<table>
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<tr>
<th>Sr. No.</th>
<th>Subject (Code No.,)</th>
<th>Teaching scheme</th>
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<tbody>
<tr>
<td>1</td>
<td>Modern Analytical Technique (910001)</td>
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<td>2</td>
<td>Subject of Specialisation Paper – I (910101 to 910107)</td>
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<tr>
<td>3</td>
<td>Subject of Specialisation Paper – II (910201 to 910207)</td>
<td>6  --  6</td>
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<td>Total</td>
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<td>18  12  30</td>
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Gujarat Technological University
M. Pharm. Syllabus
Semester I
Paper Code 910001
MODERN ANALYTICAL TECHNIQUES
(Common to all disciplines)

Theory
(Four hours per week, 6 Credits)

1. **UV-VISIBLE SPECTROSCOPY:** 5 Hours.

2. **INFRARED SPECTROPHOTOMETRY:** 5 Hours.
   Introduction, basic principles, and sampling techniques, interpretation of spectra, applications in Pharmacy. FT-IR, Attenuated Total Reflectance (ATR), Near infra red Spectroscopy (NIR) -theory and applications.

3. **NUCLEAR MAGNETIC RESONANCE SPECTROSCOPY:** 7 Hours.
   Fundamental Principle and Theory, Instrumentation, solvents, chemical shift, and factors affecting chemical shift, spin-spin coupling, coupling constant, and factors influencing the value of coupling constant, spin-spin decoupling, proton exchange reactions, simplification of complex spectra, FT-NMR, 2D -NMR and applications in Pharmacy, interpretation of spectra. C13 NMR-Introduction, Natural abundance, C13 NMR Spectra and its structural applications.

4. **MASS SPECTROMETRY:** 7 Hours.
   Basic principles and instrumentation, ion formation and types, fragmentation processes and fragmentation pattern, Chemical ionization mass spectroscopy (CIMS), Field Ionization Mass Spectrometry (FIMS), Fast Atom Bombardment MS (FAB MS), Matrix Assisted laser desorption / ionization MS (MALDI-MS), interpretation of spectra and applications in Pharmacy.

5. **ATOMIC ABSORPTION AND PLASMA EMISSION SPECTROSCOPY:**
   Principle, instrumentation, interferences and applications in Pharmacy. 3 Hours.

6. **X-RAY DIFFRACTION METHODS:** 3 Hours.
   Introduction, generation of X-rays, X-ray diffraction, Bragg’s law, X-ray powder diffraction, interpretation of diffraction patterns and applications.

7. **OPTICAL ROTARY DISPERSION:** 3 Hours.
   Principle, Plain curves, curves with cotton effect, octant rule and its applications with example, circular dichroism and its relation to ORD.

8. **THERMAL METHODS OF ANALYSIS:** 4 Hours.
   Theory, instrumentation and applications of Thermo Gravimetric Analysis (TGA), Differential Thermal Analysis (DTA), Differential Scanning Calorimetry (DSC), and Thermo Mechanical Analysis (TMA).
9. CHROMATOGRAPHIC TECHNIQUES: 15 Hours.
   a) Classification of chromatographic methods based on mechanism of separation. Theories of chromatographic separation.
   b) Principles, elution techniques, instrumentation, derivatization and applications of gas chromatography, HPLC and HPTLC.
   c) Principles, elution techniques, applications of ion exchange and ion pair chromatography, affinity chromatography, size exclusion chromatography, chiral chromatography, super fluid chromatography (SFC), GC-MS and LC-MS.

10. ELECTROPHORESIS: 3 Hours.
    Theory and principles, classifications, instrumentation, moving boundary electrophoresis, Zone Electrophoresis (ZE), Isoelectric focusing (IEF) and applications.

11. RADIO IMMUNO ASSAY: 3 Hours.
    Introduction, Principle, Theory and Methods in Radio Immuno Assay, Related Immuno Assay procedures and applications of RIA Techniques. Enzyme immuno assay- ELISA and EMIT.

12. Reference standards source, preparation, characterization, usage, storage and records.  2 Hours.

MODERN ANALYTICAL TECHNIQUES
Practicals
(Four hours per week, 6 Credits)

1. Use of colorimeter for analysis of Pharmacopoeial compounds and their formulations.
2. Use of Spectrophotometer for analysis for Pharmacopoeial compounds and their formulations.
3. Simultaneous estimation of combination formulations (minimum of 4 experiments): e.g.
   a. Vitamins
   b. Oral antidiabetics
   c. NSAIDs
   d. Antimicrobials
   e. Antihistamines
   f. Antihypertensive etc.
4. Effect of pH and solvent on UV Spectrum of certain drugs.
5. Experiments on flame photometry.
6. Use of fluorimeter for analysis of Pharmacopoieal compounds.
8. Experiments of Chromatography.
   (a) Thin Layer Chromatography.
   (b) Paper Chromatography.
9. Experiments based on HPLC & GC.
10. IR, NMR and Mass Spectroscopy – Interpretation of spectra & Structural elucidation (atleast for 4 compounds each).
11. Any other relevant exercises based on theory.

Recommended books:

8. Instrumental Methods of Analysis – Willard, Merritt, Dean, CBS, Delhi.
15. Indian Pharmacopoeia
16. British Pharmacopoeia
17. U.S. Pharmacopoeia
Gujarat Technological University
M. Pharm. Syllabus
Semester I
Paper code-910102
Subject: - Specialization Paper-I
Pharmaceutical Formulation, Development & Biopharmaceutics
Theory
(Four hours per week, 6 Credits)

1. Preformulation studies 8 hr
   (a) Physical, Chemical and Pharmaceutical factors influencing formulation
   (b) Solid-state characterization: Crystallinity, hygroscopicity, Particle size and particle size distribution, compaction properties
   (c) Crystalline and polymorphism and its evaluation. Rationale for selecting the preferred polymorph/crystalline form
   (d) General principles and applications of various characterization techniques viz: Differential thermal analysis Differential scanning calorimetry, X-Ray diffraction, FTIR in Preformulation study.
   (e) Drug-excipient compatibility study
   (f) Traces of organic volatile impurities (OVIs) and their regulatory limits (residual solvents).
   (g) Preformulation studies of Biotechnological derived products and reference guidelines.

2. Solubilization and solubilized system 8 hr
   (a) Theoretical aspects and applications.
   (b) Techniques for improvement in drug solubilization for development of various dosage forms.

3. Dissolution study 8 hr
   (a) Importance, objectives, equipments,
   (b) Biological classification system (BCS); its significance on dissolution study and application in dosage form development.
   (c) Selection of dissolution media and conditions.
   (d) Comparison of dissolution profile by model independent (similarity and dissimilarity factor) and dependent methods.

4. Stability Study 8 hr
   (a) Basic concept and objectives of stability study,
   (b) Order of reaction and their applications in predicting shelf life and half life of pharmaceutical formulations,
   (c) Importance of accelerated stability study,
   (d) Effect of various environmental/ processing factors like light, pH, temperature, etc. on stability of the formulation and techniques for stabilization of product against the same.
   (e) Regulatory requirements related to stability testing with emphasis on matrixing / bracketting techniques, climates zone, impurities in stability study, photostability testing etc.,
   (f) Applications of microcalorimetry in stability study.
5. **Drug Absorption** 8 hr
   (a) Factors affecting drug absorption; i.e. Physicochemical, Physicality and Pharmaceutical.
   (b) Method of studying bioavailability and bioequivalence.
   (c) Transport across CACO 2 monolayers, Other Cell-lines to predict- Biological, Pharmaceutical and Analytical considerations

6. **Pharmacokinetic parameters** 8 hr
   (a) Basic concept and importance of biological half-life, volume of distribution, renal clearance, total body clearance, plasma protein binding, absorption rate constant, elimination rate constant.
   (b) Analysis of blood and urine data, compartment models, kinetics of one and two compartment model.

7. **In-vitro In-vivo Correlation (IVIVC)** 6 hr
   (a) Methods of establishing IVIVC
   (b) Factors affecting IVIVC

8. **Cosmetic, Dental and Herbal products** 6 hr
   (a) Formulation and evaluation of various cosmetic and dental products
   (b) Formulation and evaluation of products containing herbal ingredients

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**Books Recommended:**

3. Pharmaceutics “The Science of Dosage form design” by Aulton
4. Pharmaceutical dispensing by Husa.
5. Modern pharmaceutics by G. S. Banker.
7. Pharmaceutical dissolution testing by Banaker.
9. Techniques of Solubilization of Drugs by Yalkowsky.
13. Pharmacokinetics by Welling and Tse.
14. Pharmacokinetics by Gibaldi and Perrier
16. Pharmacokinetics for pharmaceutical scientist by John Wagner.
17. Dissolution, Bioavailability and Bioequivalence by Abdul.
18. Clinical Pharmacokinetics, Concepts and applications by Rowland and Tozer.
21. Perfumes, Cosmetics and Soaps by Poucher.

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**Pharmaceutical Formulation, Development & Biopharmaceutics Practicals**

*(Four hours per week, 6 Credits)*

1. To prepare, evaluate and supply microspheres.
2. To prepare, evaluate and supply Aspirin microspheres.
3. To prepare, evaluate and supply microcapsules.
4. To prepare, evaluate and supply Aspirin Effervescent Tablets.
5. To prepare, evaluate and supply Chewable Antacid Tablets.
6. To prepare, evaluate and supply Floating Tablets.
7. Direct Warm Spheronization.
8. To prepare and evaluate Suppositories.
9. To prepare, evaluate and supply Cold Cream.
10. To optimize the formula for vanishing cream and to evaluate it.
11. To prepare Toothpaste.
12. To optimize the formula for gel and to evaluate it.
13. To optimize the formula for Lather Shaving Cream and to evaluate it.
14. Tablet Coating ( Dip Coating )
15. Preparation and evaluation of multiple emulsion.
16. To carry out pan coating of tablets.
17. Preparation and evaluation of Fast Dispersible Tablets.
Gujarat Technological University
M. Pharm. Syllabus
Semester I
Paper code-910202
Subject: - Specialization Paper-II
Industrial Pharmacy
Theory
Four hours per week, 6 Credits

1. Pharmaceutical factory location: Selection, layout and planning. Utility services, Service facilities, HVAC and personnel facilities.
2. Preparation of qualitative and quantitative departmental layout with equipments required for different dosage forms, solids, liquids, semisolids, sterile.
3. Detailed study of the equipments required in the manufacture of different dosage forms as per Schedule-M.
4. Preparation of documents like batch manufacturing record, batch packing record, validation protocols.
5. Preparation of standard operative procedure (SOPs) for equipments and manufacturing or processing steps.
6. GMP and its implementation
7. Production planning and materials control.
8. Pilot plant, scale up technique.

References:
1. Lachman “The theory and Practice of Industrial Pharmacy
2. Remingtons “Pharmaceutical Sciences”
3. Bentley’s Pharmaceutics.
4. Pilot plants model and scale-up methods, by Johnstone and Thring.
5. GMP practices for pharmaceutical – James Swarbrick.
6. How to practice GMPs by P.P. Sharma.
7. Chemical Engineering Plant Design by Vibrant.
1. Molecular structure of biological membrane and, transport mechanism across the cell membrane 3

2. Molecular biology of receptor system: structure, receptor pharmacology, signal transduction mechanism and termination of receptor activity, regulation of receptor, their involvement in various biological processes including diseases resulting from receptor malfunction and their role in pharmacotherapeutics. Radio ligand binding studies. Theories of drug receptor interaction. Dose response relationship, potency and efficacy and different types of antagonisms 15

3. Classification of cholinergic and adrenergic receptors, their signal transduction mechanism, agonists and antagonists 4

4. NMDA, GABA, Glycine, Serotonin, Dopamine, Histamine and Endothelin (ET) receptors, their classification, signal transduction mechanism, agonists and antagonists 10

5. Pharmacology of sodium, calcium and potassium channels and their modulators 5

6. The role of nitric oxide in various physiological functions and its importance in pharmacotherapy of disorders like hypertension, angina and erectile dysfunction. 4

7. Pharmacology of purines and peptides. 3

8. Role of Cytokines, Prostaglandins, TNF-α, Bradykinins, Leucotrienes, PAF, Interferons and Adhesion molecules in various immunological and inflammatory disorders. 6

9. Cellular and molecular pharmacology of apoptosis and necrosis, stress induced expression of genes and their role in neurochemistry of aging and anti-aging drugs. (With special emphasis on CNS) 7

10. Gene therapy 3

910103 : : Cellular and Molecular Pharmacology Practical

Four hours per week, 6 Credits

1. Introduction to experimental animals, ethics in pharmacological experiments, CPCSEA Guidelines

2. Methods for euthanasia, anesthesia, dosing (i.v., oral, i.p., s.c., i.m.) and blood collection by various techniques
3. To study the effects of various agonists ($pD_2$) and antagonist ($pA_2$) using isolated preparations (rat ileum, guinea pig ileum, rat fundus strip, rat anococcygeus muscle, rat vas deference, rat uterus, guinea pig taenia coli, rat/guinea pig heart, guinea pig tracheal chain, rat aortic strip)

4. To study the effects of calcium channel blockers on responses of various agonists on rat/guinea pig ileum

5. To study the effect of various drugs on rat blood pressure by invasive/non invasive techniques

Books recommended (Latest Edition):

1. Pharmacological Basis of Therapeutics-Goodman and Gilman
2. Pharmacology-Rang and Dale
3. Basic and Clinical Pharmacology – Bertam G. Katzung
4. Principles of Pharmacology – Paul L. Munson
5. Lewis’s Pharmacology – James Crossland – Churchil Livingstone
6. Review of Medical Physiology – Ganong William F.
7. Fundamentals of Experimental Pharmacology- Ghosh M.N.
8. Basic and Clinical Immunology- Peakman, Mark
11. Pharmacology and Toxicology- Kale S.R.
Gujarat Technological University
M. Pharm. Syllabus
Semester I
910203 : Subject of Specialization Paper- II
Advances in Pharmacology
Theory
(Four hours per week, 6 Credits)

Recent advances in pharmacology of the following:

1. **Drugs acting on the peripheral nervous system**: Sympathomimetics, Sympatholytics, Parasympathomimetics, Parasympatholytics, Ganglion blockers & Stimulants, Neuromuscular blockers. 15

2. **Autacoids**: Eicosanoids, Polypeptides, Histamine, 5-HT 7

3. **Antimicrobial and Antineoplastic agents**: Introduction to infectious disease, general Principles of Chemotherapy and management of infectious disease, Sulphonamides & Co-trimoxazole, Penicillins, Cephalosporins, Macrolide antibiotics, Aminoglycosides, Quinolones, Tetracycline & Chloramphenicol, Chemotherapy of Tuberculosis & Leprosy, Antifungal agents, Anti-viral agents, Anti-protozoal agents, Anthelmintics, Chemotherapy of Sexually Transmitted Disease (STD), Types of cancers, and radiation therapy. 30

4. **Immunopharmacological agents**:
   Immunostimulants, Immunosuppressant 8

Books recommended (Latest Edition):

1. Pharmacological basis of Therapeutics-Goodman and Gilman
2. Pharmacology-Rang and Dale
3. Principles of Pharmacology – Paul L. Munson
4. Lewis’s Pharmacology – James Crossland – Churchil Livingstone
5. Modern Pharmacology with clinical applications- Craig, Charles R.
6. Lippincott’s illustrated reviews of Pharmacology- Mycek Mary J.
7. Goth’s Medical Pharmacology- Wesley G. Clark
8. Principles of pharmacology.--H. L. Sharma
9. Essentials of medical pharmacology --K. D. Tripathi
1. Chemical Bonding and Structure: 6
Chemical Bonding, Bond Energies, Orbital Theory, Orbital Hybridization, Resonance, Electronegativity, Polarity, Hyperconjugation.

2. Chemical Reactivity and Molecular Structure 6
Kinetics, Stearic, Inductive and electrostatic effect on reactivity, Acids and Bases.

3. Various Reaction Mechanisms
   a. Substitution Reaction: Nucleophilic substitution reaction in aliphatic systems, $S_N1$, $S_N2$ reactions, Hydride transfer reaction, Cram’s rule, Participation of neighbouring group in nucleophilic substitution reaction and rearrangements. Aromaticity, electrophilic and nucleophilic substitution in aromatic systems, Reactivity, orientation in electrophilic substitution. 12
   b. Elimination Reaction: Beta Elimination reactions, $E_1$, $E_2$ and $E_1cb$ mechanisms, Hoffman and saytzeff’s rule for elimination. 6
   c. Addition Reaction: Electrophilic and Nucleophilic additions, Stereochemistry involved, Markonikov’s rule. 3
   d. Rearrangement Reactions: Transannular rearrangement, Pinacol rearrangements, Beckman rearrangement, Hofmann rearrangement. 5
   e. Free Radical Reaction: Formation, Detection, Reactions, Homolysis and free radical displacements, addition and rearrangements of free radicals. 4

4. Reactions of carboxylic acids and esters
BAC2, AAC2, BAL2, BAL1, AAL1, Claisen condensation, decarboxylation, carbanions, enolisation, keto-enol equilibria 8

5. Y-lides: Introduction, generation and reactions involving phosphorus, sulphur and nitrogen y-lides. 5

6. Photochemistry: Theory, energy transfer, characteristics of photoreactions, typical photochemical reactions 5
910101 : Advanced Organic Chemistry – 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.

Books Recommended: (Latest Edition)
7. Vogel's textbook of practical organic chemistry, Pearson Education Ltd.

M. Pharm. Semester – I
910201 : Chemistry of Natural Products
Theory
Four hours per week, 6 Credits

1. Carbohydrates: 10
   Brief introduction, Configuration of monosaccharids, ring structure of monosaccharides, disaccharides – determination of structures of sucrose, maltose and lactose, Polysaccharides – cellulose and starch, Introduction to pectin and pectic substances

2. Amino acids and polypeptides: 12
   Introduction, classification, synthesis of amino acids, protein classification, Synthesis of naturally occurring proteins, structure of polypeptides, amino and carboxyl end degradation, polypeptide synthesis, composition, structure and chemistry of oxytocin, insulin and angiotensin, peptides of medicinal importance.

3. Alkaloids: 8
   Classification, general methods of degradation and structure determination, morphine, ergotamine, reserpine, colchicine, vinca and podophyllum alkaloids.
4. Steroids: 8
Stereochemistry, conformational studies of steroidal nucleus, chemistry of cholesterol, stereochemistry of side chain at C-17, cholic acid, vit. D₃, cortisone, aldosterone.

5. Anthocyanins: 5
Introduction, general nature, synthesis, structure of anthocyanidin, flavones, isoflavones and depsides.

6. Purines and nucleic acids 3

7. Heterocyclic Chemistry 14
Introduction, nomenclature, properties, synthesis and reactions involved in five and six member heterocycles. Heterocycles with one, two or more than two heteroatoms, biological importance of heterocles.

Books Recommended:
   ____4 Hours____

   ____4 Hours____

   ____5 Hours____

4. Analysis of drugs from biological samples including, selection of biological sample, extraction of drugs by various methods as LLE, SPE and Membrane filtration.  
   ____5 Hours____

   ____6 Hours____

6. Radio immunoassay: General principles, scope and limitations, radio immunoassay of some drugs like insulin, digitalis etc.  
   ____4 Hours____

7. Preclinical Drug Evaluation, acute, sub acute and chronic toxicity studies, LD50 & ED50 determination, evaluation of compound for its biological activity, study of special toxicities like teratogenicity and mutagenicity.  
   ____7 Hours____

8. Clinical Research—  
   b. Helsinki declaration, US-FDA & ICH guideline for Clinical trials for drugs and dosage forms, reviews and approval of Clinical Study.  
   c. Good Clinical Practices.  
   ____10 Hours____

9. Bioavailability:- Objectives and consideration in bio-availability studies, Concept of equivalents, Measurements of bio-availability, Determination of the rate of absorption, Bioequivalence and its importance, Regulatory aspects of bio-availability and bioequivalence studies for conventional dosage forms and controlled drug delivery systems.  
   ____7 Hours____

    ____8 Hours____
BIOLOGICAL EVALUATION AND CLINICAL RESEARCH
Practical
(Four hours per week, 6 Credits)

1. Bio-analytical method development and its validation.
2. Analysis of biological fluids.
3. Analysis of drug in biological fluids.
4. Dissolution study of simple and modified release solid oral dosage forms.
5. Any other relevant exercises based on theory.

Recommended books:

1. Indian Pharmacopoeia
2. British Pharmacopoeia
3. U.S. Pharmacopoeia
10. Leon Shargel, “Applied Biopharmaceutics and Pharmacokinetics”.
11. Welling and Tse.-Pharmacokinetic
12. Gibaldi and Perrier-Pharmacokinetics
14. Rowland and Tozer-Clinical Pharmacokinetics, concepts and application.
1. Concepts of Philosophy of QA, GMP, GLP ................................................. 3 Hours
2. Good Manufacturing Practices: 
   a. Organization & Personnel, responsibilities, training, hygiene. .................. 3 Hours
   b. Premises: Location, design, Plant Layout, Construction, Maintenance and Sanitation, Environmental control, utilities and services like gas, water, maintenance of sterile areas, and control of contamination. .............. 4 Hours
   c. Equipments: Selection, purchase specifications, maintenance, clean in place, sterilize in place, Methods (TP & STP). ................................................................. 4 Hours
   d. Raw Materials: Purchase specifications, maintenance of Stores, selection of Vendors, control on raw materials and finished dosage forms. ............. 2 Hours
   e. Manufacture of & control on dosage forms: manufacturing documents, master formula, batch formula records, standard operating procedures, quality audits of manufacturing processes and facilities. \( \text{8 Hours} \)
   f. In Process quality controls on various dosage forms: Sterile and non sterile, standard operating procedures for various operations like cleaning, filling, drying, compression, coating, disinfections, sterilization, membrane filtration etc. \( \text{5 Hours} \)
   g. Packaging and labeling control, Line clearance, reconciliation of labels, cartons and other packaging materials. ................................. 2 Hours
   h. Quality control Laboratory: Responsibilities. Routine controls instruments, reagents, sampling plans, standard test Procedures, protocols, data generation and storage, quality control documents, retention samples, records, audits of quality control facilities. \( \text{6 Hours} \)
   i. Finished product release, quality review, quality audits and batch release documents. \( \text{3 Hours} \)
   j. Warehousing, design, construction, maintenance and sanitation; good warehousing practice, materials and management. ....................... 2 Hours
   k. Distribution and distribution records, handling of returned goods, recovered materials and reprocessing. .......................... 2 Hours
   l. Complaints and recalls, evaluation of complaints, recall procedures, related records and documents. ................................................. 2 Hours
   m. Waste disposal, scrap disposal procedures and records. ............... 2 Hours

3. Good Laboratory Practices. ......................................................... 4 Hours
4. WHO certification. ................................................................. 2 Hours
5. Testing of Packaging materials. ................................................. 2 Hours
6. Quality Audit. ........................................................................ 2 Hours
7. Specifications for materials, intermediates and finished product. .......... 2 Hours
Recommended books:

5. P. P. Sharma “How to practice GLP” Vandana Publication.
7. WHO’s “Drug” Bulletins.
8. Remingtons “Pharmaceutical Sciences”.
9. GMP practices for pharmaceutical-James Swarbrick.
1. Study of different biogenetic pathways of therapeutically important
   (15)
   active constituents.

2. Classification, Isolation, structure determination
   (30)
   stereochemistry, biological activity of following categories of Naturally
   occurring components:
   a. Carbohydrates, Mono, di, oligo- and polysaccharides, Glycoproteins,
      lipoproteins and glycopeptidolipids.
   b. Lipids and autocoids
   d. Glycosides: Calanolides, Glycyrhrhetic acid,
   e. Resins: Podophyllotoxin.
   f. Terpenoids: Taxol
   g. Antibiotics: Gresiofulvin, Penicilllin, Sterptomycin

3. Advanced methods of extraction of plant metabolites.
   (15)

4. Immunoglobins from Natural source specifically from plants.
   (8)

   Chemistry of Medicinal Natural Products
   Practical
   (Four hours per week, 6 Credits)

   Practical exercises based on the relevant topics mentioned in theory syllabus.
Gujarat Technological University
M. Pharm. Syllabus
Semester I
Paper Code 910205
Biotechnology and Cultivation of Medicinal Plants.

Theory
(Four hours per week, 6 Credits)

1. Factors affecting quality of plant drugs, safe and economical methods (15)
   for documentation and preservation of herbs and herbal products detection of common adulterants, microbial contamination, toxic trace metals, pesticides and insect infestation in whole and powdered drugs.

2. Cultivation of Taxus baccata, Ginseng, Artemisia annua, Boswellic serrata, Curcuma longa. (08)


4. Medicinal Plant Biotechnology. (08)

5. Plant tissue culture techniques: including types, media, methodology, micropropagation, hairy root culture, protoplast culture, biotransformation, immobilization, Role of elicitors, artificial seeds, transgenic plants and commercial applications. (12)

6. Phytomics and metabolomics (08)
Books recommended

1. Recent progress in medicinal plants: Volumes-1 to 22.
2. Ramstad-Modern pharmaconosy
3. Herskowitz- Principles of Genetics
4. Stricknerger- Genetics
5. Hess-Plant Physiology
6. Kruse Patterson- Tissue culture methods and Applications
7. Handa SS and Kaul KS – Supplement to cultivation and utilization of medicinal plants
8. Wealth of India, raw materials
10. Purthi JS- Major spices of India.
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<tr>
<th>Course Code</th>
<th>Course Title</th>
<th>Hours</th>
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<tbody>
<tr>
<td>1</td>
<td>Definitions, development and scope of clinical pharmacy</td>
<td>2</td>
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<td>2</td>
<td>Pharmaceutical care concept</td>
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<td>3</td>
<td>Role of clinical Pharmacist in the health care system</td>
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<td>4</td>
<td>Routine activities of clinical Pharmacist</td>
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<td></td>
<td>a) Drug Therapy monitoring: Medication chart review, Clinical review, Pharmacists interventions.</td>
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<td>b) Ward round participation</td>
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<td>c) Recording of Medical History</td>
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<td>d) Adverse drug reaction monitoring</td>
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<td>e) Communication skills including patient counseling techniques</td>
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<td>f) Drug utilization evaluation and review</td>
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<tr>
<td>5</td>
<td>Quality assurance of clinical pharmacy services</td>
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<td>6</td>
<td>Concept of essential drugs and rational drug usage</td>
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<td>7</td>
<td>Self-medication and non-prescription drug usage</td>
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<td>8</td>
<td>Prescription monitoring and medication errors</td>
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<tr>
<td>9</td>
<td>Patient Compliance</td>
<td>2</td>
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<tr>
<td>10</td>
<td>Interpretation of clinical laboratory tests</td>
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<td></td>
<td>Hematological, liver function, renal function, thyroid function tests</td>
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<td>Tests associated with cardiac disorders</td>
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<td>Fluid and electrolyte balance</td>
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<td>Micorbiological culture sensitivity tests</td>
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<td>Pulmonary function tests</td>
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<td>11</td>
<td>Patient data analysis and Case presentation</td>
<td>2</td>
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<tr>
<td>12</td>
<td>Drug induced diseases</td>
<td>2</td>
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<tr>
<td>13</td>
<td>Drug interactions</td>
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Documentation and other methods for minimizing clinically relevant drug interactions

14 Pharmacovigilance  7 Hours

Scope, definition and aims of pharmacovigilance
Adverse drug reactions – Classification, mechanism, predisposing factors and causality assessment.
Role of clinical pharmacist in Reporting, evaluation, monitoring, prevention and management of ADR

15 Pharmacoeconomics  7 Hours

Definition, history, needs of pharmacoconomic evaluations
Applications of pharmacoconomics: case study

16 Critical evaluation of biomedical literature  2 Hours

CLINICAL PHARMACY PRACTICE
PRACTICAL
(Four hours per week, 6 Credits)

In order to gain practice in clinical setting, students have to undergo compulsory postings in clinical settings, utilizing prior understanding and knowledge attained in identifying and resolving the pharmaceutical care issues.

It is mandatory that each student has to complete and maintain a record of at least 15 case studies based on the following theory topics;
* Patient medication history interview
Case studies related to laboratory investigations (Haematological, Bio-chemical, Pathological and Diagnostic Tests)
Patient medication counseling
Pharmacoconomics : case study
Pharmacovigilance : case study
Medication and administration record review
ADR/Medication error identification and documentation

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

3 Clinical Pharmacy and Therapeutics. Roger Walker and Clive Edwards, Churchill Livingstone publication
5 Practice Standards and Definitions – The Society of Hospital Pharmacists of Australia.
6 Basic Skills in interpreting laboratory data – Scott LT, American Society of Health System Pharmacists Inc.
8 A textbook of Clinical Pharmacy Practice; Essential concepts and skills, Dr. G. Parthasarthi et al.
11 Clinical Pharmacokinetics- Rowland Tozer, Williams and Wilkins Publication.
12 Pharmaceutical Statistics. Practical and clinical applications. Sanford Bolton, Marcel Dekker Inc.
14 Hand Book of Pharmacy Health Care. The Pharmaceutical Press
1 Pharmacoepidemiology 10 Hours

Definition, Origin and evaluation of pharmacoepidemiology, aims and applications, need for pharmacoepidemiology.

Prevalence, incidence and incidence rate. Monetary units, number of prescriptions, units of drugs dispensed, defined daily doses and prescribed daily doses, medication adherence measurement.

Measurement of risk, attributable risk and relative risk, time-risk relationship and odds ratio.

Drug utilization review, surveys of drug use, case reports, case series, cross-sectional studies, cohort studies, case control studies, meta-analysis studies, spontaneous reporting, prescription event monitoring and record linkage system.

2 Clinical Pharmacokinetics and therapeutic drug monitoring 15 Hours

Clinical Pharmacokinetics
Introduction to clinical pharmacokinetics

Normograms and tabulations in designing dosage regimen, conversion from intravenous to oral dosing, determination of dose and dosing interval, drug dosing in the elderly and pediatrics and obese patients.

Pharmacokinetic drug interactions, Inhibition and induction of drug metabolism, Inhibition of biliary excretion

Therapeutic drug monitoring
Introduction
Individualization of drug dosage regimen (variability – genetic, age and weight, disease, interacting drugs).
Indications for TDM, Protocol for TDM
Pharmacokinetic/Pharmacodynamic correlation in drug therapy
TDM of drugs use in the following disease conditions: cardiovascular disease, CNS conditions etc
**Dosage adjustment in renal and hepatic disease**
- Renal impairment
- Pharmacokinetic considerations
- General approach for dosage adjustment in renal disease
- Measurement of glomerular filtration rate and creatinine clearance
- Effect of hepatic disease of pharmacokinetics

### 3 Clinical Toxicology 8 Hours
- General principles involved in the management of poisoning
- Antidotes and their clinical applications
- Supportive care in clinical toxicology
- Gut decontamination
- Elimination enhancement
- Toxicokinetics

### 4 Clinical symptoms and management of acute poisoning with the following agents: 7 Hours
- Pesticide poisoning: organophosphorus compounds, carbamates, organochlorines, pyrethroids
- Opiate overdose
- Antidepressants, Barbiturates and benzodiazepines
- Alcohol: ethanol, methanol, Paracetamol and salicylates
- Non-steroidal anti-inflammatory drugs, Radiation poisoning

### 5 Clinical symptoms and management of chronic poisoning with the following agents: 5 Hours
- Heavy metals: Arsenic, lead, mercury, iron, copper
- Food poisoning

**HOSPITAL PHARMACY**

### 6 Hospital pharmacy – organization and management 3 Hours
- Organisational structure – staff, infrastructure & work load statistics
- Management of materials and finance
- Roles & responsibilities of hospital pharmacist
- **The budget** – Preparation and implementation

### 7 Hospital drug policy 2 Hours
- Pharmacy and therapeutic committee (PTC)
- Hospital formulary
- Hospital committees: Infection committee, Research and Ethical committee

### 8 Hospital pharmacy services 5 Hours
Procurement & warehousing of drugs and pharmaceuticals
Inventory control: definition, methods of inventory control, ABC, VED, EOQ, lead time, safety stock.

9 Drug distribution in the hospital 5 Hours

Individual prescription method
Floor stock method
Unit dose drug distribution method
Distribution of Narcotic and other controlled substances
Central sterile supply services – role of pharmacist
Radio pharmaceuticals – handling and packaging

ASSIGNMENTS

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

BOOKS RECOMMENDED

1 Malcolm Rowland & Thomas Tozer. Clinical Pharmacokinetics & Concepts and Applications Lippincott Williams & Wilkins 1995
3 Hospital Pharmacy by William E. Hassan
6 Toxicology - The basic science of poisons, international edition, Curtis D.Klaassen, 6th edition
7 Toxicology – Principles and Applications, Raymond J.M.Niesink, John de.Vries, Mannfred A. Hollinger
9 Toxicology - The basic science of poisons, international edition, Curtis D.Klaassen, 6th edition
10 Toxicology – Principles and Applications, Raymond J.M.Niesink, John de.Vries, Mannfred A. Hollinger
1) Application of instrumental methods in the development of medicines, concept of analytical method development.  

5 Hrs.

2) Validation and calibration of various instruments used for drug analysis such as UV-Visible Spectrophotometer, IR Spectrophotometer, Spectrofluorimeter, HPLC, HPTLC and GC.

10 Hrs.

3) Ion Selective electrodes: Classification, instrumentation and applications in drug analysis.

2 Hrs.

4) Principles and procedures involved in quantitative determination of following groups

(a) Hydroxyl, (b) Aldehyde, (c) Ketone, (d) Ester (e) Amine.

5 Hrs.

5) A detailed study of principle and procedures involved in various physicochemical methods of analysis including instrumental methods of analysis of Pharmaceutical dosage forms containing the following classes of drugs:

a. Sulphonamides.
b. Barbiturates - i.e., Barbituric acid derivatives and Xanthine derivatives.
c. Steroids such as Adrenocortical steroids, Progesterone, Androgens and Cholesterol.
d. Vitamins like Vitamin A, B1, B2, B12, C & E.
e. Antibiotics like Chloramphenicol, Erythromycin, Penicillin & Streptomycin.
g. Glycosides such as Digitoxin, Digoxin & Strophanthin.

20 Hrs.

6) Elemental analysis such as determination of sodium, potassium, calcium, phosphorous, sulphur, chlorine, bromine and iodine.

5 Hrs.

7) Principles and procedures involved in the use of the following reagents in Pharmaceutical analysis:

8 Hrs.

a. N1-naphthyl ethylene diamine.
b. p-dimethylaminobenzaldehyde (PDAB).
c. 2,6-Dichloro quinone chlorimide.
d. 1,2-Naphtho quinone 4-sulphonate.
e. 2,3,5-Triphenyl Tetrazolium Salt.
f. Ninhydrin.
g. Folin - Ciocalteau reagent.
h. P-dimethylaminocinnamaldehyde.
i. 3-methyl-2-benzothiazoline hydrazone (MBTH).
j. 2,4-dinitrophenylhydrazine.

8) Analysis of excipients in solid state - Particle size analysis, X-ray diffraction.

5 Hrs.
Pharmaceutical Analysis-I
PRACTICALS
4 Hours per week, 6 Credits
1. Calibration and validation of UV-Visible, IR, Flourimeter, HPLC & HPTLC.
2. Assays of official compounds by fluorimetry:
   a) Quinine b) Codeine c) Thiamine and d) Riboflavin.
4. Determination of 'Sodium' in Sodium chloride injection.
5. Colorimetric estimation of Sulphacetamide in 'eye drops' using NED.
6. Assay of Reserpine injection IP.
7. Quantitative Analysis of drugs in the following 'Multicomponent dosage form' - Ibuprofen
   & Paracetamol Tablet, Paracetamol and Nimesulide Tablet, Ciprofloxacin and Tinidazole
   Tablet.
8. Quantitative Determination of functional groups like:
   a) Hydroxyl group b) Carbonyl group c) Amine.
9. Quantitative Colorimetric determination of suitable drugs using following reagents:
   a) P-dimethylaminocinnamaldehyde b) MBTH c) F-C reagent
   d) 2,6-dichloroquinonechlorimide e) Ninhydrin.
10. Assay of the following official formulations:
     a) Frusemide Tablet b) Metformin Tablet c) Chloroquine Tablet
     d) Chloramphenicol Capsule e) Digoxin Tablet.
11. HPLC & HPTLC analysis of drugs.

BOOKS RECOMMENDED
1. Basic principles, instrumentation and application of Chemiluminescence 5 Hrs.
2. Basic principles, classification, instrumentation and application of LASER. 5 Hrs.
3. Electron spin resonance (ESR) principle, instrumentation, correlation with proton magnetic resonance, derivative curves, interpretation and application. 8 Hrs.
4. **Raman Spectroscopy**: Introduction, Principle and application of Raman Spectroscopy. 6 Hrs.
5. **Photoacoustic Spectroscopy**: Principles, instrumentation and application. 5 Hrs.
6. **Radiochemical Analysis**: Instruments used-analytical and screening, isotopic dilution, neutron activation and positron emission tomography (PET) 8 Hrs.
7. **Nuclear Magnetic Resonance Spectroscopy**: Effect of stereochemistry on the spectrum, shift reagent. Introduction to the following techniques would be covered DEPT, APT, COSY, NOESY and INADEQUATE. 13 Hrs.
8. **13C Nuclear Magnetic Resonance (13C - NMR)**
   Natural abundance of 13C, resolution and multiplicity FT mode, RF mode, uses of proton coupled, decoupled and off resonance decoupling techniques, deuterium substitution, chemical equivalence in peak assignment, chemical shift, Effect of substitution on chemical shifts, position of alkanes, alkenes, alkynes and benzene spin coupling and C13-H1 coupling 10 Hrs.

**BOOKS RECOMMENDED**