SYLLABUS

SPECIFIC TO

POST GRADUATE DEGREE

M. Tech. (Chemical) Drugs & Pharmaceuticals

[CREDIT SYSTEM]

SECOND REVISION

With effect from

August 2018

Excellence and Social Commitment

ISO 9001 : 2008

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

Core I

Subject Name: Dosage Form Design

Subject Code: MDP-1101

Credits: 3

Work load: 3 hr/week

Theory

Course Objectives:

The learning objectives of the Dosage Form Design course are

1. To understand the process of product development and testing of various dosage forms.
2. To learn the high speed, continuous operations related to solid dosage forms
3. To Understand importance of cutaneous and topical drug delivery systems
4. To Understand Mechanism of TDDS, Occular drug delivery system and Mucoadhesive drug delivery system
5. To learn product development from an industrial point of view

Course Outcomes:

Upon completion of the Dosage Form Design course, student will be able to -

1. Explain the Process of product development and testing of various dosage forms
2. Understand the high-speed continuous operations related solid dosage forms
3. Identify and imply the importance of Cutaneous and topical drug delivery.
4. Learn the various mechanism of TDDS, Occular drug delivery system and protein peptide drug delivery system.
5. Understand the concept of product development in line with industrial scale

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 tableting.
- 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) Parenteral: SVP, LVP

- Methods of preparation and production facilities
- Evaluation
- Stability

ii) Packaging Ophthalmic

- 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: Developmental 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
Core II
Subject Name: Herbal Drug Technology
Subject Code: MDP-1102
Credits: 3
Work load: 3 hr/week

Theory

Course Objectives:

The learning objectives of the Herbal drug technology course are

1. To Understand importance of extraction, isolation and purification using analytical techniques.
2. To isolate and purify various Phytochemicals and Marine natural product.
3. To understand Herbal Product development procedure
4. To learn screening procedures of various phytoconstituents

Course Outcomes:

Upon completion of this course the student should be able to

1. Know and learn importance of extraction, isolation and purification using analytical techniques
2. isolate and purify various Phytochemicals and Marine natural product
3. Learn herbal drug product development process
4. Learn and understand screening procedures of various phytoconstituents

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*

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, anti- inflammatory 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: **I**

Elective I

Subject Name: Pharmaceutical Biotechnology

Subject Code: **MDP-1103**

Credits: **2**

Work load: **2 hr/week**

Theory

Course Objectives:

The learning objectives of the Pharmaceutical Biotechnology course are

1. To correlate the genetic organization in Prokaryotes and eukaryotes
2. To understand protein biosynthesis gene transcription, Protein immobilization, R-DNA Technology
3. To Understand mechanism of drug resistance
4. To Know importance of transgenic plants and Fermentation technology

Course Outcomes:

Upon completion of this course student will be able to,

1. Understand importance of genetic organization in prokaryote sand eukarytoes
2. Know and learn importance of Protein biosynthesis, gene transcription, Protein immobilization, R-DNA Technology.
3. Interpret mechanism of drug resistance.
4. Understand importance and utilization of transgenic plants and Fermentation technology

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.
15. Fermentation and Biochemical Engineering Handbook by Vogel, H. C

Syllabus [Credit System]

Course Name: M. Tech. (Chemical) Drugs & Pharmaceuticals

Year: **First**

Semester: **I**

Elective I

Subject Name: Advanced Pharmaceutical Chemistry

Subject Code: **MDP-1104**

Credits: **2**

Work load: **2 hr/week**

Theory

Course Objectives:

The learning objectives of the Advance Pharmaceutical Chemistry course are

1. To learn & identify Enzyme and Enzyme inhibitors
2. To understand & learn molecular modeling & drug design, combinatorial chemistry & QSAR
3. To understand high throughput Screening, genomics and Proteomics in drug design
4. To understand synthon approach in drug synthesis

Course Outcomes:

Upon completion of this course student will be able to

1. Understand Enzyme and Enzyme inhibitors
2. Know importance of molecular docking, drug design, combinatorial chemistry & QSAR
3. Identify high throughput screening, genomics & proteomics in designing of drug
4. Learn and understand Synthon approach in drug synthesis

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 and 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**
Elective I
Subject Name: Stability Testing
Subject Code: **MDP-1105**
Credits: **3**
Work load: **3 hr/week**

Theory

Course Objectives:

The learning objectives of the Stability testing course are

1) To understand drug development cycles and stability testing of drugs
2) To learn and interpret stability -indicating methods and stability testing protocols
3) To understand photostability and stability testing of biotechnological products
4) To understand post-approval changes in formulation.

Course Outcomes:

Upon completion of this course student will be able to

1. Know and learn drug development cycles and stability testing of drugs
2. Understand stability -indicating methods and stability testing protocols
3. Analyze photostability and stability testing of various biotechnological products
4. Learn post-approval changes in formulation.

Unit 1 Drug development cycles and stability testing: Role and types of stability studies during different stages of drug and product development. Stress testing: Role, regulatory aspects, protocols/approaches, practical considerations.

Unit 2 Stability-indicating methods: Definition, regulatory requirement, steps in development, practical considerations. Role of kinetics studies: Important mechanistic and

stability-related information provided by results of study of factors like temperature, pH, buffering species, ionic strength, dielectric constant, etc. on the reaction rates.

Unit 3 Stability testing protocols: Selection of batches, container orientation, test parameters, sampling frequency, specifications, storage conditions, recording of results, concept of stability commitment, etc. Retest period/shelf-life determination: Evaluation of stability data.

Unit 4 Photostability: Photostability testing of new active substances and medicinal products, light sources and options, types of chambers, presentation of samples, practical considerations, confirmatory testing.

Unit 5 Stability testing of biotechnological products: Typical stability testing issues of biotechnological vis-à-vis conventional products, considerations in ICH Q5C guideline. Stability testing of phytopharmaceuticals: Regulatory requirements, protocols, HPTLC/HPLC finger printing, Interactions and complexity.

Unit 6 post-approval changes: Nature of post-approval changes. Regulatory requirements of stability re-workup. Reduced stability-testing plans:
Bracketing and matrixing designs for multiple strength, packaging, etc.
Ongoing and follow-up stability testing: Definitions, applicability, requirements in WHO 2009 stability testing guideline. Stability test equipment:
Types of stability chambers (walk-in, stand-alone, photostability), design considerations, qualification and other critical issues.

Recommended Books:

1. Stability and Characterization of Protein & Peptide of Drugs by Y. John Wang

2. Peptide and Protein Drug Analysis by Ronald Reid

3. Pharmaceutical Stress Testing (Predicting Drug Degradation) by Steven Baertschi and Karen
Alsante

4. Drug Stability (Principles and Practices) by S. James, Jens Thurø Carstensen

5. Stability-indicating HPLC Methods for Drug Analysis by Quanyun A. Xu, Lawrence A. Trissel

6. Stability of Drugs and Dosage Forms by Sumic Yoshioka, Valentino Stella

7. Physical Pharmacy and Pharmaceutical Sciences by Patrick Sinko, Alfred Martin

8. New Drug Approval Process (Chapter 7) by Richard Guarino

9. Handbook of Stability Testing in Pharmaceutical Development: Regulations, Methodologies,
and Best Practices by Kim Huynh-Ba

Syllabus [Credit System]

Course Name: M. Tech. (Chemical) Drugs & Pharmaceuticals

Year: **First**
Semester: **I**
Elective II
Subject Name: Drug Regulatory Affairs
Subject Code: **MDP-1106**
Credits: **2**
Work load: **2 hr/week**

Theory

Course Objectives:

The learning objectives of the Drug Regulatory Affairs course are

1. To understand need of drug regulations and various drug regulatory authorities worldwide.
2. To learn and implement drug development cycle, dossier preparation and their submission to different regulatory authorities
3. To identify and implement importance of GMP compliance and ICH-Guidelines (Quality, Safety, Efficacy)
4. To learn & understand in- vivo studies, Intellectual Property rights and Patet system in india

Course Outcomes:

Upon completion of this course student will be able to

1. Understand importance of drug regulation & various drug regulatory authorities worldwide.
2. Learn importance of dossier preparation and their submission to different regulatory authorities.
3. Understand importance of GMP compliance and ICH-Guidelines
4. Understand in- vivo studies and Intellectual Property rights and patent system in India

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
c. 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: I

Elective II

Subject Name: Biopolymers

Subject Code: MDP-1107

Credits: 2

Work load: 2 hr/week

Theory

Course Objectives:

The learning objectives of the Biopolymer course are

1. To understand the chemistry and biochemistry of polymer biodegradation
2. To learn and understand particulate starch-based product and testing methods
3. To know test method for biodegradable plastics & Standard for biodegradable plastic

Course Outcomes:

Upon completion of this course student will be able to

1. Understand Importance of a chemistry and biochemistry of polymer biodegradation.
2. Learn & identify particulate starch-based products and testing methods for biodegradable polymer
3. Understand importance of biopolyster and biodegradable plastic in various industry including pharmaceutical industry

Unit 1 Chemistry and Biochemistry of Polymer Degradation: Introduction, enzymes – enzyme nomenclature – enzyme specificity – physical factors affecting the activity of enzymes – enzyme mechanism, Chemical degradation initiates biodegradation, Hydrolysis of synthetic biodegradable polymers.

Unit 2 Particulate Starch Based Products - Development of Technology, Current objectives, relative starch technology, Manufacture of master batch, Conversion technology

– processing precautions – moisture and temperature – rheological considerations, cyclic conversion process, physical properties of products – sample preparation –

Unit 3 Testing Methods - physical testing methods – test results, Quality control testing of degradation – auto oxidation measurement – biodegradation assessment – soil burial test.

Unit 4 Biopolyesters: Introduction, History, biosynthesis, Isolation – solvent extraction – sodium hypo chloride digestion, enzymatic digestion, Properties – crystal structure – nascent morphology, degradation - Intracellular biodegradation - extra cellular biodegradation –thermal degradation – hydrolytic degradation – environmental degradation – effects of recycling, applications, economics, future prospects.

Unit 5 Test Methods for Biodegradable Plastics Introduction, defining biodegradability, criteria used in the evaluation of biodegradable polymers, tiered systems for evaluating biodegradability, choice of environment, choosing the most appropriate methodology

Unit 6 Standards for Biodegradable Plastics description of current test methods – screening test for ready biodegradability, tests for inherent biodegradability, tests for simulation studies, other methods for assessing biodegradability – petri dish screen – environmental chamber method – soil burial tests, Test method developments for the future.

Recommended Books:

1. G.J.L Griffin Blackie(ed.), Chemistry & Technology of biodegradable polymers Academic & Professional London 1994.

2. Yoshiharu Doi, Kazuhiko Fukuda(ed.) Biodegradable plastics & Polymers Elsevier 1994

3. Abraham J. Donb & others(ed.) Handbook of Biodegradable polymers Harvard academic publishers Australia 1997.

Syllabus [Credit System]

Course Name: M. Tech. (Chemical) Drugs & Pharmaceuticals

Year: First
Semester: I
Elective II
Subject Name: Clinical Biochemistry
Subject Code: MDP-1108
Credits: 2
Work load: 2 hr/week

Theory

Course Objectives:

The learning objectives of the Clinical biochemistry course are

1. To understand basic concepts of biochemical reactions & it's mechanism.
2. To learn carbohydrates, lipids, proteins & it's composition, structure and metabolism in body.
3. To learn and understand protein disorder and enzymes.

Course Outcomes:

Upon completion of this course student will be able to

1) Know and learn various biochemical reactions along with mechanism.
2) Understand carbohydrate, lipids, proteins structure & composition.
3) Examine protein disorders and various enzymes.

UNIT I - Basic Concepts of Biochemical Reactions Organic reaction mechanisms (Group-transfer reactions, oxidation and reductions, coupled reactions, Elimination, Isomerization and rearrangements), Thermodynamics of phosphate compounds (Phosphoryl-transfer reactions, High energy compounds and biological energy transducers (ATP, NADH, NADPH, FADH, CoASH), ATP cycle, structural basis of free energy change during hydrolysis of ATP. Nernst equation and Redox-potentials.

UNIT II – Carbohydrates: Composition, structure, metabolism and disorders Carbohydrate structure, classification, properties, chemical reactions, Isomerism and

functions. Carbohydrate Metabolism- basic concepts, Glycolysis, Krebs cycle, Pentose phosphate pathway, Gluconeogenesis, Glycogenesis, Glycogenolysis, Regulation of carbohydrate metabolism. Inborn errors of carbohydrate metabolism, Galactosemia and Glycogen storage diseases.

UNIT III – Lipids: Composition, structure, metabolism and disorders Classification, structure, properties, and functions of fatty acids, triacylglycerols, phospholipids, sterols. Terpenes and prostaglandins. Lipids with specific biological functions, lipoproteins, micelle and liposome, Lipid metabolism: Biosynthesis and degradation of odd carbon and even carbon: saturated and unsaturated fatty acids. Ketone bodies: formation and utilization. Biosynthesis and degradation of cholesterol. Disorders of Lipids: Clinical features and laboratory findings in disorders of triglyceride, lipoprotein and cholesterol metabolism, lipoprotein and apolipoprotein metabolism; HDL, LDL, VLDL, apoA, apoB, apoC, apoE and their receptors. Fat absorption, transport, storage and metabolism, Investigation and principles of treatment of hyperlipidemias

UNIT IV - Proteins Composition, structure and metabolism Amino acids: Structure, classification, properties and functions, peptides and polypeptides. Proteins: properties, primary, secondary, tertiary and quaternary structure, protein folding, Protein stabilizing interactions (Van der Waals, electrostatic, hydrogen bonding, hydrophobic interaction), Reverse turns and Ramachandran plot. Domains and motifs, Amino acid metabolism: Biosynthesis and degradation of amino acids and their regulation; Transamination and oxidative deamination, urea cycle

UNIT V- Protein disorders Clinical features and laboratory findings in disorders of the plasma proteins, acute phase proteins, serum proteins and albumin, serum and urine protein electrophoresis, hypo and hyper-albuminemia; hypo- and hyperglobulinemias, Alpha-1-antitrypsin deficiency, Homozygotes vs. heterozygotes e.g. phenylketonuria, tyrosinemia, cystic fibrosis and sweat tests, amino-acidurias, organic acidurias. Protein folding disorders (Alzheimers, prions and amyloid)

UNIT VI–Enzymes Classification and nomenclature, prosthetic groups, cofactors,

Mechanism of enzyme action and properties of enzymes as catalysts. Enzyme kinetics (equilibrium and steady state theory, rate equation and determination of Km and Vmax.), specific activity, turn over number and catalytic center activity, Enzyme regulation: Principles of catalysis, mechanism of enzyme catalysis, Factors affecting rate of enzyme catalyzed reactions: pH, temperature, etc. Enzyme inhibition: reversible and irreversible inhibition, Allosteric enzymes: Model of allostery, types and kinetics; Isoenzymes and isozymes.

Recommended Books:

1. Principles of Biochemistry by Geoffrey Zubay. Publisher: McGraw Hill College. Biochemistry By Lubert Stryer. WH Freeman and Co.

2. Fundamentals of Biochemistry: Life at the Molecular Level 5th Ed. By Donald Voet, Judith G. Voet and Charlotte W. Pratt. Publisher: Wiley.

3. Fundamentals of Enzymology: Cell and Molecular Biology of Catalytic Proteins by Nicholas C. Price and Lewis Stevens. Oxford University Press.

4. Fundamentals of Enzymology: Cell and Molecular Biology of Catalytic Proteins by Nicholas C. Price and Lewis Stevens. Oxford University Press.

5. Enzymes: Biochemistry, Biotechnology and Clinical Chemistry by Trevor Palmer.

6. Enzyme Kinetics and Mechanisms (Hardcover)By Kenneth B. Taylor. Kluwer Academic Publishers.

7. Devlin: Textbook of Biochemistry (with clinical correlation) (John Wiley and Sons Publishers). 8. Cantrow and Trumper: Clinical Biochemistry.

9. Henry. R. D: Clinical Chemistry- Principles and Techniques (Harfer and Row)

Syllabus [Credit System]

Course Name: M. Tech. (Chemical) Drugs &Pharmaceuticals

Year: **First**

Semester: **I**

Subject Name: Research Methodology & IPR

Subject Code: **MDP-1109**

Credits: **2**

Work load: **2 hr/week**

Theory

Course Objectives:

The learning objectives of the Research Methodology &IPR course are

1. To learn and understand different types of research
2. To understand & explore different methods and tools used in research.
3. To understand & analyze research paper /thesis writing
4. To understand different methods of data analysis.
5. To learn different sources of procurement of research grants
6. To learn and understand IPR

Course Outcomes:

Upon completion of this course student will be able to

1. Understand & correlate various types of research
2. Learn different tools & methods used in research.
3. Implement and learn research paper & thesis writing.
4. Learn and identify different methods of data analysis
5. Understand procurement sources of research grants and IPR

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 Research paper /Thesis writing:

Different parts of the research paper.

Presentation: Oral, poster.

Unit 5 Sources of procurement of research grants.

Industrial Institution Interaction.

Unit 6 Introduction to IPR:

Patents, its Legislation, Types, Patentability, various components of a patent, general process of patent in India, Introduction to PTC and USPTO

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 by Leland 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
12. The Patent Act, 1970 along with The Patent Rules, 2003

Syllabus [Credit System]

Course Name: M. Tech. (Chemical) Drugs & Pharmaceuticals

Year: **First**

Semester: **I**

Lab I

Subject Name: Dosage Form Design

Subject Code: **MDP-1110**

Credits: **3**

Work load: **6 hr/week**

Practical

Course Objectives:

The learning objectives of the Dosage Form Design course are

1. To formulate different types of dosage forms and cosmetic product
2. To perform quality control test and stability studies.
3. To formulate and evaluate cosmetic products (shampoo, moisturizer, sunscreen etc.)
4. To study effect of various permeation enhancer on diffusion of drug.
5. To study working of extrusion-Spheronization.
6. To perform film coating and air suspension coating.

Course Outcomes:

Upon completion of this course student will be able to

1. Formulate dosage forms and cosmetic products
2. Carry out quality control test and stability studies.
3. Understand effect of various permeation enhancer on diffusion of drug through membrane/skin.
4. Understand proper handling of extrusion-Spheronization.
5. Understand different types of coating.

EXPERIMENTS

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
Lab II
Subject Name: Herbal Drug Technology
Subject Code: MDP-1111
Credits: 2
Work load: 6 hr/week

Practical

Course Objectives:

The learning objectives of the Herbal drug technology course are

1. To learn herbal drug technology laboratory instruments/equipment.
2. To prepare different plant extracts & concentrate extract using various techniques
3. To concentrate extract using various techniques.
4. To perform & learn isolation techniques of intended phytochemicals.

Course Outcomes:

Upon completion of this course student will be able to

1. Understand instruments/equipment's used in herbal drug technology laboratory.
2. Understand different extraction techniques for different plant extracts
3. Understand isolation techniques for different phytoconstituents.

EXPERIMENTS:

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: I

Audit Course I

Subject Name: Constitution of India

Subject Code: MDP-0110

Theory

Course Objectives:

The learning objectives of the Constitution of India course are

1. To Understand the Indian Constitution
2. To identify the importance of fundamental rights as well as fundamental duties
3. To understand the functioning of union, state and local governments in Indian federal system
4. To learn procedure and effects of emergency, composition and activities of election commission and amendment

Course Outcomes:

Upon completion of this course student will be able to

1. Understand and explain the significance of Indian constitution.
2. Exercise his/her fundamental rights in a proper sense at the same time identify responsibilities in nation building
3. Analyze the Indian political system, the powers and functions of the union, state and Local Government in detail
4. Understand the Electoral Process, Emergency provision and amendment procedure.

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

Course Objective:

The learning objectives of the Advanced Pharmaceutical Analysis course are

1. To Learn principles of various advance analytical Techniques
2. To identify Instrumentation of Various Advance analytical Techniques
3. To know Working of Various Advance analytical Techniques
4. To Understand & learn Advantages and Disadvantages of various advance analytical Techniques

Course Outcome: Upon Completion of this Course Student will be able understand

1. principles of various advance analytical Techniques
2. Instrumentation of Various Advance analytical Techniques
3. Working of Various Advance analytical Techniques
4. Merits and Demerits of various Advance analytical Techniques.

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. Ham

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

Course Objective:

The learning objectives of the course are

1. To handle UV-vis spectrophotometer
2. To handle HPLC, HPTLC, LC-MS/MS, GC, GC-MS, IR
3. To handle various Surface Chemistry methods like XRD
4. To handle scanning electron microscopy

Course Outcome:

Upon Completion of this Course Student will be able understand

1. Various Spectroscopic Instruments like UV, FTIR
2. Various Chromatographic methods like HPTLC, HPLC, LC-MS, GC-MS.
3. various surface chemistry methods like XRD.
4. Working of scanning electron microscopy

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: Bio-pharmaceutics and Pharmacokinetics

Subject Code: MDP-0115

Credits: 4

Work load: 4 hr/week

Theory

Course Objectives:

The learning objectives of the Biopharmaceutics and Pharmacokinetics course are

1. To learn various pharmacokinetic parameters like ADME
2. To learn absorption & rate release of drug in the body
3. To understand and learn BABE studies
4. To learn various pharmacokinetic models

Course Outcomes:

Upon completion of this course student will be able to

1. Understand pharmacokinetic parameters (ADME)
2. Understand rate release & absorption of drug
3. Correlate & understand BABE studies
4. Identify and understand different pharmacokinetic models

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- Π 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

Course Objectives:

The learning objectives of the Medicinal Chemistry and Drug Discovery course are

1. To learn the mechanism of various chemical reaction
2. To understand & learn the Stereochemistry of various chemical reaction
3. To learn the receptors in drug discovery and development process
4. To Understand the drug discovery Process
5. To get familiar with technology involved in pharmaceutical manufacturing

Course Outcomes:

Upon completion of this course student will be able to

1. Understand mechanism of various chemical reaction
2. Analyze Stereochemistry of various chemical reaction
3. Understand receptors in drug discovery & development process
4. learn & identify drug discovery process
5. Understand technology involved in pharma industry

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, alkylation amination, halogenation, 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

Course Objectives:

The learning objectives of the Medicinal Chemistry and Drug Discovery course are

1.To understand molecular modeling

2. To demonstrate docking studies

3. To demonstrate QSAR Studies

4. To demonstrate ADMET

Course Outcomes:

Upon completion of this course student will able to

1.Perform molecular modeling studies

2. Understand & learn docking studies

3. Understand & perform QSAR Studies

4. Perform & understand ADMET

EXPERIMENTS

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

Course Objectives:

The learning objectives of the Quality Assurance and Validation course are

1. To understand basic concept principle of quality management and technology transfer.
2. To appreciate the importance of documentation.
3. To implement GMP in pharmaceutical industry.
4. To learn Concept of quality control, validation & technology transfer

Course Outcomes:

Upon completion of this course student will be able to,

1. Explain the responsibilities of QA and QC Department.
2. Identify and understand importance of documentation and Validation in pharmaceutical industry.
3. Learn cGMP aspects in Pharmaceutical Industry.
4. Understand Importance of validation, Qc & Technology transfer

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

Theory

Course Objectives:

The learning objectives of the Advanced Pharmacology course are

1. To learn general principles of principle of pharmacology
2. To learn and identify drugs affecting major organ system
3. To learn classification, mechanism of various chemotherapeutic drugs
4. To understand various chemical mediators
5. To understand drug interactions in body

Course Outcomes:

Upon completion of this course student will be able to

1. Understand principles of pharmacology
2. Understand major organs which can be affected by drugs
3. Classify various drugs classes including chemotherapeutic agents
4. Know chemical mediators
5. Learn mechanism of drug interaction in body

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

Course Objectives:

The learning objectives of the Biopharmaceutics & Pharmacokinetics course are

1. To learn analytical techniques & tools used in pharmacokinetic studies.
2. To understand pharmacokinetic data of drug.
3. To study bioavailability and bioequivalence study.
4. To study in- vitro, In- Vivo, ex- Vivo, In-Situ Pharmacokinetics of drug.

Course outcomes:

Upon completion of this course student will be able to

1. Understand & use analytical techniques used in pharmacokinetic studies.
2. Analyzing pharmacokinetic data of drug.
3. Understand bioavailability and bioequivalence studies.
4. Understand and learn various in/ex-vitro, in/ex-vivo, pharmacokinetics of drugs

EXPERIMENTS

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: Dissertation Part-I
Subject Code: MDP-2301
Credits: 14
Work load:

Dessertation part- 1

Course Objective:

The learning objectives of the Dessertation course- 1 course are

1.To identify existing gap in research.

2.To analyse and develop independent research skills among students during their master's degree.

3.To discover new facts or to make fresh interpretations of known facts.

4.To test the independent research skills students have acquired during their time at university.

Course Outcomes:

Upon completion of this course student will be able to

1. Understand and investigate research problem

2. learn research skills.

3. learn and interpret new facts and findings.

4. Develop independent research skills

Syllabus [Credit System]

Course Name: M. Tech. (Chemical) Drugs & Pharmaceuticals
Year: Second
Semester: III
Subject Name: Techno-Economic Feasibility Report
Subject Code: MDP-2302
Credits: 06
Work load:

Course Objectives:

The learning objectives of the Techno-Economic Feseability Report course are

1.To understand Technical and commercial viability.

2.To know cost of the project.

3.To Estimate market feasibility

4.To integrate risk management into project planning and implementation.

Course Outcomes:

Upon completion of this course student will be able to

1. Examine technical requirments and challenges.

2. Understand detailed cost estimation for project.

3. Understand market potential

4. Assess risk management.

Syllabus [Credit System]

Course Name: M. Tech. (Chemical) Drugs & Pharmaceuticals
Year: Second
Semester: III
Subject Name: Dissertation Part-II
Subject Code: MDP-2401
Credits: 03
Work load:

Course Objectives:

The learning objectives of the Dissertation part-II course are

1.To enhance the practical knowledge and result analysis skills.

2. To enable the students experience a real-life problem solving under the supervision of faculty members.

3. To prepare the students perform functions that demand higher competence in national/international organizations.

4. To train the students in scientific research.

5.Develop research/ experimentation skills as well as enhancing project writing and oral presentation skills

Course Outcomes:

Upon completion of this course student will be able to

1. Develop analytical skill.
2. Understand problem, study design, methodology/experimentation, significance of reproducibility of results.
3. Understand ethics of science and research for supporting higher studies.
4. Learn effective project organizational skills along with discussions, result interpretation and paper writing.
5. Analyse the results.