SEVEN HILLS COLLEGE OF PHARMACY

[AUTONOMOUS]

Venkatramapuram, Ramachandrapuram (Mandal), Tirupati (Dist), **TIRUPATI** - 517 561, A.P, INDIA

Approved by PCI, New Delhi & Govt. of A.P.

Awarding University: JNT University Anantapur – Ananthapuramu

Recognized by UGC Under Sections 2(f) & 12(B) of UGC Act 1956

SHCP R23 Regulations

M.Pharmacy – Pharmaceutics
Pre-Ph.D. Course Work

COURSE STRUCTURE AND SYLLABUS

Effective from Academic Year 2023-2024

(From 2023-24 Admitted Batch)

I Semester

S. No	Course Code	Subjects	Type of Course (C/CBS)	Contact (Hrs/ Week)	Credits	IA	ESE
1	23S03101	Drug Delivery Systems	C	3L+1T	4	30S+10Obj	60
2	23S03102	Modern Pharmaceutics	C	3L+1T	4	30S+10Obj	60
3	23S03103	Regulatory Affairs	C	3L+1T	4	30S+10Obj	60

II Semester

S. No	Course Code	Subjects	Type of Course (C/CBS)	Contact (Hrs/ Week)	Credits	IA	ESE
1	23S03201	Molecular Pharmaceutics (Nano Tech and Targeted DDS)	C	3L+1T	4	30S+10Obj	60
2	23S03202	Advanced Biopharmaceutics &Pharmacokinetics	C	3L+1T	4	30S+10Obj	60
3	23S03203	Computer Aided Drug Delivery System	C	3L+1T	4	30S+10Obj	60
4	23S03204	Cosmetic and Cosmeceuticals	C	3L+1T	4	30S+10Obj	60

Course Code	DRUG DELIVERY SYSTEMS	L	T	P	C
23S03101		4	0	0	4
	Semester	**I**			

Course Objectives:

This course is designed to impart knowledge on the area of advances in novel drug delivery systems.

Course Outcomes (CO): Student will be able to

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.

UNIT - I	10hrs	
Self-Study	*Introduction & basic concepts, advantages/disadvantages*	

Sustained Release (SR) and Controlled Release (CR)formulations: Factors influencing, Physicochemical & biological approaches for SR/CR formulation, Mechanism of Drug Delivery from SR/CR formulation. Polymers: introduction, definition, classification, properties and application Dosage Forms for Personalized Medicine: Introduction, Definition, Pharmacogenetics, Categories of Patients for Personalized Medicines: Customized drug delivery systems, Bioelectronic Medicines, 3D printing of pharmaceuticals, Telepharmacy, **Pelletization and design and evaluation of multiparticulate oral systems**

UNIT - II	10hrs	
Self-Study	*Principles &Fundamentals, Types*	

Rate Controlled Drug Delivery Systems: Activation Modulated Drug Delivery Systems; Mechanically activated, pH activated, Enzyme activated, and Osmotic activated Drug Delivery Systems Feedback regulated Drug Delivery Systems- Principles & Fundamentals, **Oro dispersible systems, Dissolution testing, medium selection and validation of dissolution apparatus.**

UNIT - III	10hrs	
Self-study	*Principle, concepts, advantages and disadvantages*	

Gastro-Retentive Drug Delivery Systems: Modulation of GI transit time, **Different Approaches- High density systems, floating systems, muco-adhesive systems, Expandable systems, Magnetic systems, Superporous Hydrogels, Evaluation of GRDDS**

Buccal Drug Delivery Systems: Principle of mucoadhesion, advantages and disadvantages, Mechanism of drug permeation, Methods of formulation and its evaluations.

UNIT - IV	16hrs	
Self-Study	*Barriers of drug permeation, Structure of skin and barriers, Penetration enhancers*	

Occular Drug Delivery Systems: Barriers of drug permeation, Methods to overcome barriers, – **Design of CR ophthalmic DDS including gels, inserts, novel DDS and evaluation, Novel ophthalmic drug delivery systems**

Transdermal Drug Delivery Systems: Transdermal Drug Delivery Systems, Formulation and evaluation, **Iontophoretic and Sonophoretic DDS, Recent advances –use of microneedles in transdermal drug delivery**

UNIT - V	14hrs	
Self-Study	*Barriers for protein delivery.*	

Protein and Peptide Delivery: Formulation and Evaluation of delivery systems of proteins and othermacromolecules. **Routes for delivery of proteins and peptides with emphasis on oral and mucosal delivery, pulmonary delivery, nasal delivery and parenteral delivery**

Vaccine delivery systems: Vaccines, uptake of antigens, single shot vaccines, mucosal and transdermal delivery of vaccines

Reference Books:

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 IntersciencePublication, John Wiley and Sons, Inc, New York!Chichester/Weinheim
4. N.K. Jain, Controlled and Novel Drug Delivery, CBS Publishers &Distributors, New Delhi, Firstedition 1997 (reprint in 2001).
5. S.P. Vyas and R.K. Khar, Controlled Drug Delivery - concepts and advances, Vallabh Prakashan, New Delhi, First edition 2002

Course Code	MODERN PHARMACEUTICS	L	T	P	C
23S03102		4	0	0	4
	Semester	**I**			

Course Objectives:

Course designed to impart advanced knowledge and skills required to learn various aspects and concepts at pharmaceutical industries

Course Outcomes (CO): Student will be able to

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

• The elements of pre-formulation 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.

UNIT - I	12hrs	
Self-Study	*Theories of dispersion and pharmaceutical Dispersion*	

a. Preformation Concepts – Drug Excipient interactions -different methods, kinetics of stability, Stability testing. **SMEDDS/SNEDDS- Formulation and Evaluation,** Preparation and stability of Large and small volume parental – physiological and formulation consideration, Manufacturing and evaluation.

b. 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

UNIT - II	12hrs	
Self-Study	*Introduction to Pharmaceutical Validation, Scope &merits of Validation*	

Validation: Validation and calibration of Master plan, ICH& WHO guidelines for calibration and validation of equipments, Validation of specific dosage form, Types of validation. Government regulation, Manufacturing Process Model, URS, DQ, IQ, OQ & P.Q. of facilities, **Validation**

Process and Equipment in formulation development

UNIT - III	12hrs	
Self-study	*Objectives and policies of current good manufacturing practices*	

cGMP & Industrial Management: Layout of buildings, services, equipments and their maintenance 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, **Submission of Pharmaceutical Development and related information in CTD format. Relevant Examples.**

UNIT - IV	12hrs	
Self-Study	*Barriers of drug permeation, Structure of skin and barriers, Penetration enhancers*	

Compression and compaction: Physics of tablet compression, compression, consolidation, **Compaction of powders- definitions of compression & consolidation, deformation mechanisms of matter, steps in compaction of tablets (in detail), theoretical aspects, Force Volume relationships/porosity –pressure equations (Heckel's Law & equation), Granulation of powders –theory, Effect of compaction pressure on various tablet properties, Energy for**

compaction & effect of lubrication of granules, instrumentation of(principles)effect of friction, distribution of forces, compaction profiles.		**tablet presses**
UNIT - V	12hrs	
Self-Study	*Calculations for shelf life based on degradation kinetics*	

Study of consolidation parameters; Diffusion parameters, Dissolution parameters and Pharmacokinetic parameters, Heckel plots, Similarity factors – f2 and f1, Higuchi and Peppas plot, Linearity Concept of significance, Standard deviation, Chi square test, students T-test, ANOVA test.

Reference Books:

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, Secondedition; 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 Pre-formulations; By J.J. Wells.
16. Applied production and operations management; By Evans, Anderson, Sweeney and Williams.
17. Encyclopaedia of Pharmaceutical technology, Vol I – III

Course Code	REGULATORY AFFAIRS	L	T	P	C
23S03103		4	0	0	4
	Semester	I			

Course Objectives:

Course designed to impart advanced knowledge and skills required to learn the concept of generic drug and their development, various regulatory filings indifferent countries, different phases of clinicaltrials and submitting regulatory documents: filing process of IND, NDA and ANDA

Course Outcomes (CO): Student will be able to

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 indifferent 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.

UNIT - I	12hrs	
Self-Study	*Case-studies on MSF and DMF*	

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 FEDERALREGULATION), drug product performance, in-vitro, ANDA regulatory approval process, NDA approval process, BE and drug product assessment, in – vivo, scale up process approval changes, post marketing surveillance, outsourcing BA and BE to CRO.

UNIT - II	12hrs	
Self-Study	*Case-studies on Product approval forms*	

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	12hrs	
Self-study	*CDSCO Guidelines*	

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

UNIT - IV	12hrs	
Self-Study	*Indian Drug Regulatory*	

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

UNIT - V	12hrs	
Self-Study	*Clinical Research Management*	

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.

Reference Books:

1. Generic Drug Product Development, Solid Oral Dosage forms, Leon Shargel and Isader Kaufer, Marcel Dekker series, Vol.143
2. The Pharmaceutical Regulatory Process, Second Edition Edited by Ira R. Berry and Robert P. Martin, Drugs and the Pharmaceutical Sciences, Vol.185, Informa Health care Publishers.
3. New Drug Approval Process: Accelerating Global Registrations By Richard A Guarino, MD,5th edition, Drugs and the Pharmaceutical Sciences, Vol.190.
4. Guidebook for drug regulatory submissions / Sandy Weinberg. By John Wiley&Sons. Inc.
5. FDA regulatory affairs: a guide for prescription drugs, medical devices, and biologics/edited By Douglas J. Pisano, David Mantus.
6. Clinical Trials and Human Research: A Practical Guide to Regulatory Compliance By Fay A. Rozovsky and Rodney K. Adams
7. www.ich.org/ 8. www.fda.gov/ 9. europa.eu/index_en.htm 10. https://www.tga.gov.au/tga-basics

Course Code	MOLECULAR PHARMACEUTICS (NANO TECHNOLOGY & TARGETED DDS) (NTDS)	L	T	P	C
23S03201		4	0	0	4
	Semester	**II**			

Course Objectives:

This course is designed to impart knowledge on the area of advances in novel drug delivery systems.

Course Outcomes (CO):

Upon completion of the course student shall be able to understand • The various approaches fordevelopment of novel drug delivery systems. • The criteria for selection of drugs and polymers for the development of NTDS • The formulation and evaluation of novel drug delivery systems.

UNIT - I	12hrs	
Self-Study	*Concepts, Events of drug targeting*	

Targeted Drug Delivery Systems: Biological process involved in drug targeting, Strategies of Tumor targeting and Brain specific delivery, **Receptor mediated drug targeting, Colon targetingapproaches and DDS, Biomedical applications of Nanotechnology**

UNIT - II	12hrs	
Self-Study	*RES Mechanisms, An overview colloidal Drug Delivery with respect to Physicochemical& Biopharmaceutical aspects*	

Targeting Methods: Molecular targets for cellular targeting, Ligands as delivery and targetingtools, Nano Particles, Liposomes, Solid Lipid nanoparticles: Types, preparation and evaluation. **Targeting in cancer and infectious diseases**

UNIT - III	12hrs	
Self-study	*Concept of Microencapsulation*	

Micro Capsules / Micro Spheres: Types, preparation and evaluation of Monoclonal Antibodies,Niosomes, Aquasomes, Phytosomes, Electrosomes, **Lipid Drug Conjugates, Theranostics**

UNIT - IV	12hrs	
Self-Study	*Anatomy and physiology of the respiratory system, Airway physiology and disposition patterns*	

Pulmonary Drug Delivery Systems: Aerosols, propellents, Containers, Types, preparation and evaluation, Intra Nasal Route Delivery systems; Types, preparation and evaluation, **Factors affecting particle disposition in the lungs, Pulmonary receptor targeting, Strategies for enhancement in nasal absorption, Animal models for nasal absorption studies**

UNIT - V	12hrs	
Self-Study	*Gene Targeting Principles*	

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. Bio-distribution and Pharmacokinetics. knowledge of therapeutic antisense molecules and aptamers as drugs of future.

Reference Books:

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, Vallabh Prakashan,New Delhi, First edition 2002.

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

Course Code	ADVANCED BIOPHARMACEUTICS & PHARMACOKINETICS	L	T	P	C
23S03202		4	0	0	4
	Semester	II			

Course Objectives:

This course is designed to impart knowledge and skills necessary for dose calculations, dose adjustments and to apply biopharmaceutics theories in practical problem solving. Basic theoretical discussions of the principles of biopharmaceutics and pharmacokinetics are provided to help the students' to clarify the concepts

Course Outcomes (CO):

Upon completion of this course it is expected that students will be able to understand, • The basic concepts in biopharmaceutics and pharmacokinetics. • The use raw data and derive the pharmacokinetic models and parameters the best describe the process of drug absorption, distribution, metabolism and elimination. • The critical evaluation of biopharmaceutic studies involving drug product equivalency. • The design and evaluation of dosage regimens of the drugs using pharmacokinetic and biopharmaceutic parameters. • The potential clinical pharmacokinetic problems and application of basics of pharmacokinetics

UNIT - I	12hrs	
Self-Study	*Gastrointestinal tract, Mechanism of drug absorption*	

Drug Absorption from the Gastrointestinal Tract: Factors affecting drug absorption, pH–partition theory of drug absorption. Formulation and physicochemical factors: Dissolution rate, Dissolution process, Noyes–Whitney equation and drug dissolution, Factors affecting the dissolution rate. 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, Formulation and processing factors, Correlation of in-vivo data with in vitro dissolution data. Transport model: Permeability-Solubility-Charge State and the pH Partition Hypothesis, Properties of the Gastrointestinal Tract (GIT), pH Microclimate Intracellular pH Environment, Tight-Junction Complex. **Detailed discussion of the variety of transporters and the role of transporters in the GI tract and liver and their role in drug absorption, Discussion of the traditional and high-throughput approaches towards estimation of solubility, dissolution rate and drug absorption.**

UNIT - II	12hrs	
Self-Study	*Introduction, biopharmaceutic factors affecting drug bioavailability, rate-limiting steps in drug absorption, physicochemical nature of the drug formulation factors affecting drug product performance*	

Biopharmaceutic considerations in drug product design and In Vitro 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. In vitro–in vivo correlation, dissolution profile comparisons, drug product stability, considerations in the design of a drug product, **Role of drug membrane interaction in pharmacokinetics & pharmacodynamics of drugs, Study of the drug membrane interactions, Automation in Dissolution.**

UNIT – III	12hrs	
Self-Study	*Basic considerations, pharmacokinetic models, compartment modeling*	

Pharmacokinetics: Basic considerations, one compartment model- IV bolus, IV infusion, extra- vascular. Multi compartment model: two compartment - model in brief, non-linear pharmacokinetics: cause of non-linearity, Michaelis – Menten equation, estimation of kmax 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. **Role of Pharmacokinetics in drug discovery; drug development and process, Metabolite Pharmacokinetics**

UNIT – IV	12hrs	
Self-Study	*Bioavailability and Bioequivalence Introduction, Purpose of bioavailability studies, relative and absolute availability*	

Drug Product Performance, In-Vivo: Bioavailability and Bioequivalence: drug product performance, Methods for assessing bioavailability, bioequivalence studies, design and evaluation of bioequivalence studies, study designs, cross over study designs, evaluation of the data, bioequivalence example, study submission and drug review process. Biopharmaceutics classification system, methods. 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. **Case studies and problem solving w.r.t. above including design of controlled release dosage forms and other novel drug delivery systems based on pharmacodynamic and pharmacokinetic rationale.**

UNIT – V	12hrs	
Self-Study	*Introduction, Proteins and peptides, Monoclonal antibodies*	

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, **Individualization of dosage regimen, conversion from IV dosing to oral dosing, determination of dose, frequency of administration and route of administration, therapeutic drug monitoring, dosing of drug in infants and elders, variability in clinical response and pharmacokinetics w.r.t. renal and hepatic diseases.**

Reference Books:

1. Biopharmaceutics and Clinical Pharmacokinetics by, Milo Gibaldi
2. Biopharmaceutics and Pharmacokinetics; By Robert F Notari
3. Applied biopharmaceutics and pharmacokinetics, Leon Shargel and Andrew B.C.YU 4thedition, Prentice-Hall International edition. USA
4. Bio pharmaceutics and Pharmacokinetics-A Treatise, By D. M. Brahmankar and SunilB.Jaiswal, Vallabh Prakashan Pitampura, Delhi
5. Hand Book of Clinical Pharmacokinetics, By Milo Gibaldi and Laurie Prescott by ADIS HealthScience Press. 6 Biopharmaceutics and Clinical Pharmacokinetics-An introduction 4th edition Revised and expanded by Rebort F Notari Marcel Dekker Inn, New York and Basel, 1987.

Course Code	COMPUTER AIDED DRUG DELIVERY SYSTEM	L	T	P	C
23S03203		4	0	0	4
Semester		II			

Course Objectives:

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.

Course Outcomes (CO):

Upon completion of this course it is expected that students will be able to understand, • History of Computers in Pharmaceutical Research and Development • Computational Modeling of Drug Disposition • Computers in Preclinical Development • Optimization Techniques in Pharmaceutical Formulation • Computers in Market Analysis • Computers in Clinical Development • Artificial
Intelligence (AI) and Robotics • Computational fluid dynamics (CFD)

UNIT - I	12hrs	
Self-Study	*Computers in Pharmaceutical Research and Development: AGeneral Overview: History of Computers in Pharmaceutical Research and Development.*	

a. **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, Quality-by-Design in Pharmaceutical Development: Introduction, ICH Q8 guideline, Regulatory and industry views on QbD, Scientifically based QbD - examples of application.

b. Computation tools for drug development- Ligand based and structure-based models.

UNIT - II	12hrs	
Self-Study	*Case Studies on in-silico models of drug absorption*	

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

UNIT - III	12hrs	
Self-Study	*Concept of optimization, Optimization parameters*	

Computer-aided formulation development: 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, **Computational Methods for studying drug metabolism: Isolated enzymes, recombinant**
enzymes, subcellular fractions, hepatocytes, perfused liver, in-vivo drug metabolism studies

UNIT – IV	12hrs	
Self-Study	*Case studies on simulation models for GI absorption*	

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

UNIT – V	12hrs	
Self-Study	*Case studies on AI*	

Artificial Intelligence (AI), Robotics and Computational fluid dynamics: General overview,Pharmaceutical Automation, Pharmaceutical applications, Advantages and Disadvantages. Current Challenges and Future Directions.

Reference Books:

1. Computer Applications in Pharmaceutical Research and Development, Sean Ekins, 2006, JohnWiley & 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 Code	COSMETICS AND COSMECEUTICALS	L	T	P	C
23S03204		4	0	0	4
Semester		II			

Course Objectives:

This course is designed to impart knowledge and skills necessary for the fundamental need for cosmetic and cosmeceutical products.

Course Outcomes (CO):

Upon completion of the course, the students shall be able to understand • Key ingredients used in cosmetics and cosmeceuticals. • Key building blocks for various formulations. • Current technologies in the market • Various key ingredients and basic science to develop cosmetics and cosmeceuticals • Scientific knowledge to develop cosmetics and cosmeceuticals with desired Safety,
stability, and efficacy.

UNIT - I	12hrs	
Self-Study	*Case Studies for regulatory approvals to cosmetics*	

Cosmetics – Regulatory: Definition of cosmetic products as per Indian regulation. Indian regulatoryrequirements 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. **Packaging materials, specialty packages for cosmetics, labelling requirements for cosmetics.**

UNIT - II	12hrs	
Self-Study	*Structure of skin, Structure of hair*	

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. Cleansing and care needs for face, eye lids, lips, hands, feet, nail, scalp, neck, body and under-arm, Advancements in formulation of cosmetics for hair and skin

UNIT - III	12hrs	
Self-Study	*Novel excipients in Cosmetics*	

Formulation Building blocks: Building blocks for different product formulations of cosmetics/cosmeceuticals. Surfactants –Classification and application. Emollients, rheological additives: classification and application. Antimicrobial used as preservatives, their merits and demerits. Factors affecting microbial 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	12hrs	
Self-Study	*Historical purview of perfumes, Approved colours as per Indian, European and US specifications*	

Design of cosmeceutical products: Sun protection, 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.

BIS guidelines for quality of finished products for cosmetics.

UNIT – V	12hrs	
Self-Study	*Discussion on Aleo vera, henna, tea tree oil, neem in various cosmetic products*	

Herbal Cosmetics: Herbal ingredients used in Hair care, skincare 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. **Safety and toxicity evaluation of cosmetic products, Current trends in use of herbal materials in cosmetics.**

Reference Books:

1. Harry's Cosmeticology. 8th edition.
2. Poucher's perfume cosmetics and Soaps, 10th edition.
3. Cosmetics - Formulation, Manufacture and quality control, PP.Sharma, 4thedition
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 Code	RESEARCH METHODOLOGY AND BIOSTATISTICS	L	T	P	C
23DRM101		4	0	0	4
Semester		III			

Course Objectives:

- To understand the research problem
- To know the literature studies, plagiarism and ethics
- To get the knowledge about technical writing
- To analyze the nature of intellectual property rights and new developments
- To know the patent rights

Course Outcomes (CO): Student will be able to

At the end of this course, students will be able to

- Design robust studies using key research methodologies, including controls, randomization, and error reduction.
- Perform statistical tests and analyze research data to validate study outcomes.
- Ensure ethical integrity in medical research by applying principles like autonomy, beneficence, and informed consent.
- Follow CPCSEA guidelines for ethical laboratory animal care and facility management.
- Uphold the Declaration of Helsinki principles for ethical medical research involving human subjects.

UNIT - I

General Research Methodology: Research, objective, requirements, practical difficulties,review of literature, study design, types of studies, strategies to eliminate errors/bias, controls,
randomization, crossover design, placebo, blinding techniques.

UNIT - II

Biostatistics: Definition, application, sample size, importance of sample size, factors influencing sample size, dropouts, statistical tests of significance, type of significance tests, parametric tests (students "t" test, ANOVA, Correlation coefficient, regression), non- parametric tests (wilcoxan rank tests, analysis of variance, correlation, chi square test), null
hypothesis, P values, degree of freedom, interpretation of P values.

UNIT - III

Medical Research: History, values in medical ethics, autonomy, beneficence, non- maleficence, double effect, conflicts between autonomy and beneficence/non-maleficence, euthanasia, informed consent, confidentiality, criticisms of orthodox medical ethics, importance of communication, control resolution, guidelines, ethics committees, cultural concerns, truth telling, online business practices, conflicts of interest, referral, vendor relationships, treatment of family members, sexual relationships, fatality.

UNIT - IV

CPCSEA guidelines for laboratory animal facility: Goals, veterinary care, quarantine, surveillance, diagnosis, treatment and control of disease, personal hygiene, location of animal facilities to laboratories, anesthesia, euthanasia, physical facilities, environment, animal
husbandry, record keeping, SOPs, personnel and training, transport of lab animals

UNIT - V

Declaration of Helsinki: History, introduction, basic principles for all medical research, and additional principles for medical research combined with medical care.

Reference Books:

1. Stuart Melville and Wayne Goddard, “Research methodology: an introduction forscience &engineering students’”
2. Wayne Goddard and Stuart Melville, “Research Methodology: An Introduction”