

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				

Gujarat Technological University

M. Pharm. Semester – III

Common Subject for all

Experimental Design and Patents

(Theory only)

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.

Subject of Specialization Paper – V (Pharmaceutics)

Novel Drug Delivery System: Part – II

Theory: 4hr/week

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, tailor made medicines, Strips, Disketts and film products. Liposomes/neosomes. Ionto and sonophoretic systems.
3. Use of Spherical Techniques, Super and sub-critical fluids, PEGylations. Biotech based products, Proteins and peptides, Immunomodulated molecules. Prodrug approach.

Subject of Specialization Paper – V (Pharmaceutics)

Novel Drug Delivery System: Part – II

Practical

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

Recommended 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, Pharmatech 2003.

10. Encyclopedia of pharmaceutical technology – volume –16
11. “Computers in Pharmaceutical Technology”, Encyclopedia of Pharmaceutical Technology, Volume 3.
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.

Advanced Medicinal Chemistry

Subject of Specialization Paper- V (Pharmaceutical Chemistry)

Theory: 4hr/week

1. Combinatorial Chemistry

Introduction, combinatorial approaches, applications, methodology, combinatorial organic synthesis, Peptide and small molecule libraries, assays and screening of combinatorial libraries, introduction to High Throughputs Screening (HTS)

2. Peptides as a Drug

Chemistry, structure and stability, Reactivity of proteins and peptides. Different methods of synthesis. Study of Insulin, Relaxin, Somatostatin, Interferon, Peptidomimetics

3. Microorganisms in Drug Synthesis and Development

Microbial conversions of drugs like steroids, prostaglandin, antibiotics, enzyme immobilization Techniques.

4. Recent advances in therapy of following

- a. Neurodegenerative diseases: Alzheimer's and Parkinsonism
- b. CVS disorders: Hypertension, Arrhythmia, Atherosclerosis.
- c. Hormonal disorder: hypoglycemic agents and steroidal agents
- d. Disorders of immune system: NSAID's, antihistamines, immunomodulators
- e. Chemotherapeutic agents: antitubercular, antimalarial, antiviral, anti-cancer, antifungal, antibacterials

Advanced Medicinal Chemistry

Subject of Specialization Paper- V (Pharmaceutical Chemistry)

Practical

Practical exercises based on the relevant topics. Synthesis of some drug and drug intermediate falls under therapeutic class mentioned in theory syllabus.

Books recommended:

1. Corwin Hansch, Peter G. Sammes, John B. Taylor; Comprehensive Medicinal Chemistry Vol. 4, Pergamon.
2. John H. Block, John M. Beale; Wilson & Gisvold's Text book of Organic Medicinal and Pharmaceutical Chemistry, 11th edition, Lippincott Williams and Wilkins.
3. Davis A. Williams, Thomas L. Lemke; Foye: Principles of Medicinal Chemistry, 5th edition, Lippincott Williams Wilkins.
4. Bernard Testa, Walter Fuhrer – Perspectives in Medicinal Chemistry.
5. Donald J. Abraham; Berger's Medicinal Chemistry and Drug Discovery, 6th edition, John Wiley and Sons.
6. Daniel Lednicer; The Organic Chemistry of Drug Synthesis, Vol. 1-6, Wiley Interscience.
7. Richard B. Silverman: The Organic Chemistry of Drug Design and Drug action; 2nd edition, Elsevier.

Clinical Research and Pharmacy Practice

Subject of Specialization Paper- V (Pharmacology)

Theory- 4hr/week

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 Pharmacoepidemiology, and Pharmacoeconomics

Interpretation of clinical laboratory test: Hematological, pathological and Biochemical investigations as markers of Disease/organ damage and their impact on drug therapy decision.

Critical care: Critical care therapy and Transplantation

Clinical Research and Pharmacy Practice

Subject of Specialization Paper- V (Pharmacology)

Practicals

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

Books recommended (Latest Edition):

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.

Applied Pharmacotherapeutics – II

Subject of Specialization Paper- V (Clinical Pharmacy)

Theory – 4hr/week

Pathophysiology, Diagnosis & Pharmacotherapeutic management of acute and chronic diseases

- 1. Haemopoetic:** Anemias, Coagulation diseases.
- 2. Joint and Connective Tissue:** Rheumatoid arthritis, osteoarthritis, gout and hyperuricemia
- 3. Neoplastic:** Acute leukemias, Hodgkins disease, carcinoma of breast, Liver tumors, gastrointestinal cancers, lung cancer, prostate cancer, pediatric solid tumors, gynecological cancers and skin cancers.
- 4. Infections:** Various infectious diseases including Tuberculosis, urinary tract infections, enteric infections, upper respiratory tract infections, Pneumonia, Intraabdominal infections, gastrointestinal infections, bone and joint infections, sepsis, parasitic infections, sexually transmitted diseases and AIDS
- 5. Renal:** Acute renal failure, chronic renal failure.
- 6. Diseases of skin:** Contact dermatitis , Acne Vulgaris, psoriasis, warts, burns.
- 7. Eye:** Glaucoma & Conjunctivitis
- 8. Reproductive System:** Male and Female reproductive system and their hormones. Physiology of menstruation, coitus and fertilization. Sex differentiation, spermatogenesis, pregnancy its maintenance and parturition
- 9. Managing ICUs, T.P.N. and Emergencies**
- 10. Concept of acute care medicine**
- 11. General treatment guideline for: Pediatric patients, geriatric patients, pregnancy & lactating mother**

Applied Pharmacotherapeutics – II

Subject of Specialization Paper- V (Clinical Pharmacy)

Practical

Each student has to undergo compulsory Hospital postings for understanding and gaining knowledge of Pathophysiology, Diagnosis & Pharmacotherapeutic management various diseases and disorders.

It is mandatory that each student has to maintain a record of at least 15 case studies based on the theory topics

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

BOOKS RECOMMENDED:

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

Traditional Drugs

Subject of Specialization Paper – V (Pharmacognosy)

Theory: 4hr/week

1. Distribution and chemotaxonomy of volatile oil in plants. Role of volatile oils in medicine, their industry and industrial importance in India.
2. Biodiversity conservation, economic development and drug discovery from traditional medicinal plants of India.
3. Plant growth regulators.
4. Methods of isolation, purification, identification, estimation, conversion to useful derivatives and importance of following phytopharmaceuticals:
 - a. Vinca alkaloids
 - b. Morphine
 - c. Reserpine
 - d. Quinine
 - e. Diosgenin
 - f. Solasodine
 - g. Glycyrrhizin
 - h. Picroside
 - i. Rutin
 - j. Vasicine
 - k. Ephedrine
 - l. Anthraquinones
5. Herbal medicine information sources, books, journals, online databases.

Traditional Drugs

Subject of Specialization Paper – V (Pharmacognosy)

Practical

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

BOOKS RECOMMENDED:

1. Stephen K. Sim, Medicinal Plant Glycosides, University of Toronto Press, Canada.
2. Stephen K. Sim, Medicinal Plant Alkaloids, University of Toronto Press, Canada.
3. Olayiwola Akerele, Vernon Heywood and Hugh Syngé (Editors), The Conservation of Medicinal Plants, Printed by Cambridge University Press, Cambridge.
4. Atal C.K. and Kapur B.M., Cultivation and Utilization of Medicinal Plants, Published by RRL, Jammu-Tawi, 1982.
5. Handa S.S & Kaul K.L., Supplement to cultivation and utilization of medicinal plants, 1996.
6. R.D. Chaudhary, Herbal Drugs Industry, Eastern Publishers, New Delhi.
7. Wagner H., Blatt S. and Zgainski, Plant Drug Analysis Springer, Verlag, New York.
8. Peach K. and Tracey M.V., Modern Methods of Plant Analysis, 1-4, Narosa Publisher House, N.D.
9. Indian Herbal Pharmacopoeia, Vol. I and II, Jointly published by RRL, Jammu and IDMA, Mumbai – 1998 and 1999.
10. British Herbal Pharmacopoeia, Published by British Herbal Medicines Association 1996.
11. Trease E and Evan's W.C., Pharmacognosy, 15th edition, Balliere Tindall. Eastbourne, U.K., 2002.
12. James E. Robbers, Varro E. Tyler, Herbs of Choice – The Therapeutic Use of Phytomedicinals.
13. Guenther, The Essential Oils, Vol. I and II, Published by D.Van Nostrand Company Inc., 1948.
14. R. H. F. Manske, The Alkaloids-Chemistry and Physiology, Published by Academic Press, London.
15. Zechmeister, Progress in the Chemistry of Organic Natural Products, Published by Springer-Verlag Wien, Austria.

Validation and Product Development

Subject of Specialization Paper – V (Quality Assurance)

Theory: 4hr/week

- 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**
- 3. 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.
- 4. Vendor Certification**
- 5. Utilities Validation**
 - a.** Validation of Pharmaceutical Water System & pure steam,
 - b.** Validation of HVAC system
 - c.** Validation of Compressed air
- 6. Cleaning Validation: Cleaning of Equipment, Cleaning of Facilities**
- 7. Analytical Method Validation**

General principles of analytical method validation.

Validation of following analytical Instruments

- HPLC
- Dissolution test apparatus
- U.V./Visible spectrophotometers

8. Process Validation

Prospective, concurrent, retrospective & revalidation, Process validation of following formulations

- Coated tablets
- Capsules
- Ointment/Creams
- Liquid Orals

9. Computer System Validation

10. 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 Specialisation Paper – V (Quality Assurance)

Practical

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.

Recommended 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.

Gujarat Technological University

M. Pharm. Semester – III

Introduction to Dissertation (For all branches)

Instructions:

- 1.** Student must complete literature search and preliminary experimental work of his/her research project and submit the synopsis, dully signed by Research Guide and Principal of Institute to University on completion of Semester – III.
- 2.** Utmost care should be taken in selection of research topic so that repetition of research work is avoided.
- 3.** For change in research topic, written permission of institute level research committee should be taken.
- 4.** Candidates work will be evaluated by the external examiner through viva-voce.