Prof S.D.S. Murthy
The Chairman
Board of Studies
SVU College of Pharmaceutical Sciences
S V University
Tirupati

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Tirupati

18.02.2022

To

The Registrar
SV University
Tirupati.

Sir,

Sub:- SVU College of Pharmaceutical Sciences – Approval of M.Pharmacy Syllabus and Regulations- Reg.

Ref:- Letter No.C-II (A, B & F)/ NEP/2021, dated 01-10-2021.

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With reference to the letter cited above, I am here by enclosing the soft & hard copies of the revised Syllabus and the regulations of the Master of Pharmacy Programme (M.Pharm) as per the NEP - 2020 guidelines and the PCI guidelines, along with the minutes of the BOS Meeting for the approval from the academic year 2021-2022

This is for your information and necessary action.

The Chairman
Board of Studies

Chairman, BOS
College of Pharmaceutical Sciences
S.V. University, Tirupati

Copy to the Dr. Registrar, Academic Branch, SV University, Tirupati.
Copy to the Principal, SVU College of Pharmaceutical Sciences, SV University, Tirupati.

SVU COLLEGE OF PHARMACEUTICAL SCIENCES : : TIRUPATI

Minutes of the meeting of the Board of Studies Committee (BOS) meeting held on 04-01-2022 at 11.00 A.M in the Chamber's of the Principal, SVU College of Pharmaceutical Sciences, Tirupati.

AGENDA:

1. To discuss the PCI recommended M.Pharmacy syllabus for implementation from 2021 -- 2022 batch
2. To discuss on evaluation process and model question papers of M.Pharmacy.
3. Any other relevant matter.

MEMBERS PRESENT

1	Prof.SDS Murthy Department of Bio-Chemistry SVU College of Science,Tirupati	-- Chairman of BOS
2	Prof.Ch.Appa Rao Principal SVU College of Pharmaceutical Sciences Tirupati	-- Member of BOS
3	Prof.M.Vidyavathi Institute of Pharmaceutical Technology SPMVV. Tirupati	-- External Member
4	Prof.C.Suresh Reddy Department of Chemistry SV University, Tirupatai	-- Member of BOS
5	Dr.M.Balaji Department of Bio-Chemistry SVU College of Science, Tirupati	-- Member of BOS
6	Prof.P.Vijaya Department of Botany SV University, Tirupatai	-- Member of BOS

MINUTES

The members of BOS have discussed the existiong M.Pharma syllabus and revised the syllabus as per PCI guidlines and NEP 2021..

1. It is resolved to approve the PCI recommended M.Pharmacy syllabus with slight modifications from the academic year 2021-2022.
2. It is resolved to continue Choice Based Credit System (CBCS) for M.Pharm course based on the PCI recommended syllabus to meet the UGC Guidelines.
3. It is resolved to approve the model question papers and evaluation process for M.Pharm course.

This syllabus and regulations will come in to effect for the batch of students to be admitted from 2021-2022 onwards.

1. Chairman, BOS
College of Pharmaceutical Sciences
S.V. University, Tirupati

2. PRINCIPAL
College of Pharmaceutical Sciences
S.V. University, Tirupati

3. 4/1/22

4. ON LEAVE

5.

6.

Programme Code	Programme name	Year of Introduction	Status of implementation of CBCS/Elective Course System (ECS)	Year of implementation of CBCS/ECS	Year of revision (if any)	If revision has been carried out in the syllabus during the last 5 years, Percentage of	Link to the relevant documents
M. Pharmacy	SVUPSF1	2006	CCS: Yes/No ECS:Yes/No	**M. Pharmacy** ECS:	**2022 for M. Pharmacy** ECS:	CBCS: 100% ECS:	CBCS: ECS:

SVU COLLEGE OF PHARMACEUTICAL SCIENCES
SRI VENKATESWARA UNIVERSITY,
Tirupati - 517502

RESTRUCTURED CURRICULUM FOR M. PHARMACY PROGRAMME (Self Supporting Course) TO BE IMPLEMENTED WITH EFFECT FROM THE ACADEMIC YEAR 2021-2022

SYLLABUS
Choice based credit system (CBCS) Pattern

M. PHARMACY PROGRAMME
Choice based credit system (CBCS) Pattern

(Pharmaceutics)

Vision

1. To impart quality and value embedded education and research in Pharmaceutical Sciences.
2. To create technologically superior and ethically strong global manpower, in the arena of Pharmacy Profession.
3. Carving the youth as dynamic, competent, valued and knowledgeable Professionals of Pharmacy field.

Mission

1. Transforming Students into Full-fledged Pharmacists and participate actively in the field of Pharmacy.
2. Promoting Quality Research in Emerging Areas of Pharmaceutical Sciences.
3. To instill scientific zeal and develop skilled human resource to meet contemporary challenges in Pharmacy Profession.
4. To facilitate young adult learners with opportunities to hone their ethics and leadership potential.
5. Imparting technical education that encourages Independent thinking, develops strong domain of knowledge, hones contemporary skills and Positive attitudes towards holistic growth of young minds.
6. Evolving the Institution into a Center of Academic and Research Excellence in Pharmaceutical Education and lead the field of pharmaceutical sciences and pharmacy practice with the mission of strengthening the healthcare of the country.

Programme Objectives

1. To uphold all laws, regulations, safety and ethical standards that apply to the experimental procedures of the pharmaceutical formulations

2. To Provide a practical knowledge of the basic pharmaceutical sciences and the skill, acquire to deal with problems in pharmaceutical field

3. To To update the knowledge through continuous learning to face the challenges for better services to the community.

4. Acquire practical knowledge in various analytical techniques

5. To prepare the students in teamwork, lifelong learning and continuous improvement

Programme Outcomes

After the completion of the M.Pharm Pharmaceutics programme the students will be able to,

1. Produce Pharmacy graduates with strong basics and high technical knowledge to cater the various areas of Pharmaceutical industry.
2. Develop an understanding for the need of pharmaceutical sciences and technology towards giving quality life to people in society through the quality of medicines.
3. Apply the knowledge and skills gained through education to gain recognition in professional course and society.
4. Impart knowledge and skills on criteria for selection of drugs, dose calculations, dose adjustments by applying biopharmaceutical theories, pharmacokinetic and bioequivalence models which gives technical skill knowledge in In-vitro and In-vivo studies using computer simulations.
5. Act efficiently as a leader in the diverse areas of the profession to demonstrate the ability to plan and implement professional activities.
6. Provide a practical knowledge of the basic pharmaceutical sciences and the skill, acquire to deal with problems in pharmaceutical field
7. Develop ability for in-depth information and critical thinking in order to identify, formulate and solve the issues related to Pharmaceutical Industry, Regulatory Agencies, Hospital Pharmacy & clinical Pharmacy for better services to the community.
8. Identify the goals and regulations involved in the drug discovery and development, manufacture, distribution and sale of medicines and develop problem-based learning approach and analytical thinking in his/her academic and professional life.
9. To update the knowledge through continuous learning to face the challenges for better services to the community.
10. Design and develop process to perform experiments in various pharmaceutical areas like Pharmacognosy, Pharmaceutical Chemistry including Analytical Chemistry, Pharmaceutical Biotechnology, Pharmacology, Formulation and Development.
11. Fill the gap with other health care communities to provide innovative solutions for the purpose of maintain public health.
12. Understand, analyze and communicate the value of their professional roles in society (e.g. health care professionals, promoters of health, educators, managers, employers, employees).

Programme Specific Outcomes

At the end of successful completion of programme, a Post graduate will

1. Have adequate knowledge and scientific information regarding basic principles of Pharmaceutical & Medicinal Chemistry, Pharmaceutics including Cosmeticology.
2. Be able to develop and assure the quality of various pharmaceutical dosage forms including those of herbal origin as per standards of official books, WHO and other regulatory agencies like USFDA, MHRA etc.
3. Be able to apply the knowledge and skill gained from various subjects and the aptitude developed throughout the course of the program in performing a job either independently or as a member of a team in various fields of pharmacy profession.
4. Be able to perform research on various medical aspects and implement the Pharmaceutical knowledge in formulating the best suitable dosage form to provide high quality medicines to the society.
5. Render the services to the public by providing patient centric effective treatments to curb the therapeutic issues with the required medicines and explain the effects of the drugs by analyzing the scientific literature for improving their health and well-being.

STRUCTURE OF COURSES MASTER OF PHARMACY

TABLE –1: COURSE OF STUDY FOR M. PHARM

I SEMESTER						
Course code	**Course**	**Credit hours**	**Credit points**	**Hrs/wk**	**Marks**	**Core/Elective**
MPL101T	Modern Pharmaceutical Analytical Techniques	4	4	4	100	Core
MPL102T	Advanced Pharmacology-I	4	4	4	100	Core
MPL103T	Pharmacological and Toxicological Screening Methods-I	4	4	4	100	Core
MPL104T	Cellular and Molecular Biology	4	4	4	100	Core
MPL105P	Pharmacology Practical I	12	6	12	150	
	Seminar/Assignment	7	4	7	100	
Total		**35**	**26**	**35**	**650**	
II SEMESTER						
Course code	**Course**	**Credit Hours**	**Credit points**	**Hrs/wk**	**Marks**	**Core/Elective**
MPL201T	Advanced Pharmacology II	4	4	4	100	Core
MPL202T	Pharmacological and Toxicological Screening Methods-II	4	4	4	100	Core
MPL204T	Clinical Research and Pharmacovigilance	4	4	4	100	Core
-	**Elective**	4	4	4	100	
MPL205P	Pharmacolog y Practical II	12	6	12	150	
	Seminar/Assignment	7	4	7	100	
Total		**35**	**26**	**35**	**650**	
ELECTIVES OFFERED						

Course code	Course	Credit Hours	Credit points	Hrs/wk	Marks	Core/Elective
MPH 203T	Computer Aided Drug Delivery System	4	4	4	**100**	Elective
MPC 203T	Computer Aided Drug Design	4	4	4	**100**	Elective
MPA 203T	Quality Control & Quality Assurance	4	4	4	**100**	Elective
MPH 204T	Cosmetic & Cosmeceuticals	4	4	4	**100**	Elective
MPL 203T	Principles of Drug Discovery	4	4	4	**100**	Elective

TABLE 2: COURSE OF STUDY FOR M. PHARM - PHARMACEUTICS

I SEMESTER						
Course code	**Course**	**Credit hours**	**Credit points**	**Hrs/wk**	**Marks**	**Core/Elective**
MPH101T	Modern Pharmaceutical Analytical Techniques	4	4	4	100	Core
MPH102T	Drug Delivery System	4	4	4	100	Core
MPH103T	Modern Pharmaceutics	4	4	4	100	Core
MPH104T	Regulatory Affairs	4	4	4	100	Core
MPH105P	Pharmaceutics Practical I	12	6	12	150	
	Seminar/Assignment	7	4	7	100	
	Total	**35**	**26**	**35**	**650**	
II SEMESTER						
Course code	**Course**	**Credit Hours**	**Credit points**	**Hrs/wk**	**Marks**	**Core/Elective**
MPH201T	Molecular Pharmaceutics (Nano Tech and Targeted DDS)	4	4	4	100	Core
MPH202T	Advance Bio Pharmaceutics and Pharmacokinetics	4	4	4	100	Core
MPH 204T	Cosmetic & Cosmeceuticals	4	4	4	100	Core
-	**Elective**	4	4	4	100	

MPH205P	Pharmaceutics Practical II	12	6	12	150	
	Seminar/Assignment	7	4	7	100	
Total		**35**	**26**	**35**	**650**	

ELECTIVES OFFERED						
Course code	**Course**	**Credit Hours**	**Credit points**	**Hrs/ wk**	**Marks**	**Core/ Elective**
MPH 203T	Computer Aided Drug Delivery System	4	4	4	**100**	Elective
MPC 203T	Computer Aided Drug Design	4	4	4	**100**	Elective
MPA 203T	Quality Control & Quality Assurance	4	4	4	**100**	Elective
MPL 204T	Clinical Research & Pharmacovigilance	4	4	4	**100**	Elective
MPL 203T	Principles of Drug Discovery	4	4	4	**100**	Elective

TABLE –3: COURSE OF STUDY FOR M. PHARM III SEMESTER (COMMON FOR ALL SPECIALIZATIONS)

Course code	**Course**	**Credit Hours**	**Credit points**	**Marks**
MRM 301T	Research Methodology and Biostatistics*	4	4	100
-	Journal club*	2	2	50
-	Research Proposal Presentation*	8	4	100
-	Viva Voce*	1	1	25
Total		15	11	275

*Non University Examination

TABLE – 4: COURSE OF STUDY FOR M. PHARM. IV SEMESTER (COMMON FOR ALL SPECIALIZATIONS)

Course code	**Course**	**Credit Hours**	**Credit points**	**Marks**
-	Thesis Evaluation	40	20	500
-	Research work and Colloquium	10	10	250
Total		50	30	750

FIRST SEMESTER

Course Code	Course Title	No of Hours Per week	No of Credits
MPA 101T	**MODERN PHARMACEUTICAL ANALYTICAL TECHNIQUES**	**04**	**04**
Sessional Marks: 15		**Continuous mode:10**	
End Semester Examination Marks: 75		**Totalmarks:100**	

OBJECTIVES:

After completion of course student is able to know about chemicals and excipients. The analysis of various drugs in single and combination dosage forms. Theoretical and practical skills of the instruments

COURSE CONTENT:

UNIT- I

UV-Visible spectroscopy: Theory, Laws, Instrumentation associated with UV- Visible spectroscopy, Choice of solvents and solvent effect and Applications of UVVisible spectroscopy, Difference/ Derivative spectroscopy.

a. IR spectroscopy: Theory, Modes of Molecular vibrations, Sample handling, Instrumentation of Dispersive and Fourier -Transform IR Spectrometer, Factors affecting vibrational frequencies and Applications of IR spectroscopy, Data Interpretation.

b. Spectroflourimetry: Theory of Fluorescence, Factors affecting fluorescence (Characterestics of drugs that can be analysed by fluorimetry), Quenchers, Instrumentation and Applications of fluorescence spectrophotometer. c.

Flame emission spectroscopy and atomic absorption spectroscopy: Principle, Instrumentation, Interferences and Applications.

UNIT-II

1HNMR spectroscopy Principle, Instrumentation, Solvent requirement in 1HNMR, Relaxation process, NMR signals in various compounds, Chemical shift, Factors influencing chemical shift, Spin-Spin coupling, Coupling constant, Applications of 1HNMR spectroscopy. Brief outline of principles of 13C NMR.

Unit III

Mass Spectroscopy: Principle, Theory, Instrumentation of Mass Spectroscopy, Different types of ionization like electron impact, chemical, field, FAB and MALDI, Mass fragmentation and its rules, Meta stable ions, Isotopic peaks and Applications of Mass spectroscopy.

UNIT-IV

Chromatography: Principle, instrumentation, chromatographic parameters, factors affecting resolution, isolation of drug from excipients, data interpretation and applications of the following: a. High Performance Thin Layer Chromatography. b. Gas chromatography c. High Performance Liquid chromatography d. Ultra-High Performance Liquid chromatography e. LC-MS f. Affinity chromatography

UNIT-V

a. Electrophoresis: Principle, Instrumentation, working conditions, factors affecting separation and applications of the following: a) Paper electrophoresis b) Gel electrophoresis c) Capillary electrophoresis d) Zone electrophoresis e) Moving boundary electrophoresis f) Iso electric focusing. b. X ray Crystallography: Production of X rays, Different X ray methods, Bragg ‘s law, Rotating crystal technique, X ray powder technique, Types of crystals and applications of X- ray diffraction.

UNIT-VI

a. Immunoassays: Principles, procedures and types of RIA, ELISA b. Thermal techniques: Principle, instrumentation and pharmaceutical applications of DTA, DSC, TGA.

REFERENCES:

1. Spectrometric Identification of Organic compounds - Robert M Silverstein, Sixth edition, John Wiley & Sons, 2004.
2. Principles of Instrumental Analysis - Doglas A Skoog, F. James Holler, Timothy A.Nieman, 5th edition, Eastern press, Bangalore, 1998.
3. Instrumental methods of analysis – Willards, 7th edition, CBS publishers. 4. Practical Pharmaceutical Chemistry – Beckett and Stenlake, Vol II,
4 th edition, CBS Publishers, New Delhi, 1997.
5. Organic Spectroscopy - William Kemp, 3rd edition, ELBS, 1991.
6. Quantitative Analysis of Drugs in Pharmaceutical formulation - P D Sethi, 3rd Edition, CBS Publishers, New Delhi, 1997.
7. Pharmaceutical Analysis - Modern Methods – Part B - J W Munson, Vol 11, Marcel. Dekker Series
8. Spectroscopy of Organic Compounds, 2nd edn., P.S/Kalsi, Wiley estern Ltd., Delhi.
9. Textbook of Pharmaceutical Analysis, KA.Connors, 3rd Edition, John Wiley & Sons, 1982

COURSE OUTCOMES:

1. Explain the importance of modern instrumentation in pharmaceutical analysis.Describe the fundamental principles and applications of spectroscopic techniques Viz., UV- Visible, IR,Students also able to demonstrate and use flame photometry, nepheloturbidometry
2. To determine the structural and functional group identification by using NMR-C13 and H1
3. Qualitative and quantitative identification of compound by Mass spectroscopy using different ionization technique
4. The chromatographic techniques for qualitative and quantitative analysis of pharmaceutical compounds.
5. The electrophoresis techniques and their applications in pharmaceutical industry.
6. Principle procedures involved in immunoassay and pharmaceutical applications: RIA, ELISA. DTA, DSC, TGA.

CO-PO Mapping

Course	PO1	PO2	PO3	PO4	PO5	PO6	PO7	PO8	PO9	PO10	PO11	PO12
CO1	2	1	3	2	1	2	1	2	3	1	2	1
CO2	3	1	2	3	2	2	1	2	3	3	2	2
CO3	1	1	2	1	3	1	2	3	1	3	1	2

CO4	3	2	3	2	1	2	3	3	1	1	2	1
CO5	3	2	3	2	1	2	3	2	1	3	1	2
CO6	2	1	2	3	1	2	3	1	2	1	2	1

Course Code	Course Title	No of Hours Per week	No of Credits
MPH 102T	**DRUG DELIVERY SYSTEM**	**04**	**04**
Sessional Marks: 15		**Continuous mode:10**	
End Semester Examination Marks: 75		**Totalmarks:100**	

OBJECTIVES:

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

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

COURSE CONTENT:

Unit I

1. a. Sustained Release (SR) and Controlled Release (CR) formulations: Introduction & basic concepts, advantages/ disadvantages, factors influencing, Physicochemical & biological approaches for SR/CR formulation, Mechanism of Drug Delivery from SR/CR formulation. b. Rate Controlled Drug Delivery Systems: Principles &Fundamentals, Types; Activation Modulated Drug Delivery Systems: Mechanically activated, pH activated, Enzyme activated, and Osmotic activated Drug Delivery Systems: Feedback regulated Drug Delivery Systems: Principles & Fundamentals.

UNIT-II

a) Gastro-Retentive Drug Delivery Systems: Principle, concepts, advantages and disadvantages, Modulation of GI transit time approaches to extend GI transit.

b) Buccal Drug Delivery Systems: Principle of muco adhesion, advantages and disadvantages, mechanism of drug permeation, Methods of formulation and its evaluations.

c) Polymers: introduction, definition, classification, Molecular weight averages, Molecular weight determination from viscosity, Polymers as thickening agent, Preparation of polymer solution, Polymers in the solid state, Fabrication technology, and applications.

Unit III

a) Occular Drug Delivery Systems: Barriers of drug permeation, Methods to overcome barriers.

b) Transdermal Drug Delivery Systems: Structure of skin and barriers, Penetration enhancers, Formulation and evaluation of Transdermal Drug Delivery Systems.

UNIT-IV

Protein and Peptide Delivery: Barriers for protein delivery. Formulation and Evaluation of Delivery systems of proteins and other macromolecules. Vaccine delivery systems: Vaccines, uptake of antigens, single shot vaccines, mucosal and transdermal delivery of vaccines

UNIT-V

Protein and Peptide Delivery: Barriers for protein delivery. Formulation and Evaluation of Delivery systems of proteins and other macromolecules. Vaccine delivery systems: Vaccines, uptake of antigens, single shot vaccines, mucosal and transdermal delivery of vaccines

UNIT-VI

Dosage Form for Personalized Medicine: Introduction, Definition, Pharmacogenetics, Categories of Patients for Personalized Medicines, Customized drug delivery systems, A brief note on Bio electronic Medicines, 3D printing of pharmaceuticals, Tele pharmacy.

REFERENCES:

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

2. Robinson, J. R., Lee V. H. L, Controlled Drug Delivery Systems, Marcel Dekker,Inc., New York, 1992. 3. Encyclopedia of controlled delivery, Editor- Edith Mathiowitz, Published by Wiley Interscience Publication, John Wiley and Sons, Inc, New York! Chichester/Weinheim

4. N.K. Jain, Controlled and Novel Drug Delivery, CBS Publishers & Distributors, New Delhi, First edition 1997 (reprint in 2001).
5. S.P.Vyas and R.K.Khar, Controlled Drug Delivery - concepts and advances, Vallabh rakashan, New Delhi, First edition 2002.
JOURNALS
1. Indian Journal of Pharmaceutical Sciences (IPA)
2. Indian drugs (IDMA)
3. Journal of controlled release (Elsevier Sciences) desirable
4. Drug Development and Industrial Pharmacy (Marcel & Decker) desirable.

COURSE OUTCOMES:

1. To understand criteria for selection of drugs, polymers, development and evaluation of novel drug delivery systems.
2. Understand the concepts and applications of Novel Drug Delivery Systems.
3. Apply knowledge in developing various novel formulations as per requirements.
4. Analyze various evaluation parameters for oral, parenteral, topical etc. drug delivery systems.
5. Evaluate the drug polymer compatibility studies
6. Formulate industrially feasible, cost-effective strategy for development of new dosage forms.

CO-PO Mapping

Course	PO1	PO2	PO3	PO4	PO5	PO6	PO7	PO8	PO9	PO10	PO11	PO12
CO1	2	1	2	3	1	2	3	2	1	3	1	3
CO2	1	2	3	1	2	1	2	3	2	3	2	2
CO3	2	2	2	1	2	1	2	3	1	2	1	2
CO4	3	2	1	2	3	2	1	2	3	1	3	2
CO5	1	2	1	2	1	3	1	2	3	3	1	2
CO6	2	1	2	3	2	1	2	3	2	3	2	3

Course Code	**Course Title**	**No of Hours Per week**	**No of Credits**
MPH 103T	**MODERN PHARMACEUTICS**	**04**	**04**
Sessional Marks: 15		**Continuous mode:10**	
End Semester Examination Marks: 75		**Totalmarks:100**	

OBJECTIVES:

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

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

COURSE CONTENT:

1. a) Preformulation Concepts – Drug Excipient interactions - different methods, kinetics of stability, Stability testing.

b) Theories of dispersion: Emulsion and Suspension, SMEDDS. Its formulation and evaluation.

c) Preparation and stability of large and small volume parenteral – physiological and formulation consideration, Manufacturing and evaluation.

2. Optimization techniques in Pharmaceutical Formulation: Concept and parameters of optimization, Optimization techniques in pharmaceutical formulation and processing. Statistical design, Response surface method, Contour designs, Factorial designs and application in formulation development.

3. Validation: Introduction to Pharmaceutical Validation, Scope &merits of Validation, Types of Validation, Government regulation, Manufacturing process Model, URS,DQ,IQ,OQ&P.Q.of facilities. Validation and calibration of Master plan, ICH & WHO guidelines for calibration and validation of equipment, Process Validation of Tablets, Capsules, Parenterals.

4. a) cGMP & Industrial Management: Objectives and policies of current good manufacturing practices, layout of buildings, services, equipment and their maintenance.
b) Production management: Production organization. Materials management: handling and transportation, inventory management and control, production and planning control, Sales forecasting, budget and cost control, industrial and personal relationship. Concept of Total Quality Management.
5. a) Compression and compaction: Physics of tablet compression, compression and consolidation, effect of friction, distribution of forces, compaction profiles.
b) Study of consolidation parameters; Diffusion parameters, Dissolution parameters and Pharmacokinetic parameters, Heckel plots, Similarity factors – f2 and f1, Higuchi and Peppa's plot.

REFERENCES

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

COURSE OUTCOMES:

1. After successful completion of this course students will be able to: Describe the physiochemical properties important for formulation of solid, liquid and sterile dosage forms.
2. Interpret formulation data and subsequent analysis data towards choice of the most relevant formulations.
3. Produce pharmaceutical formulations from known reference sources in a quality that is suitable for patient use.
4. Explain the concept and importance of testing of product performance, and the ability to interpret such data.
5. Describe the principles of sterile production and explain why quality assurance and validation of critical steps in the production process are of particular importance.
6. Develop cosmetics and with desired Safety, stability, and efficacy.

CO-PO Mapping

Course	PO1	PO2	PO3	PO4	PO5	PO6	PO7	PO8	PO9	PO10	PO11	PO12
CO1	3	2	1	2	3	1	2	3	1	2	1	2
CO2	2	1	2	1	2	3	1	2	3	1	1	1
CO3	1	2	1	2	1	2	3	1	2	3	1	3
CO4	3	2	2	2	1	2	1	3	1	3	2	1
CO5	2	1	2	1	2	1	1	3	1	3	1	3

Course Code	**Course Title**	**No of Hours Per week**	**No of Credits**
MPH 104T	**REGULATORY AFFAIRS**	**04**	**04**

Sessional Marks: 15 **Continuous mode:10**
End Semester Examination Marks: 75 **Totalmarks:100**

OBJECTIVES:

Upon completion of the course, it is expected that the students will be able to understand

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

COURSE CONTENT:

UNIT-I

Documentation in Pharmaceutical industry: Master formula record, DMF (Drug Master File), distribution records. Generic drugs product development: Introduction, Hatch Waxman act and amendments, CFR (CODE OF FEDERAL REGULATION), in-vitro drug product performance.

UNIT-II

Regulatory requirement for product approval: API, biologics, novel therapies, obtaining NDA, ANDA for generic drugs, ways and means of US registration for foreign drugs.

UNIT-III

CMC, post approval regulatory affairs: Regulation for combination products and medical devices.CTD and ECTD format, industry and FDA liaison. ICH - Guidelines of ICHQ, S E, M Regulatory requirements of EU, MHRA, TGA and ROW countries.

UNIT-IV

Non clinical drug development: Global submission of IND, NDA, ANDA. Investigation of medicinal products dossier, (IMPD) and investigator brochure (IB).

UNIT-VI

Clinical trials: Developing clinical trial protocols. Institutional review board/ independent ethics committee Formulation and working procedures, informed Consent process and procedures. HIPAA- new, requirement to clinical study process, pharmacovigilance, safety monitoring in clinical trials.

REFERENCES

1. Theory and Practice of Industrial Pharmacy By Lachmann and Libermann
2. Pharmaceutical dosage forms: Tablets Vol. 1-3 by Leon Lachmann.
3. Pharmaceutical Dosage forms: Disperse systems, Vol, 1-2; By Leon Lachmann.
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8. Physical Pharmacy; By Alfred martin
9. Bentley's Textbook of Pharmaceutics – by Rawlins.
10. Good manufacturing practices for Pharmaceuticals: A plan for total quality control, Second edition; By Sidney H. Willig.

COURSE OUTCOMES:

1. After successful completion of this course students will be able to:
2. Take independent responsibility for the development of novel drug and generic drug along with their drug products, from concepts to clinics.
3. Independently initiate and carry out proper actions between regulatory authorities and the marketing application authorization applicant/holder.
4. Critically examine and evaluate scientific data and conclusions intended for regulatory review
5. Enable improvement of the regulatory environment by implementing and upholding good regulatory practices.
6. Knowledge on developing clinical trial protocols, ethics committee, monitoring clinical trials and pharmacovigilance.
7. Knowledge on procedures for registration of Indian drug products in overseas market, CTD.

CO-PO Mapping

Course	PO1	PO2	PO3	PO4	PO5	PO6	PO7	PO8	PO9	PO10	PO11	PO12
CO1	3	2	1	2	3	12	1	2	2	3	2	3
CO2	2	2	1	2	2	1	2	3	1	1	2	1

CO3	1	1	2	1	2	1	3	1	2	3	1	3
CO4	2	1	2	1	2	3	1	2	3	1	3	2
CO5	2	3	1	2	3	1	3	2	3	1	2	1
CO6	3	2	1	1	2	1	2	3	1	2	1	2

Course Code	**Course Title**	**No of Hours Per week**	**No of Credits**
MPH 105P	**Pharmaceutics Practical-I**	**04**	**04**
Sessional Marks: 15			**Continuousmode:10**
End Semester Examination Marks: 75			**Totalmarks:100**

OBJECTIVES:

1. After completion of course student is able to know about chemicals and excipients. The analysis of various drugs in single and combination dosage forms.
2. The criteria for selection of drugs and polymers for the development of delivering system
3. The Active Pharmaceutical Ingredients and Generic drug Product development
4. Preparation of Dossiers and their submission to regulatory agencies in different countries
5. Clinical trials requirements for approvals for conducting clinical trials

COURSE CONTENT:

1. Analysis of pharmacopoeial compounds and their formulations by UV Vis spectrophotometer
2. Simultaneous estimation of multi component containing formulations by UV spectrophotometry
3. Experiments based on PC, TLC & HPLC
4. Experiments based on Gas Chromatography
5. Estimation of riboflavin/quinine sulphate by fluorimetry
6. Estimation of sodium/potassium by flame photometry
7. To perform In-vitro dissolution profile of CR/ SR marketed formulation
8. Formulation and evaluation of sustained release matrix tablets
9. Formulation and evaluation osmotically controlled DDS
10. Preparation and evaluation of Floating DDS- hydro dynamically balanced DDS
11. Formulation and evaluation of Mucoadhesive tablets.
12. Formulation and evaluation of trans dermal patches.
13. To carry out preformulation studies of tablets.
14. To study the effect of compressional force on tablets disintegration time.
15. To study Micromeritic properties of powders and granulation.
16. To study the effect of particle size on dissolution of a tablet.
17. To study the effect of binders on dissolution of a tablet.
18. To plot Heckal plot, Higuchi and peppas plot and determine similarity factors.

COURSE OUTCOMES:

1. Qualitative and quantitative identification of compound by Mass spectroscopy using different ionization technique
2. Formulate industrially feasible, cost-effective strategy for development of new dosage forms.
3. Interpret formulation data and subsequent analysis data towards choice of the most relevant formulations.
4. Independently initiate and carry out proper actions between regulatory authorities and the marketing application authorization applicant/holder.
5. Knowledge on developing clinical trial protocols, ethics committee, monitoring clinical trials and pharmacovigilance.

CO-PO Mapping

Course	PO1	PO2	PO3	PO4	PO5	PO6	PO7	PO8	PO9	PO10	PO11	PO12
CO1	2	1	1	3	2	1	2	3	1	2	1	2
CO2	2	1	2	3	1	2	3	1	3	1	2	1

CO3	1	2	1	2	3	1	2	1	2	3	2	3
CO4	2	1	3	1	2	3	1	2	3	1	2	1
CO5	1	2	2	1	2	3	1	3	3	1	3	2

Course Code	**Course Title**	**No of Hours Per week**	**No of Credits**
MPH	**SEMINARS AND ASSIGNMENT**	**07**	**04**
Total marks: 100			

OUTCOMES:

1. 1.Description of key goals to be accomplished by the assignment
2. Introduce students to different types of scholarly sources and how to access them
3. Explore an appreciation of the self in relation to its larger diverse social and academic contexts.

SECOND SEMESTER

Course Code	Course Title	No of Hours Per week	No of Credits
MPH 201T	**MOLECULAR PHARMACEUTICS (NANO TECH AND TARGETED DDS)**	04	04
Sessional Marks: 15		**Continuous mode:10**	
End Semester Examination Marks: 75		**Total marks:100**	

OBJECTIVES:

Upon completion of the course student shall be able to understand

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

COURSE CONTENT:

Unit I

Targeted Drug Delivery Systems: Concepts, Events and biological process involved in drug targeting. Tumor targeting and Brain targeting.

Unit II

Targeting Methods: Introduction, types, preparation evaluation. Nano Particles & Liposomes, Niosomes.

Unit III

Micro Capsules / Micro Spheres: Types, preparation and evaluation, and applications of Monoclonal Antibodies:Aquasomes, Phytosomes, Electrosomes.

Unit IV

a) Pulmonary Drug Delivery Systems:Types, Preparation and Evaluation of Aerosols, propellents, Containers, Types, preparation and evaluation.

b) Intra Nasal Route Delivery systems; Types, preparation and evaluation.

Unit V

Nucleic acid based therapeutic delivery system: Gene therapy, introduction (ex-vivo & in-vivo gene therapy). Potential target diseases for gene therapy (inherited disorder and cancer). Gene expression systems (viral and nonviral gene transfer). Liposomal gene delivery systems and its Biodistribution and Pharmacokinetics. Knowledge of therapeutic antisense molecules and aptamers as drugs of future.

REFERENCES:

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

2. S.P.Vyas and R.K.Khar, Controlled Drug Delivery - concepts and advances, VallabhPrakashan, New Delhi, First edition 2002.

3. N.K. Jain, Controlled and Novel Drug Delivery, CBS Publishers & Distributors, NewDelhi, First edition 1997 (reprint in 2001)..

Course outcomes:

1.Basics of medical devices and IVDs, process of development, ethical and quality considerations harmonization initiatives for approval and marketing of medical devices and IVDs regulatory approval process for medical devices and IVDs in India, US, Canada, EU, Japan and ASEAN clinical evaluation and investigation of medical devices and IVDs.

2. The various approaches for development of novel drug delivery systems.

3. The criteria for selection of drugs and polymers for the development of NTDS

4. The formulation and evaluation of novel drug delivery systems.

5.Development and validation of the UV spectroscopic analytical method of drug.

CO-PO Mapping

Course	PO1	PO2	PO3	PO4	PO5	PO6	PO7	PO8	PO9	PO10	PO11	PO12
CO1	2	2	3	1	1	2	3	1	2	3	1	3
CO2	3	2	1	2	1	3	3	2	2	1	1	1
CO3	2	2	2	3	1	2	1	3	1	2	1	2
CO4	3	2	1	2	1	2	3	1	2	1	2	1
CO5	2	1	1	2	3	3	3	2	2	3	1	3

Course Code	**Course Title**	**No of Hours Per week**	**No of Credits**
MPH 202T	**ADVANCE BIO PHARMACEUTICS AND PHARMACOKINETICS**	04	04
Sessional Marks: 15 Continuous mode:10 **End Semester Examination Marks :75 Total marks:100**			

Objectives:

Upon completion of this course it is expected that students will be able to understand,

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

Course Content:

Unit I

Drug Absorption from the Gastrointestinal Tract: Gastrointestinal tract, Mechanism of drug absorption, Factors affecting drug absorption, Formulation and Physicochemical factors. pH–partition theory of drug absorption. Dissolution rate, Dissolution process, Noyes–Whitney equation, Factors affecting the dissolution rate, Formulation and processing factors.

Gastrointestinal absorption: role of the dosage form, Solution (elixir, syrup and solution) as a dosage form, Suspension as a dosage form, Capsule as a dosage form, Tablet as a dosage form, Dissolution methods, Correlation of invivo data with in vitro dissolution data. Transport model: Permeability, Solubility, Charge State, Properties of the Gastrointestinal Tract (GIT), pH Microclimate, Intracellular pH Environment, Tight-Junction Complex, Oral Absorption enhancers.

Unit II

Biopharmaceutic considerations in drug product design and In Vitro Drug Product performance: Introduction, biopharmaceutic factors affecting drug bioavailability, rate- limiting steps in drug absorption, physicochemical nature of the drug formulation, factors affecting drug product performance, in vitro: dissolution and drug release testing, compendial methods of dissolution, alternative methods of dissolution testing, meeting dissolution requirements, problems of variable control in dissolution testing, performance of drug products, dissolution profile comparisons, drug product stability, considerations in the design of a drug product.

Unit III

a) Drug Product Performance, In Vivo: Bioavailability and Bioequivalence: drug product performance, purpose of bioavailability studies, relative and absolute availability, methods for assessing bioavailability, bioequivalence studies, design and evaluation of bioequivalence studies, study designs, crossover study designs, evaluation of the data of bioequivalence example, study submission and drug review process. Biopharmaceutics classification system and methods.

b) Permeability: In-vitro, in-situ and In-vivo methods. generic biologics (biosimilar drug products), clinical significance of bioequivalence studies, special concerns in bioavailability and bioequivalence studies, generic substitution, Bio waivers.

Unit IV

Pharmacokinetics: Basic considerations, pharmacokinetic models, compartment modeling: one compartment model- IV bolus, IV infusion, extra-vascular; two compartment - model in brief, Non-linear pharmacokinetics: causes of non-linearity, Michaelis – Menten equation, estimation of Km and Vmax.

Drug interactions: introduction, the effect of protein binding interactions, the effect of tissue- binding interactions, cytochrome p450-based drug interactions, drug interactions linked to transporters. Drug interactions involving digoxin, warfarin, theophylline.

Unit V

a) Application of Pharmacokinetics: Modified-Release Drug Products, Targeted Drug Delivery Systems and Biotechnological Products. Introduction to Pharmacokinetics and pharmacodynamic drug interactions. Pharmacokinetics and pharmacodynamics of biotechnology drugs.

b) Chrono Therapeutic Drug Delivery System: Introduction, classification, physiology of circadian rhythmicity, circadian rhythm changes in cardiac and liver diseased conditions. Chronopharmacokinetics of anti-hypertensives and anti-asthmatics.

Books recommended:

REFERENCES

1. Biopharmaceutics and Clinical Pharmacokinetics by Milo Gibaldi, 4th edition,Philadelphia, Lea and Febiger, 1991
2. Biopharmaceutics and Pharmacokinetics, A. Treatise, D .M. Brahmankar and Sunil B. aiswal., VallabPrakashan, Pitampura, Delhi
3. Applied Biopharmaceutics and Pharmacokinetics by Shargel. Land YuABC, 2ndedition, Connecticut Appleton Century Crofts, 1985
4. Textbook of Biopharmaceutics and Pharmacokinetics, Dr. Shobha Rani R. Hiremath,Prism Book
5**.** Pharmacokinetics by Milo Gibaldi and D. Perrier, 2nd edition, Marcel Dekker Inc.,New York, 1982

6. Current Concepts in Pharmaceutical Sciences: Biopharmaceutics, Swarbrick. J, LeaandFebiger, Philadelphia, 1970
7. Clinical Pharmacokinetics, Concepts and Applications 3rd edition by MalcolmRowland and Thom~ N. Tozer, Lea and Febiger, Philadelphia, 1995
8. Dissolution, Bioavailability and Bioequivalence, Abdou. H.M, Mack PublishingCompany, Pennsylvania 1989
9. Biopharmaceutics and Clinical Pharmacokinetics, An Introduction, 4th edition,revised and expande by Robert. E. Notari, Marcel Dekker Inc, New York and Basel,1987.
10. Biopharmaceutics and Relevant Pharmacokinetics by John. G Wagner and M.Pemarowski, 1st edition, Drug Intelligence Publications, Hamilton, Illinois, 1971.
11. Encyclopedia of Pharmaceutical Technology, Vol 13, James Swarbrick, James. G.Boylan, Marcel Dekker Inc, New York, 1996.
12. Basic Pharmacokinetics,1 stedition,Sunil S JambhekarandPhilip J Breen,pharmaceutical press, RPS Publishing,2009.
13. Absorption and Drug Development- Solubility, Permeability, and Charge State, Alex Avdeef, John Wiley & Sons, Inc,2003.

Course Outcomes:

The basic concepts in biopharmaceutics and pharmacokinetics.

1. The use raw data and derive the pharmacokinetic models and parameters the best describe the process of drug absorption, distribution, metabolism and elimination.
2. The critical evaluation of biopharmaceutic studies involving drug product equivalency.
3. The design and evaluation of dosage regimens of the drugs using pharmacokinetic and biopharmaceutic parameters.
4. The potential clinical pharmacokinetic problems and application of basics of pharmacokinetic
5. Understand the concept of linear and non-linear pharmacokinetics.
6. Study the concept of quality control, quality assurance & total quality controls.
7. CO-PO Mapping

Course	PO1	PO2	PO3	PO4	PO5	PO6	PO7	PO8	PO9	PO10	PO11	PO12
CO1	3	2	3	1	2	3	2	3	3	2	1	1
CO2	1	2	1	2	3	1	2	3	1	3	1	3
CO3	1	2	3	1	2	1	2	3	3	2	2	1
CO4	2	1	1	2	3	1	1	1	2	1	1	2
CO5	1	1	3	1	1	3	1	1	2	1	2	1

Course Code	Course Title	No of Hours Per week	No of Credits
MPH 204T	**COSMETICS & COSMECEUTICALS**	**04**	**04**
Sessional Marks: 15 Continuous mode:10			
End Semester Examination Marks: 75		**Total marks:100**	

Objectives:

Upon completion of the course, the students shall be able to understand

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

Course Content:

Unit I

Cosmetics – Regulatory: Definition of cosmetic products as per Indian regulation. Indian regulatory requirements for labeling of cosmetics. Regulatory provisions relating to import of cosmetics, Misbranded and spurious cosmetics. Regulatory provisions relating to manufacture of cosmetics – Conditions for obtaining license, prohibition of manufacture and sale of certain cosmetics, loan license, offences and penalties.

Unit II

Cosmetics - Biological aspects: Structure of skin relating to problems like dry skin, acne, pigmentation, prickly heat, wrinkles and body odor. Structure of hair and hair growth cycle. Common problems associated with oral cavity. Products for Cleansing and care for face, eye lids, lips, hands, feet, nail, scalp, neck, body and under-arm.

Unit III

Building blocks for different product formulations of cosmetics/cosmeceuticals: Surfactants – Classification and application. Emollients, rheological additives: classification and application. Antimicrobials, preservatives, their merits and demerits. Factors affecting preservative efficacy. Building blocks for formulation of a moisturizing cream, vanishing cream, cold cream, shampoo and toothpaste, Soaps and syndet bars. Perfumes; Classification of perfumes. Perfume ingredients listed as allergens in EU regulation. Controversial ingredients: Parabens, formaldehyde liberators, dioxane.

Unit IV

Design of cosmeceutical products: Sunscreens- classification and regulatory aspects. Addressing dry skin, acne, sun-protection, pigmentation, prickly heat, wrinkles, body odor, dandruff, dental cavities, bleeding gums, mouth odor and sensitive teeth through cosmeceutical formulations.

Unit V

Herbal Cosmetics: Herbal ingredients used in Hair care, skin care and oral care. Review of guidelines for herbal cosmetics by private bodies like cosmos with respect to preservatives, emollients, foaming agents, emulsifiers and rheology modifiers. Challenges in formulating herbal cosmetics.

REFERENCES

1. Harry's Cosmeticology. 8th edition.

2. Poucher'sperfumecosmeticsandSoaps,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. 3 rd edition

5. Cosmetic and Toiletries recent suppliers catalogue.

6. CTFA directory.

Course Outcomes:

Key ingredients used in cosmetics and cosmeceuticals.

1. Key building blocks for various formulations.

2.Various key ingredients and basic science to develop cosmetics and cosmeceuticals.

3.Scientific knowledge to develop cosmetics and with desired Safety, stability, and efficacy.

4.Learn formulation, manufacture & evaluation of baby cosmetics like baby oils, powders etc.

5.Understand formulation of manicure products like nail lacquer, remover etc.

6. Explain the concept of cosmeceuticals, history, difference between cosmetics & cosmeceuticals & cosmeceutical agents.

CO-PO Mapping

Course	PO1	PO2	PO3	PO4	PO5	PO6	PO7	PO8	PO9	PO10	PO11	PO12
CO1	2	2	3	1	2	3	1	2	3	1	2	1
CO2	1	2	3	1	2	3	2	2	1	1	3	2
CO3	2	1	2	1	2	3	1	2	3	2	1	1
CO4	3	2	1	2	3	1	2	3	1	2	1	2
CO5	2	1	2	3	1	2	3	1	3	1	3	1

Course Code	**Course Title**	**No of Hours Per week**	**No of Credits**
MPH 205P	**PHARMACEUTICS PRACTICAL II**	**04**	**04**
Sessional Marks: 15	**Continuous mode:10 End Semester**		
Examination Marks: 75	**Total marks:100**		

OBJECTIVES:

1. The various approaches for development of novel drug delivery systems.
2. The criteria for selection of drugs and polymers for the development of NTDS
3. The critical evaluation of biopharmaceutic studies involving drug product equivalency.
4. The potential clinical pharmacokinetic problems and application of basics of pharmacokinetic
5. Scientific knowledge to develop cosmetics and cosmeceuticals with desired Safety, stability, and efficacy.

Course contents

1. To study the effect of temperature change, non solvent addition, incompatible polymer addition in microcapsules preparation.

2. Preparation and evaluation of Alginate beads

3. Formulation and evaluation of gelatin /albumin microspheres

4. Formulation and evaluation of liposomes/niosomes

5. Formulation and evaluation of spherules

6. Improvement of dissolution characteristics of slightly soluble drug by Solid dispersion technique.

7. Comparison of dissolution of two different marketed products /brands

8. Protein binding studies of a highly protein bound drug & poorly protein bound drug

9. Bioavailability studies of Paracetamol in animals.

10. Pharmacokinetic and IVIVC data analysis by Winnoline R software

11. In vitro cell studies for permeability and metabolism

12. DoE Using Design Expert® Software

13. Formulation data analysis Using Design Expert® Software

14. Quality-by-Design in Pharmaceutical Development

15. Computer Simulations in Pharmacokinetics and Pharmacodynamics

16. Computational Modeling of Drug Disposition

17. To develop Clinical Data Collection manual

18. To carry out Sensitivity Analysis, and Population Modeling.

19. Development and evaluation of Creams

20. Development and evaluation of Shampoo and Toothpaste base

21. To incorporate herbal and chemical actives to develop products

22. To address Dry skin, acne, blemish, Wrinkles, bleeding gums and dandruff.

Course outcomes:

1. Development and validation of the UV spectroscopic analytical method of drug.
2. The design and evaluation of dosage regimens of the drugs using pharmacokinetic and biopharmaceutic parameters.
3. The potential clinical pharmacokinetic problems and application of basics of pharmacokinetic
4. The potential clinical pharmacokinetic problems and application of basics of pharmacokinetic
5. Explain the concept of cosmeceuticals, history, difference between cosmetics & cosmeceuticals & cosmeceutical agents.
6. CO-PO Mapping

Course	PO1	PO2	PO3	PO4	PO5	PO6	PO7	PO8	PO9	PO10	PO11	PO12
CO1	2	1	2	3	1	2	3	1	2	3	1	1
CO2	2	3	2	1	3	2	1	2	3	1	3	1
CO3	3	1	2	3	2	1	2	3	2	1	1	2
CO4	1	2	1	2	1	2	3	1	2	2	2	2
CO5	2	1	2	1	2	1	3	2	1	3	1	3

Course Code	**Course Title**	**No of Hours Per week**	**No of Credits**
MPH	**SEMINAR/ASSIGNMENT**	**07**	**04**
Total marks:100			

OUTCOMES:

1. Provide students with preliminary skills to do further research in the field of international relations
2. Teach students to break down a piece of writing into its component parts and analyze the arguments.

3. Give students the opportunity to read in depth on a topic and understand how different pieces of scholarship are engaged in conversation with one another.

ELECTIVES

Course Code	Course Title	No of Hours Per week	No of Credits
(MPH 203T)	**COMPUTER AIDED DRUG DELIVERY SYSTEMS**	**04**	**04**
Sessional Marks: 15	**Continuous mode:10**		
End Semester Examination Marks: 75		**Total marks:100**	

SCOPE

The subject is designed to impart knowledge on the current state of the art techniques involved in computer assisted drug design.

OBJECTIVES

1. At completion of this course it is expected that students will be able to understand
2. Role of CADD in drug discovery
3. Different CADD techniques and their applications
4. Various strategies to design and develop new drug like molecules.
5. Working with molecular modelling softwares to design new drug molecules
6. The in silico virtual screening protocols

Course Content:

Unit I

a. Introduction to Computer Aided Drug Design (CADD) History, different techniques and applications. Quantitative Structure Activity Relationships: Basics History and development of QSAR: Physicochemical parameters and methods to calculate physicochemical parameters: Hammett equation and electronic parameters (sigma), lipophilicity effectsand parameters (log P, pi-substituent constant), steric effects (Taft steric and MR parameters) Experimental and theoretical approaches for the determination of these physicochemical parameters.

Unit II

Quantitative Structure Activity Relationships: Applications Hansch analysis, Free Wilson analysis and relationship between them, Advantages and disadvantages; Deriving 2D- QSAR equations.3D-QSAR approaches like COMFA and COMSIA.

QSAR statistical methods: regression analysis and partial least square analysis.

Unit III

Molecular Modelling and Docking

1. Molecular and Quantum Mechanics in drug design. Energy Minimization Methods: comparison between global minimum conformation and bioactive conformation
2. Methods to derive three-dimensional structure of protein : X-Ray Crystallography, NMR, homologous modeling.
3. Molecular docking and drug receptor interactions: Rigid docking, flexible docking, manual docking and extra-precision docking. Agents acting on enzymes such as DHFR, HMG-Co A reductase and HIV protease, choline esterase (AchE&BchE)

Unit IV

Molecular Properties and Drug Design

1. Prediction and analysis of ADMET properties of new molecules and its importance in drug design.
2. De novo drug design: Receptor/enzyme-interaction and its analysis, Receptor/enzyme cavity size prediction, predicting the functional components of cavities, Fragment based drug design.

Unit V

Pharmacophore Mapping and Virtual Screening

1. Concept of pharmacophore, pharmacophore mapping,identification of Pharmacophore features and Pharmacophore modeling; Conformational search used in pharmacophore mapping.
2. Virtual Screening Techniques

3. Drug-likeness screening, Similarity based methods and Pharmacophore based screening, structure based in-silico virtual screening protocols.

REFERENCES

1. Computational and structural approaches to drug discovery, Robert MStroud and Janet. F Moore, RCS Publishers.
2. Introduction to Quantitative Drug Design by Y.C. Martin, CRC Press,Taylor& Francis group..
3. Drug Design by Ariens Volume 1 to 10, Academic Press, 1975, ElsevierPublishers.
4. Principles of Drug Design by Smith and Williams, CRC Press, Taylor &Francis.
5. The Organic Chemistry of the Drug Design and Drug action by Richard B.Silverman, Elsevier Publishers.
6. Medicinal Chemistry by Burger, Wiley Publishing Co.
7. An Introduction to Medicinal Chemistry –Graham L. Patrick, OxfordUniversity Press.
8. Wilson and Gisvold's Text book of Organic Medicinal and PharmaceuticalChemistry, Ippincott Williams & Wilkins.
9. Comprehensive Medicinal Chemistry – Corwin and Hansch, PergamonPublishers.
10. Hugo Kubiny. QSAR: Hansch Analysis and Related Approaches. Methods and Principles in Medicinal Chemistry. Publisher Wiley-VCH
11. Klaus Gubernator, Hans-Joachim Böhm. Structure-Based Ligand Design. Methods and Principles in Medicinal Chemistry. Publisher Wiley-VCH
12. Abby L . Parrill. M . Rami Reddy. Rational Drug Design. Novel Methodology and Practical Applications. ACS Symposium Series; American Chemical Society: Washington, DC, 1999.
13. J. Rick Turner. New drug development design, methodology and, analysis. John Wiley & Sons,Inc.,NewJersey.

Course Outcomes:

1. History of Computers in Pharmaceutical Research and Development
2. Computational Modeling of Drug Disposition
3. Computers in Preclinical Development
4. Optimization Techniques in Pharmaceutical Formulation
5. Computers in Market Analysis
6. CO-PO Mapping

Course	PO1	PO2	PO3	PO4	PO5	PO6	PO7	PO8	PO9	PO10	PO11	PO12
CO1	3	2	1	2	3	1	2	3	1	2	1	2
CO2	2	1	2	1	2	3	1	2	3	1	2	2
CO3	1	2	1	2	1	2	3	1	2	3	2	3
CO4	3	2	2	2	1	2	1	3	1	3	1	2
CO5	2	1	2	1	2	1	1	2	3	1	1	3

Course Code	Course Title	No of Hours Per week	No of Credits
(MPC 203T)	COMPUTER AIDED DRUG DESIGN	04	04
Sessional Marks: 15 Continuous mode:10 End Semester Examination Marks: 75 Total marks:100			

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

OBJECTIVES

1. Upon completion of this course it is expected that students will be able to understand,
2. History of Computers in Pharmaceutical Research and Development
3. Computational Modeling of Drug Disposition
4. Computers in Preclinical Development
5. Optimization Techniques in Pharmaceutical Formulation
6. Computers in Market Analysis
7. Computers in Clinical Development
8. Artificial Intelligence (AI) and Robotics
9. Computational fluid dynamics(CFD)

Course Content:

Unit I

a. Computers in Pharmaceutical Research and Development: A General Overview: History of Computers in Pharmaceutical Research and Development. Statistical modeling in Pharmaceutical research and development: Descriptive versus Mechanistic Modeling, Statistical Parameters, Estimation, Confidence Regions, Nonlinearity at the Optimum, Sensitivity Analysis, Optimal Design, Population Modeling.
b. Quality-by-Design in Pharmaceutical Development: Introduction, ICH Q8 guidelines, Regulatory and industry views on QbD, Scientifically based QbD - examples of application.

Unit II

Computational Modeling of Drug Disposition: Introduction,Modeling Techniques: Drug Absorption, Solubility, Intestinal Permeation, Drug Distribution
Drug Excretion, Active Transport; P-gp, BCRP, Nucleoside Transporters, hPEPT1, ASBT, OCT, OATP,BBB-Choline Transporter.

Unit III

Computer-aided formulation development: Concept of optimization, Optimization parameters, Factorial design, Optimization technology & Screening design. Computers in Pharmaceutical Formulation: Development of pharmaceutical emulsions, microemulsion drug carriers. Legal Protection of Innovative Uses of Computers in R&D, The Ethics of Computing in Pharmaceutical Research, Computers in Market analysis.

Unit IV

Computer-aided biopharmaceutical characterization: Gastrointestinal absorption simulation. Introduction, Theoretical background, Model construction, Parameter sensitivity analysis, Virtual trial, Fed vs. fasted state, In vitro dissolution and in vitro- invivo correlation, Biowaiver considerations.

Unit V

Computer Simulations in Pharmacokinetics and Pharmacodynamics: Introduction, Computer Simulation: Whole Organism, Isolated Tissues, Organs, Cell, Proteins and Genes. Computers in Clinical Development: Clinical Data Collection and Management, Regulation of Computer Systems.

REFERENCES

1. Computer Applications in Pharmaceutical Research and Development, Sean Ekins, 2006, John Wiley & Sons.
2. Computer-Aided Applications in Pharmaceutical Technology, 1st Edition, Jelena Djuris, Woodhead Publishing
3. Encyclopedia of Pharmaceutical Technology, Vol 13, James Swarbrick, James. G.Boylan, Marcel Dekker Inc, New York, 1996.

Course Outcomes:

1. To utilize various molecular modeling softwares in the design of novel drug-like molecules.
2. To apply the various softwares for physicochemical property prediction.
3. To understand how current drugs were developed by using pharmacophores modeling and docking technique.
4. Computers in Clinical Development
5. Artificial Intelligence (AI) and Robotics
6. Computational fluid dynamics(CFD)
7. CO-PO Mapping

Course	PO1	PO2	PO3	PO4	PO5	PO6	PO7	PO8	PO9	PO10	PO11	PO12
CO1	2	1	1	3	2	1	2	3	1	2	1	2
CO2	2	1	2	3	1	2	3	1	3	2	3	1
CO3	1	2	1	2	3	1	2	1	2	3	2	3
CO4	2	1	3	1	2	3	1	2	3	1	2	1
CO5	1	2	2	1	2	3	1	3	3	1	3	2

Course Code	Course Title	No of Hours Per week	No of Credits
(MPL 203T)	**PRINCIPLES OF DRUG DISCOVERY**	**04**	**04**
Sessional Marks: 15	**Continuous mode:10**		
End Semester Examination Marks: 75		**Total marks:100**	

SCOPE : The subject imparts basic knowledge of drug discovery process. This informationwill makethe student competent in drug discovery process.

OBJECTIVES

1. Upon completion of the course, the student shall be able to,
2. Explain the various stages of drug discovery.
3. Appreciate the importance of the role of genomics, proteomics and bioinformatics indrug discovery
4. Explain various targets for drug discovery.
5. Explain various lead seeking method and lead optimization
6. Appreciate the importance of the role of computer aided drug design in drug discovery

Course Content:

Unit I

An overview of modern drug discovery process:

Target identification, target validation, lead identification and lead Optimization. Economics of drug discovery. Target Discovery and validation- Role of Genomics, Proteomics and Bioinformatics. Role of Nucleic acid microarrays, Protein microarrays, Antisense technologies, siRNAs, antisense oligonucleotides, Zinc finger proteins. Role of transgenic animals in target
validation.

Unit II

Lead Identification- combinatorial chemistry & high throughput screening, in silico leaddiscovery techniques, Assay development for hit identification.

Protein structure

Levels of protein structure, Domains, motifs, and folds in protein structure. Computational prediction of protein structure: Threading and homology modeling methods. Application ofNMR and X-ray crystallography in protein structure prediction.

Unit III

Rational Drug Design

Traditional vs rational drug design, Methods followed in traditional drug design, High throughput screening, Concepts of Rational Drug Design,Rational Drug Design Methods: Structure and Pharmacophore based approaches Virtual Screening techniques: Drug likenessscreening, Concept of pharmacophore mapping and pharmacophore based Screening

Molecular docking: Rigid docking, flexible docking, manual docking; Docking basedscreeningDe novo drug design.

Quantitative analysis of Structure Activity Relationship

History and development of QSAR, SAR versus QSAR, Physicochemical parameters, Hanschanalysis, Fee Wilson analysis and relationshipbetween them.

Unit IV

QSAR Statistical methods – regression analysis, partial least square analysis (PLS) andother multivariate statistical methods. 3D-QSAR approaches like COMFA and COMSIA Prodrug design-Basic concept, Prodrugs to improve patient acceptability, Drug solubility, Drug absorption and distribution, site specific drug delivery and sustained drug action.

Rationale of prodrug design and practical consideration of prodrug design.

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3. Johanna K. DiStefano. Disease Gene Identification. Methods and Protocols. Springer NewYork Dordrecht Heidelberg London.
4. Hugo Kubiny. QSAR: Hansch Analysis and Related Approaches. Methods and Principlesin Medicinal Chemistry. Publisher Wiley-VCH
5. Klaus Gubernator, Hans-Joachim Böhm. Structure-Based Ligand Design. Methods andPrinciples in Medicinal Chemistry. Publisher Wiley- VCH
6. Abby L . Parrill. M . Rami Reddy. Rational Drug Design. Novel Methodology and Practical Applications. ACS Symposium Series
7. American Chemical Society: Washington,DC, 1999.
8. J. Rick Turner. New drug development design, methodology and, analysis. John Wiley &Sons, Inc., New Jersey

Course Outcomes:

1. The students would appreciate the knowledge on the basics of drug discovery.
2. They would have better understanding on the various stages of drug discovery.
3. They would have studied the importance of the role of genomics, proteomics and bioinformatics in drug discovery.
4. They would have studied on the various targets for drug discovery.
5. They would have better understanding on the lead seeking method and lead optimization
6. They would have learnt the importance of the role of computer aided drug design in drug discovery.

CO-PO Mapping

Course	PO1	PO2	PO3	PO4	PO5	PO6	PO7	PO8	PO9	PO10	PO11	PO12
CO1	2	1	1	3	2	1	2	3	1	2	1	2

CO2	2	1	2	3	1	2	3	1	3	1	3	1
CO3	1	2	1	2	3	1	2	1	2	3	2	3
CO4	2	1	3	1	2	3	1	2	3	2	2	3
CO5	1	2	2	1	2	3	1	3	3	1	3	1