M.Pharm OLD SYLLABUS

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**

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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, 4 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: 06

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

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VAPI.

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 Pharmacopoeal 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 Douglas 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

PRINCIPAL

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 deferencc, rat uterus, guinea pig taenia coli, rat/guinea pig heart, guinea pig tracheal chain, rat aortic strip)

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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 Civoisland – 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.

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Gujarat Technological University
M. Pharm. Syllabus
Semester I

916203 : Subject of Specialization Paper- II

Advances in Pharmacology

Theory

(Four hours per week, 4 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 & Chloramphenicol, 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

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Gujarat Technological University
M. Pharm. Syllabus
Semester I

Paper Code 910001

MODERN ANALYTICAL TECHNIQUES

(Common to all Disciplines)

Theory

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10. ELECTROPHORESIS: 03

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Theory and principles, classifications, instrumentation, moving boundary electrophoresis, Zone Electrophoresis (ZE), Isoelectric focusing (IEF) and applications. **03**

11. RADIO IMMUNO ASSAY:
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
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7. Experiments on Electrophoresis.
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13. Modern Methods of Pharmaceutical Analysis, Vol.1, 2, RE Schirmer,Franklin Book

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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, Bioassays 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.

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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, "Preclinical 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., Marcel 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.

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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.

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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., Marcel Dekker Inc., N.Y.
7. WHO's "Drug" Bulletins.
8. Remingtons "Pharmaceutical Sciences".
9. GMP practices for pharmaceutical-James Swarbrick.

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Gujarat Technological University

M. Pharm.
Semester – I

Structure for First Semester of Master of Pharmacy Course

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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.

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

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Introduction, Principle, Theory and Methods in Radio Immuno Assay. Reliquot Immuno Assay procedures and applications of RIA Techniques. Enzyme immune 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
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   d. Antimicrobials
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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

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M. Pharm. Syllabus

Semester I

Paper code 910103

Subject: - Specialization Paper-I

Pharmaceutical Formulation, Development & Bio pharmaceutics

Theory

(Four hours per week, 4 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 / bracketing 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.

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(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. Biopharmaceutics 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.

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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 GMPs **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.

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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.

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Gujarat Technological University

M. Pharm.
Semester – II

Structure for Second Semester of Master of Pharmacy Course

Sr. No.	Subject	Teaching Scheme Credits		Marking Scheme Theory		Practical	
		Theory	Practical	Ext	Int	Ext	Int
1.	Research Methodology	07	--	80	20	--	--
2.	Subject Specialization of Paper – III	07	08	80	20	80	20
3.	Subject Specialization of Paper – IV	08	--	80	20	--	--
	Total	**22**	**08**				

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Gujarat Technological University

Master of Pharmacy

Semester – II

Paper code -2920001

Research Methodology

(Common to all discipline)

Theory

(Four hours per week, 7 credits)

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

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References Books:

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

PRINCIPAL

Gujarat Technological University

Master of Pharmacy

Semester – II

Paper code -2928103

Specialization paper - III

Pharmacometrics and Methods of biological evaluation of drugs

Theory

(Six hours per week, 7 credits)

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

Specialization paper - III

Pharmacometrics and Methods of biological evaluation of drugs

Practical

(Six hours per week, 8 credits)

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

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Illustrative examples

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

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

References Books:

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

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Gujarat Technological University
Master of Pharmacy
Semester – II
Paper code -2920203
Specialization paper - IV
Pharmacotherapeutics

Theory
(Six hours per week, 8 credits)

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

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

Reference Books:

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

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M. Pharm.
Semester – II

Structure for Second Semester of Master of Pharmacy Course

Sr. No.	Subject	Teaching Scheme Credits		Marking Scheme Theory		Practical	
		Theory	Practical	Ext	Intl	Ext	Intl
1.	Research Methodology	07	-	80	20	--	--
2.	Subject Specialization of Paper – III	07	08	80	20	80	20
3.	Subject Specialization of Paper – IV	08	--	80	20	--	--
	Total	**22**	**08**				

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Gujarat Technological University

Master of Pharmacy

Semester – II

Paper code -2920001

Research Methodology

(Common to all discipline)

Theory

(Four hours per week, 7 credits)

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

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2. Practical Introduction o copyright. - Gavin Mcfarlane
3. Thesis projects in Science & Engineering – Richard M. Davis
4. Scientist in legal Systems- Ann labor science
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Gujarat Technological University
Master of Pharmacy
Semester – II
Paper code -2920104
Specialization paper - III
Modern Pharmaceutical Analysis

Theory
(Six hours per week, 7 credits)

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

Specialization paper - III
Modern Pharmaceutical Analysis
Practical
(Six hours per week, 8 credits)

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

References Books:

1. Harry G Brittain, Spectroscopy of Pharmaceutical Solids. Drugs andPharmSci Series,Vol. 160, Taylor and Francis, 2006 N.Y.
2. S. Ahuja, Modern Pharmaceutical Analysis

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3. Lena Ohannesian and Anthony J. Streeter, Hand Book of Pharmaceutical Analysis, Pharm Sci series, Vol. 117, Marcel Dekker Inc., N.Y.
4. Peptide and Protein Drug Analysis, by Reid, (Marcel Dekker).
5. Classification of cosmetics raw materials and adjuncts IS 5958 of Indian Standards Institution (BIS).
6. Cosmetic and toilet goods – methods of sampling IS 5958 of Indian Standards Institution (BIS).
7. Methods of sampling and test for various cosmetics as laid down by Indian Standard Institution (BIS).
8. Indian Pharmacopoeia Vol. I and Vol. II - 1996 The Controller of Publications, New Delhi, Govt. of India.
9. The International Pharmacopoeia Vol. 1,2,3,4, 3rd Edition. General methods of analysis and quality specifications for pharmaceutical substances, excipients, dosage forms.
10. Quality Assurance of Pharmaceuticals – A compendium of guidelines and related materials Vol.1 and Vol.2, WHO, (1999).
11. Basic tests for pharmaceutical substances – WHO (1988).
12. Basic tests for pharmaceutical dosage forms – WHO (1991).
13. Physicochemical Methods by J.B Hansbrow.
14. Pharmacopoeial standards for Ayurvedic Formulation (Council of Research in Indian Medicine & Homeopathy).

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Gujarat Technological University
Master of Pharmacy
Semester – II
Paper code -2920204
Specialization paper - IV
Regulatory Affairs and New Drug Application

Theory
(Six hours per week, 8 credits)

A) **REGULATORY AFFAIRS**

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

B) **Approval of New drugs**

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

References Books:

1. Drugs and Cosmetics Laws by Krishnan Arora, Professional Book Publishers, New Delhi
2. Mittal B.M., A Textbook of Forensic Pharmacy, 9th Ed., Vallabh Prakashan
3. Deshpande S.W., Drugs and Cosmetic Act.1940.
4. Guarino Richard A, New Drug Approval Process, 3rd Ed., Marcel Dekker Inc.
5. P. Narayan, Intellectual Property Laws, Eastern Law House.
6. Drug and Cosmetic Act 1940, Eastern Book company by Vijay Malik, 11th Ed. Patents for Medicine, by N. B. Zareri, Indian Drug Manufacturers Association (IDMA)
7. Ira R. Berry, "Introduction to the Pharmaceutical Regulatory Process", Drugs and Pharm Sci. Series, Vol. 144, Marcel Dekker Inc., N.Y.
8. The Drugs and Cosmetic Act 1940 – Vijay Malik

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Gujarat Technological University

M. Pharm.
Semester – II

Structure for Second Semester of Master of Pharmacy Course

Sr. No.	Subject	Teaching Scheme Credits		Marking Scheme Theory		Practical	
		Theory	Practical	Ext	Intl	Ext	Intl
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2.	Subject Specialization of Paper – III	07	08	80	20	80	20
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	Total	**22**	**08**				

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Gujarat Technological University

Master of Pharmacy

Semester – II

Paper code -2920001

Research Methodology

(Common to all discipline)

Theory

(Four hours per week, 7 credits)

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

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References Books:

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

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Gujarat Technological University

Master of Pharmacy

Semester – II

Paper code -2920102

Specialization paper - III

Novel Drug Delivery System Part-I

Theory

(Six hours per week, 7 credits)

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

   e.g.: Tablets: Osmotic, Colon target, Gastro-retentive, Buccal, and Sublingual.
   Capsules: Modified release.
   Semi-solids.
   Parenterals.
   Powders: Particle coating, Taste-masking.
   Liquids.

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

Subject of Specialization paper - III
Novel Drug Delivery System Part-I
Practical
(Six hours per week, 8 credits)

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

References 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 Bannker.**
8. United States Pharmacopeia.
9. Drug stability (Principles and Practices) **by Jens. T. Carstensen.**

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Master of Pharmacy

Semester – II

Paper code -2920202

Specialization paper - IV

Global Regulatory Requirements

Theory

(Six hours per week, 8 credits)

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

Reference Book:

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

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GUJARAT TECHNOLOGICAL UNIVERSITY

M. Pharm.

Semester – III

Structure for Third Semester of Master of Pharmacy Course

Sr. No.	Subject	Teaching Scheme		Marking Scheme			
		Credits		Theory		Practical	
		Theory	Practical	Ext	Intl	Ext	Intl
1.	Experimental Design and Patents	07	-	80	20	--	--
2.	Subject Specialization of Paper – V	07	08	80	20	80	20
3.	Introduction to Dissertation	--	08	--	--	80	20
	Total	**14**	**16**				

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M. Pharm.

Semester – III

Paper code -930001

Common Subject for all

Experimental Design and Patents

(Theory only)

(Four hours per week, 7 credits)

1. **Experimentals Designs**
   Introduction to full and fractional factorial designs, Central composite designs, Evolution of full and reduced mathematical models in experimental designs, Applications of the experimental designs for the subject mentioned under Pharmacoinformatics, Introduction to contour plots.
2. **Patents**
   Definition, Need for patenting, Types of Patents, Condition to be satisfied by an invention to be patentable, Introduction to patent search,
   The essential elements of patents, Guidelines for preparations of laboratory notebook, non-obviousness in patents, Drafting of patent claims, important patent related websites.
3. **Brief introduction to trademark protection and WO patents,**
   Introduction to "The Patents Act 1970" and "The Patents Rule 2003", with special emphasis on the forms to be submitted along with a patent application.

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M. Pharm.

Semester – III

Paper code -930103

Clinical Research and Pharmacy Practice

Subject of Specialization Paper- V (Pharmacology)

Theory

(Four hours per week, 7 credits)

1. Clinical development of drug

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

2. Clinical Pharmacy Practice

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

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Clinical Research and Pharmacy Practice

Subject of Specialization Paper- V (Pharmacology)

Practicals

(Six hours per week, 8 credits)

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

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

Reference Books:

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

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Evaluation Scheme for M.Pharm.

SEMESTER – IV (W.e.f -Jan 2012)

Sr.No.	Subject Code	Subject Name	Credits	Evaluation Scheme			TOTAL
				External		Internal	
				Thesis Progress Review	Final Dissertation	Internal Thesis Evaluation	
1	940001 to 940008	Dissertation	30	60	100	40	200

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GUJARAT TECHNOLOGICAL UNIVERSITY

M. Pharm.

Semester – III

Structure for Third Semester of Master of Pharmacy Course

Sr. No.	Subject	Teaching Scheme		Marking Scheme			
		Credits		Theory		Practical	
		Theory	Practical	Ext	Intl	Ext	Intl
1.	Experimental Design and Patents	07	-	80	20	--	--
2.	Subject Specialization of Paper – V	07	08	80	20	80	20
3.	Introduction to Dissertation	--	08	--	--	80	20
	Total	**14**	**16**				

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M. Pharm.

Semester – III

Paper code -930001

Common Subject for all

Experimental Design and Patents

(Theory only)

(Four hours per week, 7 credits)

1. **Experimentals Designs**
   Introduction to full and fractional factorial designs, Central composite designs, Evolution of full and reduced mathematical models in experimental designs. Applications of the experimental designs for the subject mentioned under Pharmacoinformatics, Introduction to contour plots.
2. **Patents**
   Definition, Need for patenting, Types of Patents, Condition to be satisfied by an invention to be patentable, Introduction to patent search,
   The essential elements of patents, Guidelines for preparations of laboratory notebook, non-obviousness in patents, Drafting of patent claims, important patent related websites
3. **Brief introduction to trademark protection and WO patents,**
   Introduction to "The Patents Act 1970" and "The Patents Rule 2003", with special emphasis on the forms to be submitted along with a patent application.

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M. Pharm.

Semester – III

Paper code -930104

Validation and Product Development

Subject of Specialization Paper – V (Quality Assurance)

Theory

(Four hours per week, 7 credits)

1. **Introduction to Pharmaceutical Validation:**
   Definition, Manufacturing Process Model, scope of Validation, Advantage of Validation, Organization for Validation, Validation Master Plan, Types of process validation, Design Qualification, Installation Qualification, Operational Qualification & Performance Qualification of facilities.
2. **Calibration Master plan**
   Validation of Equipment
   Concept of URS, DQ, IQ, OQ & PQ,
   Validation of following equipment
   - Dry Powder Mixers
   - Fluid Bed and Tray dryers.
   - Tablet Compression (Machine)
   - Dry Heat Sterilization/Tunnels
   - Autoclaves
   - Membrane filtration
   - Capsule filling machines.
   - Validation of Integrated lines by media fill test.
   - Validation of existing equipment.
3. **Vendor Certification**
4. **Utilities Validation**
   a. Validation of Pharmaceutical Water System & pure steam,
   b. Validation of HVAC system
   c. Validation of Compressed air
5. **Cleaning Validation:** Cleaning of Equipment, Cleaning of Facilities
6. **Analytical Method Validation**
   General principles of analytical method validation.
   Validation of following analytical Instruments
   - HPLC
   - Dissolution test apparatus
   - U.V./Visible spectrophotometers
7. **Process Validation**
   Prospective, concurrent, retrospective & revalidation, Process validation of following formulations
   - Coated tablets
   - Capsules
   - Ointment/Creams

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- Liquid Orals

8. **Computer System Validation**
9. **Product development**
   a. In-process controls in manufacturing process design and development of:
      Tablets,
      Capsule
      Liquid orals
      Ophthalmic applications
      Aerosols
      Sterile parenteral
   b. Scale up operations, SUPAC guide line.

Validation and Product Development

Subject of Specialization Paper – V (Quality Assurance)

Practical

(Six hours per week, 8 Credits)

1. Validation of following equipment
   a. Autoclave b. Hot air oven c. Powder Mixer (Dry)
   c. Tablet Compression Machine
2. Pre-formulation studies of a model Drug.
3. Validation of analytical method (minimum four exercises).
4. Validation of a processing area.
5. Validation of at least two analytical instruments.
6. Cleaning validation of one equipment.

Reference Books:

1. B. T. Loftus & R. A. Nash, "Pharmaceutical Process Validation", Drugs and Pharm Sci. Series, Vol. 129, 3rd Ed., Marcel Dekker Inc., N.Y.
2. The Theory & Practice of Industrial Pharmacy, 3rd edition, Leon Lachman, Herbert A. Lieberman, Joseph. L. Karig, Varghese Publishing House, Bombay.
3. Validation Master plan by Terveeks or Deeks, Davis Harwood International publishing.
4. Validation of Aseptic Pharmaceutical Processes, 2nd Edition, by Carleton & Agalloco, (Marcel Dekker).
5. Michael Levin, Pharmaceutical Process Scale-Up", Drugs and Pharm. Sci. Series, Vol. 157, 2nd Ed., Marcel Dekker Inc., N.Y.

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GUJARAT TECHNOLOGICAL UNIVERSITY

Evaluation Scheme for M.Pharm.

SEMESTER – IV (W.e.f -Jan 2012)

Sr.No.	Subject Code	Subject Name	Credits	Evaluation Scheme			TOTAL
				External		Internal	
				Thesis Progress Review	Final Dissertation	Internal Thesis Evaluation	
1	940001 to 940008	Dissertation	30	60	100	40	200

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GUJARAT TECHNOLOGICAL UNIVERSITY

M. Pharm.

Semester – III

Structure for Third Semester of Master of Pharmacy Course

Sr. No.	Subject	Teaching Scheme Credits		Marking Scheme Theory		Practical	
		Theory	Practical	Ext	Intl	Ext	Intl
1.	Experimental Design and Patents	07	-	80	20	--	--
2.	Subject Specialization of Paper – V	07	08	80	20	80	20
3.	Introduction to Dissertation	--	08	--	--	80	20
	Total	**14**	**16**				

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Gujarat Technological University

M. Pharm.

Semester – III

Paper code -930001

Common Subject for all

Experimental Design and Patents

(Theory only)

(Four hours per week, 7 credits)

1. **Experimentals Designs**
   Introduction to full and fractional factorial designs, Central composite designs, Evolution of full and reduced mathematical models in experimental designs, Applications of the experimental designs for the subject mentioned under Pharmacoinformatics, Introduction to contour plots.
2. **Patents**
   Definition, Need for patenting, Types of Patents, Condition to be satisfied by an invention to be patentable, Introduction to patent search,
   The essential elements of patents, Guidelines for preparations of laboratory notebook, non-obviousness in patents, Drafting of patent claims, important patent related websites.
3. **Brief introduction to trademark protection and WO patents,**
   Introduction to "The Patents Act 1970" and "The Patents Rule 2003", with special emphasis on the forms to be submitted along with a patent application.

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Gujarat Technological University

M. Pharm.

Semester – III

Paper code -930102

Subject of Specialization Paper – V (Pharmaceutics)

Novel Drug Delivery System: Part – II

Theory

(Four hours per week, 7 credits)

1. Polymer Science Application: Classification, Properties, IIG status and impurity profile, Mechanisms of biodegradation and application in dosage forms.
2. Basic Techniques for development of NDDS: Nanotechnology, Bioadhesive systems, Insitu gels, intelligent drug delivery, and tailor made medicines, Strips, Disketts and film products. Liposomes/niosomes, Ionto and sonophoretic systems.
3. Use of Spherical Techniques, Super and sub-critical fluids, PEGylations. Biotech based products, Proteins and peptides, Immunomoduated molecules. Prodrug approach.

Subject of Specialization Paper – V (Pharmaceutics)

Novel Drug Delivery System: Part – II

Practical

(Six hours per week, 8 credits)

Development of NDDS using novel polymers and technologies studied in theory (as described above)

Reference Books:

1. Encyclopedia of pharmaceutical technology; volume 9 Metered dose inhalers
2. Praveen Tyle , Drug delivery devices: fundamentals and applications, Marcel Dekker.
3. Robinson & Lee, controlled drug delivery: fundamentals and applications, 2nd edition
4. Chien Y.W., Novel fundamentals, developmental concepts, biomedical assessments.
5. Lachman L., Liberman H. A., Kanig J. L., The theory and practise of industrial pharmacy. 2nd Edition 1991, Varghese publishing house,
6. Remington:the science and practice of pharmacy.
7. James Swarbrick, James C. Boylan, Encyclopedia of Pharmaceutical Technology, Marcel Dekker, III.
8. G.S.Banker, Modern Pharmaceutics, 3rd edition.
9. Delivery of Protein Therapeutics, Ajay K.Banga, Phanmatech 2003.
10. Encyclopedia of pharmaceutical technology – volume –16
11. "Computers in Pharmaceutical Technology", Encyclopedia of Pharmaceutical Technology, Volume 3.

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12. The theory & practice of industrial Pharmacy by L.Lachman J.L. Kanning 3rd edition.
New Drug Approval Process, Fifth Edition, edited by Richard A. Guarino
13. Protein Formulation and Delivery, Second Edition, edited by Eugene J. McNally and Jayne E. Hastedt
14. Oral-Lipid Based Formulations: Enhancing the Bioavailability of Poorly Water-soluble Drugs, edited by David J. Hauss
15. Microencapsulation: Methods and Industrial Applications, Second Edition, edited by Simon Benita
16. Supercritical fluid technology for drug product development edited by peter york, uday b. kompella, and boris y. shekunov,drug and the pharmaceutical sciences. Vol 138
17. Polymeric drug delivery systems, edited by glen s. kwon drug and the pharmaceutical sciences. Vol 148
18. Transdermal drug delivery system: 2nd edition, revised and expanded, edited by Richard h.guy and jonathan hadgraft. Drug and the pharmaceutical sciences. Vol 123
19. Bioadhesive drug delivery system, fundamental novel approaches and development, edited by edith mathiowitz, Donald e. chickering III, claus michael lehr. Drug and the pharmaceutical sciences. Vol 98.

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Evaluation Scheme for M.Pharm.

SEMESTER – IV (W.e.f -Jan 2012)

Sr.No.	Subject Code	Subject Name	Credits	Evaluation Scheme			TOTAL
				External		Internal	
				Thesis Progress Review	Final Dissertation	Internal Thesis Evaluation	
1	940001 to 940008	Dissertation	30	60	100	40	200

M.PHARM NEW SYLLABUS

Gujarat Technological University

University Academic

TEACHING SCHEME / DETAIL SYALLBUS

MPHARM - 20 - PHARMACEUTICS

Academic Year - Subject Code Enter Subject Name

L-Lecture; T-Tutorial; P-Practical; E-Theory External; M-Theory Internal; I-Practical Internal; V-Practical External; On Job Training(OJT) is equivalent to Practical

Sr.No	Subcode	Branch code	Eff. From	Subject Name	Category	Sem Year	L	T	P	Total	E	M	I	V	Total
☐	MAT101T	20	2017-18	Modern Pharmaceutical Analytical Techniques	Compulsory	1	4	0	0	4	80	20	0	0	100
☐	MPH102T	20	2017-18	Drug Delivery System	Compulsory	1	4	0	0	4	80	20	0	0	100
☐	MPH103T	20	2017-18	Modern Pharmaceutics	Compulsory	1	4	0	0	4	80	20	0	0	100
☐	MPH104T	20	2017-18	Regulatory Affairs	Compulsory	1	4	0	0	4	80	20	0	0	100
☐	MPH105P	20	2017-18	Pharmaceutics Practical I	Compulsory	1	0	0	12	6	0	0	50	100	150
☐	MSA106P	20	2017-18	Seminar/Assignment	Compulsory	1	0	0	8	4	0	0	100	0	100

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GUJARAT TECHNOLOGICAL UNIVERSITY

M Pharm

SEMESTER: I

Subject Name: MODERN PHARMACEUTICAL ANALYTICAL TECHNIQUES
Subject Code: MAT1013

Scope: This subject deals with various advanced analytical instrumental techniques for identification, characterization and quantification of drugs. Instruments dealt are NMR, Mass spectrometer, IR, HPLC, GC etc.

Objectives: Upon completion of this course the student should be able to

1. Chemicals and Excipients
2. The analysis of various drugs in single and combination dosage forms
3. Theoretical and practical skills of the instruments

Sr. No	Course Contents	Total Hrs
1	**UV-Visible spectroscopy:** Introduction, Theory, Laws, Instrumentation associated with UV-Visible spectroscopy, Choice of solvents and solvent effect and Applications of UVVisible Spectroscopy **IR spectroscopy:** Theory, Modes of Molecular vibrations, Sample handling, Instrumentation of Dispersive and Fourier - Transform IR Spectrometer, Factors affecting vibrational frequencies and Applications of IR spectroscopy **Spectrofluorimetry:** Theory of Fluorescence, Factors affecting fluorescence, Quenchers, Instrumentation and Applications of fluorescence spectrophotometer **Flame emission spectroscopy and Atomic absorption spectroscopy:** Principle, Instrumentation, Interferences and Applications	11
2	**NMR spectroscopy:** Quantum numbers and their role in NMR, Principle, Instrumentation, Solvent requirement in NMR, Relaxation process, NMR signals in various compounds,Chemical shift, Factors influencing chemical shift, Spin-Spin coupling, Coupling constant, Nuclear magnetic double resonance, Brief outline of principles of FT-NMR and 13C NMR, Applications of NMR spectroscopy	10
3	**Mass Spectroscopy:** Principle, Theory, Instrumentation of Mass Spectroscopy, Different types of ionization like electron impact, chemical, field, FAB and MALDI, APCI, ESI, APPI Analyzers of Quadrupole and Time of Flight, Mass fragmentation and its rules, Meta stable ions, Isotopic peaks and Applications of Mass Spectroscopy	10
4	**Chromatography:** Principle, apparatus, instrumentation, chromatographic parameters, factors affecting resolution and applications of the following: a) Paper chromatography b) Thin Layer chromatography c) Ion exchange chromatography d) Column chromatography e) Gas chromatography f) High Performance Liquid chromatography g) Affinity chromatography	11
5	a. **Electrophoresis:** Principle, Instrumentation, Working conditions, factors affecting separation and applications of the following: a) Paper electrophoresis b) Gel electrophoresis c) Capillary electrophoresis d) Zone electrophoresis e) Moving boundary electrophoresis f) Iso electric focusing b. **X ray Crystallography:** Production of X rays, Different X ray diffraction methods, Bragg's law, Rotating crystal technique, X ray powder technique, Types of crystals and applications of Xray diffraction.	9

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6	**Potentiometry**: Principle, thermal transitions and instrumentation (heat flux and power compensation differential) working, Ion selective Electrodes and Application of potentiometry. **Thermal Analysis**: Polymer behavior, factors effecting and instrumentation, and working, application of TGA	9

REFERENCES:

1. Spectrometric Identification of Organic compounds - Robert M Silverstein, Sixth edition, John Wiley & Sons, 2004.
2. Principles of Instrumental Analysis - Douglas A Skoog, F. James Holler, Timothy A. Nieman, 5th edition, Harcourt press, Bangalore, 1998.
3. Instrumental methods of analysis - Willards, 7th edition, CBS publishers.
4. Practical Pharmaceutical Chemistry - Beckett and Stenlake, Vol II, 4th edition, CBS Publishers, New Delhi, 1997.
5. Organic Spectroscopy - William Kemp, 3rd edition, ELBS, 1991.
6. Quantitative Analysis of Drugs in Pharmaceutical formulation - P D Sethi, 3rd Edition, CBS Publishers, New Delhi, 1997.
7. Pharmaceutical Analysis- Modern methods – Part B - J W Munson, Volume 11, Marcel Dekker Series

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M.Pharm
PHARMACEUTICS
SEMESTER: I

Subject Name: DRUG DELIVERY SYSTEMS
Subject Code: MPH102T

SCOPE: This course is designed to impart knowledge on the area of advances in novel drug delivery systems.

OBJECTIVES: Upon completion of the course, student shall be able to understand

1. The various approaches for development of novel drug delivery systems.
2. The criteria for selection of drugs and polymers for the development of delivering system
3. The formulation and evaluation of Novel drug delivery systems.

Sr.No	Course content	Total Hrs
1.	Sustained Release(SR) and Controlled Release (CR) formulations: Introduction & basic concepts, advantages/ disadvantages, factors influencing, Physicochemical & biological approaches for SR/CR formulation, Mechanism of Drug Delivery from SR/CR formulation. Polymers: introduction, definition, classification, properties and application Dosage Forms for Personalized Medicine: Introduction, Definition, Pharmacogenetics, Categories of Patients for Personalized Medicines: Customized drug delivery systems, Bioelectronic Medicines, 3D printing of pharmaceuticals, Telepharmacy	10
2.	Rate Controlled Drug Delivery Systems: Principles & Fundamentals, Types, Activation; Modulated Drug Delivery Systems;Mechanically activated, pH activated, Enzyme activated, and Osmotic activated Drug Delivery Systems Feedback regulated Drug Delivery Systems: Principles & Fundamentals	10
3.	Gastro-Retentive Drug Delivery Systems: Principle, concepts advantages and disadvantages, Modulation of GI transit time approaches to extend GI transit. Buccal Drug Delivery Systems: Principle of muco adhesion, advantages and disadvantages, Mechanism of drug permeation, Methods of formulation and its evaluations.	10
4.	Ocular Drug Delivery Systems: Barriers of drug permeation, Methods to overcome barriers.	6
5.	Transdermal Drug Delivery Systems: Structure of skin and barriers, Penetration enhancers, Transdermal Drug Delivery Systems, Formulation and evaluation	10
6	Protein and Peptide Delivery: Barriers for protein delivery. Formulation and Evaluation of delivery systems of proteins and other macromolecules.	8
7	Vaccine delivery systems: Vaccines, uptake of antigens, single shot vaccines, mucosal and transdermal delivery of vaccines.	6

REFERENCES:

1. Y W. Chien, Novel Drug Delivery Systems, 2nd edition, revised and expanded, Marcel Dekker, Inc., New York, 1992.

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2. Robinson, J. R., Lee V. H. L, Controlled Drug Delivery Systems, Marcel Dekker,Inc., New York, 1992.
3. Encyclopedia of controlled delivery. Editor- Edith Mathiowitz, Published by WileyInterscience Publication, John Wiley and Sons, Inc. New York/ Chichester/Weinheim
4. N.K. Jain, Controlled and Novel Drug Delivery, CBS Publishers & Distributors, New Delhi, First edition 1997 (reprint in 2001).
5. S.P.Vyas and R.K.Khar, Controlled Drug Delivery - concepts and advances, Vallabh Prakashan, New Delhi, First edition 2002

JOURNALS:

1. Indian Journal of Pharmaceutical Sciences (IPA)
2. Indian drugs (IDMA)
3. Journal of controlled release (Elsevier Sciences) desirable
4. Drug Development and Industrial Pharmacy (Marcel & Decker) desirable

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M.Pharm

PHARMACEUTICS

SEMESTER: I

Subject Name: MODERN PHARMACEUTICS
Subject Code: MPH103T

SCOPE: Course designed to impart advanced knowledge and skills required to learn various aspects and concepts in pharmaceutical industries

OBJECTIVES: Upon completion of the course, student shall be able to understand

1. The elements of preformulation studies.
2. The Active Pharmaceutical Ingredients and Generic drug Product development
3. Industrial Management and GMP Considerations
4. Optimization Techniques & Pilot Plant Scale Up Techniques
5. Stability Testing, sterilization process & packaging of dosage forms.

Sr.No	Course content	Total Hrs
1.	a. Preformation Concepts – Drug Excipient interactions – different methods, kinetics of stability, Stability testing. Theories of dispersion and pharmaceutical Dispersion (Emulsion and Suspension, SMEDDS) preparation and stability Large and small volume parental – physiological and formulation consideration, Manufacturing and evaluation. b. Optimization techniques in Pharmaceutical Formulation: Concept and parameters of optimization, Optimization techniques in pharmaceutical formulation and processing. Statistical design, Response surface method, Contour designs, Factorial designs and application in formulation	10 10
2.	Validation : Introduction to Pharmaceutical Validation, Scope & merits of Validation, Validation and calibration of Master plan, ICH & WHO guidelines for calibration and validation of equipments. Validation of specific dosage form, Types of validation. Government regulation. Manufacturing Process Model, URS, DQ, IQ, OQ & P.Q. of facilities.	10
3.	cGMP & Industrial Management: Objectives and policies of current good manufacturing practices, layout of buildings, services, equipments and their maintenance Production management: Production organization, , materials management, handling and transportation, inventory management and control, production and planning control, Sales forecasting, budget and cost control, industrial and personal relationship. Concept of Total Quality Management.	10
4.	Compression and compaction: Physics of tablet compression, compression, consolidation, effect of friction, distribution of forces, compaction profiles. Solubility	10
5.	Study of consolidation parameters; Diffusion parameters, Dissolution parameters and Pharmacokinetic parameters, Heckel plots, Similarity factors – f2 and f1, Higuchi and Peppas plot, Linearity Concept of significance, Standard deviation , Chi square test, students T-test , ANOVA test	10

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REFERENCES:

1. Theory and Practice of Industrial Pharmacy By Lachmann and Liberman
2. Pharmaceutical dosage forms: Tablets Vol. 1-3 by Leon Lachmann.
3. Pharmaceutical Dosage forms: Disperse systems, Vol, 1-2, By Leon Lachmann
4. Pharmaceutical Dosage forms: Parenteral medications Vol. 1-2. By Leon Lachmann.
5. Modern Pharmaceutics, By Gilbert and S. Banker
6. Remington's Pharmaceutical Sciences.
7. Advances in Pharmaceutical Sciences Vol. 1-5, By H.S. Bean & A.H.Beckett
8. Physical Pharmacy, By Alfred martin
9. Bentley's Textbook of Pharmaceutics – by Rawlins
10. Good manufacturing practices for Pharmaceuticals: A plan for total quality control, Second edition. By Sidney H. Willig
11. Quality Assurance Guide; By Organization of Pharmaceutical producers of India.
12. Drug Stemulation manual; By D.P.S. Kohli and D.H.Shah. Eastern publishers, New Delhi.
13. How to practice GMPs; By P.P.Sharma. Vandhana Publications, Agra.
14. Pharmaceutical Process Validation; By Fra. B. Berry and Robert A. Nash.
15. Pharmaceutical Preformulations; By J.J. Wells.
16. Applied production and operations management; By Evans, Anderson, Sweeney and Williams.
17. Encyclopaedia of Pharmaceutical technology, Vol I – III.

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GUJARAT TECHNOLOGICAL UNIVERSITY

M.Pharm
PHARMACEUTICS
SEMESTER: I

Subject Name: REGULATORY AFFAIRS
Subject Code: MPH104T

SCOPE: Course designed to impart advanced knowledge and skills required to learn the concept of generic drug and their development, various regulatory filings in different countries, different phases of clinical trials and submitting regulatory documents : filing process of IND, NDA and ANDA

OBJECTIVES: Upon completion of the course, student shall be able to understand

1. The Concepts of innovator and generic drugs, drug development process.
2. The Regulatory guidance's and guidelines for filing and approval Process
3. Preparation of Dossiers and their submission to regulatory agencies in different countries
4. Post approval regulatory requirements for actives and drug products
5. Submission of global documents in CTD/ eCTD formats
6. Clinical trials requirements for approvals for conducting clinical trials
7. Pharmacovigilence and process of monitoring in clinical trials.

Sr.No	Course content	Total Hrs
1.	a. Documentation in Pharmaceutical industry: Master formula record, DMF (Drug Master File), distribution records. Generic drugs product development Introduction , Hatch- Waxman act and amendments, CFR (CODE OF FEDERAL REGULATION) ,drug product performance, in-vitro, ANDA regulatory approval process, NDA approval process, BE and drug product assessment, in –vivo, scale up process approval changes, post marketing surveillance, outsourcing BA and BE to CRO. b. Regulatory requirement for product approval: API, biologics, novel, therapies obtaining NDA, ANDA for generic drugs ways and means of US registration for foreign drugs	15
2.	CMC, post approval regulatory affairs. Regulation for combination Products and medical devices.CTD and ECTD format, industry and FDA liaison. ICH - Guidelines of ICH-Q, S E, M. Regulatory requirements of EU, MHRA, TGA and ROW countries	15
3.	Non clinical drug development: Global submission of IND, NDA, ANDA. Investigation of medicinal products dossier, dossier (IMPD) and investigator brochure (IB).	15
4.	Clinical trials: Developing clinical trial protocols. Institutional review board/ independent ethics committee Formulation and working procedures informed Consent process and procedures. HIPAA- new, requirement to clinical study process, pharmacovigilance safety monitoring in clinical trials.	15

REFERENCES:

1. Generic Drug Product Development, Solid Oral Dosage forms, Leon Shargel and IsaderKaufer,Marcel Dekker series, Vol.143
2. The Pharmaceutical Regulatory Process, Second Edition Edited by Ira R. Berry and Robert P.Martin, Drugs and the Pharmaceutical Sciences,Vol.185, Informa Health care Publishers.

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3. New Drug Approval Process: Accelerating Global Registrations By Richard A Guarino, MD,5th edition, Drugs and the Pharmaceutical Sciences,Vol 190.
4. Guidebook for drug regulatory submissions / Sandy Weinberg. By John Wiley & Sons Inc.
5. FDA regulatory affairs: a guide for prescription drugs, medical devices, and biologics/edited By Douglas J. Pisano, David Mantus.
6. Clinical Trials and Human Research: A Practical Guide to Regulatory Compliance By Fay A.Rozovsky and Rodney K. Adams
7. www.ich.org/
8. www.fda.gov/
9. europa.eu/index_en.htm
10. https://www.tga.gov.au/tga-basics

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GUJARAT TECHNOLOGICAL UNIVERSITY

M.Pharm
PHARMACEUTICS
SEMESTER: I

Subject Name: PHARMACEUTICS PRACTICALS - I
Subject Code: MPH11015T

List of Practicals:

PART A:

1. Analysis of pharmacopoeial compounds and their formulations by UV Vis spectrophotometer
2. Simultaneous estimation of multi component containing formulations by UV spectrophotometry
3. Experiments based on HPLC
4. Experiments based on Gas Chromatography
5. Estimation of riboflavin/quinine sulphate by fluorimetry
6. Estimation of sodium/potassium by flame photometry

PART B:

1. To perform In-vitro dissolution profile of CR/ SR marketed formulation
2. Formulation and evaluation of sustained release matrix tablets
3. Formulation and evaluation osmotically controlled DDS
4. Preparation and evaluation of Floating DDS- hydro dynamically balanced DDS
5. Formulation and evaluation of Muco adhesive tablets.
6. Formulation and evaluation of trans dermal patches.
7. To carry out preformulation studies of tablets.
8. To study the effect of compressional force on tablets disintegration time.
9. To study Micromeritic properties of powders and granulation.
10. To study the effect of particle size on dissolution of a tablet.
11. To study the effect of binders on dissolution of a tablet.
12. To plot Heckal plot, Higuchi and peppas plot and determine similarity factors.
13. To perform stability testing of drug in liquid formulation.
14. To prepare and evaluate self-micro emulsifying drug delivery system (SMEDDS).
15. To perform calibration study of dissolution test apparatus.
16. To calculate standard deviation; perform Chi square test, students T-test and ANOVA test for given data.

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University Academic

TEACHING SCHEME / DETAIL SYALLBUS

MPharmM - 24 - PHARMACEUTICAL QUALITY ASSURANCE - 1 -

Academic Year - Subject Code Enter Subject Name

*L-Lectures,T-Tutorial,P-Practical,E-TheoryExternal,M-TheoryInternal,I-Practical Internal,V-Practical External,OI-Job Training(OJT) is equivalent to Practical

	MAT101T	24	2017-18	Modern Pharmaceutical Analytical Techniques	Compulsory	1	4	0	0	4	80	20	0	0	100
	MQA102T	24	2017-18	Quality Management System	Compulsory	1	4	0	0	4	80	20	0	0	100
	MQA103T	24	2017-18	Quality Control and Quality Assurance	Compulsory	1	4	0	0	4	80	20	0	0	100
	MQA104T	24	2017-18	Product Development and Technology Transfer	Compulsory	1	4	0	0	4	80	20	0	0	100
	MQA105P	24	2017-18	Pharmaceutical Quality Assurance Practical I	Compulsory	1	0	0	12	6	0	0	50	100	150
	MSA106P	24	2017-18	Seminar/Assignment	Compulsory	1	0	0	8	4	0	0	100	0	100

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GUJARAT TECHNOLOGICAL UNIVERSITY

M.Pharm

SEMESTER: I

Subject Name: MODERN PHARMACEUTICAL ANALYTICAL TECHNIQUES
Subject Code: MAT101T

Scope: This subject deals with various advanced analytical instrumental techniques for identification, characterization and quantification of drugs. Instruments dealt are NMR, Mass spectrometer, IR, HPLC, GC etc...

Objectives: Upon completion of this course the student should be able to

1. Chemicals and Excipients
2. The analysis of various drugs in single and combination dosage forms
3. Theoretical and practical skills of the instruments

Sr. No	Course Contents	Total Hrs
1	**UV-Visible spectroscopy:** Introduction, Theory, Laws, Instrumentation associated with UV-Visible spectroscopy, Choice of solvents and solvent effect and Applications of UVVisible Spectroscopy **IR spectroscopy:** Theory, Modes of Molecular vibrations, Sample handling, Instrumentation of Dispersive and Fourier - Transform IR Spectrometer, Factors affecting vibrational frequencies and Applications of IR spectroscopy **Spectrofluorimetry:** Theory of Fluorescence, Factors affecting fluorescence, Quenchers, Instrumentation and Applications of fluorescence spectrophotometer **Flame emission spectroscopy and Atomic absorption spectroscopy:** Principle, Instrumentation, Interferences and Applications	11
2	**NMR spectroscopy:** Quantum numbers and their role in NMR, Principle, Instrumentation, Solvent requirement in NMR, Relaxation process, NMR signals in various compounds,Chemical shift, Factors influencing chemical shift, Spin-Spin coupling, Coupling constant, Nuclear magnetic double resonance, Brief outline of principles of FT-NMR and 13C NMR, Applications of NMR spectroscopy	10
3	**Mass Spectroscopy:** Principle, Theory, Instrumentation of Mass Spectroscopy, Different types of ionization like electron impact, chemical, field, FAB and MALDI, APCI, ESI, APPI Analyzers of Quadrupole and Time of Flight, Mass fragmentation and its rules, Meta stable ions, Isotopic peaks and Applications of Mass Spectroscopy	10
4	**Chromatography:** Principle, apparatus, instrumentation, chromatographic parameters, factors affecting resolution and applications of the following: a) Paper chromatography b) Thin Layer chromatography c) Ion exchange chromatography d) Column chromatography e) Gas chromatography f) High Performance Liquid chromatography g) Affinity chromatography	11
5	a. **Electrophoresis:** Principle, Instrumentation, Working conditions, factors affecting separation and applications of the following: a) Paper electrophoresis b) Gel electrophoresis c) Capillary electrophoresis d) Zone electrophoresis e) Moving boundary electrophoresis f) Iso electric focusing b. **X ray Crystallography:** Production of X rays, Different X ray diffraction methods, Bragg's law, Rotating crystal technique, X ray powder technique, Types of crystals and applications of Xray diffraction.	9

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6	**Potentiometry**: Principle, thermal transitions and instrumentation (heat flux and power compensation anddesigns) working, Ion selective Electrodes and Application of potentiometry. **Thermal Analysis**: Polymer behavior, factors affecting and instrumentation, and working, applications of TGA	9

REFERENCES:

1. Spectrometric Identification of Organic compounds - Robert M Silverstein, Sixth edition, John Wiley & Sons, 2004.
2. Principles of Instrumental Analysis - Douglas A Skoog, F. James Holler, Timothy A. Nieman, 5th edition, Eastern press, Bangalore, 1998.
3. Instrumental methods of analysis - Willards, 7th edition, CBS publishers.
4. Practical Pharmaceutical Chemistry – Beckett and Stenlake, Vol II, 4th edition, CBS Publishers, New Delhi, 1987.
5. Organic Spectroscopy - William Kemp, 3rd edition, ELBS, 1991.
6. Quantitative Analysis of Drugs in Pharmaceutical formulation - P D Sethi, 3rd Edition, CBS Publishers, New Delhi, 1997.
7. Pharmaceutical Analysis- Modern methods – Part B - J W Munson, Volume 11, Marcel Dekker Series

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GUJARAT TECHNOLOGICAL UNIVERSITY

M.Pharm

PHARMACEUTICAL QUALITY ASSURANCE

SEMESTER: I

Subject Name: QUALITY MANAGEMENT SYSTEMS
Subject Code: MQA102T

Scope: This course deals with the various aspects of quality control and quality assurance aspects of pharmaceutical industries. It covers the important aspects like cGMP, QC tests, documentation, quality certifications, GLP and regulatory affairs.

Objectives: Upon completion of this course the student should be able to

1. Understand the cGMP aspects in a pharmaceutical industry
2. To appreciate the importance of documentation
3. To understand the scope of quality certifications applicable to Pharmaceutical industries
4. To understand the responsibilities of QA & QC departments.

Sr No	Course Contents	Total Hrs
1	Introduction to Quality: Evolution of Quality, Definition of Quality, Dimensions of Quality Quality as a Strategic Decision: Meaning of strategy and strategic quality management, mission and vision statements, quality policy, Quality objectives, strategic planning and implementation, McKinsey 7s model, Competitive analysis, Management commitment to quality Customer Focus: Meaning of customer and customer focus, Classification of customers, Customer focus, Customer perception of quality, Factors affecting customer perception, Customer requirements, Meeting customer needs and expectations, Customer satisfaction and Customer delight, Handling customer complaints, Understanding customer behavior, concept of internal and external customers. Case studies. Cost of Quality: Cost of quality, Categories of cost of Quality, Models of cost of quality, Optimising costs, Preventing cost of quality.	12
2	Pharmaceutical quality Management: Basics of Quality Management, Total Quality Management (TQM), Principles of Six sigma, ISO 9001:2008, 9001:2015, ISO 14001:2004, Pharmaceutical Quality Management – ICH Q10, Knowledge management, Quality Metrics, Operational Excellence and Quality Management Review, OSHAS guidelines, NABL certification and accreditation, CFR-21 part 11, WHO-GMP requirements.	12
3	Six System Inspection model: Quality Management system, Production system, Facility and Equipment system, Laboratory control system, Materials system, Packaging and labeling system. Concept of self inspection. Quality systems: Change Management/ Change control, Deviations, Out of Specifications (OOS), Out of Trend (OOT), Complaints - evaluation and handling, Investigation and determination of root cause, Corrective & Preventive Actions (CAPA), Returns and Recalls, Vendor Qualification, Annual Product Reviews, Batch Review and Batch Release. Concept of IPQC, area clearance/ Line clearance.	12

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4	Drug Stability: ICH guidelines for stability testing of drug substances and drug products. Study of ICH Q8, Quality by Design and Process development report Quality risk management: Introduction, risk assessment, risk control, risk review, risk management tools, HACCP, risk ranking and filtering according to ICH Q9 guidelines.	12
5	Statistical Process control (SPC): Definition and Importance of SPC, Quality measurement in manufacturing, Statistical control charts - concepts and general aspects, Advantages of statistical control, Process capability, Estimating Inherent or potential capability from a control chart analysis, Measuring process control and quality improvement, Pursuit of decreased process variability.	8
6	Regulatory Compliance through Quality Management and development of Quality Culture Benchmarking: Definition of benchmarking, Reasons for benchmarking, Types of Benchmarking, Benchmarking process, Advantages of benchmarking, Limitations of benchmarking.	4

REFERENCES:

1. Implementing Juran's Road Map for Quality Leadership: Benchmarks and Results, By Al Endres, Wiley, 2000
2. Understanding, Managing and Implementing Quality: Frameworks, Techniques and Cases, By Jiju Antony, David Preece, Routledge, 2002
3. Organizing for High Performance: Employee Involvement, TQM, Reengineering, and Knowledge Management in the Fortune 1000: The CEO Report By Edward E. Lawler, Susan Albers Mohrman, George Benson, Jossey-Bass, 2001
4. Corporate Culture and the Quality Organization By James W. Fairfield- Sonn, Quorum Books, 2001
5. The Quality Management Sourcebook: An International Guide to Materials and Resources By Christine Avery, Diane Zabel, Routledge, 1997
6. The Quality Toolbox, Second Edition, Nancy R. Tague, ASQ Publications
7. Juran's Quality Handbook, Sixth Edition, Joseph M. Juran and Joseph A. De Feo, ASQ Publications
8. Root Cause Analysis, The Core of Problem Solving and Corrective Action, Duke Okes, 2009, ASQ Publications.

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GUJARAT TECHNOLOGICAL UNIVERSITY

M.Pharm

PHARMACEUTICAL QUALITY ASSURANCE

SEMESTER: I

Subject Name: QUALITY CONTROL AND QUALITY ASSURANCE
Subject Code: MQA103T

Scope: This course is designed to impart fundamental knowledge and concepts about various quality management principles and systems utilized in the manufacturing industry. It also aids in understanding the quality evaluation in the pharmaceutical industries.

Objectives: Upon completion of this course the student should be able to

1. The importance of quality
2. ISO management systems
3. Tools for quality improvement
4. Analysis of issues in quality
5. Quality evaluation of pharmaceuticals
6. Stability testing of drug and drug substances
7. Statistical approaches for quality

Sr No	Course Contents	Total Hrs
1	Introduction: Concept and evolution and scopes of Quality Control and Quality Assurance, Good Laboratory Practice, GMP, Overview of ICH Guidelines - QSEM, with special emphasis on Qseries guidelines. Good Laboratory Practices: Scope of GLP, Definitions, Quality assurance unit, protocol for conduct of non clinical testing, control on animal house, report preparation and documentation. CPCSEA guidelines.	12
2	cGMP guidelines according to schedule M, USFDA (inclusive of CDER and CBER) Pharmaceutical Inspection Convention(PIC), WHO and EMEA covering: Organization and personnel responsibilities, training, hygiene and personal records, drug industry location, design, construction and plant lay out, maintenance, sanitation, environmental control, utilities and maintenance of sterile areas, control of contamination and Good Warehousing Practice.	12
3	Analysis of raw materials, finished products, packaging materials, in process quality control (IPQC), Developing specification (ICH Q6 and Q3), purchase specifications and maintenance of stores for raw materials. In process quality control and finished products quality control for following dosage forms in Pharma industry according to Indian, US and British pharmacopoeias: tablets, capsules, ointments, suppositories, creams, parenterals, ophthalmic and surgical products (How to refer pharmacopoeias).	12
4	Documentation in pharmaceutical industry: Three tier documentation, Policy, Procedures and Work instructions, and records (Formats). Basic principles- How to maintain, retention and retrieval etc. Standard operating procedures (How to write), Master Batch Record, Batch Manufacturing	12

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	Record, Quality audit plan and reports. Specification and test procedures, Protocols and reports. Distribution records. Electronic data handling. Concepts of controlled and uncontrolled documents. Submission documents for regulatory DMFs, as Common Technical Document and Electronic Common Technical Documentation (CTD, eCTD). Concept of regulated and non regulated markets.	
5.	Manufacturing operations and controls: Sanitation of manufacturing premises, mix-ups and cross contamination, processing of intermediates and bulk products, packaging operations, IPQC, release of finished product, process deviations, charge-in of components, time limitations on production, drug product inspection, expiry date calculation, calculation of yields, production record review, change control, sterile products, aseptic process control, packaging, reprocessing, salvaging, handling of waste and scrap disposal. Introduction, scope and importance of intellectual property rights. Concept of trade mark, copyright and patents.	12

REFERENCES:

1. Quality Assurance Guide by organization of Pharmaceutical Procedures of India, 3rd revised edition, Volume I & II, Mumbai, 1996.
2. Good Laboratory Practice Regulations, 2nd Edition, Sandy Weinberg Vol. 69, Marcel Dekker Series, 1995.
3. Quality Assurance of Pharmaceuticals- A compedium of Guide lines and Related materials Vol I & II, 2nd edition, WHO Publications, 1999.
4. How to Practice GMP's – P P Sharma, Vandana Publications, Agra, 1991.
5. The International Pharmacopoeia – vol I, II, III, IV & V - General Methods of Analysis and Quality specification for Pharmaceutical Substances, Excepients and Dosage forms, 3rd edition, WHO, Geneva, 2005.
6. Good laboratory Practice Regulations – Allen F. Hirsch, Volume 38, Marcel Dekker Series, 1989.
7. ICH guidelines
8. ISO 9000 and total quality management
9. The drugs and cosmetics act 1940 – Deshpande, Nilesh Gandhi, 4th edition, Susmit Publishers, 2006.
10. QA Manual – D.H. Shah, 1st edition, Business Horizons, 2000.
11. Good Manufacturing Practices for Pharmaceuticals a plan for total quality control – Sidney H. Willig, Vol. 52, 3rd edition, Marcel Dekker Series.
12. Steinborn L. GMP/ISO Quality Audit Manual for Healthcare Manufacturers and Their Suppliers, Sixth Edition, (Volume 1 - With Checklists and Software Package). Taylor & Francis; 2003.
13. Sarker DK. Quality Systems and Controls for Pharmaceuticals. John Wiley & Sons; 2008.
14. Packaging of Pharmaceuticals.
15. Schedule M and Schedule N.

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GUJARAT TECHNOLOGICAL UNIVERSITY

M.Pharm

PHARMACEUTICAL QUALITY ASSURANCE

SEMESTER: I

Subject Name: PRODUCT DEVELOPMENT AND TECHNOLOGY TRANSFER
Subject Code: MQA104T

Scope: This deal with technology transfer covers the activities associated with Drug Substance, Drug Product and analytical tests and methods, required following candidate drug selection to completion of technology transfer from R&D to the first receiving site and technology transfer related to post-marketing changes in manufacturing places.

Objectives: Upon completion of this course the student should be able to

1. To understand the new product development process
2. To understand the necessary information to transfer technology from R&D to actual manufacturing by sorting out various information obtained during R&D
3. To elucidate necessary information to transfer technology of existing products between various manufacturing places

Sr No	Course Contents	Total Hrs
1	Principles of Drug discovery and development. Introduction, Clinical research process, Development and informational content for Investigational New Drugs Application (IND), New Drug Application (NDA), Abbreviated New Drug Application (ANDA), Supplemental New Drug Application (SNDA), Scale Up Post Approval Changes (SUPAC) and Bulk active chemical Post approval changes (BACPAC), Post marketing surveillance, Product registration guidelines – CDSCO, USFDA	12
2	Pre-formulation studies: Introduction/concept, organoleptic properties, purity, impurity profiles, particle size, shape and surface area. Solubility, Methods to improve solubility of Drugs: Surfactants & its importance, co-solvency. Techniques for the study of Crystal properties and polymorphism. Pre-formulation protocol. Stability testing during product development	12
3	Pilot plant scale up: Concept, Significance, design, layout of pilot plant scale up study, operations, large scale manufacturing techniques (formula, equipment, process, stability and quality control) of solids, liquids, semisolid and parenteral dosage forms. New era of drug products: opportunities and challenges.	12
4	Pharmaceutical packaging: Pharmaceutical dosage form and their packaging requirments, Pharmaceutical packaging materials, Medical device packaging, Enteral Packaging, Aseptic packaging systems, Container closure systems, Issues facing modern drug packaging, Selection and evaluation of Pharmaceutical packaging materials. Quality control test: Containers, closures and secoodary packing materials.	12
5	Technology transfer: Development of technology by R & D, Technology transfer from R & D to production, Optimization and Production, Qualitative and quantitative technology models, Documentation in technology transfer: Development report, technology transfer plan and Exhibit.	12

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REFERENCES:

1. The process of new drug discovery and development. I and II Edition (2006) by Charles G. Smith, James T and O. Donnell. CRC Press, Group of Taylor and Francis.
2. Leon Lac Lachman, Herbert A. Liberman. Theory and Practice of Industrial Pharmacy. Marcel Dekker Inc. New York.
3. Sidney H Willing, Murray M. Tuckerman. William Hitchings IV, Good manufacturing of pharmaceuticals (A Plan for total quality control) 3rd Edition. Bhalani publishing house Mumbai.
4. Tablets Vol. I, II, III by Leon Lachman, Herbert A. Liberman, Joseph B. Schwartz, 2nd Edn. (1989) Marcel Dekker Inc. New York.
5. Text book of Bio- Pharmaceutics and clinical Pharmacokinetics by Milo Gibaldi, 3rd Edn, Lea & Febriger, Philadelphia.
6. Pharmaceutical product development. Vandana V. Patrevale. John I. Dsouza. Maharukh T.Rustomji. CRC Press, Group of Taylor and Francis.
7. Dissolution, Bioavailability and Bio-Equivalence by Abdou H.M. Mack Publishing company, Eastern Pennsylvania.
8. Remingtons Pharmaceutical Sciences, by Alfonso & Gennaro, 19th Edn.(1995)OO2C Lippincott, Williams and Wilkins A Wolters Kluwer Company, Philadelphia.
9. The Pharmaceutical Sciences; the Pharma Path way 'Pure and applied Pharmacy' by D. A Sawant, Pragathi Books Pvt. Ltd.
10. Pharmaceutical Packaging technology by D.A. Dean. E.R. Evans, I.H. Hall. 1st Edition(Reprint 2006). Taylor and Francis. London and New York.

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GUJARAT TECHNOLOGICAL UNIVERSITY

M.Pharm

PHARMACEUTICAL QUALITY ASSURANCE

SEMESTER: I

Subject Name: PHARMACEUTICAL QUALITY ASSURANCE
Subject Code: MQA103P

List of Practicals:

PART A:

1. Analysis of pharmacopoeial compounds and their formulations by UV Vis spectrophotometer
2. Simultaneous estimation of multi component containing formulations by UV spectrophotometry
3. Experiments based on HPLC
4. Experiments based on Gas Chromatography
5. Estimation of riboflavin/quinine sulphate by fluorimetry
6. Estimation of sodium/potassium by flame photometry

PART B:

1. Case studies on
   a. Total Quality Management
   b. Six Sigma
   c. Change Management/ Change control. Deviations,
   d. Out of Specifications (OOS)
   e. Out of Trend (OOT)
   f. Corrective & Preventive Actions (CAPA)
   g. Deviations
2. Development of Stability study protocol
3. Estimation of process capability
4. In process and finished product quality control tests for tablets, capsules,
5. parenterals and semisolid dosage forms.
6. Assay of raw materials as per official monographs
7. Testing of related and foreign substances in drugs and raw materials
8. To carry out pre formulation study for tablets, parenterals (2 experiment).
9. To study the effect of pH on the solubility of drugs, (1 experiment)
10. Quality control tests for Primary and secondary packaging materials
11. Accelerated stability studies (1 experiment)
12. Improved solubility of drugs using surfactant systems (1 experiment)
13. Improved solubility of drugs using co-solvency method (1 experiment)
14. Determination of Pka and Log p of drugs.

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TEACHING SCHEME / DETAIL SYALLBUS

MPHARM - 25 - PHARMACOLOGY - I -

Academic Year - Subject Code Enter Subject Name

*L=Lectures,T=Tutorial,P=Practical,T=Theory(Internal),M=Theory(Internal),I=Practical Internal,V=Practical External,On Job Training(OJT) is equivalent to Practical

Sem	Subject code	Subject credits	Eff. from	Subject Name	Category	Exam Year	L	T	P	Total	E	M	I	V	Total
☐	MAT101T	25	2017-18	Modern Pharmaceutical Analytical Techniques	Compulsory	1	4	0	0	4	80	20	0	0	100
☐	MPL102T	25	2017-18	Advanced Pharmacology-I	Compulsory	1	4	0	0	4	80	20	0	0	100
☐	MPL103T	25	2017-18	Pharmacological and Toxicological Screening Methods-I	Compulsory	1	4	0	0	4	80	20	0	0	100
☐	MPL104T	25	2017-18	Cellular and Molecular Pharmacology	Compulsory	1	4	0	0	4	80	20	0	0	100
☐	MPL105P	25	2017-18	Pharmacology Practical I	Compulsory	1	0	0	12	6	0	0	50	100	150
☐	MSA106P	25	2017-18	Seminar/Assignment	Compulsory	1	0	0	8	4	0	0	100	0	100

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VAPI.

GUJARAT TECHNOLOGICAL UNIVERSITY

M.Pharm

SEMESTER: I

Subject Name: MODERN PHARMACEUTICAL ANALYTICAL TECHNIQUES
Subject Code: MA71011

Scope: This subject deals with various advanced analytical instrumental techniques for identification, characterization and quantification of drugs. Instruments dealt are NMR, Mass spectrometer, IR, HPLC, GC etc.

Objectives: Upon completion of this course the student should be able to

1. Chemicals and Excipients
2. The analysis of various drugs in single and combination dosage forms
3. Theoretical and practical skills of the instruments

Sr. No	Course Contents	Total Hrs
1	**UV-Visible spectroscopy:** Introduction, Theory, Laws, Instrumentation associated with UV-Visible spectroscopy, Choice of solvents and solvent effect and Applications of UVVisible Spectroscopy **IR spectroscopy:** Theory, Modes of Molecular vibrations, Sample handling, Instrumentation of Dispersive and Fourier - Transform IR Spectrometer, Factors affecting vibrational frequencies and Applications of IR spectroscopy **Spectroflourimetry**: Theory of Fluorescence, Factors affecting fluorescence, Quenchers, Instrumentation and Applications of fluorescence spectrophotometer **Flame emission spectroscopy and Atomic absorption spectroscopy:** Principle, Instrumentation, Interferences and Applications	11
2	**NMR spectroscopy:** Quantum numbers and their role in NMR, Principle, Instrumentation, Solvent requirement in NMR, Relaxation process, NMR signals in various compounds,Chemical shift, Factors influencing chemical shift, Spin-Spin coupling, Coupling constant, Nuclear magnetic double resonance, Brief outline of principles of FT-NMR and 13C NMR. Applications of NMR spectroscopy	10
3	**Mass Spectroscopy:** Principle, Theory, Instrumentation of Mass Spectroscopy, Different types of ionization like electron impact, chemical, field, FAB and MALDI, APCI, ESI, APPI Analyzers of Quadrupole and Time of Flight, Mass fragmentation and its rules, Meta stable ions, Isotopic peaks and Applications of Mass Spectroscopy	10
4	**Chromatography**: Principle, apparatus, instrumentation, chromatographic parameters, factors affecting resolution and applications of the following: a) Paper chromatography b) Thin Layer chromatography c) Ion exchange chromatography d) Column chromatography e) Gas chromatography f) High Performance Liquid chromatography g) Affinity chromatography	11
5	a. **Electrophoresis**: Principle, Instrumentation, Working conditions, factors affecting separation and applications of the following: a) Paper electrophoresis b) Gel electrophoresis c) Capillary electrophoresis d) Zone electrophoresis e) Moving boundary electrophoresis f) Iso electric focusing b. **X ray Crystallography**: Production of X rays, Different X ray diffraction methods, Bragg's law, Rotating crystal technique, X ray powder technique, Types of crystals and applications of Xray diffraction.	9

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6	**Potentiometry**: Principle, thermal transitions and instrumentation (heat flux and power compensation anddesigns) working, Ion selective Electrodes and Application of potentiometry. **Thermal Analysis:** Polymer behavior, factors affecting and instrumentation, and working, application of TGA	9

REFERENCES:

1. Spectrometric Identification of Organic compounds - Robert M Silverstein, Sixth edition, John Wiley & Sons, 2004.
2. Principles of Instrumental Analysis - Douglas A Skoog, F. James Holler, Timothy A. Nieman, 5th edition, Eastern press, Bangalore, 1998.
3. Instrumental methods of analysis – Willards, 7th edition, CBS publishers.
4. Practical Pharmaceutical Chemistry – Beckett and Stenlake, Vol II, 4th edition, CBS Publishers, New Delhi, 1997.
5. Organic Spectroscopy - William Kemp, 3rd edition, ELBS, 1991.
6. Quantitative Analysis of Drugs in Pharmaceutical formulation - P D Sethi, 3rd Edition, CBS Publishers, New Delhi, 1997.
7. Pharmaceutical Analysis- Modern methods – Part B - J W Munson, Volume 11, Marcel Dekker Series

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GUJARAT TECHNOLOGICAL UNIVERSITY

M.Pharm

Pharmacology

SEMESTER: I

Subject Name: ADVANCED PHARMACOLOGY-I
Subject Code: MPL102T

Scope: The subject is designed to strengthen the basic knowledge in the field of pharmacology and to impart recent advances in the drugs used for the treatment of various diseases. In addition, this subject helps the students to understand the concepts of drug action and mechanisms involved.

Objectives: Upon completion of this course the student should be able to

1. Discuss the pathophysiology and pharmacotherapy of certain diseases
2. Explain the mechanism of drug actions at cellular and molecular level
3. Understand the adverse effects, contraindications and clinical uses of drugs used in treatment of diseases

Sr No	Course Contents	Total Hrs
1	**General Pharmacology** a. Pharmacokinetics: The dynamics of drug absorption, distribution, biotransformation and elimination. Concepts of linear and non-linear compartment models. Significance of Protein binding. b. Pharmacodynamics: Mechanism of drug action and the relationship between drug concentration and effect. Receptors, structural and functional families of receptors, quantitation of drug receptors interaction and elicited effects.	12
2	Neurotransmission a. General aspects and steps involved in neurotransmission. b. Neurohumoral transmission in autonomic nervous system (Detailed study about neurotransmitters- Adrenaline and Acetyl choline). c. Neurohumoral transmission in central nervous system (Detailed study about neurotransmitters- histamine, serotonin, dopamine, GABA, glutamate and glycine]. d. Non adrenergic non cholinergic transmission (NANC). Cotransmission **Systemic Pharmacology** A detailed study on pathophysiology of diseases, mechanism of action, pharmacology and toxicology of existing as well as novel drugs used in the following systems **Autonomic Pharmacology** Parasympathomimetics and lytics, sympathomimetics and lytics, agents affecting neuromuscular junction	12
3	**Central nervous system Pharmacology** General and local anesthetics Sedatives and hypnotics, drugs used to treat anxiety. Depression, psychosis, mania, epilepsy, neurodegenerative diseases. Narcotic and non-narcotic analgesics	12
4	**Cardiovascular Pharmacology**	12

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	Diuretics, antihypertensives, antiischemics, anti- arrhythmics, drugs for heart failure and hyperlipidemia. Hematinics, coagulants , anticoagulants, fibrinolytics and antiplatelet Drugs	
5	**Autocoid Pharmacology** The physiological and pathological role of Histamine, Serotonin, Kinins Prostaglandins Opioid autocoids. Pharmacology of antihistamines, 5HT antagonistsS	12

REFERENCES:

1. The Pharmacological Basis of Therapeutics, Goodman and Gillman's
2. Principles of Pharmacology. The Pathophysiologic basis of drug Therapy by David E Golan, Armen H, Tashjian Jr, Ehrin J,Armstrong, April W, Armstrong, Wolters, Kluwer-Lippincott Williams & Wilkins Publishers.
3. Basic and Clinical Pharmacology by B.G Katzung
4. Hand book of Clinical Pharmacokinetics by Gibaldi and Prescott.
5. Applied biopharmaceutics and Pharmacokinetics by Leon Shargel and Andrew B.C.Yu.
6. Graham Smith. Oxford textbook of Clinical Pharmacology.
7. Avery Drug Treatment
8. Dipiro Pharmacology, Pathophysiological approach
9. Green Pathophysiology for Pharmacists.
10. Robbins & Cortan Pathologic Basis of Disease, 9th Ed. (Robbins Pathology)
11. A Complete Textbook of Medical Pharmacology by Dr. S.K Srivastava published by APC Avichal Publishing Company
12. KD.Tripathi. Essentials of Medical Pharmacology.
13. Modern Pharmacology with Clinical Applications, Craig Charles R. & Stitzel Robert E., Lippincott Publishers.
14. Clinical Pharmacokinetics & Pharmacodynamics : Concepts and Applications – Malcolm Rowland and Thomas N.Tozer, Wolters Kluwer, Lippincott Williams & Wilkins Publishers.
15. Applied biopharmaceutics and Pharmacokinetics, Pharmacodynamics and Drug metabolism for industrial scientists.
16. Modern Pharmacology, Craig CR. & Stitzel RE, Little Brown & Company.

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M.Pharm

Pharmacology

SEMESTER: I

Subject Name: PHARMACOLOGICAL AND TOXICOLOGICAL SCREENING METHODS-I
Subject Code: MPL103T

Scope: This subject is designed to impart the knowledge on preclinical evaluation of drugs and recent experimental techniques in the drug discovery and development. The subject content helps the student to understand the maintenance of laboratory animals as per the guidelines, basic knowledge of various in-vitro and in-vivo preclinical evaluation processes.

Objectives: Upon completion of this course the student should be able to

1. Appraise the regulations and ethical requirement for the usage of experimental animal
2. Describe the various animals used in the drug discovery process and good laboratory practices in maintenance and handling of experimental Animals
3. Describe the various newer screening methods involved in the drug discovery process
4. Appreciate and correlate the preclinical data to humans

Sr No	Course Contents	Total Hrs
1	**Laboratory Animals** Common laboratory animals: Description, handling and applications of different species and strains of animals. Transgenic animals: Production, maintenance and applications Anaesthesia and euthanasia of experimental animals. Maintenance and breeding of laboratory animals. CPCSEA guidelines to conduct experiments on animals Good laboratory practice. Bioassay-Principle, scope and limitations and methods	12
2	**Preclinical screening of new substances for the pharmacological activity using in vivo, in vitro, and other possible animal alternative models.** General principles of preclinical screening. CNS Pharmacology: behavioral and muscle co ordination, CNS stimulants and depressants, anxiolytics, anti-psychotics, anti epileptics and nootropics. Drugs for neurodegenerative diseases like Parkinsonism, Alzheimers and multiple sclerosis. Drugs acting on Autonomic Nervous System	12
3	**Preclinical screening of new substances for the pharmacological activity using in vivo, in vitro, and other possible animal alternative models.** Respiratory Pharmacology: anti-asthmatics, drugs for COPD and anti allergics. Reproductive Pharmacology: Aphrodisiacs and antifertility agents Analgesics, antiinflammatory and antipyretic agents. Gastrointestinal drugs: anti ulcer, anti -emetic, antidiarrheal and laxatives.	12
4	**Preclinical screening of new substances for the pharmacological activity using in vivo, in vitro, and other possible animal alternative models.** Cardiovascular Pharmacology: antihypertensives, antiarrythmics, antianginal, antiatherosclerotic agents and diuretics. Drugs for metabolic disorders like anti-diabetic, antidyslipidemic agents. Anti cancer agents. Hepatoprotective screening methods	12

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5	**Preclinical screening of new substances for the pharmacological activity using in vivo, in vitro, and other possible animal alternative models.** Immunomodulators, Immunosuppressants and immunostimulants General principles of immunoassay: theoretical basis and optimization of immunoassay, heterogeneous and homogenous immunoassay systems. Immunoassay methods evaluation, protocol outline, objectives and preparation. Immunoassay for digoxin and insulin Limitations of animal experimentation and alternate animal experiments. Extrapolation of in vitro data to preclinical and preclinical to humans.	12

REFERENCES:

1. Biological standardization by J.H. Burn D.J. Finney and I.G. Goodwin
2. Screening methods in Pharmacology by Robert Turner. A
3. Evaluation of drugs activities by Laurence and Bachrach
4. Methods in Pharmacology by Arnold Schwartz.
5. Fundamentals of experimental Pharmacology by M.N.Ghosh
6. Pharmacological experiment on intact preparations by Churchill Livingstone
7. Drug discovery and Evaluation by Vogel H.G.
8. Experimental Pharmacology by R.K Goyal.
9. Preclinical evaluation of new drugs by S.K. Guta
10. Handbook of Experimental Pharmacology, SK.Kulkarni
11. Practical Pharmacology and Clinical Pharmacy, SK.Kulkarni, 3rd Edition.
12. David R.Gross. Animal Models in Cardiovascular Research, 2nd Edition, Kluwer Academic Publishers, London, UK.
13. Screening Methods in Pharmacology, Robert A.Turner.
14. Rodents for Pharmacological Experiments, Dr.Tapan Kumar chatterjee.
15. Practical Manual of Experimental and Clinical Pharmacology by Bikash Medhi (Author), Ajay Prakash (Author)

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GUJARAT TECHNOLOGICAL UNIVERSITY

M.Pharm

Pharmacology

SEMESTER: I

Subject Name: CELLULAR AND MOLECULAR PHARMACOLOGY
Subject Code: MPL104T

Scope: The subject imparts a fundamental knowledge on the structure and functions of cellular components and help to understand the interaction of these components with drugs. This information will further help the student to apply the knowledge in drug discovery process.

Objectives. Upon completion of this course the student should be able to

1. Explain the receptor signal transduction processes
2. Explain the molecular pathways affected by drugs
3. Appreciate the applicability of molecular pharmacology and biomarkers in drug discovery process
4. Demonstrate molecular biology techniques as applicable for pharmacology

Sr No	Course Contents	Total Hrs
1	**Cell biology** Structure and functions of cell and its organelles, Genome organization. Gene expression and its regulation, importance of siRNA and micro RNA, gene mapping and gene sequencing Cell cycles and its regulation. Cell death– events, regulators, intrinsic and extrinsic pathways of apoptosis. Necrosis and autophagy.	12
2	**Cell signaling** Intercellular and intracellular signaling pathways. Classification of receptor family and molecular structure ligand gated ion channels; G-protein coupled receptors, tyrosine kinase receptors and nuclear receptors. Secondary messengers: cyclic AMP, cyclic GMP, calcium ion, inositol 1, 4, 5-trisphosphate, (IP3), NO, and diacylglycerol. Detailed study of following intracellular signaling pathways: cyclic AMP signaling pathway, mitogen-activated protein kinase (MAPK) signaling, Janus kinase (JAK)/signal transducer and activator of transcription (STAT) signaling pathway.	12
3	**Principles and applications of genomic and proteomic tools** DNA electrophoresis, PCR (reverse transcription and real time), Gene sequencing, micro array technique, SDS page, ELISA and western blotting, Recombinant DNA technology and gene therapy Basic principles of recombinant DNA technology-Restriction enzymes, various types of vectors. Applications of recombinant DNA technology. Gene therapy- Various types of gene transfer techniques, clinical applications and recent advances in gene therapy.	12
4	**Pharmacogenomics:** Gene mapping and cloning of disease gene. Genetic variation and its role in health/ pharmacology Polymorphisms affecting drug metabolism Genetic variation in drug transporters Genetic variation in G protein coupled receptors Applications of proteomics science: Genomics, proteomics, metabolomics, functionomics, nutrigenomics Immunotherapeutics	12

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	Types of immunotherapeutics, humanisation antibody therapy, Immunotherapeutics in clinical practice	
5	a. **Cell culture techniques** Basic equipments used in cell culture lab. Cell culture media, various types of cell culture, general procedure for cell cultures; isolation of cells, subculture, cryopreservation, characterization of cells and their application. Principles and applications of cell viability assays, glucose uptake assay, Calcium influx assays Principles and applications of flow cytometry b. Biosimilars	12

REFERENCES:

1. The Cell, A Molecular Approach. Geoffrey M Cooper.
2. Pharmacogenomics: The Search for Individualized Therapies. Edited by J. Licinio and M -L. Wong
3. Handbook of Cell Signaling (Second Edition) Edited by Ralph A. et.al
4. Molecular Pharmacology: From DNA to Drug Discovery. John Dickenson et.al
5. Basic Cell Culture protocols by Cheril D.Helgason and Cindy L.Miller
6. Basic Cell Culture (Practical Approach) by J. M. Davis (Editor)
7. Animal Cell Culture: A Practical Approach by John R. Masters (Editor)
8. Current porotocols in molecular biology vol I to VI edited by Frederick M.Ausuvel et la.

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M.Pharm

Pharmacology

SEMESTER: I

Subject Name: Pharmacology Practical I
Subject Code: MPL105P

List of Practicals:

PART A:

1. Analysis of pharmacopoeial compounds and their formulations by UV Vis spectrophotometer
2. Simultaneous estimation of multi component containing formulations by UV spectrophotometry
3. Experiments based on HPLC
4. Experiments based on Gas Chromatography
5. Estimation of riboflavin/quinine sulphate by fluorimetry
6. Estimation of sodium/potassium by flame photometry

PART B:

Handling of laboratory animals.

1. Various routes of drug administration.
2. Techniques of blood sampling, anesthesia and euthanasia of experimental animals.
3. Functional observation battery tests (modified Irwin test)
4. Evaluation of CNS stimulant, depressant, anxiogenics and anxiolytic, anticonvulsant activity.
5. Evaluation of analgesic, anti-inflammatory, local anesthetic, mydriatic and miotic activity.
6. Evaluation of diuretic activity.
7. Evaluation of antiulcer activity by pylorus ligation method.
8. Oral glucose tolerance test.
9. Isolation and identification of DNA from various sources (Bacteria, Cauliflower, onion, Goat liver).
10. Isolation of RNA from yeast
11. Estimation of proteins by Braford/Lowry's in biological samples.
12. Estimation of RNA/DNA by UV Spectroscopy
13. Gene amplification by PCR.
14. Protein quantification Western Blotting.
15. Enzyme based in-vitro assays (MPO, AChEs, α amylase, α glucosidase).
16. Cell viability assays (MTT/Trypan blue/SRB).
17. DNA fragmentation assay by agarose gel electrophoresis.
18. DNA damage study by Comet assay.
19. Apoptosis determination by fluorescent imaging studies.
20. Pharmacokinetic studies and data analysis of drugs given by different routes of administration using softwares
21. Enzyme inhibition and induction activity
22. Extraction of drug from various biological samples and estimation of drugs in biological fluids using different analytical techniques (UV)
23. Extraction of drug from various biological samples and estimation of drugs in biological fluids using different analytical techniques (HPLC)

REFERENCES

1. CPCSEA, OECD, ICH, USFDA, Schedule Y, EPA guidelines.
2. Fundamentals of experimental Pharmacology by M.N.Ghosh
3. Handbook of Experimental Pharmacology by S.K. Kulkarni.
4. Drug discovery and Evaluation by Vogel H.G.

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5. Spectrometric Identification of Organic compounds - Robert M Silverstein,
6. Principles of Instrumental Analysis - Doglas A Skoog, F. James Holler, Timothy A. Nieman,
7. Vogel's Text book of quantitative chemical analysis - Jeffery, Basset, Mendham, Denney.
8. Basic Cell Culture protocols by Cheril D. Helgason and Cindy L.Mille
9. Basic Cell Culture (Practical Approach) by J. M. Davis (Editor)
10. Animal Cell Culture: A Practical Approach by John R. Masters (Editor)
11. Practical Manual of Experimental and Clinical Pharmacology by Bikash Medhi(Author), Ajay Prakash (Author) Jaypee brothers' medical publishers Pvt. Ltd

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GUJARAT TECHNOLOGICAL UNIVERSITY

M.Pharm

Pharmaceutics (20)

SEMESTER: II

Subject Name: Molecular Pharmaceutics(Nano Tech and Targeted DDS)
Subject Code: MPH201T

Scope: This course is designed to impart knowledge on the area of advances in novel drug delivery systems

Objectives: Upon completion of the course student shall be able to understand

1. The various approaches for development of novel drug delivery systems.
2. The criteria for selection of drugs and polymers for the development of NTDS
3. The formulation and evaluation of novel drug delivery system

Sr.	Topic	Hr
1.	Targeted Drug Delivery Systems: Concepts, Events and biological process involved in drug targeting. Tumor targeting and Brain specific delivery.	12
2.	Targeting Methods: introduction preparation and evaluation. Nano Particles & Liposomes: Types, preparation and evaluation.	12
3.	Micro Capsules / Micro Spheres: Types, preparation and evaluation, Monoclonal Antibodies, preparation and application, Preparation and application of Niosomes, Aquasomes, Phyotosomes, Electrosomes	12
4.	Pulmonary Drug Delivery Systems : Aerosols, propellents, ContainersTypes, preparation andevaluation, Intra Nasal Route Deliverysystems;Types,preparationandevaluation	12
5.	Nucleic acid based therapeutic delivery system : Gene therapy, introduction (ex-vivo & in-vivo gene therapy). Potential target diseases for genetherupy (inherited disorder andcancer). Gene expression systems (viral andnonviral genetransfer). Liposomal gene deliverysystems. Biodistribution and Pharmacokinetics. knowledge of therapeutic antisensemoleculesandaptamersasdrugs offuture	12

REFERENCES:

1. Y W. Chien, Novel Drug Delivery Systems, 2nd edition, revised and expanded,Marcel Dekker,Inc.,NewYork,1992
2. S.P.Vyas and R.K.Khar, Controlled Drug Delivery - concepts and advances,VallabhPrakashan,New Delhi,Firstedition 2002
3. N.K. Jain, Controlled and Novel Drug Delivery, CBS Publishers & Distributors,NewDelhi,Firstedition 1997 (reprint in2001).

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M.Pharm

Pharmaceutics (20)

SEMESTER: II

Subject Name: Advanced Biopharmaceutics & Pharmacokinetics
Subject Code: MPH202T

Scope: This course is designed to impart knowledge and skills necessary for dose calculations, dose adjustments and to apply biopharmaceutics theories in practical problem solving. Basic theoretical discussions of the principles of biopharmaceutics and pharmacokinetics are provided to help the students' to clarify the concepts.

Objectives: Upon completion of the course student shall be able to understand

1. The basic concepts in biopharmaceutics and pharmacokinetics.
2. The use raw data and derive the pharmacokinetic models and parameters the best describe the process of drug absorption, distribution, metabolism and elimination.
3. The critical evaluation of biopharmaceutic studies involving drug product equivalency.
4. The design and evaluation of dosage regimens of the drugs using pharmacokinetic and biopharmaceutic parameters.
5. The potential clinical pharmacokinetic problems and application of basics of pharmacokinetic

Sr.	Topic	Hr
1.	Drug Absorption from the Gastrointestinal Tract: Gastrointestinal tract, Mechanism of drug absorption, Factors affecting drug absorption, pH–partition theory of drug absorption. Formulation and physicochemical factors: Dissolution rate, Dissolution process, Noyes–Whitney equation and drug dissolution, Factors affecting the dissolution rate. Gastrointestinal absorption: role of the dosage form: Solution (elixir, syrup and solution) as a dosage form ,Suspension as a dosage form, Capsule as a dosage form, Tablet as a dosage form ,Dissolution methods ,Formulation and processing factors, Correlation of in vivo data with in vitro dissolution data. Transport model: Permeability-Solubility-Charge State and the pH Partition Hypothesis, Properties of the Gastrointestinal Tract (GIT), pH Microclimate Intracellular pH Environment, Tight-Junction Complex.	12
2.	Biopharmaceutic considerations in drug product design and In Vitro Drug Product Performance: Introduction, biopharmaceutic factors affecting drug bioavailability, rate-limiting steps in drug absorption, physicochemical nature of the drug formulation factors affecting drug product performance, in vitro: dissolution and drug release testing, compendial methods of dissolution, alternative methods of dissolution testing, meeting dissolution requirements, problems of variable control in dissolution testing performance of drug products. In vitro–in vivo correlation, dissolution profile comparisons, drug product stability, considerations in the design of a drug product.	12
3.	Pharmacokinetics: Basic considerations, pharmacokinetic models, compartment modeling: one compartment model- IV bolus, IV infusion, extra-vascular. Multi compartment model: two compartment - model in brief, non-linear pharmacokinetics: cause of non-linearity, Michaelis – Menten equation, estimation of kmax and vmax. Drug interactions: introduction, the effect of protein binding interactions, the effect of tissue-binding interactions, cytochrome p450-based drug interactions, drug interactions linked to transporters	12

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4.	Drug Product Performance, In Vivo: Bioavailability and Bioequivalence: drug product performance, purpose of bioavailability studies, relative andabsolute availability, methods for assessing bioavailability, bioequivalence studies, design and evaluation of bioequivalence studies, study designs, crossover study designs, evaluation of the data, bioequivalence example, study submission and drug review process. biopharmaceutics classification system, methods. Permeability: In-vitro, in-situ and In-vivo methods. generic biologics (biosimilar drug products),clinical significance of bioequivalence studies, special concerns in bioavailability and bioequivalence studies, generic substitution	12
5.	Application of Pharmacokinetics: Modified-Release Drug Products, Targeted Drug Delivery Systems and Biotechnological Products. Introduction to Pharmacokinetics and pharmacodynamic, drug interactions. Pharmacokinetics and pharmacodynamics of biotechnology drugs. Introduction, Proteins andpeptides, Monoclonal antibodies, Oligonucleotides, Vaccines (immunotherapy),Genetherapies	12

REFERENCES:

1. Biopharmaceutics and Clinical Pharmacokinetics by Milo Gibaldi, 4th edition,Philadelphia,LeaandFebiger,1991
2. Biopharmaceutics and Pharmacokinetics, A Treatise, D .M. Brahmankar and Sunil B. Jaiswal.,Vallab Prakashan, Pitampura, Delhi
3. Applied Biopharmaceutics and Pharmacokinetics by Shargel. Land YuABC,2ndedition,ConnecticutAppletonCenturyCrofts,1985
4. Textbook of Biopharmaceutics andPharmacokinetics, Dr. Shobha Rani R. Hiremath,PrismBook
5. Pharmacokinetics by Milo Gibaldi and D. Perrier, 2nd edition, Marcel DekkerInc.,New York,1982
6. Current Concepts in Pharmaceutical Sciences: Biopharmaceutics, Swarbrick,J.LeaandFebiger,Philadelphia,1970
7. Clinical Pharmacokinetics, Concepts and Applications 3rd edition by MalcolmRowland and Thom~N. Tozer, Lea and Febiger, Philadelphia, 1995
8. Dissolution, Bioavailability and Bioequivalence, Abdou. H.M, Mack PublishingCompany,Pennsylvania1989
9. Biopharmaceutics and Clinical Pharmacokinetics, An Introduction, 4th edition,revised andexpande byRobert. E. Notari, Marcel Dekker Inc,New YorkandBasel,1987
10. BiopharmaceuticsandRelevantPharmacokineticsbyJohn.G Wagnerand M.Pernarowski, 1st edition, Drug Intelligence Publications, Hamilton, Illinois, 1971
11. Encyclopedia of Pharmaceutical Technology, Vol 13, James Swarbrick, James.G.Boylan,MarcelDekkerInc,New York,1996
12. Basic Pharmacokinetics,1 st edition,Sunil S JambhekarandPhilip J Breen,pharmaceuticalpress,RPS Publishing,2009
13. Absorption and Drug Development- Solubility, Permeability, and Charge State,AlexAvdeef,JohnWiley&Sons,Inc,2003

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GUJARAT TECHNOLOGICAL UNIVERSITY

M.Pharm

Pharmaceutics (20)

SEMESTER: II

Subject Name: COMPUTER AIDED DRUG DEVELOPMENT
Subject Code: MPH203T

Scope: This course is designed to impart knowledge andskills necessary for computer Applications in pharmaceutical research and development who want to understand the application of computers across the entire drug research and development process. Basic theoretical discussions of the principles of more integrated and coherent use of computerized information (informatics) in the drug development process are provided to help the students to clarify the concepts.

Objectives: Upon completion of the course student shall be able to understand

1. History of Computers in Pharmaceutical Research and Development
2. Computational Modeling of Drug Disposition
3. Computers in Preclinical Development
4. Optimization Techniques in Pharmaceutical Formulation
5. Computers in Market Analysis
6. Computers in Clinical Development
7. Artificial Intelligence(AI) and Robotics
8. Computational fluiddynamics (CFD)

Sr.	Topic	Hr
1.	a. Computers in Pharmaceutical Research and Development: A General Overview: History of Computers in Pharmaceutical Research and Development. Statistical modeling in Pharmaceutical research and development: Descriptive versus Mechanistic Modeling, Statistical Parameters, Estimation, Confidence Regions, Nonlinearity at the Optimum, Sensitivity Analysis, Optimal Design, Population Modeling b. Quality-by-Design In Pharmaceutical Development: Introduction, ICH Q8guideline, Regulatory and industry views on QbD, Scientifically based QbD-examples of application	12
2.	Computational Modeling Of Drug Disposition: Introduction ,Modeling Techniques: Drug Absorption, Solubility, Intestinal Permeation, Drug Distribution ,Drug Excretion, Active Transport, P-gp, BCRP, Nucleoside Transporters, hPEPT1, ASBT, OCT, OATP,BBB-CholineTransporter	12
3.	Computer-aided formulation development:: Concept of optimization, Optimization parameters, Factorial design, Optimization technology & Screening design. Computers in Pharmaceutical Formulation: Development of pharmaceutical emulsions, micro emulsion drug carriers Legal Protection of Innovative Uses of Computers in R&D, The Ethics of Computing in Pharmaceutical Research, Computers in Market analysis	12
4.	a. Computer-aided biopharmaceutical characterization: Gastrointestinal absorption simulation. Introduction, Theoretical background, Model construction, Parameter sensitivity analysis, Virtual trial, Fed vs. fasted state, In vitro dissolution and in vitroin vivo correlation, Biowaiver considerations b. Computer Simulations in Pharmacokinetics and Pharmacodynamics: Introduction, Computer Simulation: Whole Organism, Isolated Tissues, Organs, Cell, Proteins and Genes. c. Computers in Clinical Development: Clinical Data Collection and Management, Regulation of Computer Systems	12

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5.	Artificial Intelligence (AI), Robotics and Computational fluid dynamics: General overview, Pharmaceutical Automation, Pharmaceutical applications, Advantages and Disadvantages, Current Challenges and Future Directions	12

REFERENCES:

1. Computer Applications in Pharmaceutical Research and Development, Sean Ekins,2006,JohnWiley&Sons.
2. Computer-Aided Applications in Pharmaceutical Technology, 1st Edition, JelenaDjuris,Woodhead Publishing 3. Encyclopedia of Pharmaceutical Technology, Vol 1
3. James Swarbrick, James G.Boylan,MarcelDekkerInc.,New York,1996.

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M.Pharm

Pharmaceutics (20)

SEMESTER: II

Subject Name: COSMETICS AND COSMECEUTICALS
Subject Code: MPH204T

Scope: This course is designed to impart knowledge and skills necessary for the fundamental need for cosmetic and cosmeceutical products

Objectives: Upon completion of the course student shall be able to understand

1. Key ingredients used in cosmetics and cosmeceuticals.
2. Key building blocks for various formulations.
3. Current technologies in the market
4. Various key ingredients and basic science to develop cosmetics and cosmeceuticals
5. Scientific knowledge to develop cosmetics and cosmeceuticals with desired Safety, stability, and efficacy

Sr.	Topic	Hr
1.	Cosmetics – Regulatory : Definition of cosmetic products as per Indian regulation. Indian regulatory requirements for labeling of cosmetics Regulatory provisions relating to import of cosmetics., Misbranded and spurious cosmetics. Regulatory provisions relating to manufacture of cosmetics – Conditions for obtaining license, prohibition of manufacture and sale of certain cosmetics, loan license, offences and penalties	12
2.	Cosmetics - Biological aspects : Structure of skin relating to problems like dry skin, acne, pigmentation, prickly heat, wrinkles and body odor. Structure of hair and hair growth cycle. Common problems associated with oral cavity. Cleansing and care needs for face, eye lids, lips, hands, feet, nail, scalp, neck, body and under-arm	12
3.	Formulation Building blocks: Building blocks for different product formulations of cosmetics/cosmeceuticals. Surfactants – Classification and application. Emollients, rheological additives: classification and application. Antimicrobial used as preservatives, their merits and demerits. Factors affecting microbial preservative efficacy. Building blocks for formulation of a moisturizing cream, vanishing cream, cold cream, shampoo and toothpaste. Soaps and syndetbars. Perfumes; Classification of perfumes. Perfume ingredients listed asallergens in EU regulation Controversial ingredients: Parabens, formaldehyde liberators, dioxane	12
4.	Design of cosmeceutical products: Sun protection, sunscreens classification and regulatory aspects. Addressing dry skin, acne, sun-protection, pigmentation, prickly heat, wrinkles, bodyodor., dandruff, dental cavities, bleeding gums, mouth odor and sensitive teeth through cosmeceutical formulations	12
5.	Herbal Cosmetics : Herbal ingredients used in Hair care, skin care andoral care. Review of guidelines for herbal cosmetics by private bodies like cosmos with respect to preservatives, emollients, foaming agents, emulsifiers and rheology modifiers. Challenges in formulating herbal cosmetics	12

REFERENCES:

1. Harry'sCosmeticology,8th edition.
2. Poucher'sperfumecosmeticsandSoaps,10th edition.
3. Cosmetics - Formulation, Manufacture and quality control, PP.Sharma,4th edition

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4. Handbook of cosmetic science and Technology A.O.Barel, M.Paye and H.I.Maibach 3rdedition
5. Cosmetic and Toiletries recent suppliers catalogue.
6. CTFA directory

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GUJARAT TECHNOLOGICAL UNIVERSITY

M.Pharm

Pharmaceutics (20)

SEMESTER: II

Subject Name: PHARMACEUTICS PRACTICALS - II

Subject Code: MPH205P

1. To study the effect of temperature change , non solvent addition, incompatible polymer additionin microcapsules preparation
2. Preparation and evaluation of Alginatebeads
3. Formulation and evaluation of gelatin /albuminmicrospheres
4. Formulation and evaluation of liposomes/niosomes
5. Formulation and evaluation of spherules
6. Improvement of dissolution characteristics of slightly soluble drug by Solid dispersion technique.
7. Comparison of dissolution of two different marketed products /brands
8. Protein binding studies of a highly protein bound drug & poorly protein bound drug
9. Bioavailability studies of Paracetamolin animals.
10. Pharmacokinetic and IVIVC data analysis by Winnolin R software
11. In vitro cells tudies for permeability and metabolism
12. DoE Using Design Expert® Software
13. Formulation data analysis Using Design Expert® Software
14. Quality-by-DesigninPharmaceuticalDevelopment
15. Computer Simulation sin Pharmacokinetics and Pharmacodynamics
16. Computational Modeling Of Drug Disposition
17. To develop Clinical Data Collection manual
18. To carry out Sensitivity Analysis, and Population Modeling.
19. Development and evaluation of Creams
20. Development and evaluation of Shampoo and Toothpaste base
21. To incorporate herbal and chemical actives to develop products
22. To address Dry skin, acne, blemish, Wrinkles, bleeding gums and dandruff

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TEACHING SCHEME / DETAIL SYALLBUS

MPHARM - 24 - PHARMACEUTICAL QUALITY ASSURANCE - 2 -

Academic Year - Subject Code Enter Subject Name

*L=Lectures,T=Tutorial,P=Practical,C=Theory/Internal,M=Theory/Internal,I=Practical Internal,V=Practical External,On Job Training(OJT) is equivalent to Practical

Sem	Subject Code	Subject Credits	Effective From Academic Year	Subject Title	Subject Category	Exam Type	L	T	P	Total Credits	TH	IA	V	J	Total
2	MQA201T	24	2017-18	Hazards and Safety Management	Compulsory	2	4	0	0	4	80	20	0	0	100
2	MQA202T	24	2017-18	Pharmaceutical Validation	Compulsory	2	4	0	0	4	80	20	0	0	100
2	MQA203T	24	2017-18	Audits and Regulatory Compliance	Compulsory	2	4	0	0	4	80	20	0	0	100
2	MQA204T	24	2017-18	Pharmaceutical Manufacturing Technology	Compulsory	2	4	0	0	4	80	20	0	0	100
2	MQA205P	24	2017-18	Pharmaceutical Quality Assurance Practical II	Compulsory	2	0	0	12	6	0	0	50	100	150
2	MSA206P	24	2017-18	Seminar/Assignment	Compulsory	2	0	0	8	4	0	0	100	0	100

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GUJARAT TECHNOLOGICAL UNIVERSITY

M.Pharm

PHARMACEUTICAL QUALITY ASSURANCE

SEMESTER: II

Subject Name: HAZARDS AND SAFETY MANAGEMENT
Subject Code: MQA201T

Scope: This course is designed to convey the knowledge necessary to understand issues related to different kinds of hazard and their management. Basic theoretical and practical discussions integrate the proficiency to handle the emergency situation in the pharmaceutical product development process and provides theprinciplebased approach tosolvethe complex tribulations.

Objectives: Upon completion of this course the student should be able to

1. Understand about environmental problems among learners.
2. Impart basic knowledge about the environment and its allied problems.
3. Develop an attitude of concern for the industry environment.
4. Ensure safety standards in pharmaceutical industry
5. Provide comprehensive knowledge on the safety management
6. Empower an ideas to clear mechanism and management in different kinds of hazard managements ystem
7. Teach the method of Hazard assessment, procedure, methodology for provide safe industrial atmosphere.

Sr No	Course Contents	Total Hrs
1	Multidisciplinary nature of environmental studies: Natural Resources, Renewable and non-renewable resources, Natural resources and associated problems, a) Forest resources; b)Water resources; c) Mineral resources; d) Energy resources e)Land resources Ecosystems: Concept of an ecosystem and Structure and function of an ecosystem. Environmental hazards: Hazards based on Air, Water, Soil and Radioisotopes	12
2	Air based hazards: Sources, Types of Hazards, Air circulation maintenance industry for sterile area and non sterile area, Preliminary Hazard Analysis (PHA) Fire protection system: Fire prevention, types of fire extinguishers and critical Hazard management system	12
3	Chemical based hazards: Sources of chemical hazards, Hazards of Organic synthesis, sulphonating hazard, Organic solvent hazard, Control measures for chemical hazards Management of combustible gases, Toxic gases and Oxygen displacing gases management, Regulations for chemical hazard, Management of over-Exposure to chemicals and TLV concept	12
4	Fire and Explosion: Introduction, Industrial processes and hazards potential, mechanical electrical, thermal and process hazards. Safety and hazards regulations, Fire protection system: Fire prevention, types of fire extinguishers and critical Hazard management system mechanical and chemical explosion, multiphase reactions, transport effects and global rates. Preventive and protective management from fires and explosion electricity	12

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	passivation, ventilation, and sprinkling, proofing, relief systems-relief valves ,flares, scrubbers	
5	Hazard and risk management: Self-protective measures against workplace hazards. Critical training for risk management, Process of hazard management, ICH guidelines on risk assessment and Risk management methods and Tools Factory act and rules, fundamentals of accident prevention, elements of safety programme and safety management, Physicochemical measurements of effluents, BOD, COD, Determination of some contaminants, Effluent treatment procedure, Role of emergency services	12

REFERENCES:

1. V.K. Sing, Environmental Science, New Age International Pvt, Publishers, Bangalore
2. "Quantitative Risk Assessment in Chemical Process Industries" American Institute of Chemical Industries, Centre for Chemical Process safety.
3. Bharucha Erach, The Biodiversity of India, Mapin Publishing Pvt. Ltd., Ahmedabad– 380 013,India,
4. Hazardous Chemicals: Safety Management and Global Regulations, T.S.S. Dikshith, CRC press

PRINCIPAL

GUJARAT TECHNOLOGICAL UNIVERSITY

M.Pharm

PHARMACEUTICAL QUALITY ASSURANCE

SEMESTER: II

Subject Name: PHARMACEUTICAL VALIDATION
Subject Code: MQA202T

Scope: The main purpose of the subject is to understand about validation and howit can be applied to industry and thus improve the quality of the products. The subject covers the complete information about validation, types, methodology and application .

Objectives: Upon completion of this course the student should be able to

1. The concepts of calibration, qualification and validation
2. The qualification of various equipments and instruments
3. Process validation of different dosage forms
4. Validation of analytical method for estimation of drugs
5. Cleaning validation of equipments employed in the manufacture of pharmaceuticals.

Sr No	Course Contents	Total Hrs
1	Introduction to validation: Definition of Calibration, Qualification and Validation, Scope, frequency and importance. Difference between calibration and validation. Calibration of weights and measures. Advantages of Validation, scope of Validation, Organization for Validation, Validation Master plan, Types of Validation, Streamlining of qualification & Validation process and Validation Master Plan. Qualification: User requirement specification, Design qualification, Factory Acceptance Test (FAT)/Site Acceptance Test (SAT), Installation qualification, Operational qualification, Performance qualification, Re-Qualification (Maintaining status Calibration Preventive Maintenance, Change management).	10
2	Qualification of manufacturing equipment: Dry Powder Mixers, Fluid Bed and Tray dryers, Tablet Compression (Machine), Dry heat sterilization/Tunnels, Autoclaves, Membrane filtration, Capsule filling machine. Qualification of analytical instruments: UV-Visible spectrophotometer, FTIR, DSC, GC, HPLC, HPTLC, LC-MS	10
3	Qualification of laboratory equipments: Hardness tester, Friability test apparatus, tap density tester, Disintegration tester, Dissolution test apparatus Validation of Utility systems: Pharmaceutical water system & pure steam, HVAC system, Compressed air and nitrogen	10
4	Process Validation: Concept, Process and documentation of Process Validation. Prospective, Concurrent & Retrospective Validation, Re validation criteria, Process Validation of various formulations (Coated tablets, Capsules, Ointment/Creams, Liquid Orals andaerosols.), Aseptic filling: Media fill validation, USFDA guidelines on Process Validation-A life cycle approach. Analytical method validation: General principles, Validation of analytical method as per ICH guidelines and USP	10

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5	Cleaning Validation: Cleaning Method development, Validation of analytical method used in cleaning, Cleaning of Equipment, Cleaning of Facilities. Cleaning in place(CIP). Validation of facilities in sterile and non-sterile plant. Computerized system validation: Electronic records and digital signature-21CFR Part11and GAMP	10
6	General Principles of Intellectual Property: Concepts of Intellectual Property (IP), Intellectual Property Protection (IPP), Intellectual Property Rights (IPR); Economic importance, mechanism for protection of Intellectual Property –patents, Copyright, Trademark; Factors affecting choice of IP protection; Penalties for violation; Role of IP in pharmaceutical industry; Global ramification and financial implications. Filing a patent applications; patent application forms and guidelines. Types patent applications-provisional and non provisional, PCT and convention patent applications;International patenting requirement procedures and costs; Rights and responsibilities of a patentee; Practical aspects regarding maintaining of a Patent file; Patent infringement meaning and scope. Significance of transfer technology (TOT), IP and ethics-positive and negative aspects of IPP; Societal responsibility, avoiding unethical practices	10

REFERENCES:

1. B. T.Loftus &R. A.Nash, "Pharmaceutical Process Validation",Drugs and Pharm Sci. Series, Vol. 129,3rdEd.,MarcelDekkerInc.,N.Y.
2. The Theory &Practice of Industrial Pharmacy, 3rd edition, Leon Lachman, Herbert A. Lieberman, Joseph. L. Karig, Varghese Publishing House, Bombay
3. Validation Master plan by Terveeks or Deeks, Davis Harwood International publishing
4. Validation of Aseptic Pharmaceutical Processes, 2ndEdition, by Carleton &Agalloco
5. Michael Levin, Pharmaceutical Process Scale-Up", Drugs and Pharm. Sci. Series, Vol. 157,2ndEd.,MarcelDekkerInc.,N.Y.
6. Validation Standard Operating Procedures: A Step by Step Guide for Achieving Compliance inthe Pharmaceutical, Medical Device, and Biotech Industries, Syed Imtiaz Haider
7. Pharmaceutical Equipment Validation: The Ultimate Qualification Handbook, Phillip A.Cloud, Interpharm Press
8. Validation of Pharmaceutical Processes: Sterile Products, Frederick J. Carlton(Ed.)and James Agalloco(Ed.),Marcel Dekker
9. Analytical Method validation and Instrument Performance Verification by Churg Chan, Heiman Lam,Y.C.Lee,Yue .Zhang, Wileyl nterscience
10. Huber L. Validation and Qualification in Analytical Laboratories. Informa Healthcare
11. Wingate G. Validating Corporate Computer Systems: Good ITPractice for Pharmaceutical Manufacturers. Interpharm Press
12. LeBlanc DA. Validated Cleaning Technologies for Pharmaceutical Manufacturing. Interpharm Press

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GUJARAT TECHNOLOGICAL UNIVERSITY

M.Pharm

PHARMACEUTICAL QUALITY ASSURANCE

SEMESTER: I

Subject Name: AUDITS AND REGULATORY COMPLIANCE
Subject Code: MQA203T

Scope: This course deals with the understanding and process for auditing in pharmaceutical industries. This subject covers the methodology involved in the auditing process of different in pharmaceutical industries.

Objectives: Upon completion of this course the student should be able to

1. To understand the importance of auditing
2. To understand the methodology of auditing
3. To carry out the audit process
4. To prepare the auditing report
5. To prepare the check list for auditing

Sr No	Course Contents	Total Hrs
1	Introduction: Objectives, Management of audit, Responsibilities, Planning process, information gathering, administration, Classifications of deficiencies	12
2	Role of quality systems and audits in pharmaceutical manufacturing environment: cGMP Regulations, Quality assurance functions, Quality systems approach, Management responsibilities, Resource, Manufacturing operations, Evaluation activities, Transitioning to quality system approach, Audit checklist for drug industries	12
3	Auditing of vendors and production department: Bulk Pharmaceutical Chemicals and packaging material Vendor audit, Warehouse and weighing, Dry Production: Granulation, tableting, coating, capsules, sterile production and packaging	12
4	Auditing of Microbiological laboratory: Auditing the manufacturing process, Product and process information, General areas of interest in the building raw materials, Water, Packaging materials	12
5	Auditing of Quality Assurance and engineering department: Quality Assurance Maintenance, Critical systems: HVAC, Water, Water for Injection systems, ETP	12

REFERENCES:

1. Compliance auditing for Pharmaceutical Manufacturers. Karen Ginsbury and Gil Bismuth, Interpharm/CRC, Boca Raton, London New York, Washington D.C
2. Pharmaceutical Manufacturing Handbook,Regulations and Quality by Shayne Cox Gad. Wiley-Interscience, A John Wiley and sons, Inc., Publications
3. Handbook of microbiological Quality control. Rosamund M.Baird, Norman A.Hodges,StephenP. Denyar.CRC Press,2000
4. Laboratory auditing for quality and regulatory compliance. Donald C. Singer, Raluca-Ioana Stefan, Jacobus F. Van Staden. Taylor andFrancis (2005).

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GUJARAT TECHNOLOGICAL UNIVERSITY

M.Pharm

PHARMACEUTICAL QUALITY ASSURANCE

SEMESTER: II

Subject Name: PHARMACEUTICAL MANUFACTURING TECHNOLOGY
Subject Code: MQA204T

Scope: This course is designed to impart knowledge and skills necessary to train the students with the industrial activities during Pharmaceutical Manufacturing.

Objectives: Upon completion of this course the student should be able to

1. The common practice in the pharmaceutical industry developments, plant layout and production planning
2. Will be familiar with the principles and practices of aseptic process technology, non sterile manufacturing technology and packaging technology
3. Have a better understanding of principles and implementation of Quality by design (QbD) and process analytical technology (PAT) in pharmaceutical manufacturing
4.

Sr No	Course Contents	Total Hrs
1	Pharmaceutical industry developments: Legal requirements and Licenses for API and formulation industry, Plant location Factors influencing. Plant layout: Factors influencing, Special provisions, Storage spacerequirements,sterile and asepticarea layout. Production planning: General principles, production systems, calculation of standard cost, process planning, routing, loading, scheduling, dispatching of records, production control	12
2	Aseptic process technology: Manufacturing, manufacturing flowcharts, in process-quality control tests for following sterile dosage forms: Ointment, Suspension and Emulsion, Dry powder, Solution (Small Volume & large Volume). Advanced sterile product manufacturing technology : Area planning & environmental control, wall and floor treatment, fixtures and machineries, change rooms, personnel flow, utilities & utilities equipment location, engineering and maintenance. Process Automation in Pharmaceutical Industry: With specific reference to manufacturing of sterile semisolids, Small Volume Parenterals & Large Volume Parenterals (SVP &LVP), Monitoring of Parenteral manufacturing facility, Cleaning in Place (CIP), Sterilization in Place (SIP), Prefilled Syringe, Powdered Jet, Needle Free Injections, and Form Fill Seal Technology (FFS). Lyophilization technology:Principles, process, equipment	12
3	Non sterile manufacturing process technology: Manufacturing, manufacturing flowcharts, in process-quality control tests for following Non-Sterile solid dosage forms: Tablets (compressed & coated),Capsules(Hard &Soft). Advance non-sterile solid product manufacturing technology: Process Automation in Pharmaceutical Industry with specific reference to manufacturing of tablets and coated products, Improved Tablet Production: Tablet production process, granulation and pelletization equipments, continuous and batch mixing, rapid mixing granulators, rota granulators, spheronizers and marumerisers, and other specialized granulation and drying	12

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	equipments. Problems encountered. Coating technology: Process, equipments, particle coating, fluidized bed coating, application techniques. Problems encountered	
4	Containers and closures for pharmaceuticals: Types, performance, assuring quality of glass; types of plastics used, Drug plastic interactions, biological tests, modification of plastics by drugs; different types of closures and closure liners; film wrapper; blister packs; bubble packs; shrink packaging; foil / plastic pouches, bottle seals, tape seals, breakable seals and sealed tubes; quality control of packaging material and filling equipment, flexible packaging, product package compatibility, transit worthiness of package, Stability aspects of packaging, Evaluation of stability of packaging material	12
5	Quality by design (QbD) and process analytical technology (PAT): Current approach and its limitations. Why QbD is required, Advantages, Elements of QbD, Terminology: QTPP, CMA, CQA, CPP, RLD, Design space, Design of Experiments, Risk Assessment and mitigation/minimization. Quality by Design, Formulations by Design, QbD for drug products, QbD for Drug Substances, QbD for Excipients, Analytical QbD. FDA initiative on process analytical technology. PAT as a driver for improving quality and reducing costs: quality by design (QbD),QA,QC and GAMP. PAT guidance, standards and regulatory requirements	12

REFERENCES:

1. Lachman L,Lieberman HA,Kanig JL. The theory and practice of industrial rd pharmacy, 3 ed., Varghese Publishers, Mumbai 1991
2. Sinko PJ. Martin's physical pharmacy and pharmaceutical sciences, 5 ed.,B.I.PublicationsPvt. Ltd,Noida,2006
3. Lieberman HA, Lachman L, Schwartz JB. Pharmaceutical dosageforms: nd tabletsVol.I-III,2 ed.,CBS Publishers & distributors ,New Delhi, 2005
4. Banker GS, Rhodes CT. Modern Pharmaceutics, 4 Inc, New York,2005
5. Sidney H Willing, Murray M, Tuckerman. Williams Hitchings IV, Good manufacturing of pharmaceuticals (A Plan for total quality control) 3rd Edition. Bhalani publishing house Mumbai
6. Indian Pharmacopoeia. Controller ofPublication.Delhi,1996
7. British Pharmacopoeia. British Pharmacopoeia Commission Office, London,2008
8. United States Pharmacopoeia. United States Pharmacopeial Convention, Inc,USA, 2003.
9. Dean D A, Evans E R and Hall I H. Pharmaceutical Packaging Technology. London, Taylor&Francis,1st Edition.UK
10. Edward J Bauer. Pharmaceutical Packaging Handbook. 2009.Informa Healthcare USA Inc. New York
11. Shaybe Cox Gad. Pharmaceutical Manufacturing Handbook. John Willey andSons,NewJersey,2008

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M.Pharm

PHARMACEUTICAL QUALITY ASSURANCE

SEMESTER: II

Subject Name: PHARMACEUTICAL QUALITY ASSURANCE
Subject Code: MQA205P

List of Practicals:

1. Organic contaminants residue analysis by HPLC
2. Estimation of Metallic contaminants by Flame photometer
3. identification of antibiotic residue by TLC
4. Estimation of Hydrogen Sulphide in Air
5. Estimation of Chlorine in Work Environment
6. SamplingandanalysisofSO2 using Colorimetric method
7. Qualification of following Pharma equipment
   A) Autoclave
   B) .Hot air oven
   C) Powder Mixer (Dry)
   D) Tablet Compression Machine
8. Validation of an analytical method for a drug
9. Validation of a processing area
10. Qualification of atleast two analytical instruments
11. Cleaning validation of one equipment
12. Qualification of Pharmaceutical Testing Equipment (Dissolution testing apparatus, Friability Apparatus, Disintegration Tester)
13. Check list for Bulk Pharmaceutical Chemicals vendors
14. Check list for tableting production
15. Check list for sterile production area
16. Check list for Water for injection
17. Design of plant layout: Sterile and non-sterile
18. Case study on application of QbD
19. Case study on application of PAT

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TEACHING SCHEME / DETAIL SYALLBUS

MPHARM | 25 - PHARMACOLOGY | 2

Academic Year | Subject Code | Enter Subject Name | Search

*L=lectures,T=tutorial,P=Practical,E=TheoryExternal,M=TheoryInternal,I=Practical Internal,O=Practical External,OJT Job Training(OJT) is equivalent to Practical

Sr. No.	Subject code	Branch code	Eff. from	Subject Name	Category	Sem. Year	L	T	P	Total	E	M	I	O	Total
☐	MPL201T	25	2017-18	Advanced Pharmacology II	Compulsory	2	4	0	0	4	80	20	0	0	100
☐	MPL202T	25	2017-18	Pharmacological and Toxicological Screening Methods-II	Compulsory	2	4	0	0	4	80	20	0	0	100
☐	MPL203T	25	2017-18	Principles of Drug Discovery	Compulsory	2	4	0	0	4	80	20	0	0	100
☐	MPL204T	25	2017-18	Clinical Research and Pharmacovigilance	Compulsory	2	4	0	0	4	80	20	0	0	100
☐	MPL205P	25	2017-18	Pharmacology Practical II	Compulsory	2	0	0	12	6	0	0	50	100	150
☐	MSA206P	25	2017-18	Seminar/Assignment	Compulsory	2	0	0	8	4	0	0	100	0	100

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GUJARAT TECHNOLOGICAL UNIVERSITY

M.Pharm

Pharmacology

SEMESTER: II

Subject Name: ADVANCED PHARMACOLOGY-II
Subject Code: MPL201T

Scope: The subject is designed to strengthen the basic knowledge in the field of pharmacology and to impart recent advances in the drugs used for the treatment of various diseases. In addition, the subject helps the student to understand the concepts of drug action and mechanism involved.

Objectives: Upon completion of this course the student should be able to

1. Explain the mechanism of drug actions at cellular and molecular Level
2. Discuss the Pathophysiology and pharmacotherapy of certain diseases
3. Understand the adverse effects, contraindications and clinical uses of drugs used in treatment of diseases

Sr No	Course Contents	Total Hrs
1	Endocrine Pharmacology Molecular and cellular mechanism of action of hormones such as growth hormone, prolactin, thyroid, insulin and sex hormones Anti-thyroid drugs, Oral hypoglycemic agents, Oral contraceptives, Corticosteroids. Drugs affecting calcium regulation	12
2	Chemotherapy Cellular and molecular mechanism of actions and resistance of antimicrobial agents such as ß-lactams, aminoglycosides, quinolones, Macrolide antibiotics. Antifungal, antiviral, and anti-TB drugs	12
3	Chemotherapy Drugs used in Protozoal Infections Drugs used in the treatment of Helminthiasis Chemo therapy of cancer Immunopharmacology Cellular and biochemical mediators of inflammation and immune response. Allergic or hypersensitivity reactions. Pharmacotherapy of asthma and COPD. Immuno suppressants and Immunostimulants	12
4	GIT Pharmacology Antiulcer drugs, Prokinetics, antiemetics, anti-diarrheals and drugs forconstipation and irritable bowel syndrome. Chronopharmacology Biological and circadian rhythms, applications of chronotherapyin various diseases like cardiovascular disease, diabetes, asthma and pepticulcer	12
5	Free radicals Pharmacology Generation of free radicals, role of free radicals inetiopathology of various diseases such as diabetes, neurodegenerative diseases and cancer. Protective activity of certain important antioxidant Recent Advances in Treatment: Alzheimer's disease, Parkinson's disease, Cancer, Diabetes mellitus	12

REFERENCES:

1. The Pharmacological basis of therapeutics-Goodman andGillman's
2. Principles of Pharmacology. ThePathophysiologic basis of drug therapy by DavidE.Golanetal.

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3. Basic and Clinical Pharmacology byB.G -Katzung
4. Pharmacology by H.P.RangandM.M. Dale.
5. Hand book of Clinical Pharmacokinetics by Gibaldi and Prescott.
6. Text book of Therapeutics, drug and disease management by E.T. Herfindaland Gourley.
7. Applied biopharmaceutics and Pharmacokinetics by Leon Shargel and AndrewB.C.Yu.
8. Handbook of Essential Pharmacokinetics, Pharmacodynamics and Drug Metabolismfor Industrial Scientists
9. Robbins & Cortan Pathologic Basis of Disease, 9th Ed. (Robbins Pathology)
1. 10.A Complete Textbook of Medical Pharmacology by Dr. S.K. Srivastava publishedbyAPC AvichalPublishingCompany.
2. 11.K.D.Tripathi.EssentialsofMedicalPharmacology
3. 12.Principles of Pharmacology. The Pathophysiologic basis of drug Therapy by David E Golan, Armen H. Tashjian Jr, Ehrin J,Armstrong, April W, Armstrong,Wolters,Kluwer-LippincottWilliams&Wilkins Publishers

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GUJARAT TECHNOLOGICAL UNIVERSITY

M.Pharm

Pharmacology

SEMESTER: II

Subject Name: PHARMACOLOGICAL AND TOXICOLOGICAL SCREENING
Subject Code: MPL2502T

Scope: This subject imparts knowledge on the preclinical safety and toxicological evaluation of drug &new chemical entity. This knowledge will make the student competent in regulatory toxicological evaluation

Objectives: Upon completion of this course the student should be able to

1. Explain the various types of toxicity studies
2. Appreciate the importance of ethical and regulatory requirements for toxicity studies
3. Demonstrate the practical skills required to conduct the preclinical toxicity studies

Sr No	Course Contents	Total Hrs
1	Basic definition and types of toxicology (general, mechanistic, regulatory and descriptive) Regulatory guidelines for conducting toxicity studies OECD, ICH, EPA and Schedule Y OECD principles of Good laboratory practice(GLP) History, concept and itsi mportance in drug development	12
2	Acute, sub-acute and chronic- oral, dermal and inhalational studies as per OECD guidelines. Acute eye irritation, skin sensitization, dermal irritation & dermal toxicity studies. Test item characterization- importance and methods in regulatory toxicology studies	12
3	Reproductive toxicology studies, Male reproductive toxicity studies, female reproductive studies (segment I and segment III), teratogenicity studies (segmentII) Genotoxicity studies(Ames Test, in vitro and in vivo Micronucleus and Chromosomal aberrations studies) In vivo carcinogenicity studies	12
4	IND enabling studies (IND studies)- Definition of IND, importance of IND, industry perspective, list of studies needed for IND submission Safety pharmacology studies- origin, concepts and importance of safety pharmacology. Tier1- CVS, CNS and respiratory safety pharmacology, HERG assay.Tier2-GI,renal and other studies	12
5	Toxicokinetics- Toxicokinetic evaluation in preclinical studies, saturation kinetics Importance and applications of toxicokinetic studies. Alternativemethodstoanimal toxicitytesting	12

REFERENCES:

1. Hand book on GLP, Quality practices for regulated non-clinical research and development (http://www.who.int/tdr/publications/documents/glphandbook.pdf
2. Schedule Y Guideline: drugs and cosmetics (secondamendment) rules, 2005, ministry of health and family welfare (department of health) New Delhi
3. Drugs from discovery to approval by RickNG.
4. Animal Models in Toxicology, 3rd Edition, Lower andBryan .
5. OECD test guidelines
6. Principles of toxicology by KarenE. Stine,ThomasM.Brown

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7. Guidance for Industry M3(R2)Nonclinical Safety Studies for the Conduct of Human Clinical Trials and Marketing Authorization for Pharmaceuticals (http://www.fda.gov/downloads/drugs/guidancecomplianceregulatoryinformation/guidances/ucm073246.pdf)

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GUJARAT TECHNOLOGICAL UNIVERSITY

M.Pharm

Pharmacology

SEMESTER: II

Subject Name: PRINCIPLES OF DRUG DISCOVERY
Subject Code: MPL203T

Scope: The subject imparts basic knowledge of drug discovery process. This information will make the student competent in drug discovery process

Objectives: Upon completion of this course the student should be able to

1. Explain the various stages of drug discovery
2. Appreciate the importance of the role of genomics, proteomics and bioinformatics in drug discovery
3. Explain the various targets for drug discovery
4. Explain the various lead Seeking method and lead optimization
5. Appreciate the importance of the role of computer aided drug design in drug discovery.

Sr No	Course Contents	Total Hrs
1	An overview of modern drug discovery process: Target identification, target validation, lead identification and lead Optimization. Economics of drug discovery. Target Discovery and validation-Role of Genomics, Proteomics and Bioinformatics. Role of Nucleic acid microarrays, Protein microarrays, Antisense technologies, siRNAs, antisense oligonucleotides, Zinc finger proteins. Role of transgenic animals in target validation.	12
2	Lead Identification- combinatorial chemistry & high throughput screening, in silico lead discovery techniques, Assay development for hit identification. Protein structure Levels of protein structure, Domains, motifs, andfolds in protein structure. Computational prediction of protein structure: Threading and homology modeling methods. Application of NMR and X-ray crystallography in protein structure prediction	12
3	Rational Drug Design Traditional vsrational drug design, Methods followed in traditional drug design, High throughput screening, Concepts of Rational Drug Design, Rational Drug Design Methods: Structure and Pharmacophore based approaches Virtual Screening techniques: Drug likeness screening, Concept of pharmacophore mapping and pharmacophore based Screening	12
4	Molecular docking: Rigid docking, flexible docking, manual docking; Docking based screening. Denovo drug design. Quantitative analysis of Structure Activity Relationship History and development of QSAR, SAR versus QSAR, Physicochemical parameters, Hansch analysis, Fee Wilson analysis and relationship between them	12
5	QSAR Statistical methods – regression analysis, partial least square analysis (PLS) and other multivariate statistical methods. 3D-QSARapproaches like COMFA and COMSIA Prodrug design-Basic concept, Prodrugs to improve patient acceptability, Drug solubility, Drug absorption and distribution, site specific drug delivery and sustained drug action. Rationale of prodrug design and practical consideration of prodrug design	12

REFERENCES:

1. Mouldy Sioud. Target Discovery and Validation Reviews and Protocols: Volume 2 Emerging Molecular Targets and Treatment Options. 2007 Humana Press Inc
2. Darryl León. Scott Markelln. Silico Technologies in Drug Target Identification and Validation.2006byTaylor and Francis Group, LLC
3. Johanna K. DiStefano. Disease Gene Identification. Methods and Protocols. Springer New York Dordrecht Heidelberg London
4. Hugo Kubiny. QSAR: Hansch Analysis and Related Approaches. Methods and Principles in Medicinal Chemistry. Publisher Wiley-VCH
5. Klaus Gubernator, Hans-Joachim Böhm. Structure-Based Ligand Design. Methods and Principles in Medicinal Chemistry. Publisher Wiley-VCH
6. Abby L . Parrill. M . Rami Reddy. Rational Drug Design. Novel Methodology and Practical Applications. ACS Symposium Series; American ChemicalSociety:Washington,DC,1999
7. J. Rick Turner. Newdrug development design, methodology and, analysis. JohnWiley&Sons,Inc.,New Jersey

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GUJARAT TECHNOLOGICAL UNIVERSITY

M.Pharm

Pharmacology

SEMESTER: II

Subject Name: CLINICAL RESEARCH AND PHARMACOVIGILANCE
Subject Code: MPL204T

Scope: This subject will provide a value addition and current requirement for the students in clinical research and pharmacovigilance. It will teach the students on conceptualizing, designing, conducting, managing and reporting of clinical trials. This subject also focuses on global scenario of Pharmacovigilance in different methods that can be used to generate safety data. It will teach the students in developing drug safety data in Pre-clinical, Clinical phases of Drug development and post market surveillance.

Objectives: Upon completion of this course the student should be able to

1. Explain the regulatory requirements for conducting clinical trial
2. Demonstrate the types of clinical trial designs
3. Explain the responsibilities of key players involved in clinical trials
4. Execute safety monitoring, reporting and close-out activities
5. Explain the principles of Pharmacovigilance
6. Detect new adverse drug reactions and their assessment
7. Perform the adverse drug reaction reporting systems and communication in Pharmacovigilance

Sr No	Course Contents	Total Hrs
1	Regulatory Perspectives of Clinical Trials: Origin and Principles of International Conference on Harmonization-Good Clinical Practice(ICH-GCP)guidelines Ethical Committee: Institutional Review Board, Ethical Guidelines for Biomedical Research and Human Participant ScheduleY, ICMR Informed Consent Process: Structure and content of an Informed Consent Process Ethical principles governing informed consent process	10
2	Clinical Trials: Types and Design Experimental Study-RCT and Non RCT, Observation Study: Cohort,Case Control, Cross sectional Clinical Trial Study Team Roles and responsibilities of Clinical Trial Personnel: Investigator, Study Coordinator, Sponsor, Contract Research Organization and its management	10
3	Clinical Trial Documentation- Guidelines to the preparation of documents, Preparation of protocol, Investigator Brochure, Case Report Forms, Clinical Study Report Clinical Trial Monitoring Safety Monitoring in CT Adverse Drug Reactions: Definition and types. Detection and reporting methods. Severity and seriousness assessment. Predictability and preventability assessment, Management of adverse drugreactions; Terminologies of ADR	10
4	Basic aspects, terminologies and establishment of pharmacovigilance History and progress of pharmacovigilance, Significance of safety monitoring, Pharmacovigilance in India and international aspects, WHO international drug monitoring programme, WHO and Regulatory terminologies of ADR, evaluation of medication safety, Establishing pharmacovigilance centres in Hospitals, Industry and National programmes related to pharmacovigilance. Roles and responsibilities in Pharmacovigilance	10
5	Methods, ADR reporting and tools used in Pharmacovigilance International classification of diseases, International Nonproprietary names	10

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	for drugs, Passive and Active surveillance, Comparative observational studies, Targeted clinical investigations and Vaccine safety surveillance. Spontaneous reporting system and Reporting to regulatory authorities, Guidelines for ADRs reporting. Argus, Aris G Pharmacovigilance, VigiFlow, Statistical methods for evaluating medication safety data.	
6	Pharmacoepidemiology, pharmacoeconomics, safety pharmacology	10

REFERENCES:

1. Central Drugs Standard Control Organization- Good Clinical Practices, Guidelines for Clinical Trials on Pharmaceutical Products in India. New Delhi: Ministry ofHealth;2001
2. International Conference on Harmonization of Technical requirements for registration of Pharmaceuticals for human use.ICH Harmonized Tripartite Guideline. Guideline for Good Clinical Practice.E6;May1996
3. Ethical Guidelines for Biomedical Research on Human Subjects 2000. Indian Council of Medical Research, NewDelhi
4. Textbook of Clinical Trials edited by David Machin, Simon Dayand Sylvan Green, March 2005,JohnWileyandSons
5. Clinical Data Management edited by R K Rondels,S AVarley,C F Webbs. Second Edition,Jan2000,WileyPublications
6. Handbook of clinical Research. Julia Lloyd andAnnRaven Ed. Churchill Livingstone.
7. Principles of Clinical Research edited by Giovanna di Ignazio, Di Giovanna and Haynes

PRINCIPAL

GUJARAT TECHNOLOGICAL UNIVERSITY

M.Pharm

Pharmacology

SEMESTER: II

Subject Name: Pharmacology Practical II
Subject Code: MPL205P

List of Practicals:

1. To record the DRC of agonist using suitable isolated tissues preparation.
2. To study the effects of antagonist/potentiating agents on DRC of agonist using suitable isolated tissue preparation.
3. To determine to the strength of unknown sample by matching bioassay by using suitable isolated tissue preparation.
4. To determine to the strength of unknown sample by interpolation bioassay by using suitable isolated tissue preparation.
5. To determine to the strength of unknown sample by bracketing bioassay by using suitable isolated tissue preparation.
6. To determine to the strength of unknown sample by multiple point bioassay by using suitable isolated tissue preparation.
7. Estimation of PA2 values of various antagonists using suitable isolated tissue preparations.
8. To study the effects of various drugs on isolated heart preparations
9. Recording of rat BP, heart rate and ECG.
10. Recording of rat ECG
11. Drug absorption studies by averted ratileum preparation.
12. Acuteoral toxicity studies as per OECD guidelines.
13. Acutedermal to toxicity studies as per OECD guidelines.
14. Repeated dose t toxicity studies - Serum biochemical, haematological, urine analysis, functional observation tests and histological studies.
15. Drug mutagenicity study using mice bone-marrow chromosomal aberration test.
16. Protocol design for clinical trial.(3Nos.)
17. Design of ADR monitoring protocol.
18. In-silico docking studies.(2Nos.)
19. In-silico pharmacophorebased screening.
20. In-silico QSAR studies.
21. ADR reporting .

REFERENCES

1. Fundamentals of experimental Pharmacology-byM.N.Ghosh
2. Hand book of Experimental Pharmacology-S.K.Kulakarni
3. Text book of in-vitro practical PharmacologybylanKitchen
4. Bioassay Techniques for Drug Development by Atta-ur-Rahman, Iqbal choudhary and William Thomsen
5. Applied biopharmaceutics and Pharmacokinetics by Leon Shargel and AndrewB.C.Yu.
6. Handbook of Essential Pharmacokinetics, Pharmacodynamics and Drug Metabolism for Industrial Scientists.

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MPHARM | 20 - PHARMACEUTICS | 3

Academic Year | Subject Code | Enter Subject Name | Search

*L=lectures,T=tutorial,P=Practical,E=TheoryExternal,M=TheoryInternal,I=Practical Internal,V=Practical External,On job Training(OJT) is equivalent to Practical

Exa.	Subcode	Branch code	Eff. from	SubjectName	Category	Sem /Year	Hours L.	Hours T.	Hours P.	Credit Total	Max Marks E	Max Marks M	Max Marks I	Max Marks V	Max Marks Total
☐	MDP303P	20	2017-18	Discussion/ Presentation (Proposal Presentation)	Compulsory	3	2	0	0	2	0	50	0	0	50
☐	MJC302P	20	2017-18	Journal Club I	Compulsory	3	1	0	0	1	0	25	0	0	25
☐	MRM301T	20	2017-18	Research Methodology and Biostatistics*	Compulsory	3	4	0	0	4	80	20	0	0	100
☐	MRW304P	20	2017-18	Research Work - Dissertation Phase I	Compulsory	3	0	0	28	14	0	0	50	300	350

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GUJARAT TECHNOLOGICAL UNIVERSITY

M.Pharm

SEMESTER: III

Subject Name: RESEARCH METHODOLOGY, BIOSTATISTICS AND IPR
Subject Code: MRM301T

Sr No	Course Contents	Total Hrs
1	**General Research Methodology** General Research Methodology: Research, objective, requirements, practical difficulties, Review of literature: Use of Library, books and journals-Medlines-Internet, and reprints of articles as a source for Literature survey. Selecting a problem and preparing Research proposals. The Research Report, Paper writing/ thesis writing, Different parts of the Research paper/Thesis Presentation (oral/poster presentation) Importance, types, different skills, content, format of model, Poster, Gestures, eye contact, facial expressions, stage fright, volume- pitch, speed, pause & language, Visual aids & seating. Questionnaire. Sources for procurement research grants –National/ international agencies, Government and private bodies	12
2	**Experimental Design (15 hours)** Terminology and definitions related to experimental design Study design, types of studies, strategies to eliminate errors/bias, controls, randomization, crossover design, placebo, blinding techniques Sampling Designs: Introduction, types of sample designs, steps, criteria of selection, characteristics, random sampling, drop outs. Advantage and disadvantage of conventional design over experimental design. Basic steps in experimental design. Screening Designs: Screening of factors, General properties for independent factor selected for experimental design, Fractional factorial design(FFD): Purpose advantage and disadvantage of fractional factorial design, Concept of Aliased Effects and Design Aliasing Structure and constructing FFD Analysis of fractional factorial design: Concept of Design Resolution for FFD Case study of factorial design Plackett–Burman designs: Purpose advantage and disadvantage and construction of matrix , Comparison between placket-Burman and FFD design, Case study Full factorial design Optimization techniques and various method of optimization Introduction to contour plots Introduction of repose surface design: Classification Characteristic of design Matrix and analysis of design with case study	15

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	Evolution of full and reduced mathematical models in experimental designs Central composite designs Taguchi and mixture design Application of experimental design in pharmacology for reduction of animal	
3	**Biostatistics** Definition, application, statistical tests of significance, type of significance tests, parametric tests(students "t" test, ANOVA, Correlation coefficient, regression), non-parametric tests (wilcoxan rank tests, analysis of variance, correlation, chi square test, Kruskal Wallis test, Mann Whitney U test), null hypothesis, P values, degree of freedom, interpretation of P values, post hoc tests for parametric and non-parametric data (Dunnett's test, Tukey's test, Dunn's test)	8
4	**Regulatory perspectives of Medical research** History of medical research (Nuremberg code, The declaration of Helsinki), initiation of ICH-GCP guidelines, advantages of ICH-GCP, core principles of ICH -GCP guidelines , Ethical Committee: Institutional Review Board, Ethical Guidelines by ICMR for Biomedical Research and Human Participants(ethical issues- informed consent process, confidentiality, payments, conflict of interest, vulnerable participants), Schedule Y, Preparation of clinical protocol, Investigator Brochure, Case Report Forms	10
5	**CPCSEA guidelines for laboratory animal facility** Objective and functions of IAEC, background and process of evolution of guidelines, statutory provisions regarding scientific experiments of animals, CPCSEA guidelines for animal experimentation and laboratory animal facility 2015, care and handling of animals, concept of 4 R, protocol preparation for Preclinical studies (Form B)	5
6	**IPR and Patents** Patents: Definition, Need for patenting, scope and importance of patents, Types of Patents, Condition to be satisfied by an invention to be patentable, Introduction to patent search and important websites, The essential elements of patents, Guidelines for preparations of laboratory notebook, non-obviousness in patents, Drafting of patent claims, important patent related websites. Copyrights and Trademark: Brief introduction to trademark protection and WTO patents, Introduction to "The Patents Act 1970" and "The Patents Rule 2003", with special emphasis on the forms to be submitted along with a patent application	10

REFERENCES:

1. Research Methodology by C.R. Kothari
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3. Presentation skills - Michael Hallon- Indian Society for Institute education
4. Pharmaceutics Statistics by Sanford Bolton, Charles Bon
5. Patent laws , By P. Narayan. Eastern law house publications
6. Pharmaceutical Experimental Design By Gareth Lewis and Didier Mathieu
7. www. ipindia.nic.in, www.uspto.gov
8. www.cpcsea.nic.in
9. www.icmr.nic.in

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TEACHING SCHEME / DETAIL SYALLBUS

MPHARM - 24 - PHARMACEUTICAL QUALITY ASSURANCE - 3 -

Academic Year - Subject Code Enter Subject Name

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Edit	Subject Code	Branch Code	Eff. from	Subject Name	Category	Sem / Year	L	T	P	Total	E	M	I	V	Total
☐	MDP303P	24	2017-18	Discussion/ Presentation (Proposal Presentation)	Compulsory	3	2	0	0	2	0	50	0	0	50
☐	MJC302P	24	2017-18	Journal Club I	Compulsory	3	1	0	0	1	0	25	0	0	25
☐	MRM301T	24	2017-18	Research Methodology and Biostatistics*	Compulsory	3	4	0	0	4	80	20	0	0	100
☐	MRW304P	24	2017-18	Research Work - Dissertation Phase I	Compulsory	3	0	0	28	14	0	0	50	300	350

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GUJARAT TECHNOLOGICAL UNIVERSITY

M.Pharm

SEMESTER: III

Subject Name: RESEARCH METHODOLOGY, BIOSTATISTICS AND IPR
Subject Code: MRM301T

Sr No	Course Contents	Total Hrs
1	**General Research Methodology** General Research Methodology: Research, objective, requirements, practical difficulties, Review of literature: Use of Library, books and journals-Medlines-Internet, and reprints of articles as a source for Literature survey. Selecting a problem and preparing Research proposals. The Research Report, Paper writing/ thesis writing, Different parts of the Research paper/Thesis Presentation oral/poster presentation) Importance, types, different skills, content, format of model, Poster, Gestures, eye contact, facial expressions, stage fright, volume- pitch, speed, pause & language, Visual aids & seating, Questionnaire. Sources for procurement research grants –National/ international agencies, Government and private bodies	12
2	**Experimental Design (15 hours)** Terminology and definitions related to experimental design Study design, types of studies, strategies to eliminate errors/bias, controls, randomization, crossover design, placebo, blinding techniques Sampling Designs: Introduction, types of sample designs, steps, criteria of selection, characteristics, random sampling, drop outs. Advantage and disadvantage of conventional design over experimental design. Basic steps in experimental design. Screening Designs: Screening of factors, General properties for independent factor selected for experimental design, Fractional factorial design(FFD): Purpose advantage and disadvantage of fractional factorial design, Concept of Aliased Effects and Design Aliasing Structure and constructing FFD Analysis of fractional factorial design: Concept of Design Resolution for FFD Case study of factorial design Plackett–Burman designs: Purpose advantage and disadvantage and construction of matrix , Comparison between placket-Burman and FFD design, Case study Full factorial design Optimization techniques and various method of optimization Introduction to contour plots Introduction of repose surface design: Classification Characteristic of design Matrix and analysis of design with case study	15

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GUJARAT TECHNOLOGICAL UNIVERSITY

M.Pharm

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Subject Name: RESEARCH METHODOLOGY, BIOSTATISTICS AND IPR
Subject Code: MRM301T

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5. Patent laws , By P. Narayan. Eastern law house publications
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7. www. ipindia.nic.in, www.uspto.gov
8. www.cpcsea.nic.in
9. www.icmr.nic.in

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TEACHING SCHEME / DETAIL SYALLBUS

MPHARM - 25 - PHARMACOLOGY - 3 -

Academic Year - Subject Code Enter Subject Name

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Exp.	Subcode	Branch code	Eff. from	Subject Name	Category	Sem /Year	Hours L.	T.	P.	Total	Credit E.	M	I	V	Total
☐	MDP303P	25	2017-18	Discussion/ Presentation (Proposal Presentation)	Compulsory	3	2	0	0	2	0	50	0	0	50
☐	MJC302P	25	2017-18	Journal Club I	Compulsory	3	1	0	0	1	0	25	0	0	25
☐	MRM301T	25	2017-18	Research Methodology and Biostatistics*	Compulsory	3	4	0	0	4	80	20	0	0	100
☐	MRW304P	25	2017-18	Research Work - Dissertation Phase I	Compulsory	3	0	0	28	14	0	0	50	300	350

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GUJARAT TECHNOLOGICAL UNIVERSITY

M.Pharm

SEMESTER: III

Subject Name: RESEARCH METHODOLOGY, BIOSTATISTICS AND IPR
Subject Code: MRM301T

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3. Presentation skills - Michael Hallon- Indian Society for Institute education
4. Pharmaceutics Statistics by Sanford Bolton, Charles Bon
5. Patent laws , By P. Narayan. Eastern law house publications
6. Pharmaceutical Experimental Design By Gareth Lewis and Didier Mathieu
7. www. ipindia.nic.in, www.uspto.gov
8. www.cpcsea.nic.in
9. www.icmr.nic.in

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TEACHING SCHEME / DETAIL SYALLBUS

MPHARM - 20 - PHARMACEUTICS - 4 -

Academic Year - Subject Code Enter Subject Name

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Edit	Subcode	Syllabus Code	Eff. from	Subject Name	Category	Exam Hour	L	T	P	Total	C	IA	I	V	Total
☐	MDP402P	20	2017-18	Discussion/ Presentation	Compulsory	4	3	0	0	3	0	75	0	0	75
☐	MDP402P	20	2018-19	Discussion/ Presentation	Compulsory	4	3	0	0	3	0	75	0	0	75
☐	MJC401P	20	2017-18	Journal Club II	Compulsory	4	1	0	0	1	0	25	0	0	25
☐	MJC401P	20	2018-19	Journal Club II	Compulsory	4	1	0	0	1	0	25	0	0	25
☐	MRW403P	20	2017-18	Research Work - Dissertation Phase II	Compulsory	4	0	0	32	16	0	0	0	400	400
☐	MRW404P	20	2018-19	Research Work - Dissertation Phase II	Compulsory	4	0	0	32	16	0	0	100	300	400

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TEACHING SCHEME / DETAIL SYALLBUS

MPHARM ~ 24 - PHARMACEUTICAL QUALITY ASSURANCE ~ 4 ~

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Exp.	Subcode	Branch code	Eff. from	Subject Name	Category	Sem /Year	Hours L.	T.	P.	Total	Credits E	M	I	V	Max Marks Total
☐	MDP402P	24	2017-18	Discussion/ Presentation	Compulsory	4	3	0	0	3	0	75	0	0	75
☐	MDP402P	24	2018-19	Discussion/ Presentation	Compulsory	4	3	0	0	3	0	75	0	0	75
☐	MJC401P	24	2017-18	Journal Club II	Compulsory	4	1	0	0	1	0	25	0	0	25
☐	MJC401P	24	2018-19	Journal Club II	Compulsory	4	1	0	0	1	0	25	0	0	25
☐	MRW403P	24	2017-18	Research Work - Dissertation Phase II	Compulsory	4	0	0	32	16	0	0	0	400	400
☐	MRW404P	24	2018-19	Research Work - Dissertation Phase II	Compulsory	4	0	0	32	16	0	0	100	300	400

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Exp.	Subcode	Branch code	Eff. from	SubjectName	Category	Sem /Year	Hours			Credits	Max Marks				
							L	T	P	Total	E	M	I	V	Total
☐	MDP402P	25	2017-18	Discussion/ Presentation	Compulsory	4	3	0	0	3	0	75	0	0	75
☐	MDP402P	25	2018-19	Discussion/ Presentation	Compulsory	4	3	0	0	3	0	75	0	0	75
☐	MJC401P	25	2017-18	Journal Club II	Compulsory	4	1	0	0	1	0	25	0	0	25
☐	MJC401P	25	2018-19	Journal Club II	Compulsory	4	1	0	0	1	0	25	0	0	25
☐	MRW403P	25	2017-18	Research Work - Dissertation Phase II	Compulsory	4	0	0	32	16	0	0	0	400	400
☐	MRW404P	25	2018-19	Research Work - Dissertation Phase II	Compulsory	4	0	0	32	16	0	0	100	300	400

PRINCIPAL

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