Gujarat Technological University

M. Pharm.
Semester – I

Structure for First Semester of Master of Pharmacy Course

Sr. No.	Subject (Code No,)	Teaching scheme		
		Theory	Practical	Credits
1	Modern Analytical Techniuqe (910001)	6	6	12
2	Subject of Specialisation Paper – I (910101 to 910108)	6	6	12
3	Subject of Specialisation Paper – II (910201 to 910208)	6	--	6
	Total	**18**	**12**	**30**

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)

Course Content: **Hours**

1. UV-VISIBLE SPECTROSCOPY: **05**

Brief review of electromagnetic spectrum and absorption of radiations. The chromophore concept, absorption law and limitations. Theory of electronic spectroscopy, absorption by organic molecules, choice of solvent and solvent effects. Applications of UV-Visible spectroscopy, Woodward –Fischer rules for calculating absorption maximum, interpretation of spectra, multi-component assay, difference spectra and derivative spectra.

2. INFRARED SPECTROPHOTOMETRY: **05**

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: **07**

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: **07**

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. **03**

6. X-RAY DIFFRACTION METHODS: **03**

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: **03**

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: **04**

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**

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, and chiral chromatography, super fluid chromatography (SFC), GC-MS and LC-MS.

10. ELECTROPHORESIS: **03**

Theory and principles, classifications, instrumentation, moving boundary electrophoresis, Zone Electrophoresis (ZE), Isoelectric focusing (IEF) and applications.

11. RADIO IMMUNO ASSAY: 03

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. **02**

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.
7. Experiments on Electrophoresis.
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:

1. Spectrometric identification of Organic Compounds, Robert. M. Silverstein, Basseler, Morril (John Wiley and Sons. N.Y).
2. Spectroscopy of Organic Compounds by P. S. Kalsi.
3. Principles of Instrumental Analysis by Donglas A. Skoog, James, J. Leary, 4th Edition.
4. Pharmaceutical Analysis – Modern Methods – Part A, Part B, James W. Munson 2001.
5. Organic Spectroscopy – William Kemp, 3rd Edition.
6. Chromatographic Analysis of Pharmaceuticals, John A. Adamovics, 2nd Edition.
7. Practical Pharmaceutical Chemistry, Part two, A. H. Beckett & J. B. Stenlake – 4th dition.
8. Instrumental Methods of Analysis – Willard, Merritt, Dean, CBS, Delhi.
9. Techniques and Practice of Chromatography – Raymond P. W. Scott, Vol. 70.
10. Identification of Drugs and Pharmaceutical Formulations by Thin Layer Chromatography – P. D. Sethi, Dilip Charegaonkar, 2nd Edition.
11. HPTLC – Quantitative Analysis of Pharmaceutical Formulations – P. D. Sethi.
12. Liquid Chromatography – Mass Spectrometry, W. M. A. Niessen, J. Van Der Greef, Vol. 58.
13. Modern Methods of Pharmaceutical Analysis, Vol.1, 2, RE Schirmer,Franklin Book

14. Colorimetric Methods of analysis- F. D. Snell and C. T. Snell (Van Nostrand Reinhold Company, N.Y.).
15. Indian Pharmacopoeia
16. British Pharmacopoeia
17. U.S. Pharmacopoeia
18. Clarke's Analysis of Drugs and Poisons, A.C.Moffat, M. David Osselton, Brain Widdop, L. Y. Galichet. 3rd edition, Pharmaceutical Press Text book of Pharmaceutical Analysis, K. A. Connors, 3rd Ed., John Wiley & Sons, New York.

Gujarat Technological University
M. Pharm. Syllabus
Semester I
Paper code-910102
Subject: - Specialization Paper-I
Pharmaceutical Formulation, Development & Bio pharmaceutics

Theory
(Four hours per week, 6 Credits)

1. **Preformulation studies** **08**
   (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** **08**
   (a) Theoretical aspects and applications.
   (b) Techniques for improvement in drug solubilization for development of various dosage forms.

3. **Dissolution study** **08**
   (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** **08**
   (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** **08**
   (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 **08**

(a) Basic concept and importance of biological half-life, volume of distribution, renal clearance, total body clearance, plasma protein binding, and 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) **06**

(a) Methods of establishing IVIVC
(b) Factors affecting IVIVC

8. Cosmetic, Dental and Herbal products **06**

(a) Formulation and evaluation of various cosmetic and dental products
(b) Formulation and evaluation of products containing herbal ingredients.

Reference Books:

1. **Remingtons** "Pharmaceutical Sciences" 19th edition.
2. **Lachman "**The theory and Practice of Industrial Pharmacy" 3rd 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. Techniques of Solubilization of Drugs **by Yalkowsky.**
10. Drug stability (Principles and Practices) **by Jens. T. Carstensen.**
11. Stability of drug and dosage forms **by Yoskioka.**
12. Applied Biopharmaceutics and pharmacokinetics by **Leon Shargel**, 4th edition.
13. Pharmacokinetics **by Welling and Tse.**
14. Pharmacokinetics **by Gibaldi and Perrier**
15. Biopharmmaceutics and pharmacokinetics: An introduction **by Notari.**
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.**
19. Novel Cosmetic Drug Delivery Systems, **by Magdassi and Touitou.**
20. Cosmetics **by Sagerin.**
21. Perfumes, Cosmetics and Soaps **by Poucher.**

Pharmaceutical Formulation, Development & Bio pharmaceutics Practical

(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

Course Content:

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

Reference Books:

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 GMP**s by P.P.Sharma.**
7. Chemical Engineering Plant Design **by Vibrant.**
8. Pharmaceutical Process Validation **by Loftus and Nash.**
9. Drug and Cosmetic Act 1940 and rules.

Gujarat Technological University
M. Pharm. Syllabus
Semester I
910103: Subject of Specialization Paper- I
Cellular and Molecular Pharmacology
Theory
(Four hours per week, 6 Credits)

Course Content:

Hours

1. Molecular structure of biological membrane and, transport mechanism across the cell membrane **03**
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 pharmaco-therapeutics. 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 **04**
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 **05**
6. The role of nitric oxide in various physiological functions and its importance in pharmacotherapy of disorders like hypertension, angina and erectile dysfunction. **04**
7. Pharmacology of purines and peptides. **03**
8. Role of Cytokines, Prostaglandins, TNF-α, Bradykinins, Leucotrienes, PAF, Interferons and Adhesion molecules in various immunological and inflammatory disorders. **06**
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) **07**
10. Gene therapy **03**

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

Reference Books:

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
9. Handbook of Experimental Pharmacology- Goyal R.K.
10. Handbook of Experimental Pharmacology- Kulkarni S.K.
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)

Course Content: **Hours**

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 **07**
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 & Chloramphanicol, Chemotherapy of Tuberculosis & Leprosy, Antifungal agents, Anti-viral agents, Anti-protozoal agents, Anthelmintics, Chemotherapy of Sexually Transmitted Disease (STD), Types of cancers ,their management with Anti- Cancer agents and radiation therapy. **30**
4. **Immunopharmacological agents:**
   Immunostimulants, Immunosuppressant **08**

Reference Books:

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

Gujarat Technological University
M. Pharm. Syllabus
Semester I
910101 : Subject of Specialization Paper – I
Advanced Organic Chemistry – I

Theory
(Four hours per week, 6 Credits)

Course Content: **Hours**

1. Chemical Bonding and Structure: **06**
Chemical Bonding, Bond Energies, Orbital Theory, Orbital Hybridization, Resonance, Electronegativity, Polarity, Hyperconjugation.

2. Chemical Reactivity and Molecular Structure **06**
Kinetics, Stearic, Inductive and electrostatic effect on reactivity, Acids and Bases.

3. Various Reaction Mechanisms

a. **Substitution Reaction:** Nucleophilic substitution reaction in aliphatic systems, SN1, SN2 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, E1, E2 and E1cb mechanisms, Hoffman and saytzeff's rule for elimination. **06**

c. **Addition Reaction:** Electrophilic and Nucleophilic additions, Stereochemiistry involved, Markonikov's rule. **03**

d. **Rearrangement Reactions:** Transannular rearrangement, Pinacol rearrangements, Beckman rearrangement, Hofmann rearrangement. **05**

e. **Free Radical Reaction:** Formation, Detection, Reactions, Homolysis and free radical displacements, addition and rearrangements of free radicals. **04**

4. Reactions of carboxylic acids and esters
BAC2, AAc2, BAL2, BAL1, AAL1, Claisen condensation, decarboxylation, carbanions, enolisation, keto-enol equilibria **08**

5. Y-lides: Introduction, generation and reactions involving phosphorus, sulphur and nitrogen y-lides. **05**

6. Photochemistry: Theory, energy transfer, characteristics of photoreactions, typical photochemical reactions **05**

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.

Reference Books:

1. Advanced Organic Chemistry – Reaction, Mechanism and Structure – J. March, John Wiley & Sons, New York.
2. Advanced Organic Chemistry Part – A & B – F. A. Carey & R. J. Sundberg, Kluwer Academic / Plenum Publishers, New York.
3. Organic Chemistry, Clayden, Greeves, Waren and Wothers, Oxford University Press, New York.
4. Organic Chemistry, G. Marc Loudon, Oxford University Press., New York.
5. Organic Synthesis, Collective Volumes, Ed. W. E. Noland, John Wiley & Sons, New York.
6. Strategic Application of named reaction in organic synthesis by Laszlo Kurti & Barbara Czako, Elsevier Academic Press.
7. Vogel's textbook of practical organic chemistry, Pearson Education Ltd.
8. "Experimental Organic Chemistry" L. M. Harwood, L. J. Moody, J. M. Percy, Blackwell Science.
9. Techniques and Experiment of Organic Chemistry, Addison Ault, University Science Books.
10. Introduction to Organic Laboratory Techniques, A Microscale Approach, Donald L. Pavia, Gary M. Lampman, George S. Kriz, Harcourt College Pub.

Gujarat Technological University
M. Pharm. Syllabus
Semester I
910201: Chemistry of Natural Products

Theory
Four hours per week, 6 Credits

Course Content: Hours

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: 08
Classification, general methods of degradation and structure determination, morphine, ergotamine, reserpine, colchicine, vinca and podophyllum alkaloids.

4. Steroids: 08
Stereochemistry, conformational studies of steroidal nucleus, chemistry of cholesterol, stereochemistry of side chain at C-17, cholic acid, vit. D_3, cortisone, aldosterone.

5. Anthocyanins: 05
Introduction, general nature, synthesis, structure of anthocyanidin, flavones, isoflavones and depsides.

6. Purines and nucleic acids 03

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 hetero atoms, biological importance of heterocles.

Reference Books:

1. Organic Chemistry, Vol. I & II by Finar, Pearson Education.
2. Organic Chemistry, R. T. Morrison, R. N. Boyd, Prentice-Hall of India Pvt. Ltd., New Delhi.
3. Organic Chemistry, G. Marc Loudon, Oxford University Press., New York.

Gujarat Technological University
M. Pharm. Syllabus
Semester I
Paper Code:910104
QUALITY ASSURANCE SPECIALISATION
Biological Evaluations and Clinical Research

Theory
(Four hours per week, 6 Credits)

Course Content: **Hours**

1. **Biological Standardization:** General Principles, Scope & limitations of Bioassays. Bio-assays of some Official Drugs. **04**
2. **Sterility Tests:** Methodology & Interpretation. **04**
3. **Pyrogen -** chemistry and properties of bacterial pyrogens and endotoxins. Mechanisms of action of pyrogens. Pharmaceutical aspects, pyrogen test of IP compared to that of BP & USP. Interpretation of data, Comparison of LAL and other pyrogen tests. **05**
4. Analysis of drugs from biological samples including, selection of biological sample, extraction of drugs by various methods as LLE, SPE and Membrane filtration. **05**
5. **Microbiological Limit Tests,** Tests for effectiveness of antimicrobial preservatives. **06**
6. **Radio immunoassay:** General principles, scope and limitations, radio immunoassay of some drugs like insulin, digitalis etc. **04**
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. **07**
8. **Clinical Research—**
   a. Clinical Research Protocols, objective and protocol design.
   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**
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. **07**
10. **Pharmacokinetics:-** Basic consideration, Pharmacokinetic models, Application of Pharmacokinetics in new drug development and designing of dosage forms and Novel drug delivery systems. **08**

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.

Reference Books:

1. Indian Pharmacopoeia
2. British Pharmacopoeia
3. U.S. Pharmacopoeia
4. Bengt Ljunggvist and Berit Davis “Microbiological Risk Assessment in Pharm. Clean rooms”. Harwood International Publishing.
5. Richard Prince, “Microbiology in Pharmaceutical Manufacturing”. Davis Harwood International Publishing.
6. Akers, “Parenteral Quality Control: Sterility, Pyrogen, and Package Integrity Testing,” 2nd Edition (Marcel Dekker).
7. D. C. Garratt, The Quantitative Analysis of Drugs, CBS Publishers, 2001, New Delhi..
8. Mark C. Rogge and David R Taft, “Prclinical Drug Development”, Drugs and Pharm. Sci. Series, Vol. 152, Marcel D
9. ekker Inc., N.Y.
11. Donald Monkhouse, Charles Carney and JimClark, “Drug Products For Clinical Trials”. 2nd Ed. v Drugs and Pharm. Sci. Series, Vol. 147, 2nd Ed., Marcel Dekker Inc., N.Y.
12. Leon Shargel, “Applied Biopharmaceutics and Pharmacokinetics”.
13. Welling and Tse.-Pharmacokinetic
14. Gibaldi and Perrier-Pharmacokinetics
15. G. S, Banker & C.T. Rhodes, "Modern Pharmaceutics", Drugs and Pharm. Sci. Series, Vol. 121, 4th Ed., Maracel Dekker Inc., N.Y.
16. Rowland and Tozer-Clinical Pharmacokinetics, concepts and application.
17. Notari.-Biopharmaceutics and Pharmacokinetics-An introduction.
18. John Wagner- Pharmacokinetics for Pharmaceutical scientist.
19. R V Smith, J T Stewart, Textbook of Bio Pharmaceutical Analysis.

Gujarat Technological University
M. Pharm. Syllabus
Semester I
Paper Code 910204
QUALITY ASSURANCE SPECIALISATION
Good Manufacturing and Good Laboratory Practice
Theory
(Four hours per week, 6 Credits)

Course Content: **Hours**

1. Concepts of Philosophy of QA, GMP, GLP **03**
2. Good Manufacturing Practices: I
   a. Organization & Personnel, responsibilities, training, hygiene. **03**
   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. **04**
   c. Equipments: Selection, purchase specifications, maintenance, clean in place, sterilize in place, Methods (TP & STP). **04**
   d. Raw Materials: Purchase specifications, maintenance of Stores, selection of Vendors, control on raw materials and finished dosage forms. **02**
   e. Manufacture of & control on dosage forms: manufacturing documents, master formula, batch formula records, standard operating procedures, quality audits of manufacturing processes and facilities. **08**
   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. **05**
   g. Packaging and labeling control, Line clearance, reconciliation of labels, cartons and other packaging materials. **02**
   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. **06**
   i. Finished product release, quality review, quality audits and batch release documents. **03**
   j. Warehousing, design, construction, maintenance and sanitation; good warehousing practice, materials and management. **02**
   k. Distribution and distribution records, handling of returned goods, recovered materials and reprocessing. **02**
   l. Complaints and recalls, evaluation of complaints, recall procedures, related records and documents. **02**
   m. Waste disposal, scrap disposal procedures and records. **02**
3. Good Laboratory Practices. **04**
4. WHO certification. **02**
5. Testing of Packaging materials. **02**
6. Quality Audit. **02**
7. Specifications for materials, intermediates and finished product. **02**

Reference Books:

1. Sidney H. Willig, "Good Manufacturing Practices for Pharmaceuticals", Drugs and Pharm. Sci. Series, Vol. 109, Marcel Dekker Inc., N.Y.

2. S. Bolton, "Pharmaceutical Statistics: Practical & Clinical Applications", Drugs and Pharm. Sci. Series, Vol. 135, 4th Ed., Marcel Dekker Inc., N.Y
3. G. S, Banker & C.T. Rhodes, "Modern Pharmaceutics", Drugs and Pharm. Sci. Series, Vol. 121, 4th Ed., Maracel Dekker Inc., N.Y.
4. P. P .Sharma “How to practice GMPs”, 3rd edition Vandana Publication.
5. P. P. Sharma “How to practice GLP” Vandana Publication.
6. S. Weinberg, “Good Laboratory Practice Regulation” Drugs and Pharm. Sci. Series, Vol. 124, 2nd Ed., Maracel Dekker Inc., N.Y.
7. WHO’s “Drug” Bulletins.
8. Remingtons “Pharmaceutical Sciences”.
9. GMP practices for pharmaceutical-James Swarbrick.

Gujarat Technological University
M. Pharm. Syllabus
Semester I
Paper Code 910105
Chemistry of Medicinal Natural Products
Theory
(Four hours per week, 6 Credits)

Course Content: **Hours**

1. **Study of different biogenetic pathways of therapeutically important Active constituents.** **15**
2. **Classification, Isolation, structure determination stereochemistry, biological activity of following categories of Naturally occurring components:** **30**
    a. Carbohydrates, Mono, di, oligo- and polysaccharides, Glycoproteins, lipoproteins and glycopeptidolipids.
    b. Lipids and autocoids
    c. Alkaloids: Camptothecin, Vincristine.
    d. Glycosides: Calanolides, Glycyrrhetinic acid,
    e. Resins: Podophyllotoxin.
    f. Terpenoids: Taxol
    g. Antibiotics: Gresiofulvin, Penicillin, Sterptomycin
3. **Advanced methods of extraction of plant metabolites.** **15**
4. **Immunoglobins from Natural source specifically from plants.** **08**

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)

Course Content: **Hours**

1. Factors affecting quality of plant drugs, safe and economical methods 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. **15**
2. Cultivation of *Taxus baccata, Ginseng, Artemisia annua*, *Boswelia serrata, Curcuma longa.* **08**
3. Importance of monographs of standards of medicinal plants and Their parts, comparative study of BHP, API, Chinese, Japanese Herbal Pharmacopoeia, European pharmacopeia, US formulary, WHO, EMEA and ESCOP guidelines for herbal medicinal products. **15**
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**

Reference Books:

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
9. Atal & Kappor- Cultivation and utilization of medicinal plants.
10. Purthi JS- Major spices of India.
11. Alan T, Howard Dalton and Murray Mao-Young—Comprehensive Biotechnology, 'The Principles, application and regulation of biotechnology in Industry,agriculture and Medicine. Vol-1 to 4.
12. Pharmacognosy and Pharmacobiotechnology. Robbers JE, Speedie MK, Tyler VE. William and Wilkins, USA; 1996.
13. Medicinal Natural Products a biosynthetic Approach. Dewick PM. John Wiley and Sons, Torronto, 1998.
14. Chemistry of Natural products. Bhat SV, Nagasampagi BA, Meenakshi S. Narosa Publishing house, New Delhi, 2005.
15. Recent Progress in medicinal Plants. Volumes 1-25. Govil JN, Singh VK, Siddiqui NT. Studim press, LLC USA; 2007.
16. Pharmacodynamic basis of herbal medicines. Ebadi M, CRC press Washington; 2002.
17. Laboratory handbook for fractionation of Natural Products. Houghton PJ and Raman A. Chapman and Hall New York; 1998.

18. Pharmacognosy and Pharmacobiotechnology. Kar A. New Age International Pvt. Ltd.; New Delhi 2003.
19. Pharmacognosy and Phytochemistry of medicinal Plants. 2nd edition. Brunreton J. Intercept Ltd.; New York; 1999.
20. Quality Control, Herbal Drugs, An approach to evaluation of Botanicals. Dr. Pulok K. Mukherjee. Business Horizons Pharmaceutical Publishers; 2002.
21. Herbs of Choice, The Theraputic use of Phytomedicinals. Robbers JE, Tyler VE. Haworth Press Inc., USA; 2002.

Gujarat Technological University

M. Pharm. Syllabus

Semester I

Paper Code 910106

CLINICAL PHARMACY SPECIALISATION

CLINICAL PHARMACY PRACTICE

Theory

(Four hours per week, 6 Credits)

Course Content:		**Hours**
1	**Definitions, development and scope of clinical pharmacy**	**02**
2	**Pharmaceutical care concept**	**02**
3	**Role of clinical Pharmacist in the health care system**	**02**
4	**Routine activities of clinical Pharmacist**	
	a) Drug Therapy monitoring: Medication chart review, Clinical review, Pharmacist interventions.	
	b) Ward round participation	
	c) Recording of Medical History	
	d) Adverse drug reaction monitoring	
	e) Communication skills including patient counseling techniques	
	f) Drug utilization evaluation and review	
5	**Quality assurance of clinical pharmacy services**	**02**
6	**Concept of essential drugs and rational drug usage**	**04**
7	**Self-medication and non-prescription drug usage**	**02**
8	**Prescription monitoring and medication errors**	**03**
9	**Patient Compliance**	**02**
10	**Interpretation of clinical laboratory tests**	**08**
	Hematological, liver function, renal function, thyroid function tests Tests associated with cardiac disorders Fluid and electrolyte balance Micorbiological culture sensitivity tests Pulmonary function tests	
11	**Patient data analysis and Case presentation**	**02**
12	**Drug induced diseases**	**02**
13	**Drug interactions**	**05**
	Documentation and other methods for minimizing clinically relevant drug interactions	
14	**Pharmacovigilance**	**07**
	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**	**07**
	Definition, history, needs of pharmacoeconomic evaluations Outcome assessment and types of phamacoeconomic evaluations: cost-minimization, cost-benefit, cost-effectiveness, cost utility. Applications of pharmacoeconomics: case study	
16	**Critical evaluation of biomedical literature**	**02**

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
Pharmacoeconomics : 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.

Reference Books:

1 Ronald D. Mann, Elizabeth B. Andrews. Pharmacovigilance. John Wiley & Sons Ltd, 2002
2 Text Book of Therapeutics: Drug and Disease Management. 7th Edition. Editors: Eric T. Herfindal and Dick R. Gourley, Williams and Wilkins
3 Clinical Pharmacy and Therapeutics. Roger Walker and Clive Edwards, Churchill Livingstone publication
4 Applied Therapeutics: The Clinical Use or Drugs Eds. Brian S.Katcher, Lioyd Yee Young, Marry Anne Koda-Kimble, Applied Therapeutics Inc. Spokane. Latest Edition.
5 Practice Standards and Definitions – The Society of Hospital Pharmacists ofAustralia.
6 Basic Skills in interpreting laboratory data – Scott LT, American Society of Health System Pharmacists Inc.
7 Biopharmaceutics and Applied Pharmacokinetics – Leon Shargel, Prentice Hall Publication.
8 A textbook of Clinical Pharmacy Practice; Essential concepts and skills, Dr. G. Parthasarthi et al.
9 Australian drug information- Procedure manual. The Society of Hospital Pharmacists of Australia.
10 Textbook of Medical laboratory Technology. Praful B. Godkar, Darshan P.Godkar, Bhalani Publication House, Mumbai. 2nd edition.
11 Clinical Pharmacokinetics- Rowland Tozer, Williams and Wilkins Publication.
12 Pharmaceutical Statistics. Practical and clinical applications. Sanford Bolton, Marcel Dekker Inc.
13 Drug Interaction Facts, 2003. David S. Tatro.
14 Hand Book of Pharmacy Health Care. The Pharmaceutical Press
15 Manual of basis techniques for a health laboratory, 2nd edition, World Health Organization, Geneva.

Gujarat Technological University
M. Pharm. Syllabus
Semester I
Paper Code 910206

CLINICAL PHARMACY SPECIALISATION

CLINICAL AND HOSPITAL PHARMACY (THEORY ONLY)
Theory
(Four hours per week, 6 Credits)

Course Content: **Hours**

1 Pharamcoepidemiology **10**

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**

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 **08**
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:** **07**

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:** **05**

Heavy metals: Arsenic, lead, mercury, iron, copper
Food poisoning

HOSPITAL PHARMACY

6 **Hospital pharmacy – organization and management** **03**

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** **02**

Pharmacy and therapeutic committee (PTC)
Hospital formulary
Hospital committees: Infection committee, Research and Ethical committee

8 **Hospital pharmacy services** **05**

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** **05**

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.

Reference Books:

1 Malcolm Rowland & Thomasn Tozer. Clinical Pharmacakinetics & Concepts and Applications Lippincott Williams & Wilkins 1995
2 Ellenhorns Medical Toxicology – Diagnosis and treatment of poisoning. Mathew J. Ellenhorn.. Williams and Willkins publication, London. Second Edition
3 Hospital Pharmacy by William E. Hassan
4 Brian L. Strom, Stephen E. Kimmel. Textbook of Pharmacoepidemiology. Wiley
5 rug Interactions. Stockley I.H. (1996). The Pharmaceutical Press
6 oxicology - The basic science of poisons, international edition, Curtis D.Klaassen, 6th edition
7 oxicology – Principles and Applications, Raymond J.M.Niesink, John de.Vries,

Mannfred A. Hollinger
8 rug Interaction Facts, 2003. David S. Tatro.
9 oxicology - The basic science of poisons, international edition, Curtis D.Klaassen, 6th edition
10 oxicology – Principles and Applications, Raymond J.M.Niesink, John de.Vries, Mannfred A. Hollinger

Gujarat Technological University

M. Pharm. Syllabus

Semester I

Paper Code - 910107

Subject:- Specialisation Paper - I

Pharmaceutical Analysis-I

Theory –

Four hours per week; 6 Credits

Course Content: **Hours**

1) Application of instrumental methods in the development of medicines, concept of analytical method development. **05**

2) Validation and calibration of various instruments used for drug analysis such as UV-Visible Spectrophotometer, IR Spectrophotometer, Spectrofluorimeter, HPLC, HPTLC and GC. **10**

3) Ion Selective electrodes: Classification, instrumentation and applications in drug analysis. **02**

4) Principles and procedures involved in quantitative determination of following groups (a) Hydroxyl, (b) Aldehyde, (c) Ketone, (d) Ester (e) Amine. **05**

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: **20**

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, B_1, B_2, B_{12}, C & E.
e. Antibiotics like Chloramphenicol, Erythromycin, Penicillin & Streptomycin.
f. Alkaloids of Cinchona, Ergot, Opium & Rauwolfia.
g. Glycosides such as Digitoxin, Digoxin & Strophanthin.

6) Elemental analysis such as determination of sodium, potassium, calcium, phosphorous, sulphur, chlorine, bromine and iodine. **05**

7) Principles and procedures involved in the use of the following reagents in Pharmaceutical analysis : **08**

a. N_1-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-dinitrophyenylhydrazine.

8) Analysis of excipients in solid state - Particle size analysis, X-ray diffraction. **05**

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.
3. Study of Quenching effect in fluorimetry : quenching of quinine by potassium Iodide.
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) Hydroxylgroupb)Carbonylgroupc)Am
      i.
9. Quantitative Colorimetric determination of suitable drugs using following reagents :
10. a) *P*-dimethylaminocinnamaldehyde b) MBTH c) F-C reagent
11. d) 2,6-dichloroquinonechlorimide e) Ninhydrin.
12. Assay of the following official formulations :
    a) a) Frusemide Tablet b) Metformin Tablet c) Chloroquine Tablet
    b) d) Chloramphenicol Capsule e) Digoxin Tablet.
13. HPLC & HPTLC analysis of drugs.

Reference Books:

1. Vogel's : Textbook of quantitative chemical analysis revised by G. H. Jeffery, J. Bassett, J. Mendham, R. C. Denney, 6th Edition, Pearson Education Publishers -New Delhi, 1989, India..
2. H. Beckett and Stenlake, Practical Pharmaceutical Chemistry, Vol. I and Vol. II, 4th Edition CBS Publishers, 1997, New Delhi.
3. K.A Connors : Text Book of Pharmaceutical Analysis, 3rd Edition, Wiley- Inter Science Publication, 1999, New York.
4. Indian Pharmacopoeia, Vol. I & II, 1996, The Controller of Publications, Government of India.
5. John H. Kennedy, Principles of Analytical Chemistry, 2nd Edition, Saunders College Publishing, 1990, New York.
6. Higuchi, Bechmman and Hassan : Pharmaceutical Analysis, 2nd Edition, John Wiley and Sons, New York.
7. D. C. Garratt, The Quantitative Analysis of Drugs, CBS Publishers, 2001, New Delhi.
8. P. D. Sethi, Quantitative Analysis of Drugs in Pharmaceutical Formulation, 3rd Edition.
9. J. W. Munson, Pharmaceutical Analysis - Modern Methods, Part - A & B, 2001.

Gujarat Technological University

M. Pharm. Syllabus

Semester I

Paper Code - 910207

Subject: - Specialization Paper - II

Advanced Spectroscopic Techniques

Theory - Four hours per week; 6 Credits

Course Content: **Hours**

1. Basic principles, instrumentation and application of Chemiluminescence **05**
2. Basic principles, classification, instrumentation and application of LASER. **05**
3. Electron spin resonance (ESR) principle, instrumentation, correlation with proton magnetic resonance, derivative curves, interpretation and application. **08**
4. **Raman Spectroscopy**: Introduction, Principle and application of Raman Spectroscopy. **06**
5. **Photoacoustic Spectroscopy:** Principles, instrumentation and application. **05**
6. **Radiochemical Analysis:** Instruments used-analytical and screening, isotopic dilution, neutron activation and positron emission tomography (PET) **08**
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**
8. **^{13}C Nuclear Magnetic Resonance (^{13}C - 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**

Reference Books:

1. R. M. Silverstein and F. X. Webster, Spectrometric identification of Organic compounds, John Wiley & Sons, New York. (Latest edition).
2. William Kemp, Organic Spectroscopy, ELBS Mac millan, Hampshire, (U. K).
3. D. L. Pavia, G. M. Lampman and G. S. Kriz, Introduction to spectroscopy- A guide for students of Organic chemistry, Harcourt college publishers. (Latest edition).
4. D. H. Williams and I. Fleming, Spectroscopic methods in Organic chemistry, Tata Mc Graw Hill publishing company Ltd, New Delhi, India. (Latest edition).

Gujarat Technological University
M. Pharm. Syllabus
Semester I

Paper code: 910108
Subject of Specialization paper –I
Industrial Pharmacy Paper-I
Theory
(Four hours per week, 6 Credits)

Course Content: **Hours**

1) Pharmaceutical factory location: Selection, layout and planning. Utility services like Humidity, Temperature, Ventilating and air conditioning (HVAC), water system (RO, WFI, hot and cold water), Steam, Electrical services, Compressed air, Vacuum systems, Dust collection, Effluent treatment plant, etc. Service facilities, and personnel facilities **10**
2) Preparation of qualitative and quantitative departmental layout with equipments required for different dosage forms, solids, liquids, semisolids, sterile.
   Plant and Machinery based on various dosage forms: Equipment design, material of plant constructions, selection criteria, factors affecting equipment design, properties and types of material used for plant construction. **10**
3) Detailed study of the equipments required in the manufacture of different dosage forms as per Schedule-M. **10**
4) Preparation of documents like batch manufacturing record (BMR), batch packing record (BPR), and validation protocols **08**
   Preparation of standard operative procedure (SOPs) for equipments and manufacturing or processing steps **08**
5) GMP and its implementation and introduction to PAT **14**
   a. Organization & Personnel, responsibilities, training, hygiene.
   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.
   c. Equipments: Selection, purchase specifications, maintenance, clean in place, sterilize in place, Methods (TP & STP).
   d. Raw Materials: Purchase specifications, maintenance of Stores, selection of Vendors, control on raw materials and finished dosage forms.
   e. Manufacture of & control on dosage forms: manufacturing documents, master formula, batch formula records, standard operating procedures, quality audits of manufacturing processes and facilities.
   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.
   g. Packaging and labeling control, Line clearance, reconciliation of labels, cartons and other packaging materials.
   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.
   i. Finished product release, quality review, quality audits and batch release documents.
   j. Warehousing, design, construction, maintenance and sanitation; good warehousing practice, materials and management.
   k. Distribution and distribution records, handling of returned goods, recovered materials and reprocessing.
   l. Complaints and recalls, evaluation of complaints, recall procedures, related records and documents.

m. Waste disposal, scrap disposal procedures and records.

Reference Books:

1. **Lachman** "The theory and Practice of Industrial Pharmacy
2. **Remingtons** "Pharmaceutical Sciences"
3. Bentley's **Pharmaceutics.**
4. Pharmaceutical facilities: Design, layouts and validation by **Manohar A Potdar**
5. GMP practices for pharmaceutical –**James Swarbrick.**
6. How to practice GMP**s by P.P.Sharma.**
7. Chemical Engineering Plant Design **by Vibrant.**
8. Pharmaceutical Process Validation **by Loftus and Nash.**
9. **G.S. Banker & C.T. Rhodes**, "Modern Pharmaceutics", Drugs and Pharm. Sci. Series, Vol. 7, Maracel Dekker Inc., N.Y.
10. SOP guidelines by D. H. Shah
11. Drug and Cosmetic Act 1940 and rules.

Industrial Pharmacy Paper-I
Practicals
(Four hours per week, 6 Credits)

Practical exercises formulated bases on the topics mentioned in the theory such as
Illustrative flow sheets of each dosage form with detailed idea of placement of equipment, men and material movement and service lines, Equipment selection factors, size and maintenance, preparation of BMR & BPR, Validation , Sampling plans (Product wise), preparation of SOP (Equipment, Process and service lines) and other records.

Gujarat Technological University

M. Pharm. Syllabus

Semester I

Paper code: 910208

Subject of Specialization paper –II

Industrial Pharmacy Paper-II

Theory

(Four hours per week, 6 Credits)

Course Content: **Hours**

1) **Pilot plant and manufacturing scale up technique:** **15**
   Significance, and general requirements, scale up study of some important dosage forms such as tablets, capsules, semi solids, liquids orals and injectables; discussion on important parameters such as formula, equipments, product uniformity, stability, and challenges.
2) **Production, Planning, Control and Documentation:** **15**
   Production scheduling and forecasting; vendor development capacity assessment (Plant, machines, raw materials, human resources); production management, production organization, objectives and policies
   Guide to pharmaceutical manufacturing practices and facilities; implications of reducing costs; documentation.
3) **Inventory Management, Material Management and Maintenance Management:** **20**
   Costs in inventory, inventory categories-special considerations, selective inventory control, recorder quality methods and EOQ, inventory models, safety stock-stock out, lead time-recorder time methods, modern inventory management systems, inventory evaluation. Material- quality and quantity, value analysis, purchasing-centralized and salvaging and disposal of scrap and surplus Selection of material handling systems, maintenance of material-handling equipment, unit-load, pelletization and containerization, types of material handling systems. Classification of maintenance, corrective (breakdown) maintenance, scheduled maintenance, preventive maintenance, predictive maintenance.
4) **Industrial hazards, safety, pollution and effective treatment:** **10**
   Introduction, Factory act and rules, fundamentals of accident prevention, organizing for safety, electrical hazards, industrial chemical and their health hazards, Material handling, Fire prevention and control. Physicochemical measurements of effluents, BOD, COD, Determination of some contaminates Effluent treatment of some characteristic effluent.

Reference Books:

1. Michael Levin, “Pharmaceutical Process Scale up”, Second edition, Marcel Dekker Inc., Volume 157.
2. Joseph F. despautz,” Automation and Validation of Information in Pharmaceutical Processing”, Marcel Dekker Inc., Volume 90.
3. L.C. Jhamb, “Industrial Management”, Everest Publications.
4. C.V.S. Subramanyam, “Pharmaceutical Production and Management”,
5. Leon Lachman, “Theory and Principles of Industrial Pharmacy”, Third edition.
6. G.S, Banker & C.T. Rhodes, "Modern Pharmaceutics", Drugs and Pharm. Sci. Series, Vol. 7, Maracel Dekker Inc., N.Y.
7. **Remingtons** “Pharmaceutical Sciences”
8. Bentley’s **Pharmaceutics.**
9. Pilot plants model and scale-up methods**, by Johnstone and Thring.**
10. How to practice GMP**s by P.P.Sharma.**
11. Chemical Engineering Plant Design **by Vibrant.**
12. Pharmaceutical Facility management **by J.P.S. kohli**