DR. BABASAHEB AMBEDKAR MARATHWADA UNIVERSITY,
CHHATRAPATI SAMBHAJINAGAR.

CIRCULAR NO.SU/Sci./University Deptt./NEP/02/2024

It is hereby inform to all concerned that, the syllabi prepared by The Departmental Committee and recommended by the Dean, Faculty of Science & Technology, **Academic Council at its meeting held on 05 June 2024 has accepted** the following Syllabi under the Faculty of Science & Technology **as per Norms of National Education Policy – 2020 run at University Department, Dr.Babasaheb Ambedkar Marathwada University, Chhatrapathi Sambhajinagar** as appended herewith.

Sr.No.	Syllabi of the Department.	Semester
1.	**Revised B.Tech. (Chemical) Food Technology**	**Ist and IInd Semester.**
2.	**Revised B.Tech. (Chemical) Pharmaceutical & Fine Chemicals Technology**	**Ist and IInd Semester.**
3.	**Revised M.Tech. (Chemical) Drugs & Pharmaceuticals**	**Ist and IInd Semester.**
4.	**Revised M.Sc. Food Technology**	**Ist and IInd Semester.**

This is effective from the Academic Year 2024-25 and onwards.

All concerned are requested to note the contents of this circular and bring the notice to the students, teachers and staff for their information and necessary action.

University Campus,
Chhatrapati Sambhajinagar - 431 004.
REF.NO.SU/NEP/2024/892-900
Date:- 18.06.2024.

★★★★★

Deputy Registrar,
Academic Section

Copy forwarded with compliments to :-

1] **Head of the Department, Department of Chemical Technology,** Dr.Babasaheb Ambedkar Marathwada University, Chhatrapati Sambhajinagar.
2] **The Director, University Network & Information Centre, UNIC**, with a request to upload this Circular on University Website.

Copy to :-

1] **The Director, Board of Examinations & Evaluation,** Dr.Babasaheb Ambedkar Marathwada University, Chhatrapati Sambhajinagar.
2] The Section Officer,[M.Sc.,Engg. Unit,] Examination Branch, Dr.Babasaheb Ambedkar Marathwada University, Chhatrapati Sambhajinagar.
3] The Programmer [Computer Unit-1] Examinations, Dr.Babasaheb Ambedkar Marathwada University, Chhatrapati Sambhajinagar.
4] The Programmer [Computer Unit-2] Examinations, Dr.Babasaheb Ambedkar Marathwada University, Chhatrapati Sambhajinagar.
5] The In-charge,[E-Suvidha Kendra], Rajarshi Shahu Maharaj Pariksha Bhavan, Dr.Babasaheb Ambedkar Marathwada University, Chhatrapati Sambhajinagar.
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Dr. Babasaheb Ambedkar Marathwada University,

Chhatrapati Sambhajinagar-431004 (MS), India

M. TECH (CHEMICAL) DRUGS & PHARMACEUTICALS

Revised Program Structure and Detail Syllabus

(In line with New Education policy 2020)

(Effective from Academic Year 2024-2025 & onwards)

Department of Chemical Technology

Chairman
Adhoc Board in Chemical Technology

In line with New Education Policy 2020

Illustrative Credit distribution structure for Two Years/ One Year PG (M.A./M.Sc./M.Com.) and Ph. D. Programme

Year (2 Yr PG)	Level	Sem. (2 Yr)	Major		RM	OJT / FP	RP	Cum. Cr.	Degree
			Mandatory	Electives					
I	6.0	Sem I	12-14 (2*4 +2*2 or 3*4+2)	4	4			20-22	PG Diploma (after 3 Yr Degree)
		Sem II	12-14 (2*4 +2*2 or 3*4+2)	4		4		20-22	
Cum. Cr. For PG Diploma			24-28	8	4	4	-	40-44	
Exit option: PG Diploma (40-44 Credits) after Three Year UG Degree									
II	6.5	Sem III	12-14 (2*4 +2*2 or 3*4+2)	4			4	20-22	PG Degree After 3-Yr UG Or PG Degree after 4-Yr UG
		Sem IV	10-12 (2*4 +2 or 3*4)	4			6	20-22	
Cum. Cr. for 1 Yr PG Degree			22-26	8			10	40-44	
Cum. Cr. for 2 Yr PG Degree			46-54	16	4	4	10	80-88	
2 Years-4 Sem. PG Degree (80-88 credits) after Three Year UG Degree or 1 Year-2 Sem PG Degree (40-44 credits) after Four Year UG Degree									
	8.0		Course Work Min. 12 (3*4)		Training in Teaching / Education/ Pedagogy: 4		16 + Ph. D. Work		Ph.D. in Subject

Abbreviations: Yr.: Year; Sem.: Semester; OJT: On Job Training: Internship/ Apprenticeship; FP: Field projects; RM: Research Methodology; Research Project: RP; Cumulative Credits: Cum. Cr.

University Department of Chemical Technology

Dr. Babasaheb Ambedkar Marathwada University, Aurangabad

M. Tech. (Chemical) Drugs & Pharmaceuticals

Full Time Four Semester Program

Credit distribution structure for Two Years PG / One Year PG Diploma in Drugs & Pharmaceuticals

Year (2 Yr. PG)	Level	Semester (2 Yr.)	Major		RM	OJT	RP	Cumulative Credits	Degree
			Mandatory	Elective					
I	6.0	Semester-I	12	4	4	-	-	20	PG Diploma (After 4 Year Degree)
		Semester-II	12	4	-	4	-	20	
Cumulative Credits for PG Diploma			**24**	**8**	**4**	**4**	-	**40**	
Exit Option: PG Diploma (40 Credits) after Four Year UG degree									
II	6.5	Semester-III	12	-	-	-	8	20	PG Degree after 4 Year UG
		Semester-IV	10	-	-	-	10	20	
Cumulative Credits for 1 Yr. PG Degree			**22**	-	-	-	**18**	**40**	
Cumulative Credits for 2 Yr. PG Degree			**46**	**8**	**4**	**4**	**18**	**80**	
Two Year Four Semester PG Degree (80 Credits) after Four Year UG degree **OR** **One Year Two Semester PG Diploma (40 Credits) after Four Year UG degree**									

M. Tech. (Chemical) Drugs & Pharmaceuticals

Full Time Four Semester Program

Curriculum Structure & Scheme of Evaluation as per NEP 2020

SEMESTER-I											
Course Code	**Name of Subject**	**Teaching Scheme Hours per Week**				**Examination Scheme-Marks**					
		Lectures	Tutorials	Lab Work	Total Credits	THEORY			Term Work	Practical	Total
						TEST	ASSIGNMENTS	END SEM			
MDP/MJ/500	Dosage form Design	2	1	-	3	-	40	60			100
MDP/MJ/501	Advanced Pharmaceutical Analysis	2	1	-	3	-	40	60			100
MDP/MJ/502	Dosage form Design	-	-	6	3	-	-	-	40	60	100
MDP/MJ/503	Advanced Pharmaceutical Analysis	-	-	6	3	-	-	-	40	60	100
MDP/DSE/504-6	Elective-I*	2	0	-	2	-	20	30			50
MDP/DSE/507-9	Elective-II**	2	0	-	2	-	20	30			50
MDP/RM/510	Research Methodology & Pharmaceutical Statistics	2	2	-	4						
MDP/511	Constitution of India	-	-	-	-	-	20	30	-	-	50
	Total of Semester-I	**10**	**4**	**12**	**20**	**-**	**140**	**210**	**80**	**120**	**550**
	Total Credit Points				**20**						

* MDP/DSE/504: Advanced Pharmaceutical Chemistry MDP/DSE/505: Novel Drug Delivery Systems MDP/DSE/506: Pharmaceutical Biotechnology	** MDP/DSE/507: Drug Regulatory Affairs MDP/DSE/508: Cosmeceuticals MDP/DSE/509: Clinical Biochemistry

SEMESTER-II											
Course Code	**Name of Subject**	**Teaching Scheme Hours per Week**				**Examination Scheme-Marks**					
		Lectures	Tutorials	Lab Work	Total Credits	THEORY			Term Work	Practical	Total
						TEST	ASSIGNMENTS	END SEM			
MDP/ MJ/550	Advanced Biopharmaceutics & Pharmacokinetics	2	1	-	3	-	40	60			100
MDP/ MJ/551	Quality Assurance & Validation	2	1	-	3	-	40	60			100
MDP/ MJ/552	Advanced Biopharmaceutics & Pharmacokinetics	-	-	6	3	-	-	-	40	60	100
MDP/ MJ/553	Quality Assurance & Validation	-	-	6	3	-	-	-	40	60	100
MDP/DSE/554-56	Elective-III*	2	0	-	2	-	20	30			50
MDP/DSE/557-59	Elective-IV**	2	0	-	2	-	20	30			50
MDP/OJT/560	In-plant Training			-	4				40	60	100
	Total of Semester-I	**8**	**2**	**12**	**20**	**-**	**120**	**180**	**120**	**180**	**600**
	Total Credit Points				**20**						

* MDP/DSE/554: Medicinal Chemistry & Drug Discovery
MDP/DSE/555: Product Development & Technology Transfer
MDP/DSE/556: Intellectual Property Rights

** MDP/DSE/557: Herbal Drug Technology
MDP/DSE/558: Pharmacological Screening Methods
MDP/DSE/559: Clinical Microbiology

Syllabus [Credit System]

Course Name	**: M. Tech. (Chemical) Drugs & Pharmaceuticals**
Year	**: First**
Semester	**: I**
Core	**: I**
Subject Name	**: Dosage Form Design**
Subject Code	**: MDP/MJ/500**
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) Parenterals: SVP, LVP

- Methods of preparation and production facilities
- Evaluation
- Stability

i) 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 equipment 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**

Subject Name : **Advanced Pharmaceutical Analysis**

Subject Code : **MDP/MJ/501**

Credits : **3**

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.

Syllabus [Credit System]

Course Name	**:M. Tech. (Chemical) Drugs & Pharmaceuticals**
Year	**:First**
Semester	**:I Lab I**
Subject Name	**:Dosage Form Design**
Subject Code	**:MDP/MJ/502**
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. 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: Developmental 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	**: Advanced Pharmaceutical Analysis**
Subject Code	**: MDP/MJ/503**
Credits	**: 3**
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, etc.
4. Working of scanning electron microscopy

EXPERIMENTS

1. Introduction of UV- Visible Spectroscopy
2. To perform UV- method development of Ibuprofen.
3. To perform Simultaneous UV-method development of Nelfinavir and Quercetin.
4. Introduction to Infrared Spectroscopy.
5. Introduction to Luminescence Spectroscopy.
6. Introduction to Fluorescence Spectroscopy.
7. Introduction to Nuclear Magnetic Resonance spectroscopy.

8. Introduction to Atomic Absorption Spectroscopy.
9. Introduction to Column Chromatography.
10. Introduction to Thin Layer Chromatography (TLC).
11. Identification of compound from given mixture by using TLC.
12. Introduction to High performance Liquid- Chromatography (HPLC).
13. Development of High-Performance Liquid Chromatography Method for Estimation of Morin in Bulk and Formulation.
14. Simultaneous estimation of Methyl salicylate and Diclofenac diethyl-amine using RP-HPLC
15. Introduction to Gas Chromatography (GC).
16. Demonstration of Liquid Chromatography Mass Spectroscopy (LC-MS).
17. Demonstration of Liquid Chromatography Mass Spectroscopy (LC-MS).
18. Demonstration of Gas Chromatography & Mass Spectroscopy (GC-MS).
19. Introduction to Scanning Electron Microscopy (SEM).

Syllabus [Credit System]

Course Name	**: M. Tech. (Chemical) Drugs & Pharmaceuticals**
Year	**: First**
Semester	**: I Elective I**
Subject Name	**: Advanced Pharmaceutical Chemistry**
Subject Code	**: MDP/SCE/504**
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	**: Novel Drug Delivery System**
Code	**: MDP/DSE/505**
Credits	**: 2**
Work load	**: 2 hr/week**

Theory

Course Objective:

The learning objectives of Novel drug delivery system course is

1) To learn drug delivery carriers
2) To Learn various drug delivery systems
3) To study various targeted drug delivery systems
4) To study biotechnology in drug delivery systems

Course Outcomes:

Upon completion of this course student will be able to -

1) Understand various carriers for drug delivery
2) Understand drug delivery systems
3) Understand and identify targeted drug delivery systems
4) Understand rope of biotechnology in drug delivery

Unit I: Carriers for Drug Delivery: Polymers / co–polymers–introduction, classification, characterization, polymerization techniques, application in CDDS / NDDS, biodegradable & natural polymers.

Study of Various DDS: Concepts, design, formulation & evaluation of controlled release oral DDS, Mucoadhesive DDS (buccal, nasal, pulmonary) Pulsatile, colon specific, liquid sustained release systems, Ocular delivery systems

Unit II: Transdermal Drug Delivery Systems: Theory, design, formulation & evaluation including iontophoresis and other latest developments in skin delivery systems.

Unit III: Sub Micron Cosmeceuticals: Biology, formulation science and evaluation of various cosmetics for skin, hair, nail, eye etc and it's regulatory aspects.

Targeted Drug Delivery Systems: Importance, concept, biological process and events involved in drug targeting, design, formulation & evaluation, methods in drug targeting - nanoparticles, liposomes, niosomes, pharmacosomes, resealed erythrocytes, microspheres, magnetic microspheres. Specialized pharmaceutical emulsions - multiple emulsions, micro–emulsions.

Unit IV: Protein / Peptide Drug Delivery Systems: Concepts, delivery techniques, formulation, stability testing, causes of protein destabilization, stabilization methods.

Biotechnology in Drug Delivery Systems: Brief review of major areas –recombinant DNA technology, monoclonal antibodies, gene therapy.

Unit V: New trends for Personalized Medicine: Introduction, Definition, Pharmacogenetics and Categories of Patients for Personalized Medicines: Customized drug delivery systems, Bioelectronic Medicines, 3D printing of pharmaceuticals, Telepharmacy.

REFERENCES

1. Novel Drug Delivery System, Y.W. Chein, Vol 50, Marcel Dekker, NY.
2. Controlled Drug Delivery Systems, Robinson, Vol 29, Marcel Dekker, NY.
3. Transdermal Controlled Systemic Medications, YW Chein, Vol 31, Marcel Dekker, NY.
4. Bioadhesive DDS, E. Mathiowitz, Vol 98, Marcel Dekker, NY.
5. Nasal System Drug Delivery, K.S.E. Su, Vol 39, Marcel Dekker, NY.
6. Drug Delivery Devices, Vol 32, P Tyle Marcel Dekker, NY.

Syllabus [Credit System]

Course Name	**: M. Tech. (Chemical) Drugs & Pharmaceuticals**
Year	**: First**
Semester	**: I Elective I**
Subject Name	**: Pharmaceutical Biotechnology**
Subject Code	**: MDP/DSE/506**
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 Technolgy
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,
5. Boffey, K.H. Goulding and P. Stanbury
6. Microbial Genetics by David Freifelder
7. Immunology by J. Kuby
8. Immunology by Weir
9. Genetic Engineering, Cloning DNA by D.M. Glover
10. Recombinant DNA by Watson.
11. Molecular Biotechnology – Principle and Application of recombinant DNA by B.R. Glick & J.J. Pasternak
12. Pharmaceutical Biotechnology-An Introduction for Pharmacists & Pharmaceutical Scientists by D.J.A. Crommelin & R.D. Sindelar
13. The Principles of Gene Manipulation by Old R.W & Primrose, S.B.
14. Molecular Biology of Gene by Watson
15. Biochemical Engineering and Biotechnology Handbook by Atkinson, B and Marituna, F.
16. Fermentation and Biochemical Engineering Handbook by Vogel

Syllabus [Credit System]

Course Name	**: M. Tech. (Chemical) Drugs & Pharmaceuticals**
Year	**: First**
Semester	**: I Elective II**
Subject Name	**: Drug Regulatory Affairs**
Subject Code	**: MDP/DSE/507**
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 Patent 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 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.

Syllabus [Credit System]

Course Name	**: M. Tech. (Chemical) Drugs & Pharmaceuticals**
Year	**: First**
Semester	**: I Elective II**
Subject Name	**: Cosmeceuticals**
Subject Code	**: MDP/DSE/508**
Credits	**: 2**
Work load	**: 2 hr/week**

Theory

Course objectives:

The learning objectives of cosmeceuticals course are

1. To learn sun protection, pigmentation and wrinkles products
2. To learn and understand acne, oral care & dandruff formulations
3. To identify and study herbal cosmetics
4. To understand dermal drug delivery

Course outcomes:

Upon completion of this course student will be able to

1. Understand various Sun protection, pigmentation wrinkle products
2. Understand various oral, acne & dandruff formulations
3. Understand herbal cosmetics
4. Learn dermal drug delivery system.

Unit I: Sun protection, pigmentation and wrinkles Sun Protection: Solar spectrum, UV A and UV B rays of the sun. Skin damages caused by over exposure to sunlight, organic and in-organic sunscreens, SPF and Tan protection. Challenges in developing sunscreen formulations. Global regulatory aspects of sunscreen products. Case study on sunscreen products in the market. Skin Pigmentation and Wrinkles: Melanogenesis and ethnic differences. Ways to control skin pigmentation. Actives and mechanism of action. Building blocks and formulation of a skin anti-blemish cream. Skin bleaches and skin lightening. Case study on skin lightening products in the market.

Skin wrinkles: Factors that leads to skin wrinkles. Role of anti-oxidants in reducing skin wrinkles. Building block and formulation of an anti-wrinkle product. Case study on antiaging/antiwrinkle product in the market.

Unit II: Acne, Prickly heat, Dandruff and oral care Causes for acne, prickly heat and dandruff and current treatment. Building blocks and formulation of products for treatment of acne, prickly heat and dandruff. Case study of marketed products. Oral care: Basic understating of the cause of Bleeding gums, sensitive teeth, plague, halitosis. 132 Role of antimicrobial agents, anti-oxidants and astringents for oral care. Denture cleansers. Building blocks and formulation of anti-cavity, tooth sensitivity relief and teeth-whitening tooth paste. Case study on the marketed products

Unit III: Herbal Cosmetics Herbal ingredients used in Hair care, skin care and oral care and nail. Guidelines for herbal cosmetics by private bodies like cosmos with respect to preservatives, emollients, foaming agents, emulsifiers and rheology modifiers. Formulation and development of herbal cosmetics.

Unit IV: Dermal Drug Delivery Factors affecting dermal drug delivery. Role of penetration enhancers in dermal delivery. Dermal drug delivery systems: Nano particles, Liposomes, patches, Iontophoresis, sonophoresis, electroporation, micro-needles.

References

1. Harry's Cosmeticology. 8th edition.

2. Poucher's perfume cosmetics and Soaps, 10th edition

3. Cosmetics - Formulation, manufacture and quality control PP. Sharma, 4th edition

4. Handbook of cosmetic science and Technology A.O.Barel, M.Paye and H.I.Maibach. 3rdedition

5. S.P.Vyas and Roop K.Khar Controlled Drug Delivery system, Concepts and Advances

6. Cosmetic and Toiletries recent suppliers catalogue. 7. CTFA directory.

Syllabus [Credit System]

Course Name	**: M. Tech. (Chemical) Drugs & Pharmaceuticals**
Year	**: First**
Semester	**: I Elective II**
Subject Name	**: Clinical Biochemistry**
Subject Code	**: MDP/DSE/509**
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, protein's 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 &Pharmaceutical Statistics**
Subject Code	**: MDP/RM/510**
Credits	**: 4**
Work load	**: 2 hr/week**

Theory

Course Objectives:

The learning objectives of the Research Methodology & Pharmaceutical Statistics 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**
Subject Name	**: Constitution of India**
Subject Code	**: MDP/511**

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.

UNIT-I: Introduction to Indian Constitution

Constitution meaning of the term - The making of the Indian Constitution - Sources and constitutional history – Philosophy of Constituent Assembly - Citizenship, Preamble, Fundamental Rights and Duties, Directive Principles of State Policy.

UNIT-II: The Union: Executive, Legislative and Judiciary

Union Government and its Administration Structure: President and Vice President: Role, power and position, PM and Council of ministers, Cabinet and Central Secretariat, Lok Sabha, Rajya Sabha, The Supreme Court and High Court: Powers and Functions.

UNIT-III: The States and The Union Territories

State Government and its Administration: Governor - Role and Position - CM and Council of ministers, State Secretariat: Organisation, Structure and Functions – Relation between the Union and the States.

UNIT-IV: Local Administration

District's Administration Head - Role and Importance, Municipalities - Mayor and role of Elected Representative – Panchayati Raj: Functions PRI: Zilla Panchayat, Elected officials and their roles - Block level Organizational Hierarchy, Village level - Role of Elected and Appointed officials - Importance of grass-root democracy

UNIT-V: Emergency Provisions and Election Commission

Emergency: Proclamation of Emergency, types of emergencies - Election Commission: Role of

Chief Election Commissioner - State Election Commission - Functions of Commissions for the welfare of SC/ST/OBC and women.

Text Books

1. Durga Das Basu, Introduction to the Constitution of India, Prentice – Hall of India
2. Pvt.Ltd.. New Delhi
3. Subash Kashyap, Indian Constitution, National Book Trust
4. J.A. Siwach, Dynamics of Indian Government & Politics
5. D.C. Gupta, Indian Government and Politics
6. H.M. Sreevai, Constitutional Law of India, 4th Edition, Universal Law Publication.

References

1. J.C. Johari, Indian Government and Politics Hans
2. J. Raj Indian Government and Politics
3. M.V. Pyle Indian Constitution Durga Das Basu, Human Rights in Constitutional Law,

2. Prentice – Hall of India Pvt.Ltd.. New Delhi

1. Noorani, A.G., (South Asia Human Rights Documentation Centre), Challenges to Civil

3. Right), Challenges to Civil Rights Guarantees in India, Oxford University Press 2012

E-Resources

1. nptel.ac.in/courses/109104074/8
2. nptel.ac.in/courses/109104045/
2. nptel.ac.in/courses/101104065/
3. www.hss.iitb.ac.in/en/lecture-details
4. www.iitb.ac.in/en/event/2nd-lecture-institute-lecture-series-indian-constitution

Syllabus [Credit System]

Course Name	**: M. Tech. (Chemical) Drugs & Pharmaceuticals**
Year	**: First**
Semester	**: II**
Subject Name	**: Advanced Biopharmaceutics and Pharmacokinetics**
Subject Code	**: MDP/MJ/550**
Credits	**: 3**
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-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-Invivo 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. Bramhankar 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	**: Advanced Bio-pharmaceutics & Pharmacokinetics**
Subject Code	**: MDP/MJ/552**
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. Understand & use analytical techniques used in pharmacokinetic studies.
5. Analysing pharmacokinetic data of drug.
6. Understand bioavailability and bioequivalence studies.
7. Understand and learn various in/ex-vitro, in/ex-vivo, pharmacokinetics of drugs

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 Rat.

Syllabus [Credit System]

Course Name	**: M. Tech. (Chemical) Drugs & Pharmaceuticals**
Year	**: First**
Semester	**: II**
Subject Name	**: Quality Assurance & Validation**
Subject Code	**: MDP/MJ/551**
Credits	**: 3**
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. Determine 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	**: Quality Assurance**
Subject Code	**: MDP/MJ/553**
Credits	**: 03**
Work load	**: 4 hr/week**

Practical-II

Course Objectives:

1. To learn various organic contaminants residues
2. To learn and understand various contaminants by using different techniques
3. To learn and identify antibiotics residue by TLC
4. To learn and understand validation of various instruments used in Pharma industry
5. To understand validation of various analytical methods for drugs

Course Outcomes:

Upon completion of this course student will be able to

1. Understand various organic contaminants residues
2. Analyze various contaminants by different techniques.
3. Analyze and estimate antibiotics residue by TLC
4. Validate various instruments used in pharma industry
5. Validate various analytical methods for drugs

Experiments

1. Organic contaminants residue analysis by HPLC
2. Estimation of Metallic contaminants by Flame photometer
2. Identification of antibiotic residue by TLC

3. Estimation of Hydrogen Sulphide in Air.

4. Estimation of Chlorine in Work Environment.

5. Sampling and analysis of SO2 using Colorimetric method

6. Qualification of following Pharma equipment

a. Autoclave b. Hot air oven c. Powder Mixer (Dry) d. Tablet Compression Machine

7. Validation of an analytical method for a drug

8. Validation of a processing area

9. Qualification of at least two analytical instruments

10. Cleaning validation of one equipment

11. Qualification of Pharmaceutical Testing Equipment (Dissolution testing apparatus, Friability Apparatus, Disintegration Tester)

12. Check list for Bulk Pharmaceutical Chemicals vendors

13. Check list for tableting production.

14. Check list for sterile production area

15. Check list for Water for injection.

16. Design of plant layout: Sterile and non-sterile

17. Case study on application of QbD

18. Case study on application of PAT 204

Syllabus [Credit System]

Course Name	**: M. Tech. (Chemical) Drugs & Pharmaceuticals**
Year	**: First**
Semester	**:II Elective III**
Subject Name	**: Medicinal Chemistry and Drug Discovery**
Subject Code	**: MDP/MJ/554**
Credits	**: 2**
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 Elective III**
Subject Name	**:Product Development and Technology Transfer**
Subject Code	**: MDP/MJ/555**
Credits	**: 2**
Work load	**: 3 hr/week**

Theory

Course objectives:

The learning objectives of product development and technology transfer are-

1. To understand the new product development process
2. To learn prefromulation studies
3. To understand necessary information to transfer technology from R & d to actual manufacturer
4. To elucidate necessary information to transfer technology of existing products

Course outcomes :

Upon completion of this course student will be able to

1. Learn and understand development process of new product
2. Understand prefromulation studies
3. Identify and learn transfer technology from R & d to actual manufacturer
4. learn and understand technology transfer of existing products

UNIT-I

Principles of Drug discovery and development: Introduction, Clinical research process. Development and informational content for Investigational New Drugs Application (IND), New Drug Application (NDA), Abbreviated New Drug Application (ANDA), Supplemental New Drug Application (SNDA), Scale Up Post Approval Changes (SUPAC) and Bulk active chemical Post approval changes (BACPAC), Post marketing surveillance, Product registration guidelines – CDSCO, USFDA.

UNIT-II

Pre-formulation studies: Introduction / concept, organoleptic properties, purity, impurity profiles, particle size, shape and surface area.

Solubility, Methods to improve solubility of Drugs: Surfactants & its importance, co-solvency. Techniques for the study of Crystal properties and polymorphism. Pre-formulation protocol, Stability testing during product development.

UNIT-III

Pilot plant scale up: Concept, Significance, design, layout of pilot plant scales up study, operations, large scale manufacturing techniques (formula, equipment, process, stability and quality control) of solids, liquids, semisolid and parenteral dosage forms. New era of drug products: opportunities and challenges.

UNIT-IV

Pharmaceutical packaging: Pharmaceutical dosage form and their packaging requirments, pharmaceutical packaging materials, medical device packaging, Enteral Packaging, Aseptic packaging systems, Container closure systems, Issues facing modern drug packaging, Selection and evaluation of pharmaceutical packaging materials.

Quality control test: Containers, closures and secondary packing materials.

UNIT-V

Technology transfer: Development of technology by R & D, Technology transfer from R & D to production, Optimization and Production, Qualitative and quantitative technology models.

Documentation in technology transfer: Development report, technology transfer plan and Exhibit.

REFERENCES

1. Charles G. Smith, James T and O. Donnell, The process of new drug discovery and development. I and II Edition (2006) CRC Press, Group of Taylor and Francis.

2. Leon Lac Lachman, Herbert A. Liberman, Theory and Practice of Industrial Pharmacy. Marcel Dekker Inc. New York.

3. Sidney H Willing, Murray M, Tuckerman. Williams Hitchings IV, good manufacturing of pharmaceuticals (A Plan for total quality control) 3rd E/d Bhalani publishing house Mumbai.

4. Leon Lachman, Herbert A. Liberman, Joseph B. Schwartz, Tablets Vol. I, II, III, 2nd E/d. (1989), Marcel Dekker Inc. New York.

5. Milo Gibaldi, Text book of Bio- Pharmaceutics and clinical Pharmacokinetics 3rd E/d Lea & Febriger, Philadelphia.

6. Vandana V. Patrevale. John I. Disouza. Maharukh T.Rustomji, Pharmaceutical product development. CRC Press, Group of Taylor and Francis.

7. Abdou H.M, Dissolution, Bioavailability and Bio-Equivalence, Mack Publishing company, Eastern Pennsylvania.

8. Alfonso & Gennaro, Remingtons Pharmaceutical Sciences, 19th Edn.(1995)OO2C Lippincott; Williams and Wilkins A Wolters Kluwer Company, Philadelphia.

9. D. A Sawant, The Pharmaceutical Sciences; the Pharma Path way Pure and applied Pharmacy, Pragathi Books Pvt. Ltd.

10. D.A. Dean. E.R. Evans, Pharmaceutical Packaging technology, I.H. Hall. 1st E/d (Reprint 2006). Taylor and Francis. London and New York. 130

Syllabus [Credit System]

Course Name	**: M. Tech. (Chemical) Drugs & Pharmaceuticals**
Year	**: First**
Semester	**: II Elective III**
Subject Name	**: Intellectual Property Rights**
Subject Code	**: MDP/MJ/556**
Credits	**: 2**
Work load	**: 4 hr/week**

Theory

Course objective:

The learning objectives of the Dosage Form Design course are

1. To learn & understand need of patents
2. To learn & understand different types of patents
3. To learn parts of patents
4. To learn & understand GATT, TRIPS, WIPO
5. To learn trademark protection
6. To learn & understand major bodies regulating Indian pharmaceutical sector

Course Outcome:

Upon completion of this course student will be able to

1. Understand what is patents
2. Understand different types of patents
3. Know GATT, TRIPS, WIPO
4. Know trademark protection
5. Understand major bodies regulating Indian pharmaceutical sector

Unit 1 Definition, need for patenting, Types of Patents, Conditions to be satisfied by an invention to be patentable, Introduction to patent search. Parts of patents. Filling of patents. The essential elements of patent; Guidelines for preparation of laboratory note book, non

obviousness in Patent.

Unit 2 Role of GATT, TRIPS, and WIPO.

Unit 3 Brief introduction to Trademark protection and WHO Patents. IPR's and its types, Major bodies regulating Indian Pharmaceutical sector,

Unit 4 Brief introduction to CDSCO. WHO, USFDA, EMEA, TGA, MHRA, MCC, ANVISA

Unit 5 Regulatory requirements for contract research organization. Regulations for Biosimilars.

Recommended books:

1. Pharmaceutical Process Validation: By Fra R. Berry and Robert A. Nash, Vol 57, 2nd Edition.
2. Applied Production and Operation Management by Evans, Anderson and Williams
3. GMP for pharmaceuticals Material Management by K.K. Ahuja Published by CBS publishers
4. ISO 9000-Norms and explanations 148
5. GMP for pharmaceuticals- Willing S.H. Marcel and Dekker
9. Dissolution methods of transdermal drug delivery systems.
10. Stability testing of solution and solid dosage forms for photo degradation.
11. Stability studies of drugs in dosage forms at 25
16. Formulation and evaluation of microspheres / microcapsules.
17. Formulation and evaluation of transdermal films.
18. Design and evaluation of face wash, body- wash, creams, lotions, shampoo, toothpaste, lipstick.

Syllabus [Credit System]

Course Name	**: M. Tech. (Chemical) Drugs & Pharmaceuticals**
Year	**: First**
Semester	**: II Elective IV**
Subject Name	**: Herbal Drug Technology**
Subject Code	**: MDP/MJ/557**
Credits	**: 2**
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*

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, 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	**: II Elective IV**
Subject Name	**: Pharmacological Screening Methods**
Subject Code	**: MDP/MJ/558**
Credits	**: 2**
Work load	**: 3 hr/week**

Theory

Course objective:

The learning objectives of pharmacological screening methods are

1. To understand screening of new drugs

2. To learn and understand regulations and ethics concerning animal studies and experiments on human beings

3.To participate in drug development process

4. To learn concepts of kinetics and various pharmacokinetics models

Course outcomes:

Upon completion of this course student will be able to-

1. Identify and analyze screening of new drugs

2.Learn regulations concerning to human and animal studies

3. Understand drug development process

4. Understand concept of kinetics and pharmacokinetics models

Unit 1 Drug Design:

a. Drug discovery development introduction

b. Modern methods of drug discovery (Introduction, Target identification, Target validation, Lead

compound identification and Optimization).

c. Study of laboratory animals including physiological parameters Regulations and ethics requirements.

Transgenic animals and other genetically prone animal models (Viz Nude Mice, SH rats and humanized

mice).

Unit 2 Preclinical models employed in the screening of new drugs belonging to following categories: (20 hours)

Antipsychotic agent; Antianxiety agents; Nootropic drugs; Antidepressant drugs; Antiparkinsonian agents; Analgesics; Antiepileptics; Anti-inflammatory agents; Antiulcer agents; Antianginals and myocardial infarction; Antiarrhythmics; Antiatherosclerosis drugs; Antimalarials; Antidiabetics; Antihypertensives; Anticancer.

Unit 3. Modern techniques to elucidate the mechanisms of drug actions:

a. Cell culture and maintenance:

Concepts of in-vitro screening, Different cell lines (animal &human) used in screening techniques.

Primary and secondary cultures, Principles of techniques involved in cell culture and its maintenance.

b. Introduction and applications of Biomarker analysis

c. Introduction to Translational pharmacology

d. High throughput screening (HTS): Introduction, Basic principles involved in cell based

to binding assays and ultra-high through put screening.

e. Alternatives to animal screening procedures, cell-line, patch-clamp technique, in-vitro models.

Unit 4: Definition and Scope of Pharmacokinetics.

Absorption, Distribution, Metabolism, Elimination and transporters

Individualization: variability, genetics, age and weight, disease, interacting drugs, and1 monitoring of the same.

Pharmacokinetic models: compartmental models, noncompartmental models and physiologic model.

Unit 5: Clinical Research: Introduction and Ethics

Nonlinear pharmacokinetics, multiple dosing and dosage regimen.

a. Definition and scope of clinical research. Role of sponsor, study director or principal investigator;

Clinical Research Associate in conduct of Clinical Research

b. Study design, ethics in patient selection and preserving their rights. Institutional Ethics Review committee its constituent members and its role in clinical research. Introduction to informed consent and its importance.

Unit: 6 Phases of Clinical Trial and Clinical Trial Design

a. Calculation of Human Equivalent Dose; Phase 0, Phase I, Phase II, Phase III, Phase IV and Phase V Clinical trial.

b. Randomized Clinical Trial, Uncontrolled Trials, Protocol Development, End points, Patient Selection and blinding, special designs like cross over design, factorial design, Equivalence design, confounding in clinical trials and ways to minimize it, Missing data and its management, occurrence of ADRs, interim monitoring and stopping of trials,

Regulatory Affairs in Clinical Research

a. Pharmacovigilance

b. Laws governing Clinical Research: preparation of Drug master files (1ND, NDA and ANDA) schedule Y, Code of Federal Regulations (CFR-USFDA) CDSCO (ICMR), EMEA

c. International Guidelines to meet the standards in Clinical Research: ICH guidelines for efficacy testing of drugs: clinical aspects and data management strategies

Syllabus [Credit System]

Course Name	**: M. Tech. (Chemical) Drugs & Pharmaceuticals**
Year	**: First**
Semester	**: II Elective IV**
Subject Name	**: Clinical Microbiology**
Subject Code	**: MDP/MJ/559**
Credits	**: 02**
Work load	**: 4 hr/week**

Theory

course objective:

The learning objectives of Clinical microbiology course are

1) To learn basics of microbiology

2) To learn and identify sterilization and disinfection techniques

3) To learn Bacteria, virus & fungus associated diseases

4) To learn immunology and R-DNA technology

Course outcomes:

Upon completion of this course student will be able to

1) Understand basic concepts of microbiology

2) Understand sterilization & disinfection techniques

3) Understand various diseases associated with bacteria, virus & fungus

4) Understand Rdna & immunology concepts

Unit I Basics of Microbiology: Golden era of microbiology, common nutrient requirements and nutritional types of microbes, culture media and its types, growth curve, continuous culture and synchronous growth, influence of environmental factors on growth, aerobic & anaerobic cultures

UNIT II Sterilization & disinfection: introduction, physical and chemical agents of sterilization/disinfection, minimum inhibitory concentration, minimum bactericidal concentration, testing of disinfectants, biosafety in microbiology lab.

Unit III Fungus associated diseases: mode of infection, pathogenesis and laboratory diagnosis of aspergillosis, candidiasis, cryptococcosis and pneumocystis Bacteria associated diseases: mode of infection, pathogenesis and laboratory diagnosis of Staphylococcus aureus, Streptococcus pneumoniae, Clostridiumspp, Escherichia coli, Pseudomonas aeruginosaand Mycobacterium tuberculosis Virus associated diseases: mode of infection, pathogenesis and laboratory diagnosis of HIV, hepatitis A and B, influenza virus, dengue virus and corona virus.

Unit IV Immunology: Innate and adaptive immunity, cells and organs of immune system, antigen, antibody, antibody diversity, antigen – antibody reactions, MHC molecules, antigen processing and presentation, cytokines, B and T cell activation, humoral and cell mediated effector responses, complement system, tolerance and autoimmunity

Unit V Molecular biology and rDNA technology: structure and functions of nucleic acids, central dogma of life, isolation, amplification, purification and storage of nucleic acids, vectors, enzymes used in rDNA technology, cloning methodologies, expression of recombinant proteins and sequencing techniques

Unit VI Analytical techniques: principle, instrumentation, types and applications of microscopy, centrifugation, chromatography, electrophoresis, spectrophotometry, FTIR, X-ray Diffraction, NMR and Surface plasmon resonance

Syllabus [Credit System]

Course Name	**: M. Tech. (Chemical) Drugs & Pharmaceuticals**
Year	**: First**
Semester	**: II**
Subject Name	**: In-plant Training**
Subject Code	**: MDP/OJT/560**
Credits	**: 04**
Work load	**: 4 hr/week**

Course objectives:

The learning objectives of the In-plant training course are -

1. To learn and recognize Industrial environment
2. Understand various career paths
3. Communicate effectively
4. Understand and learn employability skills required

Course outcome:

Upon completion of this course student will be able to

1.Understand and learn Industrial Environment

2.Identify career path taking into account their individual career path

3.Communicate effectively through technical presentation

4.Enhance employability skills