SYLLABUS

SPECIFIC TO

POST GRADUATE DEGREE IN

M. Tech. (Chemical) Drugs & Pharmaceuticals

[CREDIT SYSTEM]

University Department of Chemical Technology
Dr. Babasaheb Ambedkar Marathwada University,
Aurangabad - 431 004
Maharashtra State, India.

Syllabus [Credit System]

Course Name: M. Tech. (Chemical) Drugs & Pharmaceuticals
Year: First
Semester: I
Subject Name: Advanced Pharmaceutical Chemistry
Subject Code: MDP-0101
Credits: 4
Work load: 4 hr/week

Theory

Unit 1 Enzyme and Enzyme inhibitors

Enzyme structure- primary, secondary, tertiary and quaternary.
Enzyme Kinetics (Revision).
Enzyme inhibitors

- Reversible enzyme inhibitors
- Irreversible
- Kcat inhibitors (Mechanism based)
- Transition state analog.

Enzyme inhibitors as drug

- ACE inhibitors
- Cytochrome P450 inhibitors
- HIV- reverse transcriptase, protease and integrase inhibitors.
- Luekotrienes nad lipooxyhgenase inhibitors.
- Aromatase inhibitors

Unit 2 Molecular modeling and Drug deign

Molecular mechanics- force field (Potential energy function)
Energy minimization methods- steepest descent, conjugate gradient and Newton Rapson method.
Conformational analysis

- Systemic search
- Montecarlos stimulation
- Molecular dynamics simulation.

Structure based and ligand based drug design approaches
3D-pharmacophore modeling.

Drug docking and design new chemical entity by use of suitable computer hardware and software.

Unit 3 Combinatorial chemistry

Introduction
Combinatorial approach to chemical diversity
Chemical compound library.
Combinatorial organic synthesis.

Unit 4 QSAR

Parameters; Lipophilicity, partition coefficient, electronic and steric, polarizability other.
Quantitative Models: Hansch analysis, free-Wilson analysis, mixed approach.
Other QSAR approach: 3D-QSAR, CoMFA, CoMSIA, GFA.
Application of Hansch analysis, free Wilson analysis.

Unit 5 Introduction to high-throughput screening, genomics and proteomics in drug design

Unit 6 Synthon approach in drug synthesis:

Defination of terms- Disconnection, synthon, functional group interconversion (FGI), functional group conversion (FGC).
Basic rules in disconnection.
By using synthon approach/retrosynthesis for the synthesized following compound: Sulfisoxazole, ibuprofen, atenolol, haloperidol, indinavir, losatan, ranitidine, proxicam, glipizide, ciprofloxacin, captopril, diltiazem, nefazodone, linezolid and paclitaxel. (Synthesis of the latest drugs to be decided by faculty).

Recommended Books

1. Medicinal Chemistry by Burger, A.
2. Organic Medicinal and Pharmaceutical Chemistry by Wilson and Gisvold
3. Drug Design by Ariens
4. Chemobiodynamic and Drug Design by Schueler
5. Principals of Medicinal Chemistry by Foye
6. QSAR by Martin, Y.
7. Principles of Medicinal Chemistry by Hansch
8. QSAR by Kubiny's
9. Molecular Modeling by Holtje. Sippl., Rognan and Folkers
10. Textbook of Drug Design and Discovery by P.K. Larsen, Tommy and U.Madsen
11. Computer Aided Drug Design by T.J. Perun and C.L. Propst

Syllabus [Credit System]

Course Name: **M. Tech. (Chemical) Drugs & Pharmaceuticals**
Year: **First**
Semester: **I**
Subject Name: **Advanced Pharmaceutical Chemistry**
Subject Code: **MDP-0102**
Credits: **3**
Work load: **6 hr/week**

Practical

1. To synthesize and characterize 5,5-diphenyl-2-thio-imidazoline-4-one from benzyl
2. To synthesize and characterize 4-methyl-7-hydroxy coumarin from resorcinol
3. To synthesize and characterize benzhydrol from benzephenone
4. To synthesize and characterize diethyl 2,6-dimethyl-4-(2-nitrophenyl)-1,4-dihydropyridine-3,5-dicarboxylate (Nifedipine Analogue) from m-nitrobenzaldehyde
5. Introduction to Microwave
6. Microwave synthesize and characterization of diethyl 2,6-dimethyl-4-(2-nitrophenyl)-1,4-dihydropyridine-3,5-dicarboxylate (Nifedipine Analogue) from m-nitrobenzaldehyde
7. To synthesize and characterize acetophenone phenylhydrazone from phenylhydrazine
8. To synthesize and characterize 2-phenylindole from acetophenone phenylhydrazone
9. To synthesize and characterize p-aminobenzoic acid from p-nitrobenzoic acid
10. To synthesize and characterize benzocaine from p-aminobenzoic acid

Reference:

1. Brian S. Furniss, Antony J. Hannaford, Peter W. G. Smith, Austin R. Tatchell, Vogel's Textbook of Practical Organic Chemistry, 5th Edition, Longman Scientific & Technical, Longman Group UK Limited.
2. Daniel Lednicer, Lester A. Mitscher, The Organic Chemistry Of Drug Synthesis, A Wiley-Interscience Publication, John Wiley & Sons.
3. Jie Jack Li,, Name Reactions: A Collection of Detailed Mechanisms and Synthetic Applications, Fourth Expanded Edition Springer Dordrecht Heidelberg London New York
4. Jeremiah P. Freeman, Organic Syntheses, Collective Volumes 1 -10 Set**,** A Wiley-Interscience Publication, John Wiley & Sons.
5. Jie-Jack Li, E. J. Corey, Name Reactions In Heterocyclic Chemistry, 2005, A John Wiley & Sons, Inc., Publication

Syllabus [Credit System]

Course Name: **M. Tech. (Chemical) Drugs & Pharmaceuticals**
Year: **First**
Semester: **I**
Subject Name: **Research Methodology**
Subject Code: **MDP-0103**
Credits: **4**
Work load: **4 hr/week**

Theory

Unit 1 Research:

Meaning, objective of research, types of research.
Selecting a problem and preparing research proposal for different types of research.
Literature survey
-Use of library, books and journals, use of internet (different useful sites), patent search.

Unit 2 Methods and tools in research:

Qualitative and quantitative studies, Inquiry forms, Questionnaire, opionnarie.

Unit 3 Data analysis:

Parametric and non-parametric data
Hypothesis testing
Descriptive and Inferential analysis
Statistical analysis of data including standard deviation, student "t"test, "f"test, ANOVA, Multiple regression and correlation coefficient.

Unit 4 Documentation:

Unit 5 Research paper /Thesis writing:

Different parts of the research paper.
Presentation: Oral, poster.

Unit 6 Sources of procurement of research grants.

Industrial Institution Interaction.

Recommended Books

1. Research In Education by John V. Best, John V. Kahn
2. Presentation skills by Michael Hallon
3. Practical Introduction to copyright by Gavin Mcfarlane
4. Thesis projects in Science & Engineering by Richard M. Davis.
5. Scientist in legal Systems by Ann labor science
6. Thesis & Assignment by Jonathan Anderson
7. Writing a technical paper by Donald Menzel
8. Effective Business Report Writing byLeland Brown
9. Protection of industrial Property rights by P. Das & Gokul Das
10. Spelling for the millions by Edna Furmess
11. Preparation for publication by King Edward Hospital Fund for London

Syllabus [Credit System]

Course Name: **M. Tech. (Chemical) Drugs & Pharmaceuticals**
Year: **First**
Semester: **I**
Subject Name: **Research Methodology**
Subject Code: **MDP-0104**
Credits: **2**
Work load: **4 hr/week**

Practical

1. To collect name of journals, publishing company and their latest impact factor related to following subjects:
   - Pharmaceutics & Bio-pharmaceutics
   - Natural Products
   - Pharmaceutical Analysis
   - Medicinal Chemistry
2. To collect any three research articles related to controlled release formulations.
3. To find out "Gap in existing research" from the collected research articles.
4. To collect any three review articles related to natural products.
5. To write a separate summary of collected review articles (Maximum 2 pages per article).
6. To perform the literature survey on "Anti-cancer/Anti-viral drugs and their oral bioavailability problems"(Maximum 10 pages).
7. To prepare power-point presentation on "Novel Drug Delivery Systems/Analytical tools and techniques used in pharmaceuticals"(Maximum 20 slides).
8. To deliver presentation on "Novel Drug Delivery Systems/Analytical tools and techniques used in pharmaceuticals" (Maximum 20 min).

9. To prepare power-point presentation on “Extraction techniques available for herbs/Pharmacokinetic drug interactions”(Maximum 20 slides).
10. To deliver presentation on “Extraction techniques available for herbs/ Pharmacokinetic drug interactions” (Maximum 20 min).

Recommended Books/Journals/Magazines/websites

1. http://www.bamu.net/journal.htm
2. www.pubmed.com
3. www.sciencedirect.com
4. http://onlinelibrary.wiley.com/
5. http://www.springer.com/?SGWID=9-102-0-0-0
6. Research In Education by John V. Best, John V. Kahn
7. Presentation skills by Michael Hallon
8. Thesis & Assignment by Jonathan Anderson
9. Writing a technical paper by Donald Menzel
10. Preparation for publication by King Edward Hospital Fund for London

Syllabus [Credit System]

Course Name: M. Tech. (Chemical) Drugs & Pharmaceuticals
Year: First
Semester: I
Subject Name: Formulation Technology
Subject Code: MDP-0105
Credits: 4
Work load: 4 hr/week

Theory

Unit 1 Product development and testing of liquid orals

- Solutions, Suspensions, Emulsions-Microemulsions
- Selection of additives
- Manufacturing
- Evaluation
- Stability considerations

Drug excipient interaction and incompatibilities.

Unit 2 Solid dosage forms with reference to high speed continuous operations.

- Tablets: Design and formulation, desirable properties of raw materials, types of tablets, Manufacturing and evaluation, recent developments in tabletting.
- Capsules, soft gelatin capsules, excipients, manufacturing, evaluation.
- Coating-Sugar, film, air suspension coating. Equipment, procedure and evaluation.

Unit 3 Product development and testing of Sterile dosage forms with reference to high speed and continuous operations

i) Parenterals : SVP, LVP

- Methods of preparation and production facilities
- Evaluation
- Stability
- Packaging

ii) Ophthalmics

- Ocular toxicity and irritation
- Preservatives
- Method of preparation
- Delivery to anterior and posterior segments

Unit 4 Cutaneous and topical drug delivery with reference to high speed and continuous operations:

- Percutaneous absorption
- Factors affecting drug absorption from skin
- Topically applied products and their formulation.
- Evaluation &Stability

Aerosol Technology

- Propellants
- Containers
- Formulation
- Evaluation
- Stability
- MDI

Cosmetic preparations: Formulation, stability, safety and performance of the following products such as

- Skin care : Moisturizers, cleansing products, sunscreens
- Hair care : Shampoos, hair dyes

Unit 5 Transdermal Drugs Delivery system (TDDS)-Concept, principle involved, permeation through skin, factors affecting permeation, permeation enhancers, basic component of TDDS,formulation approaches and evaluation of TDDS. **Mucoadhesive Drug delivery System:-** -Buccal drugs delivery system, transmucosal permeability, models of mucosal membrane, in vivo and in vitro methods of buccal absorptions,Nasal and pulmonary drug delivery system and its applications.

Ocular Drug Delivery System –formulation and evaluation of ocular drug delivery of drugs,pilocarpine delivery system, ophthalmic inserts.

Protein-peptide drug delivery:Preformulation, characterization of drug molecule, stability aspects, protein degradation pathways, General protein formulation strategies, routes of delivery.

Unit 6 R & D to pilot scale to plant scale. Pilot plant scale up studies-significance along with dosage forms like liquid orals, solid dosage forms and sterile dosage forms with equipments and SOPs, Technology transfer from one plant to other, ICH SUPAC.

Preparation of flow diagram, material balance sheets, technical data sheets, material and inventory control, Master formula generation and maintenance, SOPs for different dosage forms and activities.

Industrial hazards, safety, pollution and effluent treatment, Hazard Analysis & and Critical Control Process (HACCP), prevention measures in pharma industries. Monitoring systems Case studies of pharma industrial accidents.

Supply chain management and Entrepreneur Resource Planning. (ERP)

Recommended Books

1. Tablet Dosage From, (Vol I –III) Liberman H A, Lachman and others
2. Parentral medication:Vol-I-III Liberman H A, Lachman and others-
3. Dispersed Systems, (vol I-III) Liberman H A, Lachman and others-
4. Pharmaceutical Inhalation Aerosol Technology, Anthony J Hickey
5. Harry's Cosmeticology, Martin M Rieger.
6. Modern Pharmaceutics by Banker and Rhodes
7. Novel Drug Delivery System, Chien
8. Controlled Drug Delivery:Fundamentals and Applications.,Joseph R Robinson & Vincent Lee
9. Transdermal Drug Delivery:Deverlopmental issues and research initiatives.,Jonathan Hadgraft. And Richard H Guy.
10. Packaging drugs and pharmaceuticals. Jenkins, Wilmer and Osborn, Kenton R.
11. Pharm. Packaging Technology. Dean, Evan and Hall I H.
12. Packaging engineering. Barail
13. Theory and Practice of Industrial Pharmacy, Liberman, Lachman
14. Pharmaceutical production facilities: design and applications. Cole, Graham
15. Safety assessment for pharmaceuticals, Gad, Shayne
16. From Bench to Pilot plant:Process research in the pharmaceutical industries,Mehdi Nafissi,John a Ragan, Keith M Devries
17. IP, BP, USP, EP
18. Method Validation in Pharmaceutical analysis by Ermer
19. Pharmaceutical Master Validation plan by Haider
20. Drugs & Cosmetic Act, 1940, and rules there under 1945, and other related Acts, Govt of India
21. New Drug Approval Process,Guarino.
22. Intellectual Property: Patents, Copyright, Trade Marks, and Allied Rights**,** W R Cornish
23. Super Critical Fluid Technology, Peter York
24. Pharm Extrusion Technology, Ghebre Sellassie

25. Polymorphism in pharmaceutical solids, Brittain
26. Pharm.Process Engineering. Anthony J Hickey
27. Topical Drug Delivery. Amman
28. Poucher's Perfumes,cosmetics and Soaps,Hilda butler
29. Handbook of Pharmaceutical Excipients,Arthur H Kibbe,
30. Good Manufacturing Practices ,James Stoker
31. Parenteral Quality Control ,Michael J Akers
32. Cosmetics Science and Technology –Marvin S Balsam and Sagarin Vol-I –III
33. Drug Delivery devices, Praveen Tyle
34. Pharm Gene Delivery System, Rolland
35. Bioadhesive drug delivery system, Edith Matheowitz
36. Modified drug delivery technology, Rathborne
37. Colloidal drug delivery system, Kreuter
38. Oral mucosal drug delivery. Rathbone
39. Drug Delivery devices, Praveen Tyle
40. Pharmaceutical inhalation aerosol technology –Hicky
41. Microencapsulation:Methods and industrial applications., Simon benita
42. Micro particulate systems for delivery of proteins and vaccines,Smadar Cohen
43. Protein Formulation and Delivery: Eugene J McNally
44. Colonic drug absorption and metabolism Peter- Bieck
45. Drug Targetting Technology:Physical, chemical biological methods, Hens , Schreier
46. Ophthalmic Drug delivery system, Mitra
47. Remington's Pharm Sciences.
48. Pharmaceutical Process Scale up,Michael Levin
49. Process Chemistry in pharma industry. Gadamasetti, kumar C
50. Chemical Plant Design, Molly Neux,
51. Multinational pharma companies: principle and practices. Spiker,bert-
52. Development and evaluation of drugs: from lab through licensure to market. Lee, hi-Jen and others
53. Principle of process research and chemical development in pharma industries. Repic,oljan
54. Careers with the pharma industries. Stonier, Peter D
55. Specialized drug delivery systems: manufacturing and production technology. Tyle, Praveen.

Syllabus [Credit System]

Course Name: **M. Tech. (Chemical) Drugs & Pharmaceuticals**
Year: **First**
Semester: **I**
Subject Name: **Formulation Technology**
Subject Code: **MDP-0106**
Credits: **3**
Work load: **6 hr/week**

Practical

1. Formulation of suspensions in structured vehicles and their quality control tests.
2. Formulation of micro-emulsions and their stability studies.
3. Preparation and evaluation of dispersible tablets.
4. Formulation of sustained release matrix tablets and its evaluation for description, hardness, friability and dissolution parameters.
5. Preparation of calcium gluconate injection and its evaluation for particulate matter test, leak test and sterility test.
6. Study of clean rooms and entry procedures for clean room.
7. Study of diffusion of drug through membrane/skin.
8. Formulation and evaluation of shampoo and moisturizer.
9. Formulation and evaluation of sunscreen lotion.
10. To study the effect of various permeation enhancers on the diffusion of a drug through membrane/skin.
11. Study of extrusion-spheronization of given mass of sample.
12. To demonstrate film coating and air suspension coating.

Recommended Books/Journals/Magazines/websites

1. http://www.bamu.net/journal.htm
2. www.pubmed.com
3. www.sciencedirect.com
4. http://onlinelibrary.wiley.com/
5. http://www.springer.com/?SGWID=9-102-0-0-0
6. Tablet Dosage From, (Vol I –III) Liberman H A, Lachman and others
7. Modern Pharmaceutics by Banker and Rhodes
8. Novel Drug Delivery System, Chien
9. Controlled Drug Delivery:Fundamentals and Applications.,Joseph R Robinson & Vincent Lee
10. Transdermal Drug Delivery:Deverlopmental issues and research initiatives.,Jonathan Hadgraft. And Richard H Guy.
11. Theory and Practice of Industrial Pharmacy, Liberman, Lachman

Syllabus [Credit System]

Course Name: **M. Tech. (Chemical) Drugs & Pharmaceuticals**
Year: **First**
Semester: **I**
Subject Name: **Pharmaceutical Biotechnology**
Subject Code: **MDP-0107**
Credits: **4**
Work load: **4 hr/week**

Theory

Unit 1 Introduction to genetic organization in prokaryotes and Eukaryotes.

Unit 2 Protein: Bio-synthesis and its regulation, gene transcription and RNA splicing, Protein immobilization, different methods like adsorption, entrapment, microencapsulation and bioreactors used in protein immobilization.
Introduction and application of diagnostic proteins.

Unit 3 Introduction to R-DNA technology and their application in synthesis of insulin, growth hormone and interferon.

Unit 4 Transgenic plants: Definition, need, production, analysis and application.

Unit 5 Genetic mechanism of drug resistance with reference to antibiotics.

Unit 6 Introduction to fermentation technology, different techniques used in detail and applications of downstream processing in production of Penicillin-G.

Recommended Books

1. Pharmaceutical Biotechnology by Vyas and Dixit
2. Gene VII by Lewin Benzamin
3. Industrial Microbiology by L.E. Casida
4. Biotechnology- The Biological Principles by M.D. Trevan, S. Boffey, K.H. Goulding and P. Stanbury
5. Microbial Genetics by David Freifelder
6. Immunology by J. Kuby
7. Immunology by Weir
8. Genetic Engineering, Cloning DNA by D.M. Glover
9. Recombinant DNA by Watson.
10. Molecular Biotechnology – Principle and Application of recombinant DNA by B.R. Glick & J.J. Pasternak
11. Pharmaceutical Biotechnology – An Introduction for Pharmacists & Pharmaceutical Scientists by D.J.A. Crommelin & R.D. Sindelar
12. The Principles of Gene Manipulation by Old R.W & Primrose, S.B.
13. Molecular Biology of Gene by Watson
14. Biochemical Engineering and Biotechnology Handbook by Atkinson, B and Marituna, F.
15. Fermentation and Biochemical Engineering Handbook by Vogel, H. C

Syllabus [Credit System]

Course Name: **M. Tech. (Chemical) Drugs & Pharmaceuticals**
Year: **First**
Semester: **I**
Subject Name: **Drug Regulatory Affairs**
Subject Code: **MDP-0108**
Credits: **2**
Work load: **2 hr/week**

Theory

Unit 1 History and need of drug regulation
Scientific and Legal aspects of Drug Regulations
Legal Aspect of drug Regulation (In India, Europe and USA)

Unit 2 Drug Development cycle (includes IND, NDA, and Generic development cycles)
Contents of Drug Dossier
Drug Registration Norms worldwide

Unit 3 GMP compliance
Manufacturing Plant Regulation need and requirements (includes Manufacturing plants of all dosage forms -solid oral to Parenterals and depot delivery systems)
Validation requirements

a. Equipment validation (includes DQ, IQ, OQ, PQ…)
b. Process validation

GLP and GCP Compliance

Unit 4 Concept and need for In-vivo studies (includes Bioavailability and Bioequivalence and Clinical Trials norms)

Unit 5 Introduction to ICH Guidance –Quality, safety and Efficacy Guidance

Unit 6 Introduction to Intellectual Property and its relation with Regulations
Introduction to Patent System in India and worldwide (Paris convention and TRIPS agreement)

Recommended Books

1. Forensic Pharmacy by B.S. Kuchekar, A. M. Khadatare and S. C. Jitkar
2. Drugs and Cosmetics Laws by Krishnan Arora
3. A Textbook of Forensic Pharmacy by Mittal B.M.
4. Encyclopedia of Pharmaceutical Technology by James Swarbrick, James C Boylon
5. Drugs and Cosmetic Act.1940 by Deshpande S.W.
6. Whatever one should know about patent by Bubuarm N.R
7. New Drug Approval Process by Gnarino Richard A.
8. Intellectual Property Laws by P. Warayan
9. Patents for Medicine, by N. B. Zareri, Indian Drug Manufacturers Association (IDMA)
10. Pharmacy Law and Ethics by Dale and Appelbes

Note: The course stresses more on scientific aspects of Regulatory affairs. Legal aspect is very complicated so it has to be decided how much of the legal aspect should be covered as this would partly cover the drug laws in India and worldwide. Yet, an introduction to legal aspect is a must.

Syllabus [Credit System]

Course Name: **M. Tech. (Chemical) Drugs & Pharmaceuticals**
Year: **First**
Semester: **II**
Subject Name: **Elective-I (Pharmaceutical Packaging Technology)**
Subject Code: **MDP-0109**
Credits: **4**
Work load: **4 hr/week**

Theory

Unit 1 Introduction to Pharmaceutical Packaging

Unit 2 Packaging Materials

Unit 3 Polymers and Plastics as packaging material

Unit 4 Glass as packaging material, ancillary material for packaging

Unit 5 Quality control, defects in packaging

Unit 6 Regulatory aspects of pharmaceutical packaging

Syllabus [Credit System]

Course Name: **M. Tech. (Chemical) Drugs & Pharmaceuticals**
Year: **First**
Semester: **II**
Subject Name: **Constitution of India**
Subject Code: **MDP-0110**
Credits: **2**
Work load: **2 hr/week**

Syllabus [Credit System]

Course Name: M. Tech. (Chemical) Drugs & Pharmaceuticals
Year: First
Semester: II
Subject Name: Advanced Pharmaceutical Analysis
Subject Code: MDP-0111
Credits: 4
Work load: 4 hr/week

Theory

Unit 1 Spectroscopic methods -

Theory, Instrumentation, Chemical applications and Structure elucidation by –

UV-visible spectroscopy

Infra-Red spectroscopy

Unit 2 Theory, Instrumentation, Chemical applications and Structure elucidation by

Mass spectroscopy

Unit 3 Theory, Instrumentation, Chemical applications and Structure elucidation by

Nuclear Magnetic Resonance spectroscopy (H-NMR and C-NMR)

ESR and Emission spectroscopy

Unit 4 Fundamental principles, Theory, Instrumentation and Pharmaceutical applications of -

HPLC

HPTLC

Unit 5 Fundamental principles, Theory, Instrumentation and Pharmaceutical applications of -

Gas-Liquid chromatography

Gel chromatography

Ion pair chromatography

Unit 6 Theory, Instrumentation and Pharmaceutical applications of-

Thermo Gravimetric analysis (TGA) and Differential Thermal analysis (DTA)

Recommended Books

1. Instrumental methods of analysis by Scoog and West.
2. Chemical Analysis – Modern Instrumentation methods and techniques by Wiley.
3. Instrumental methods of analysis by Willard Dean & Merrit.
4. Hand book of Instrumental techniques for analytical chemistry edited by Frank settle
5. A text book of Pharmaceutical analysis by K.A.Conners
6. Spectrometric identification of organic compounds by silver stein
7. Pharmaceutical analysis edited by Higuchi and Brochmann
8. Organic Spectroscopy by William Kemp
9. Practical Pharmaceutical chemistry by Beckett & Stenlake
10. Spectroscopy of organic compounds by Kalsi P. S.
11. Pharmaceutical analysis, Modern methods part A & B by Munson, J. W.
12. Text book of HPLC by Sinder
13. Instrumental methods of Chemical Analysis by Ewing
14. Introduction to High Performance Liquid Chromatography by R.J. Hamilton

Syllabus [Credit System]

Course Name: **M. Tech. (Chemical) Drugs & Pharmaceuticals**
Year: **First**
Semester: **II**
Subject Name: **Advanced Pharmaceutical Analysis**
Subject Code: **MDP-0112**
Credits: **4**
Work load: **4 hr/week**

Practical

1. To Identify the given compound from a mixture by using Thin Layer Chromatography.
2. To perform assay of given compound by using Ultra Violet Spectrophotometer.
3. To perform the assay of given compound by using high performance liquid chromatography.
4. To demonstrate the supercritical fluid extraction (SFE) system.
5. To perform the IR analysis of given compound.
6. To demonstrate the Scanning Electron Microscope.
7. To demonstrate the LC-MS.
8. To demonstrate the powder X-RD.

Recommended Books

15. Instrumental methods of analysis by Scoog and West.
16. Chemical Analysis – Modern Instrumentation methods and techniques by Wiley.
17. Instrumental methods of analysis by Willard Dean & Merrit.
18. Hand book of Instrumental techniques for analytical chemistry edited by Frank settle
19. A text book of Pharmaceutical analysis by K.A.Conners
20. Spectrometric identification of organic compounds by silver stein
21. Pharmaceutical analysis edited by Higuchi and Brochmann
22. Organic Spectroscopy by William Kemp
23. Practical Pharmaceutical chemistry by Beckett & Stenlake
24. Spectroscopy of organic compounds by Kalsi P. S.
25. Pharmaceutical analysis, Modern methods part A & B by Munson, J. W.
26. Text book of HPLC by Sinder
27. Instrumental methods of Chemical Analysis by Ewing
28. Introduction to High Performance Liquid Chromatography by R.J. Hamilton

Syllabus [Credit System]

Course Name: M. Tech. (Chemical) Drugs & Pharmaceuticals
Year: First
Semester: II
Subject Name: Herbal Drug Technology
Subject Code: MDP-0113
Credits: 4
Work load: 4 hr/week

Theory

Unit 1 General methods of extraction, isolation and purification of phytoconstituents

Isolation, identification tests and estimation methods for the following phytoconstituents with special emphasis on HPLC, HPTLC and other advanced techniques

a. Aloin from Aloes
b. Vasicine from *Adhatoda vasica*
c. Andrographolides from *Andrographis paniculata*
d. Curcumin from *Curcuma longa*
e. Piperine from *Piper longum*

Unit 2 Phytochemical study

Definition, occurrence, chemistry, isolation, estimation and biogenesis of alkaloids, glycosides, plant phenols, resins, terpenes and terpenoids, phospholipids and steroids

Unit 3 Marine natural products

Introduction, chemistry and biology of marine natural products

Marine toxins, marine biomedicinals falling under the class of cardiovascular, anticancer, antimicrobial, antiinflammatory and antibiotic drugs

Unit 4 Screening procedures for Herbal drugs with current innovations in following therapeutic classess

a) Antihypertensive,
b) Antioxidant ,
c) Antipyretic & anti-inflammatory,
d) Antidiabetic,
e) Anticancer,

f) Antihepatotoxic,
g) Immunomodulatory,

Unit 5 Herbal product development

Liquid orals, tablets, capsules, dermatologic and herbal cosmetics

Methods involved in monoherbal and Polyherbal formulations with their merits and demerits.

Excipients used in herbal formulations

Unit 6 Herbal product development

Compatibility studies

Stability studies

Bioavailability & pharmacokinetic aspects for herbal drugs with examples of well known documented, clinically used herbal drugs

Phytoequivalence & pharmaceutical equivalence

Quality control of finished herbal medicinal products.

Recommended Books

1. Pharmacognosy by Trease and Evans
2. Pharmacognosy by Tyler, Brady, and Robbers
3. Text Book of Pharmacognosy by Wallis T. E.
4. Pharmacognosy by Kokate, Purohit, Gokhale
5. Pharmacognosy & Phytochemistry, Vol I, II, by Rangari V.D.
6. Chemistry of Organic Natural Product by Agrawal O.P.
7. Modern Pharmacognosy by E. Ramstad
8. Plant drug analysis by Wagner
9. Text Book of Pharmacognosy by Shah and Quadri
10. Indigenous drug of India by Chopra
11. Material Medica by Nadkarni
12. Herbal Drug Industry by Chaudhari R D
13. WHO, Quality Control methods for medicinal plant material
14. Quality Control of Herbal Drugs by Mukherjee Pulok
15. Screening Methods of Pharmacology by Robert Turner
16. Biological Standardisation by J. N. Barn, D. J. Finley and L. G. Goodwin
17. Ayurvedic Pharmacopoeia.
18. Indian Pharmacopoeia.
19. British Pharmacopoeia.
20. Martindale Extra Pharmacopoeia.

Syllabus [Credit System]

Course Name: **M. Tech. (Chemical) Drugs & Pharmaceuticals**
Year: **First**
Semester: **II**
Subject Name: **Herbal Drug Technology**
Subject Code: **MDP-0114**
Credits: **2**
Work load: **6 hr/week**

Practical

1. Introduction to Herbal Drug Technology
2. Introduction to Herbal Drug Technology laboratory instruments/equipments
3. Unit operations in Herbal Drug Technology Lab
   - Part-I: To prepare different extract(s) of selected plant(s)/plant material
   - Part-II: To concentrate the extract(s) using various techniques
   - Part-III: To fractionate the extract(s) using various techniques
   - Part-IV: To develop monitoring technique(s) for the isolation of intended phytochemical(s)

Recommended Books

1. Pharmacognosy by Trease and Evans
2. Pharmacognosy by Tyler, Brady, and Robbers
3. Text Book of Pharmacognosy by Wallis T. E.
4. Pharmacognosy by Kokate, Purohit, Gokhale
5. Pharmacognosy & Phytochemistry, Vol I, II, by Rangari V.D.
6. Chemistry of Organic Natural Product by Agrawal O.P.
7. Modern Pharmacognosy by E. Ramstad
8. Plant drug analysis by Wagner
9. Text Book of Pharmacognosy by Shah and Quadri
10. Indigenous drug of India by Chopra
11. Material Medica by Nadkarni
12. Herbal Drug Industry by Chaudhari R D
13. WHO, Quality Control methods for medicinal plant material
14. Quality Control of Herbal Drugs by Mukherjee Pulok
15. Screening Methods of Pharmacology by Robert Turner
16. Biological Standardisation by J. N. Barn, D. J. Finley and L. G. Goodwin
17. Ayurvedic Pharmacopoeia.
18. Indian Pharmacopoeia.
19. British Pharmacopoeia.
20. Martindale Extra Pharmacopoeia.

Syllabus [Credit System]

Course Name: M. Tech. (Chemical) Drugs & Pharmaceuticals
Year: First
Semester: II
Subject Name: Bio-pharmaceutics and Pharmacokinetics
Subject Code: MDP-0115
Credits: 4
Work load: 4 hr/week

Theory

Unit 1 Absorption.

Cell membrane, absorption mechanism, transcellular, diffusion paracellular transport, carrier mediated transport, ion-pair transport, endocytosis.

Factors affecting drug absorption:-

-Physiological factors: Unstirred water layer, gastric emptying, presystemic metabolism, afflux system.

-Physicochemical factors: Drug lipophilicity, PKa, Dissolution of drug, drug stability, complexation, absorption.

-formulation factors

Cell culture and other biopharmaceutical evaluation techniques.

Drug absorption through other routes such as transdermal, nasal, buccal, ocular and sublingual.

Unit 2 Drug distribution and Metabolism

Tissue permeation of drug, volume of distribution,

Physiological barrier to the drug distribution: Capillary endothelial barrier, cell membrane barrier, barrier of the distribution of a drug to the brain, placental barrier, blood testis barrier.

Factors affection drug distribution: Physiological properties, tissue size and perfusion and drug-protein binding.

Characteristics of drug metabolism: General pathway of drug metabolism i.e. phase-I and phase- II reaction's, enzymes in drug metabolism.

Factors affection drug metabolism: Physicochemical properties, size induction and inhibition of biological factors.

Unit 3 Excretion of drug

Useful concept in the study of excretion mechanism, mechanism of renal drug excretion, factors affection renal drug excretion, Non-renal route of drug excretion, dose adjustment in renal failure, mode of testing drug excretion.

Unit 4 Pharmacokinetics

Introduction to pharmacokinetics,

Pharmacokinetics models: Compartmental model, 1 compartmental model, 2 compartmental model and multi-compartmental, perfusion model, Non-compartmental model, statistical movement theory, Area under curve.

Method of Laplace transformation: 1 compartmental model, detail deviation from laplace transforms to obtain pharmacokinetics parameters for I.V injections or infusion.

First order absorption including methods of residual and sigma minus methods for pharmaceutical and urinary data.

Introduction to multi-compartmental model and non-linear pharmacokinetics.

Unit 5 Bioavailability and Bioequivalence

Definition's, factors affecting bioavailability, significance of bioavailability, measurement of bioavailability, extent of bioavailability and rate of bioavailability, % absorbed v/s time plots: Wagler-Nelson method, loop-Reigerman method, deconvolution method.

Unit 6 Bioavailability-Bioequivalence Studies (BABE)

BABE testing methods, study design, significance, regulatory consideration, statistical treatment and determination, Invitro-Invovo correlation.

Recommended Books

1. Biopharmaceutics and Clinical Pharmacokinetics by Milo Gibaldi
2. Remington's Pharmaceutical Sciences by Mack publishing company
3. Biopharmaceutics and Pharmacokinetics by Robert E.Notari
4. Applied Biopharmaceutics and Pharmacokinetics by Leon. Shargel, Andrew B.C.Yes
5. Dissolution, Bioavailability and Bioequivalence by Abdou, H.M.
6. Clinical Pharmacokinetics – Concepts and applications by Rowland, M. and Tozer, T.N.
7. Biopharmaceutics and Pharmacokinetic, A Treatise by, D. M. Brahmankar and Sunil B. Jaiswal
8. Current Concepts in Pharmaceutical Sciences: Biopharmaceutics by Swarbick. J, Lea and Febiger
9. Clinical Pharmacokinetics Concepts and Applications by Malcolm Rowland and Thomas N.
10. Biopharmaceutics and relevant Pharmacokinetics by John. G. Wagner and M. Pernarowski
11. Encyclopedia of Pharmaceutical Technology, Vol 13 by James Swarbrick, James. C. Boylan
12. Applied Biopharmaceutics and Pharmacokinetics by Shargel. L and Yu ABC
13. Textbook of Biopharmaceutics and Pharmacokinetics, Dr. Shobha Rani R. Hiremath

Syllabus [Credit System]

Course Name: M. Tech. (Chemical) Drugs & Pharmaceuticals
Year: First
Semester: II
Subject Name: Medicinal Chemistry and Drug Discovery
Subject Code: MDP-0116
Credits: 4
Work load: 4 hr/week

Theory

Unit 1 Mechanisms, Stereochemistry and application of

Rearrangements: Pinacol and related, rearrangements involving migration to electron deficient nitrogen.

Unit 2 Mechanisms, Stereochemistry and application of

Oxidation: oppennaur.

Reductions: Birch, Clemmensons, MPV, Wolf-Kishner using metallic hydrides.

Unit 3 Commercial syntheses of

chloroquine, thambutaol, ibuprofen ,diazepam, mebendazole, Vit.B6, dapsone.

Unit 4 Receptors in drug discovery and development

Receptor concept, theories, nomenclature and types.

Unit 5 Technology involved in pharmaceutical manufacturing (unit processes in synthesis)

Acylation,esterification,alkylationamination,halogination,esterification,alkylation, amination,hydrolysis,nitration,reduction,oxidation.

Unit 6 Production-detailed manufacturing aspects, processes and operations involved in aspirin, benzocaine, chloramphenicol, adrenaline.

Recommended Books

1. Advanced Organic Chemistry by Jerrry March
2. Structure & mechanism in Organic Chemistry by Ingold
3. In Introductions to Chemistry of Heterocyclic Compounds by Acheson
4. Heterocyclic Compounds by Elderfield
5. Structure & reactions of heterocyclic Compounds by Piamer
6. Stereochemistry of carbon Compounds by Eliel
7. Organic Chemistry by Morrison & Byod
8. Reactions & reagents by O.P. Agarwal
9. Organic synthesis by Michael. B .Smith
10. Vogel's A text book of Practical Organic Chemistry
11. The Organic Chemistry of Drug Synthesis (3 volumes) by Daniel Lednicer & Laster A. Mitscher
12. Burgers Medicinal chemistry-The Basis of Medicinal chemistry by Manfred E. Wolff

Syllabus [Credit System]

Course Name: **M. Tech. (Chemical) Drugs & Pharmaceuticals**
Year: **First**
Semester: **II**
Subject Name: **Medicinal Chemistry and Drug Discovery**
Subject Code: **MDP-0117**
Credits: **2**
Work load: **4 hr/week**

Practical

1. Introduction to Medicinal Chemistry & Drug Discovery
2. Introduction to Molecular modeling studies
3. Introduction to QSAR studies
4. Introduction to docking studies
5. Introduction to ADMET prediction studies
6. To demonstrate ADMET prediction of selected series of compounds
7. To demonstrate QSAR studies of selected series of compounds
8. To demonstrate docking studies of selected series of compounds
9. To present ADMET prediction of selected series of compounds
10. To present docking studies of selected series of compounds

Syllabus [Credit System]

Course Name: **M. Tech. (Chemical) Drugs & Pharmaceuticals**
Year: **First**
Semester: **II**
Subject Name: **Quality Assurance & Validation**
Subject Code: **MDP-0118**
Credits: **4**
Work load: **4 hr/week**

Theory

Unit 1 Basic concept & principles of quality management-

- Total quality management
-Quality assurance
-Quality control
-Quality audit

Unit 2 Good manufacturing practices in pharmaceutical industry

Unit 3 Documentation related to NDA application, ANDA application,

SOP Document
Introduction to drug master file &contents
Introduction to quality system
-ISO, WHO, USFDA, ICH

Unit 4 Technology transfer from R&D to manufacture

Unit 5 Concept of statistical quality control

Unit 6 Validation

- Definition, Types
Process validation: Types, Approaches, Organization, Scope, Validation protocol & report
Validation of process like mixing, granulation, drying, compressing, filling
Analytical method validation
Validation of electronic data

Recommended Books

1. Pharmaceutical Quality Assurance by M.A. Potdar
2. Current Good Manufacturing Practices by M.A. Potdar
3. GMP for Pharmaceuticals by Sidney H. Willing
4. Regulatory guidelines related to GMP by
    a. Australian code of GMP for medicinal products
    b. 21 Code of Federal Regulation, parts 210, 211 & 58 (USFDA guidelines)
    c. MHRA, UK Guidelines on GMP
    d. GMP Guidelines by Medicines Control Council of South Africa
    e. Schedule M of D & C Act 1940
5. Assurance of Quality, Pharmaceutical Total Quality Approach by M. S. P. Khan
6. The International Pharmacopoeia Vol 1,2,3,4, 3rd Edition General methods of analysis and quality specifications for pharmaceutical substances, excipients, dosage forms.
7. Quality Assurance of Pharmaceuticals – A compendium of guidelines and related materials Vol.1 and Vol.2, WHO, (1999)
8. Basic tests for pharmaceutical substances – WHO (1988)
9. Basic tests for pharmaceutical dosage forms – WHO (1991)
10. GMP by Mehra
11. How to Practice GMPs by P.P.Sharma
12. The Drugs and Cosmetic Act 1940 by Vijay Malik
13. Pharmaceutical Process Validation by Berry and Nash.
14. Q.A. Mannual by D.H.Shah
15. SOP Guidelines by D.H.Shah
16. Quality Assurance Guide by OPPI

Syllabus [Credit System]

Course Name: M. Tech. (Chemical) Drugs & Pharmaceuticals
Year: First
Semester: II
Subject Name: Elective-II (Advanced Pharmacology)
Subject Code: MDP-0119
Credits: 4
Work load: 4 hr/week

Unit 1 General principles of pharmacology

Unit 2 Chemical mediators

Unit 3 Drugs affecting major organ system

Unit 4 Drugs affecting nervous system

Unit 5 Chemotherapeutic agents

Unit 6 Special topics

- **Individual variation**
- **Drug interactions**
- **Lifestyle drugs**
- **Biopharmaceuticals**

Recommended Books

1. Rang & Dale's Pharmacology
2. Harrison's Principles of Internal Medicine

Syllabus [Credit System]

Course Name: M. Tech. (Chemical) Drugs & Pharmaceuticals
Year: Second
Semester: III
Subject Name: Bio-pharmaceutics and Pharmacokinetics
Subject Code: MDP-0220
Credits: 03
Work load: 4 hr/week

Practical

1	Introduction to pharmacokinetics
2	Introduction to pharmacokinetic constants and their use/application
3	Introduction to analytical tools and techniques used in pharmacokinetic studies
4	Bio-analytical HPLC method validation of Rifampicin
5	In-vitro recovery study of acyclovir
6	To study in-vivo pharmacokinetics of rifampicin after oral administration in rat
7	To analyze oral pharmacokinetic data of rifampicin
8	To study ex-vivo absorption of Paclitaxel
9	Demonstration of in-situ absorption study of acyclovir
10	Introduction to pharmacokinetic correlation (PK/PD)
11	Introduction to bioavailability and bioequivalence studies

Syllabus [Credit System]

Course Name: M. Tech. (Chemical) Drugs & Pharmaceuticals
Year: Second
Semester: III
Subject Name: Techno-Economic Feasibility Report
Subject Code: MDP-0221
Credits: 23
Work load:

Syllabus [Credit System]

Course Name: M. Tech. (Chemical) Drugs & Pharmaceuticals
Year: Second
Semester: III
Subject Name: Seminar
Subject Code: MDP-0222
Credits: 03
Work load:

Syllabus [Credit System]

Course Name: M. Tech. (Chemical) Drugs & Pharmaceuticals
Year: Second
Semester: III
Subject Name: Service Course
Subject Code: MDP-0223
Credits: 03
Work load:

Syllabus [Credit System]

Course Name: **M. Tech. (Chemical) Drugs & Pharmaceuticals**
Year: **Second**
Semester: **IV**
Subject Name: **Dissertation**
Subject Code: **MDP-0224**
Credits: **32**
