practical examination in general course illustrative of theory section in the syllabus.

#### References Books:

1. **Remingtons** “Pharmaceutical Sciences” 19<sup>th</sup> edition.
2. **Lachman** “The theory and Practice of Industrial Pharmacy” 3<sup>rd</sup> edition.
3. **Pharmaceutics** “The Science of Dosage form design” by **Aulton**
4. **Pharmaceutical dispensing** by **Husa**.
5. **Modern pharmaceutics** by **G. S. Banker**.
6. **Encyclopedia of pharmaceutical technology** Volumes: 1 to 19.
7. **Pharmaceutical dissolution testing** by **Banaker**.
8. **United States Pharmacopeia**.
9. **Drug stability (Principles and Practices)** by **Jens. T. Carstensen**.

# **Gujarat Technological University**

## **Master of Pharmacy**

### **Semester – II**

#### **Specialization paper - IV**

### **Global Regulatory Requirements**

#### **Theory**

**(Four hours per week, 6 credits)**

1. Validation of Pharmaceutical Processes, equipments/apparatus, basic concept in analytical method development for dosage forms., Computer System validation, ERP and SAP systems.
2. Basics in Drug approval process with reference to: Orange book, Freedom of information, IIG, DMF, Historical aspects with Various phases of drug development and approval.
3. IND, NDA, ANDA , Concept of para I to IV, exclusivity: Content, format and Application.
4. Brief and comparative introduction to various regulatory agencies: USFDA, MCA, TGA, MHRA, ANVISA, CTD, WHO, ICH, SUPAC etc.

#### **References Books:**

**The guidance documents shall be procured from the website of the respective Government.**

**Gujarat Technological University**  
**Master of Pharmacy**  
**Semester – II**  
**Specialization paper - III**  
**Pharmacometrics and Methods of biological evaluation of drugs**

**Theory**  
**(Four hours per week, 6 credits)**

1. Biological standardization, general principles, Scope and limitation of bio-assay, bioassay of some official drugs.
2. Preclinical drug evaluation of its biological activity, potency and toxicity-Toxicity test in animals including acute, sub-acute and chronic toxicity, ED50 and LD50 determination, special toxicity test like teratogenicity and mutagenicity. Various guidelines for toxicity studies. Animal experiments assessing safety of packaging materials.
3. Pyrogens: Sources, Chemistry and properties of bacterial pyrogens and endotoxins, Official pyrogen tests
4. Microbiological assay of antibiotics and vitamins.
5. Biological evaluation of drugs--Screening and evaluation ( including principles of screening , development of models for diseases : In vivo models / In vitro models / cell line study ) techniques of the following:
6. Parasympathomimetics, Parasympathetic blocking agents, Sympathomimetics, Sympathetic blocking agents, Ganglion stimulants and blockers, Neuromuscular stimulants and blockers.
7. General and local Anesthetics, Sedatives and Hypnotics, Antiepileptics, Psychopharmacological agents, Analgesics, Anti-inflammatory agents, Anti-Parkinson's drugs, CNS Stimulants.
8. Cardiotonics, Anti-hypertensive drugs, Anti-arrhythmic drugs, Drugs used in Ischemic Heart Diseases, Drugs used in Atherosclerosis.
9. Drugs used in Peptic Ulcer, Respiratory disorders, Hormone and Endocrine disorders. Anti fertility agents and diuretics.
10. Various models for Cataract, glaucoma, inflammatory bowel disease

**Specialization paper - III**  
**Pharmacometrics and Methods of biological evaluation of drugs**  
**Practical**  
**(Four hours per week, 6 credits)**

- 1. Bioassays of drugs:** Bioassay of agonists (Graphical, Matching, 3 Point, 4 point method) and Bioassay of antagonists using various isolated preparations.
- 2. Toxicity studies**
- 3. Evaluation of drugs based on theory syllabus.**

**Illustrative examples**

Evaluation of the antiepileptic activity of drug using maximum electro convulsive shock seizures (M. E. S.) and chemical induced convulsions methods.

1. Determination of the time required for induction and recovery from anesthesia for various volatile general anesthetics.
2. Evaluation of the effect of pentobarbitone sodium and diazepam in mice.
3. Evaluation of the effect of various tranquilizers and sedatives on motor co-ordination by rota rod test in mice.
4. Evaluation of the effects of drugs on spontaneous motor activity and to evaluate their nature as CNS stimulants or depressants.
5. Evaluation of the antiparkinsonian activity of drugs by pheno-thiazine induced catatonia.
6. Evaluation of the effect of psychotropic drugs on condition avoidance response.
7. Evaluation of the compulsive behavior (stereotypy) induced by apomorphine and its modification by chlorpromazine in mice.
8. Evaluation of anxiolytic (antianxiety) effect of diazepam in mice using elevated plus-maze apparatus.
9. Study the effect of caffeine in human volunteers.
10. Evaluation of the effect of cimetidine in drug induced gastric (peptic) and duodenal ulcers and hyper secretion of gastric acid in rats.
11. Evaluation of the antisecretory and ulcer protective effect of cimetidine in pylorus-ligated rats.
12. Evaluation of the analgesic potency of drug by thermal method.
13. Evaluation of analgesic effect of morphine in mice using hot plate method.
14. Evaluation of the analgesic effect of drugs by acetic acid induced writhing method in mice.
15. Evaluation of the anti-inflammatory property of indomethacin against carrageenan-induced acute paw oedema in rats.
16. Evaluation of the effects of various drugs (diuretics) on the output of the urine in rats.

**References Books: (Latest Edition):**

1. Screening methods in pharmacology (vol I & II)–R.A. Turner
2. Drug Discovery and Evaluation in Pharmacology assay: Vogel
3. Design and analysis of animal studies in pharmaceutical development, Chow, Shein, Ching.
4. Evaluation of Drug Activity: Pharmacometrics D.R. Laurence
5. Animal and Clinical pharmacologic Techniques in Drug Evaluation-Nodine and Siegler
6. Pharmacology and Toxicology- Kale S.R.
7. Fundamentals of experimental Pharmacology- Ghosh M.N.
8. Handbook of Experimental Pharmacology- Goyal R.K.
9. Handbook of Experimental Pharmacology- Kulkarni S.K.

**Gujarat Technological University**  
**Master of Pharmacy**  
**Semester – II**  
**Specialization paper - IV**  
**Pharmacotherapeutics**

**Theory**  
**(Four hours per week, 6 credits)**

Important disorders/conditions (etiology, pathophysiology, complications, diagnosis, Prognosis), their control and management with special emphasis on pharmacology of drugs (mechanism of action, ADME, therapeutics use, and adverse effects, toxicities and possible drug interaction) of the following:

1. Central Nervous system: Neurodegenerative Disorders (Parkinson's disease, Alzheimer's disease, Huntington's chorea, Spasticity), behavioral disorder- (Anxiety, Insomnia, Depression and Mania), Psychoses, Epilepsy, Migraine
2. Cardiovascular and hemopoietic system ; Hypertension, Acute Coronary Syndrome, Angina Pectoris, Atherosclerosis, Congestive Heart Failure, Arrhythmias, Thromboembolic disorder, Anaemia
3. Endocrine system : Disorders of thyroid gland and Parathyroid gland, Diabetes, Adrenocortical dysfunction
4. Gastro-intestinal System :Peptic Ulcer, Inflammatory Bowel Disease, Vomiting, Achlorhydria, Constipation, Diarrhea, Liver diseases
5. Respiratory system: Bronchial Asthma, Chronic Obstructive Pulmonary Disease (COPD), Allergic Rhinitis, Common cold & Cough, Cystic fibrosis
6. Urogenital system: Renal Failure, Infertility, Benign Prostatic Hypertrophy, dysmenorrhea, Menopause
7. Disorders of eye: Glaucoma

**References Books: (Latest Edition):**

1. Principles of Pharmacology –The Pathophysiologic Basic –Golan David E.
2. Pharmacological Basis of Therapeutics-Goodman and Gilman
3. Pharmacology-Rang and Dale
4. Essentials of Pharmacotherapeutics-F.S. Barar
5. Principles of Pharmacology – Paul L. Munson
6. Pharmacology and Pharmacotherapeutics-R.S.Satoskar
7. Pharmacotherapy- A Pathophysiological Approach-Joseph T. Dipiro.
8. Lewis's Pharmacology – James Crossland – Churchil Livingston
9. Modern Pharmacology with Clinical Applications- Craig, Charles R.
10. Principles of Pharmacology--H. L. Sharma

# Gujarat Technological University

## Master of Pharmacy

### Semester – II

### Paper code No. 20303

### Specialization paper - III

## Advanced Organic Chemistry - II

### Theory

(Four hours per week, 6 credits)

1. Detailed study of individual reactions - allylic rearrangement, Aldol condensation, Aldol condensation-Bayer-Villiger rearrangement, benzilic acid rearrangement – Curtius rearrangement- Dimorth rearrangement, Heck reaction, Lossen – Schmidt rearrangement, Pinner reaction, Reformatsky reaction, Sharpless oxidation, Suzuki reaction, Sonogashira reaction, Swern oxidation, Vilsmeier-Haack reaction.
2. Stereochemistry and Chiral Techniques.
  - a. Principles of stereochemistry including geometric isomerism, optical isomerism and conformational isomerism.
  - b. Stereochemistry of compounds with asymmetric plane.
  - c. Concept of chiral drugs, resolution of racemic mixtures, racemic switches, asymmetric synthesis of following drugs: Vit.C, Nifedipine, Atenolol, Ethambutol, Omeprazole, Ampicillin and Thalidomide.
  - d. Role of stereochemistry in pharmacokinetics and pharmacodynamics
3. Synthon Approach:  
Definition, terms and abbreviation, rules and guidelines used in synthesis of following drugs.  
Primethamine, Ibuprofen, Diclofenac, Rosiglitazone, Cetirizine, Ciprofloxacin, Captopril, and Losartan
4. Green Chemistry:: Solvent free reaction, water as a solvent, ionic liquids, supercritical liquids, supported reagents and catalyst.
5. Introduction to microwave reactions, ultrasound reactions, nanochemistry

**Specialization paper - III**  
**Advanced Organic Chemistry - II**  
**Practical**  
**(Four hours per week, 6 credits)**

Laboratory examination including oral and practical examination in general course illustrative of theory section in the syllabus.

**References Books:**

1. March Jerry– Advance Organic Chemistry - Reaction Mechanism and Structure, McGraw-Hill International Book Company
2. F. A. Carey and R. J. Sundberg – Advance Organic Chemistry Part – A & B, Plenum Press.
3. Clayden Greeves and others – Organic Chemistry, Oxford University Press.
4. Jie Jack Li - Name Reactions, Springer
5. Eliel – Stereochemistry of Carbon Compounds
6. S. Warren - Designing Organic Synthesis, Wiley India Ltd.
7. P. T. Anastas and J. C. Warner – Green Chemistry theory and Practice, Oxford University Press.
8. C. Oliver Kappe and others – Practical Microwave Synthesis for Organic Chemist, Willey Interscience.
9. G. B. Sergeev – Nanochemistry, Elsevier publication\

# Gujarat Technological University

## Master of Pharmacy

### Semester – II

#### Specialization paper - IV

### Drug Design and Discovery

#### Theory

(Four hours per week, 6 credits)

1. General Introduction to drug discovery concept/process and importance of drug design approaches in drug discovery.
2. Various targets for drug action and theory of drug action –agonist, antagonism/ blockers and enzyme inhibition (IC<sub>50</sub>, EC<sub>50</sub> concept)- an overview
3. A general study of stereochemistry and physicochemical properties of the drug/drug-like molecules and their importance in drug action. Correlation between physicochemical properties and drug action, establishing structure activity relationship (SAR) and its analysis. Isosterism and bio-isosterism as guides to structural variations and Prodrug design its application in lead optimization.
4. Various approaches to drug discovery
5. Quantitative Structure Activity Relationship QSAR- brief introduction to various methods of QSAR – Physicochemical parameters – lipophilic, electronic and steric. Detail study on Hansch LFER model, Free Wilson analysis and mixed approach. Various basic statistical methods useful in QSAR development.  
3D QSAR – importance and various models (COMFA, MSA, HASL, Apex 3D, DISCO, GFA) used for it.
6. Computer Aided Drug Design (CADD) – Molecular modeling  
Basic concepts of computational chemistry like Quantum Mechanics, Molecular Mechanics, Force Field, Energy minimization, Conformational generation and analysis, geometry optimization, Molecular Dynamics  
Ligand based drug design, Analogue approach, Pharmacophore Mapping, importance of ligand shape and Excluded volume techniques, Artificial intelligence methods.  
Structure based drug design, requirement of SBDD, utilization of target structure derived from NMR and X-ray Crystallography techniques, understanding of drug–receptor/enzyme/target interactions, preparation of protein/target along with active site analysis, docking process, various docking methods. De-novo drug design.  
Drug design based on antagonism and enzyme inhibition. Various software used in CADD.
7. Virtual screening of huge compound databases by using Pharmacophore mapping as well as docking methods
8. Pharmacokinetics (Absorption, Distribution, Metabolism Elimination i.e. ADME) in drug discovery.

## References Books:

1. Ariens – Drug Design, vol. VII, Academic Press.
2. H Smith & H J William – Introduction to the Principal of Drug Design, John Wright & Sons Ltd.
3. Burgers Medicinal Chemistry – The Basis of Medicinal Chemistry by Manfred S. Wolff, Part – I, John Wiley & Sons
4. Copmuter assisted Drug Design by Edward C. Olson (America Chemical Society, ACD symposium series 112).
5. W. O. Foye - Principles of Medicinal Chemistry, Lipincott Williams and Wilkins.
6. C. Hansch and Leo - Comprehensive Medicinal Chemistry Vol. 4, Pergamon Press.
7. Molecular Modeling in Drug Design by Cohen N. C.
8. C. G. Wermuth - The Practice of Medicinal Chemistry, Elsevier publication.
9. E. H. Kerns and L. Di - Drug like properties, concepts, structure design and methods, Academic Press.

# **Gujarat Technological University**

## **Master of Pharmacy**

### **Semester – II**

#### **Specialization paper - III**

### **Modern Pharmaceutical Analysis**

#### **Theory**

**(Four hours per week, 6 credits)**

1. Application of analytical methods to product obtained through genetic engineering , Amino acid sequence analysis, Tryptic mapping, ion exchange amino acid analysis, isoelectric focusing etc.
2. Regulatory requirement in pharmaceutical analysis – US-FDA, ICH
3. Solid state analysis of drug substance including related substances, and impurities present in drugs and their effect on drug stability and therapeutic action.
4. Applications of various analytical techniques in preformulation analysis and its importance.
5. Analysis of solid oral dosage form
6. Analysis of injectable dosage form
7. Compendial testing
8. Automated analysis
9. Compendial methods for evaluation of crude drug and herbal formulation
10. Quality control of radio pharmaceuticals and radio chemical method in analysis.
11. Analysis of cosmetics

**Specialization paper - III**  
**Modern Pharmaceutical Analysis**  
**Practical**  
**(Four hours per week, 6 credits)**

1. Assay of Ibuprofen Tablet I.P., Tolbutamide Tablet I.P., Calcium Lactate and Ferrous Fumerate I.P.
2. Determination of Water in Sorbitol, Sodium Citrate & Ampicillin.
3. Determination of Total Chloride in Thiamine Chloride Hydrochloride.
4. Quality control Tests for Tablets, Capsules, Injections, Ointments and Suppositories.
5. Detection and Determination of Preservatives, Antioxidants and Colouring materials in Pharmaceuticals.
6. Determination of related substances in Albendazole, Amiloride, Metronidazole,
7. Betamethazone, Carbamazepine, Diclofenac, Ephedrine, Ibuprofen, Paracetamol, Eucalyptus oil, Phenylbarbitone and Sulphafurazone, Rifampicin as per I.P. Determination of active constituents in crude drugs. E.G. Caffeine from tea powder, curcumin from curcuma longa, quinine from cinchona bark etc.
8. Quality Control tests for some herbal formulations.
9. Quality Control tests for some cosmetics.

**References Books:**

1. Harry G Brittain, Spectroscopy of Pharmaceutical Solids, Drugs and Pharm Sci. Series, Vol. 160, Taylor and Francis, 2006 N.Y.
2. S. Ahuja, Modern Pharmaceutical Analysis
3. Lena Ohannesian and Anthony J. Streeter, Hand Book of Pharmaceutical Analysis, Pharm Sci. series, Vol. 117, Maarcel Dekker Inc., N.Y
4. Peptide and Protein Drug Analysis, by Reid,(Marcel Dekker).
5. Classification of cosmetics raw materials and adjuncts IS 3958 of Indian Standards Institution (BIS).
6. Cosmetic and toilet goods – methods of sampling IS 3958 of Indian Standards Institution (BIS).
7. Methods of sampling and test for various cosmetics as laid down by Indian Standard Institution (BIS).
8. Indian Pharmacopoeia, Vol. I and Vol. II - 1996. The Controller of Publications; New Delhi, Govt. of India,
9. The International Pharmacopoeia Vol 1,2,3,4, 3rd Edition General methods of analysis and quality specifications for pharmaceutical substances, excipients, dosage forms.
10. Quality Assurance of Pharmaceuticals – A compendium of guidelines and related materials Vol.1 and Vol.2, WHO, (1999)
11. Basic tests for pharmaceutical substances – WHO (1988)
12. Basic tests for pharmaceutical dosage forms – WHO (1991)
13. Phytochemical Methods by J.B.Harborne
14. Pharmacopoeal standards for Ayurvedic Formulation (Council of Research in Indian Medicine & Homeopathy)

**Gujarat Technological University**  
**Master of Pharmacy**  
**Semester – II**  
**Specialization paper - IV**  
**Regulatory Affairs and New Drug Application**

**Theory**  
**(Four hours per week, 6 credits)**

**a. REGULATORY AFFAIRS**

- 1 Legislation to regulate the profession of pharmacy – The Pharmacy Act 1948.
- 2 Legislation to regulate, import, manufacture distribution and sales of drugs, cosmetics- The Drugs & Cosmetic Act 1940 & rules 1945 with amendments.
- 3 Regulatory aspects of pharmaceutical and bulk drug manufacture and biotechnology derived product.
- 4 Quality safety and legislation for cosmetic and herbal products.
- 5 Aims, objects and salient features of following legislations governing Pharmaceutical Industry-  
Pollution Control Act  
Prevention of Food Adulteration Act 1954  
Industrial Development & Regulation Act 1951  
Consumer Protection Act
- 6 Standard institutes & certification agencies like ISI, BSS, ASTM, SO, WHO, US-FDA, UK-MCA, TGA
- 7 Drug Master File (Case Study-3 examples)
- 8 Material Safety Data Sheet (MSDS) preparation
- 9 Industrial Safety & Health
- 10 Guide lines for filing in countries like US & EU
- 11 Drug Regulatory Agencies-Historical perspectives, organization structure activities & responsibilities: India, US, EU, Japan, ICH
- 12 Study of compendia – Evolution, Study of parts of compendia like: Policies, General notices, Monographs, Comparative picture of IP, USP, BP, EP&GP

**b. Approval of New drugs:**

Investigational New Drug (IND) submission, format & content of IND, content of Investigator Brochure, general consideration of New Drug Approval (NDA), specific requirements, content & format of NDA, manufacturing control requirement of NDA.

## References Books:

1. Drugs and Cosmetics Laws by Krishnan Arora, Professional Book Publishers, New Delhi
2. Mittal B.M., A Textbook of Forensic Pharmacy, 9th Ed., Vallabh Prakashan
3. Deshpande S.W., Drugs and Cosmetic Act.1940.
4. Gnarino Richard A, New Drug Approval Process, 3rd Ed., Marcel Dekker Inc.
5. P. Warayan, Intellectual Property Laws, Eastern Law House.
- 6 Drug and Cosmetic Act 1940, Eastern Book company by Vijay Malic, 11th Ed. Patents for Medicine, by N. B. Zareri, Indian Drug Manufacturers Association (IDMA)
7. Ira R. Bery, "Introduction to the Pharmaceutical Regulatory Process", Drugs and Pharm Sci. Series, Vol. 144, Marcel Dekker Inc., N.Y.
8. The Drugs and Cosmetic Act 1940 – Vijay Malik
9. Indian Pharmacopoeia, Vol. 1-3, 2007.The Indian Pharmacopoeia commission, Gahaziabad, Govt. of India.
- 10.The International Pharmacopoeia Vol 1,2,3,4,5 3rd Edition
11. Pollution Control Act,1974
12. Prevention of Food Adulteration Act 1954
13. Industrial Development & Regulation Act 1951
14. Consumer Protection Act 1986
- 15."WHO Expert Committee on specification on Pharmaceutical Preparation"34th report, Geneva, World Health Organisation, 1996 (WHO Technical Report Series, No. 863
16. Quality Assurance of Pharmaceuticals – A compendium of guidelines and related materials Vol.1 and Vol.2, WHO, (1999)
17. A.C. Cartwright and Brian Mathews,"International Pharmaceutical Registration" Taylor and Francis Ltd. UK, 2002
18. United State Pharmacopoeia (USP) 32,NF27, 2009
19. Industrial Health and Safety, Dr. A.M. Sarma, Himalaya Publication.

**Gujarat Technological University**  
**Master of Pharmacy**  
**Semester – II**  
**Specialization paper - III**  
**Advanced Analytical Pharmacognosy**

**Theory**

**(Four hours per week, 6 credits)**

1. Standardization of herbal medicines, traditional and folklore remedies, preparation and their quality, safety and efficacy assessment and intended use for acceptance by FDA.
2. Stability testing of natural products, procedures, predictable chemical and galenic changes, technical limitation, testing methods and combination products.
3. Marine Pharmacognosy
4. Principles of Ayurveda and standardization of formulation of Ayurvedic dosage form as per Ayurvedic and Herbal Pharmacopoeia.
5. Regulatory and safety measures with herbal, Ayurvedic and other drugs of traditional origin.

**Specialization paper - III**  
**Advanced Analytical Pharmacognosy**  
**Practicals**  
**(Four hours per week, 6 credits)**

Practical exercises based on the relevant topics mentioned in theory syllabus.

**References Books:**

1. Evans W. C – Trease and Evans pharmacognosy (15<sup>th</sup> ed)
2. Wallis T.E, Practical Pharmacognosy, J & A Churchill Ltd.
3. Wagner H., Blatt S. and Zgainski, Plant Drug Analysis Springer, Verlag, New York.
4. Peach K. and Tracey M.V., Modern Methods of Plant Analysis, 1-4, Narosa Publisher House, N.D.
5. Kalia A. N – Textbook of Industrial Pharmacognosy.
6. Handa S.S & Kaul K.L., Supplement to cultivation and utilization of medicinal plants, 1996.
7. R.D. Chaudhary, Herbal Drugs Industry, Eastern Publishers, New Delhi.

8. Clark, E.C.G., Isolation and Identification of Drugs, The Pharmaceutics Press, London.
9. Brain K.R., and Turner R.D., The Practical Evaluation of Phytopharmaceutics, Wriyth-Sciencetechnics Bristol.
10. WHO Publication.
11. The Ayurvedic Pharmacopoeia of India, Part I, (Vol. I–V) , part II (I & II) Govt. of India, Ministry of Health and Family Welfare, Dept. of Indian Systems of Medicine and Homeopathy, New Delhi 2008.
12. Indian Herbal Pharmacopoeia, revised new edition 2002, Published by RRL, Jammu and IDMA, Mumbai – 2002
13. British Herbal Pharmacopoeia, Published by British Herbal Medicines Association 1996.
14. Ayurvedic Formulary of India, Vol. I and II, Ministry of Health, New Delhi.
15. Stahl E, Thin Layer Chromatography – A Laboratory Hand Book, Springer – Verlag Berlin.
16. Steimser Richard – Folk Medicines
17. Rao Ramchandra – Encyclopedia of Indian Medicine Vol. I

**Gujarat Technological University**  
**Master of Pharmacy**  
**Semester – II**  
**Specialization paper - IV**  
**Advances in Pharmaceutical Science**  
**Theory**  
**(Four hours per week, 6 credits)**

1. Nutraceuticals from herbal sources
2. Insecticides and pesticides from natural sources
3. Phytochemical screening technique
4. Advances drug from natural sources of following categories:
  - i. Antidiabetic
  - ii. Cardiotonic
  - iii. Immunomodulators
  - iv. Anti-inflammatory
  - v. Anti-ulcer
  - vi. Anti-malarial
  - vii. Diuretics
  - viii. Anti-oxidant
  - ix. Urolithiatics
  - x. Anti-lipidemic
  - xi. Brain tonic
  - xii. Hepatoprotective
  - xiii. Anti-cancer
  - xiv. Anti-AIDS

**References Books:**

1. Chatterjee T. K – Herbal options
2. Journals-
  - a. Indian Drugs
  - b. Indian Journal of pharmaceutical Education
  - c. Planta Medica
3. Evans W. C – Trease and Evans pharmacognosy (15<sup>th</sup> ed)
4. Kalia A. N – Textbook of Industrial Pharmacognosy.
5. Handa S.S & Kaul K.L. – Supplement to cultivation and utilization of medicinal plants, 1996.
6. Govil J. N, Singh V.K, Siddiqui N. T– Recent Progress in Medicinal plants, Vol., 1-25, , Studim Press , LLC USA.

7. Brunreton J– Pharmacognosy and Phytochemistry of medicinal Plants, (2<sup>nd</sup> ed.), Intercept limited, Newyork, 1999.
8. Robbers J. E, Speedie M. K, Tyler V. E– Pharmacognosy and Pharmacobiotechnology, William and wikins, USA, 2005.
9. Bhat S. V, Nagasampagi B. A, Meenakshi S– Chemistry of Natural Products, Narosa Publishing House.
10. Robbers J. E, Tyler V. E– Herbs of Choice, Haworth Press In. USA-2002.
11. Reinhold L– Progress in Phytochemistry.
12. Wealth of India,Raw Material.

# **Gujarat Technological University**

## **Master of Pharmacy**

### **Semester – II**

#### **Specialization paper - III**

#### **Applied Pharmacotherapeutics - I**

##### **Theory**

**(Four hours per week, 6 credits)**

**Pathophysiology, Diagnosis & Pharmacotherapeutic management of following acute and chronic diseases and disorders**

#### **1. Basic Concepts of Pathophysiology and Pharmacotherapeutics**

#### **2 Cardiovascular**

Hypertension, angina pectoris, congestive heart failure, myocardial infarction, cardiac arrhythmias.

#### **3 Gastrointestinal**

Peptic ulcer disease, Inflammatory Bowel diseases, hepatitis, cirrhosis, nausea and vomiting, constipation and diarrhea.

#### **4 Respiratory**

Chronic obstructive pulmonary disease, bronchial asthma, cystic fibrosis.

#### **5 CNS**

Epilepsy, Parkinsonism, schizophrenia, migraine, Alzheimer disease, Huntington's chorea, Spasticity), behavioral disorder-(Anxiety, Insomnia, Depression and Mania).

#### **6 Endocrine**

Endocrinal disorders including Diabetes mellitus, thyroid (hyperthyroidism and hypothyroidism), parathyroid diseases, hyperlipidemia and Adrenocortical dysfunction.

**Specialization paper - III**  
**Applied Pharmacotherapeutics - I**  
**Practical**  
**(Four hours per week, 6 credits)**

- Each student has to undergo compulsory Hospital postings for understanding and gaining knowledge of Pathophysiology, Diagnosis & Pharmacotherapeutic management of various diseases and disorders.
- It is mandatory that each student has to maintain a record of at least 15 case studies based on the theory topics

**ASSIGNMENTS**

The students are required to submit a minimum of two written assignments selected from the topics given to them.

**References Books:**

- 1 Clinical Pharmacy and Therapeutics. Roger Walker and Clive Edwards, Churchill Livingstone publication
- 2 Text Book of Therapeutics: Drug and Disease Management. 7th Edition. Editors: Eric T. Herfindal and Dick R. Gourley, Williams and Wilkins
- 3 Pathology & Therapeutics for Pharmacists. Russel. J. Greene and Normal F. Harris. Chapman & Hall, London/ Glasgow/ Madras.
- 4 Robbins Pathologic Basis of Disease. Cartran, Kumar, Collins, W.B.Saunders. Latest edition.
- 5 Applied Therapeutics: The Clinical Use of Drugs Eds. Brian S.Katcher, Lloyd Yee Young, Marry Anne Koda-Kimble, Applied Therapeutics Inc. Spokane. Latest Edition.
- 6 Pharmacotherapy: A Pathophysiologic approach – Joseph T. Dipiro et al. Appleton & Lange
- 7 Harrisons Principles of Internal Medicine. Medical Toxicology (Ellen Horns)
- 8 Davidson's Principle and Practice of Medicine, Eds. Christopher R. W., Edwards & Ian A.D. Boucher ELBS with Churchill Living stone. Edinburgh. Latest Edition.
- 9 Avery's Drug Treatment, 4<sup>th</sup> End, 1997 Adis International Limited
- 10 Relevant review articles from recent medical and pharmaceutical literature.

# **Gujarat Technological University**

## **Master of Pharmacy**

### **Semester – II**

#### **Specialization paper - IV**

#### **Clinical Research and Regulatory Affairs**

##### **Theory**

**(Four hours per week, 6 credits)**

**1. Introduction to Drug Discovery and drug Development**

**2. Clinical trials**

Introduction and designing

Various phases of clinical trials

Post Marketing surveillance – methods

Principles of sampling

Inclusion and exclusion criteria

Methods of allocation and randomization

Informed consent process

Monitoring treatment outcome

Termination of trial

Safety monitoring in clinical trials

**3 Documents in clinical study**

Investigator Brochure (IB),

Protocol & Amendment in Protocol ,

Case Report Form (CRF),

Informed Consent Form (ICF) ,

Content of Clinical Trial Report

Essential Documents in Clinical Trial

**4 Data Management in clinical Research**

**5 Ethical guidelines in clinical research**

History

ICH-GCP & its Principles

Indian GCP (CDSCO Guidelines)

ICMR Guidelines - Ethical Guidelines for Biomedical Research on Human Subjects Schedule Y

- 6 Roles & Responsibility of various clinical trial personnel as per ICH GCP**  
Sponsor  
Investigator  
Monitor  
Auditors
- 7 Institution Ethics Committee / Independent Ethics Committee**
- 8 Quality Assurance in clinical Research**
- 9 BA/BE studies: Introduction, Regulatory requirements and methodology**
- 10 Clinical Trial Application in India**  
Import & Export of Drug in India
- 11 Investigational New Drug application (IND)**
- 12 Abbreviated New Drug Application (ANDA)**
- 13 New Drug Application (NDA)**

## ASSIGNMENTS

The students are required to submit a minimum of two written assignments selected from the topics given to them.

### References Books:

1. Rick NG. Drugs From Discovery To Approval. John Wiley & Sons, Inc 2004
2. Allen Cato, Lynda Sutton Clinical Drug Trials and Tribulations Second Edition, Revised and Expanded. Marcel Dekker, Inc. 2002
3. Deborah Rosenbaum, Michelle Dresser. Clinical Research Coordinator Handbook Second Edition Practical Clinical Trials Series GCP Tools and Techniques Interpharm/CRC New York Washington, D.C.© 2002
4. Tamas Bartfai, Graham V. Lees. Drug Discovery from Bedside to Wall Street. Elsevier Academic Press. London 2006
5. Ronald D. Mann, Elizabeth B. Andrews. Pharmacovigilance. John Wiley & Sons Ltd, 2002
6. Shayne C. Gad. Drug Safety Evaluation. A John Wiley & Sons, Inc., Publication
7. Bert Spilker. Guide to Clinical Trials.
8. Sandy Weinberg. Guidebook For Drug Regulatory Submissions. A John Wiley & Sons, inc.,2009
9. Duolao Wang and Ameet Bakhai Clinical Trials A Practical Guide to Design, Analysis, and Reporting. Remedica 2006
10. Textbook of Clinical Trial edited by David Machin, Simon Day and Sylvan Green, March 2005, John Wiley and Sons.

11. Principals of Clinical Research edited by Giovanna di Ignazio, Di Giovanna and Haynes.
12. Clinical Data Management edited by R K Rondels, S A Varley, C F Webbs. Second Edition, 2000, Wiley Publications.
13. Various Guidelines like:
  - ✓ ICH – GCP- International Conference on Harmonisation of Technical requirements for registration of pharmaceuticals for human use. ICH Harmonised Tripartite Guideline. Guideline for Good Clinical Practice. E6 1996.
  - ✓ ICMR Guideline – Ethical Guidelines for Biomedical Research on Human Subjects.
  - ✓ Indian GCP – Central Drugs Standard Control Organization. Good Clinical Practices – Guidelines for Clinical Trials on Pharmacuetical Products in India. New Delhi: Ministry of Health; 2001.

Schedule Y