# MASTER OF PHARMACY(PHARMACEUTICS)

## SRI SATYA SAI UNIVERSITY OF TECHNOLOGY AND MEDICAL SCIENCES

**Outcome based Curriculum for**

**Postgraduate Degree Courses in Pharmacy**

**(1) Vision**: To prepare tomorrow's leaders through innovative teaching, research and clinical practices that translate scientific discoveries into new treatments and models of care to improve both health and quality of life.

**(2) Mission:**

To develop pharmacists, educators and scientists whose leadership, knowledge and innovations improve the health of our communities.

**(3) Program Educational Objectives (PEO's):**

**PEO 1:** To offer academic programs of high fundamental principles and their applications in the area of Pharmaceutical Sciences and Technology

**PEO 2**: The Post-Graduates will master the key concepts in the discipline of their interest in pharmaceutical sciences. They will demonstrate these skills to use modern pharmaceutical tools, software, and equipments to analyze & solve problems.

**PEO 3**: The Post-Graduates will demonstrate the impact of pharmacy knowledge on the society and also will be aware of modern issues. They will create awareness of healthcare issues through interactions with others and will gain a sense of self-respect towards community and citizenship.

**(4) Programme Outcomes (PO's):**

**POs1: Pharmaceutical Sciences knowledge:** To understand the knowledge of mathematics, science, Pharmaceutical fundamentals, and a Pharmacy specialization to the solution of complex Pharmaceutical problems.

**POs2: Physicochemical properties of Formulations:** To understand the importance of physical and chemical properties of the different pharmaceutical ingredients and the factors influencing them is very valuable for pharmaceutical dosage form design.

**POs3: Entrepreneurship:** The knowledge on different pharmaceutical dosage forms are imparted on students. This knowledge comes while handling a pharmacy or a manufacturing unit or in the further courses.

**POs4: Design/Development of solutions:** The information on solid dosage forms like tablets and capsules, their formulation and quality control serves as an important perquisite for dosage form design.

**POs5: Application oriented Knowledge:** To understand Biopharmaceutics enables the students the effect of pharmacokinetic (ADME) parameters on the biological effect of the drug. The correlation of pharmacokinetics and pharmacodynamics is thus introduced.

**POs6: Environment and Sustainability:** Enable extension of pharmaceutical dosage forms, and enables the students to learn about different packaging materials used in pharmaceutical industry and the factors governing their use.

**POs7: Conduct investigations of complex problems:** To understand biopharmaceutical principles and pharmacokinetic principles through different compartment models, multiple dosage regimens, non-linear pharmacokinetics, and assessment of bioavailability and bioequivalence.

**POs8: Effective Citizenship:** Determine assumed social concern and equity centred national development, and the ability to act with an informed awareness of issues and participate in civic life through volunteering.

**POs9. Ethics:** Recognize different value systems including your own, understand the moral dimensions of your decisions, and accept responsibility for them.

**POs10: Self-directed and Life-long Learning:** Acquire the ability to engage in independent and life-long learning in the broadest context socio-technological changes

## (5) Program Specific Outcomes (PSOs)

These outcomes are specific to a program in addition to NBA defined POs Pharmacy can have PSOs as:

**PSO1:** Impart knowledge on the novel drug delivery systems, approaches, criteria for selection of polymers and drugs and their formulation and evaluation.

**PSO2:** To know various preformulation elements, industrial management and GMP considerations, Pilot Plant Scale up Techniques, Stability testing, sterilization and packaging of dosage forms.

**PSO3:** To impart knowledge and skills in generic drug development, various regulatory filings the approval process, and concept of generics across the globe.

**PSO4:** To impart knowledge and skills for dose calculations, dose adjustments and apply biopharmaceutics theories in practical problem solving. The pharmacokinetic models, bioequivalence and potential clinical pharmacokinetic problem analysis

**PSO5:** Skill development in Pharmaceutical research, Pharmacoinformatics, in drug development in Computational modeling, Preclinical development, clinical development, Artificial Intelligence, advanced Pharmaceutical instruments and Computational fluid dynamics.

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### (6)Mapping of POs and PSOs of Pharmaceutics

One way of verifying this to prepare a match matrix as shown below.

| Semester | M. Pharma (Pharmaceutics) | Course Code | Programme Outcomes | | | | | | | | | | Specific Programme outcomes | | | | | Credit Points |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | | POs-1 | POs-2 | POs-3 | POs-4 | POs-5 | POs-6 | POs-7 | POs-8 | POs-9 | POs-10 | PSO-1 | PSO-2 | PSO-3 | PSO-4 | PSO-5 | |
| FIRST | Modern Pharmaceutical Analytical Techniques | MPH 101T | * | | | | | | | * | * | * | * | | | | * | 4 |
| | Drug Delivery System | MPH 102T | * | | * | * | | * | | * | * | * | * | * | | | * | 4 |
| | Modern Pharmaceutics | MPH 103T | * | * | * | * | | * | | * | * | * | | * | | | * | 4 |
| | Regulatory Affair | MPH 104T | | | | | | | | | * | * | | | * | | | 4 |
| | Pharmaceutics Practical I | MPH 105P | * | | * | * | | * | | * | * | * | * | | | | * | 6 |
| | Seminar /Assignment | MPH 106P | | | | | | | | | | | | | | | | 4 |
| | **Total** | | | | | | | | | | | | | | | | | **26** |
| SECOND | Molecular Pharmaceutics (Nano Tech and Targeted DDS) | MPH 201T | * | | * | * | | * | | * | * | * | * | | | | * | 4 |
| | Advanced | MPH | * | | | | * | | * | * | * | * | | | | * | * | 4 |

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### Outcome based Curriculum for

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|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | Biopharmaceutics & Pharmacokinetics | 202T | | | | | | | | | | | | | | | | |
| | Computer Aided Drug Delivery System | MPH 203T | * | * | * | * | * | * | * | * | * | * | * | | | | * | 4 |
| | Cosmetic and Cosmeceuticals | MPH 204T | * | | * | * | | * | | * | * | * | * | | | | * | 4 |
| | Pharmaceutics Practical II | MPH 205T | * | | * | * | | * | | * | * | * | * | | | | * | 6 |
| | Seminar /Assignment | MPH 206T | | | | | | | | | | | | | | | | 4 |
| | **Total** | | | | | | | | | | | | | | | | | **26** |
| **THIRD** | Research Methodology and Biostatistics | MPH 301T | * | * | * | * | * | * | * | * | * | * | * | * | * | * | * | 4 |
| | Journal Club | MPH 302T | * | * | * | * | * | * | * | * | * | * | * | * | * | * | * | 1 |
| | Discussion / Presentation (Proposal Presentation) | MPH 303T | * | * | * | * | * | * | * | * | * | * | * | * | * | * | * | 2 |
| | Research work | MPH 304P | * | * | * | * | * | * | * | * | * | * | * | * | * | * | * | 14 |
| | **Total** | | | | | | | | | | | | | | | | | 21 |
| **FOURTH** | Journal club | MPH 401T | * | * | * | * | * | * | * | * | * | * | * | * | * | * | * | 1 |
| | Discussion / Final Presentation | MPH 402T | * | * | * | * | * | * | * | * | * | * | * | * | * | * | * | 3 |
| | Research work and Colloquium | MPH 403P | * | * | * | * | * | * | * | * | * | * | * | * | * | * | * | 16 |

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## Course Outcomes Pharmaceutics: (Cos)

| SEMESTER | SUBJECT CODE | SUBJECT | OUTCOME |
|---|---|---|---|
| FIRST | MPH 101T | Modern Pharmaceutical Analytical Techniques | **Cos1:** To understand the basic knowledge on assay of single and multiple component pharmaceuticals by using various analytical instruments. To develop basic practical skills using instrumentation techniques Skills in selecting the suitable techniques for analysis of drugs and pharmaceuticals To expand the theoretical knowledge on various instrumental techniques available for analysis of organic substances. To apply the knowledge learnt in developing new procedures of their own design. Comparing various methods of analysis and their outcomes |
| | MPH 102T | Drug Delivery System | **Cos2:** To understand the Principles & Fundamentals in development on novel drug delivery systems. To understand the various approaches for development of novel drug delivery systems. To understand the criteria for selection of drugs and polymers for the development of delivering system. To understand the formulation and evaluation of Novel drug delivery systems |
| | MPH 103T | Modern Pharmaceutics | **Cos3:** To understand the elements of preformulation studies and to optimization techniques in pharmaceutical formulation and processing. To Understand the Pharmaceutical Validation, policies of current good manufacturing practices and concept of Total Quality Management. To understand the Physics of tablet compression, Dissolution parameters and Pharmacokinetic parameter and linearity Concept of significance. |

| | | | |
|---|---|---|---|
| | MPH 104T | Regulatory Affair | **Cos4:** To know, the concepts of innovator and generic drugs, drug development process, regulatory guidance‟s and guidelines for filing and approval process and documentation in pharmaceutical industry. To know, Preparation of dossiers and their submission to regulatory agencies in different countries. To Know about the post approval regulatory requirements for actives and drug products and submission of global documents in CTD/ eCTD formats. To Know about the clinical trials requirements for approvals for conducting clinical trials pharmacovigilence and process of |
| | MPH 105P | Pharmaceutics Practical I | **Cos5:** Analysis of pharmacopoeial compounds and their formulations by UVV is spectrophotometer/HPLC/Gas Chromatography. To carry out formulation and evaluation of sustained release matrix tablets. To carry out the formulation and evaluation of Trans dermal patches preformulation studies of tablets, effect of compressional force and to plot Heckal plot, Higuchi and peppas factors. |
| | MPH 201T | Molecular Pharmaceutics (Nano Tech and Targeted DDS) | **Cos6:** To know the basic concepts of Targeting and Targeted Drug Delivery Systems. To know the preparation and evaluation of Micro Capsules / Micro Spheres/ Niosomes, Aquasomes. To know the preparation and evaluation of Pulmonary Drug Delivery Systems. To know the preparation and evaluation of Veterinary Drug Delivery Systems. |

| | | | |
|---|---|---|---|
| **SECOND** | MPH 202T | Advanced Biopharmaceutics and pharmacokinetics | **Cos7:** To know the basic concepts in biopharmaceuticsand pharmacokinetics. To Know the use raw data and de rive the pharmacokinetic models and parameters the best describe the process of drug absorption, distribution, metabolism and elimination. To Know the critical evaluation of biopharmaceutic studies involving drug product equivalency. To Know the design and evaluation of dosage regimens of the drugs using pharmacokinetic and biopharmaceutic parameters and potential clinical pharmacokinetic problems and application of basics of pharmacokinetic. |
| | MPH 203T | Computer Aided Drug Delivery System | **Cos8:** To Know the history of Computers in Pharmaceutical Research and Development. To Know the computational Modeling of Drug Disposition. To Know the computers in Preclinical Development. To Know the optimization Techniques in Pharmaceutical Formulation. |
| | MPH 204T | Cosmetic and Cosmeceuticals | **Cos9:** To know, regulatory requirement of cosmetics product and biological aspects of skin, hair and oral cavity with their problems and remedial formulation.<br>To know, Key ingredients used in cosmetics and cosmeceuticals and key building blocks for various formulations. Know about the current technologies in the market and various key ingredients and basic science to develop and design cosmetics and cosmeceuticals. Know about the scientific knowledge to develop herbal cosmetics and cosmeceuticals with desired safety, stability, and efficacy. |

| | | | |
|---|---|---|---|
| | MPH 205P | Pharmaceutics Practical II | **Cos10:** To Know and Carry out the formulation and evaluation of novel drug delivery systems such as: Alginate beads/ liposomes/Neosomes. To Know and Carry out the Solubility studies and Bioavailability studies of many drugs. To Know and carry out the development and evaluation of cosmetic formulations such as: Creams/Shampoo and Toothpaste etc.<br>To Know and carry out the Formulation data analysis Using Design Expert®Software and Computer Simulations studies. |
| **THIRD** | MPH 301T | Research Methodology and Biostatistics | **Cos11:** To know and recollect transport mechanisms and factors affecting absorption, distribution, metabolism and excretion. To analyze and evaluate protein drug binding, drug-drug, drug – food interaction and clearance.<br>To know and evaluate bioavailability and bioequivalence. To evaluate pharmacokinetic parameters in compartment modelling and non-linear pharmacokinetics. |
| | MPH 302T | Journal Club | **Cos12:** To know the Implementation journal clubs, group discussions, participation in laboratory and experimental work and involvement in research studies in the concerned speciality and exposure to the applied aspects of the subject relevant to the specialties. |
| | MPH 303T | Discussion / Presentation (Proposal Presentation) | **Cos13:** To know the Implementation group discussions, participation in laboratory and experimental work and involvement in research studies in the concerned speciality and exposure to the applied aspects of the subject relevant to the specialties. |

| | | | |
|---|---|---|---|
| | MPH 304P | Research work | **Cos14:** To understand about the research work under the guidance of a Teacher, Work for writing the Thesis is aimed at contributing to the development of a spirit of enquiry, besides exposing the candidate to the techniques of research, critical analysis, acquaintance with the latest advances in medical science and the manner of identifying and consulting available literature. |

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## Co's and Po's Mapping of Pharmaceutics

| Semester | M. Pharma (Pharmaceutics) | Programme Outcomes | | | | | | | | | | Specific Programme outcomes | | | | | Course Outcom |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | POs-1 | POs-2 | POs-3 | POs-4 | POs-5 | POs-6 | POs-7 | POs-8 | POs-9 | POs-10 | PSO-1 | PSO-2 | PSO-3 | PSO-4 | PSO-5 | |
| FIRST | Modern Pharmaceutical Analytical Techniques | * | | | | | | | * | * | * | * | | | | * | Cos1 |
| | Drug Delivery System | * | | * | * | | * | | * | * | * | * | * | | | * | Cos2 |
| | Modern Pharmaceutics | * | * | * | * | | * | | * | * | * | | * | | | * | Cos3 |
| | Regulatory Affair | | | | | | | | | * | * | | | * | | | Cos4 |
| | Pharmaceutics Practical I | * | | * | * | | * | | * | * | * | * | | | | * | Cos5 |
| | | | | | | | | | | | | | | | | | |
| SECOND | Molecular Pharmaceutics (Nano Tech and Targeted DDS) | * | | * | * | | * | | * | * | * | * | | | | * | Cos6 |
| | Advanced Biopharmaceutics & Pharmacokinetics | * | | | | | | * | * | * | * | | | | * | * | Cos7 |
| | Computer Aided Drug Delivery System | * | * | * | * | * | * | * | * | * | * | * | | | | * | Cos8 |
| | Cosmetic and Cosmeceuticals | * | | * | * | | * | | * | * | * | * | | | | * | Cos9 |
| | Pharmaceutics Practical II | * | | * | * | | * | | * | * | * | * | | | | * | Cos10 |
| | | | | | | | | | | | | | | | | | |
| THIRD | Research Methodology and Biostatistics | * | * | * | * | * | * | * | * | * | * | * | * | * | * | * | Cos11 |
| | Journal Club | * | * | * | * | * | * | * | * | * | * | * | * | * | * | * | Cos12 |
| | Discussion / Presentation | * | * | * | * | * | * | * | * | * | * | * | * | * | * | * | Cos13 |

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|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | (Proposal Presentation) | | | | | | | | | | | | | | | | |
| | Research work | * | * | * | * | * | * | * | * | * | * | * | * | * | * | * | Cos14 |
| | | | | | | | | | | | | | | | | | |
| **FOURTH** | Journal club | * | * | * | * | * | * | * | * | * | * | * | * | * | * | * | Cos12 |
| | Discussion / Final Presentation | * | * | * | * | * | * | * | * | * | * | * | * | * | * | * | Cos13 |
| | Research work and Colloquium | * | * | * | * | * | * | * | * | * | * | * | * | * | * | * | Cos14 |

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**Outcome based Curriculum for Postgraduate Degree Courses in Pharmacy**

**Scheme of Studies: Pharmaceutics**

**Table 1-: Course of study for semester I**

| Course Code | Course Title | CONTENT TREATMENT MODE | | | | | CREDITS | MARKS |
|---|---|---|---|---|---|---|---|---|
| | | Lectures/Week | Assignment & Seminar Presentations | ICT enabled Learning | Practicals | Works-hops | | |
| MPH 101T | Modern Pharmaceutical Analytical Techniques | 4 | - | NA | - | NA | 4 | 100 |
| MPH 102T | Drug Delivery System | 4 | - | NA | - | | 4 | 100 |
| MPH 103T | Modern Pharmaceutics | 4 | - | NA | - | | 4 | 100 |
| MPH 104T | Regulatory Affair | 4 | - | NA | - | | 4 | 100 |
| MPH 105P | Pharmaceutics Practical I | - | - | NA | 12 | | 6 | 150 |
| MPH 106P | Seminar /Assignment | - | 7 | NA | - | | 4 | 100 |
| Total | | | | | | | 26 | 650 |

**Table 2-: Course of study for semester II**

| Course Code | Course Title | CONTENT TREATMENT MODE | | | | | CREDITS | MARKS |
|---|---|---|---|---|---|---|---|---|
| | | Lectures/Week | Assignment & Seminar Presentations | ICT enabled Learning | Practicals | Works-hops | | |
| MPH 201T | Molecular Pharmaceutics (Nano Tech and Targeted DDS) | 4 | - | NA | - | NA | 4 | 100 |
| MPH 202T | Advanced Biopharmaceutics & Pharmacokinetics | 4 | - | NA | - | | 4 | 100 |
| MPH 203T | Computer Aided Drug Delivery System | 4 | - | NA | - | | 4 | 100 |
| MPH 204T | Cosmetic and Cosmeceutic als | 4 | - | NA | - | | 4 | 100 |
| MPH 205P | Pharmaceutics Practical II | - | - | NA | 12 | | 6 | 150 |
| MPH 206P | Seminar /Assignment | - | 7 | NA | - | | 4 | 100 |
| | | | | | | Total | 26 | 650 |

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**Table 4-: Course of study for semester III**

| Course Code | Course Title | CONTENT TREATMENT MODE | | | | | CREDITS | MARKS |
|---|---|---|---|---|---|---|---|---|
| | | Lectures/Week | Assignment & Seminar Presentations | ICT enabled Learning | Practicals | Works-hops | | |
| MPH 301T | Research Methodology and Biostatistics* | 4 | | NA | - | NA | 4 | 100 |
| MPH 302T | Journal Club | 1 | | - | - | | 1 | 25 |
| MPH 303T | Discussion / Presentation (Proposal Presentation) | - | 2 | - | - | | 2 | 50 |
| MPH 304P | Research work* | - | 14 | - | - | | 14 | 350 |
| | | | | | | Total | 21 | 525 |

**Table 4-: Course of study for semester IV**

| Course Code | Course Title | CONTENT TREATMENT MODE | | | | | CREDITS | MARKS |
|---|---|---|---|---|---|---|---|---|
| | | Lectures/Week | Assignment & Seminar Presentations | ICT enabled Learning | Practicals | Works-hops | | |
| MPH 401T | Journal Club | 1 | | - | - | | 1 | 25 |
| MPH 402T | Discussion / Presentation (Proposal Presentation) | - | 3 | - | - | | 3 | 75 |
| MPH 403P | Research work* | - | 16 | - | - | | 16 | 400 |
| Total | | | | | | | 20 | 650 |

# DEPARTMENT OF PHARMACY

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| | | | | |
|---|---|---|---|---|
| **MPH 101T** | **Modern Pharmaceutical Analytical Techniques** | **4L:0T:0P** | **4 credits** | **4Hrs/Week** |

## MODERN PHARMACEUTICAL ANALYTICAL TECHNIQUES

**Scope: This** subject deals with various advanced analytical instrumental techniques for identification, characterization and quantification of drugs. Instruments dealt are NMR, Mass spectrometer, IR, HPLC, GC etc.

**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.

**THEORY** 60 Hrs

1 a. UV-Visible spectroscopy: Introduction, Theory, Laws, Instrumentation associated with UV-Visible spectroscopy, Choice of solvents and solvent effect and Applications of UV-Visible spectroscopy. — 11 Hrs

b. 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

c. Spectroflourimetry: Theory of Fluorescence, Factors affecting fluorescence, Quenchers, Instrumentation and Applications of fluorescence spectrophotometer.

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

2 NMR spectroscopy: Quantum numbers and their role in NMR, Principle, Instrumentation, Solvent requirement in NMR, Relaxation process, NMR signals in various compounds, Chemical shift, Factors influencing chemical shift, Spin-Spin coupling, Coupling constant, Nuclear magnetic double resonance, Brief outline of principles of FT-NMR and 13C NMR.Applications of NMR spectroscopy. — 11 Hrs

3 Mass Spectroscopy: Principle, Theory, Instrumentation of Mass Spectroscopy, Different types of ionization like electron impact, chemical, field, FAB and MALDI, APCI, ESI, APPI Analyzers of Quadrupole and Time of Flight, Mass fragmentation and its rules, Metastable ions, Isotopic peaks and Applications of Mass spectroscopy — 11 Hrs

| | | |
|---|---|---|
| 4 | Chromatography: Principle, apparatus, instrumentation, chromatographic parameters, factors affecting resolution and applications of the following:<br>a) Paper chromatography<br>b) Thin Layer chromatography<br>c) Ion exchange chromatography<br>d) Column chromatography<br>e) Gas chromatography<br>f) High Performance Liquid chromatography<br>g) Affinity chromatography | 10 Hrs |
| 5 | a. Electrophoresis: Principle, Instrumentation, Working conditions, factors affecting separation and applications of the following:<br>a) Paper electrophoresis b) Gel electrophoresis c) Capillary electrophoresis d) Zone electrophoresis e) Moving boundary electrophoresis f) Iso electric focusing<br>b. X ray Crystallography: Production of X rays, Different X ray diffraction methods, Bragg,,s law, Rotating crystal technique, X ray powder technique, Types of crystals and applications of Xray diffraction. law, Rotating crystal technique, X ray powder technique, Types of crystals and applicationsof Xray diffraction. | 11 Hrs |
| 6 | Immunological assays : RIA (Radio immuno assay), ELISA, Bioluminescence assays. | 05 Hrs |

**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, 4th 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.

Pharmaceutical Analysis- Modern methods – Part B - J W Munson, Volume 11, Marcel Dekker Series

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|---|---|---|---|---|
| **MPH 102T** | **Drug Delivery Systems** | **4L:0T:0P** | **4 credits** | **4Hrs/Week** |

### DRUG DELIVERY SYSTEMS (MPH 102T)

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

**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..

**THEORY** 60 Hrs

| | | |
|---|---|---|
| 1 | 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. 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. | 10 Hrs |
| 2 | 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. | 10 Hrs |
| 3 | Gastro-Retentive Drug Delivery Systems: Principle, concepts advantages and disadvantages, Modulation of GI transit time approaches to extend GI transit. Buccal Drug Delivery Systems: Principle of muco adhesion, advantages and disadvantages, Mechanism of drug permeation, Methods of formulation and its evaluations. | 10 Hrs |
| 4 | Occular Drug Delivery Systems: Barriers of drug permeation, Methods to overcome barriers | 06 Hrs |
| 5 | Transdermal Drug Delivery Systems: Structure of skin and barriers, Penetration enhancers, Transdermal Drug Delivery Systems, Formulation and evaluation. | 10 Hrs |
| 6 | Protein and Peptide Delivery: Barriers for protein delivery. Formulation and Evaluation of delivery systems of proteins and other macromolecules. | 08 Hrs |
| 7 | Vaccine delivery systems: Vaccines, uptake of antigens, single shot vaccines, mucosal and transdermal delivery of vaccines. | 06 Hrs |

**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 WileyInterscience 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 Prakashan, 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.

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|---|---|---|---|---|
| **MPH 103T** | **Modern Pharmaceutics** | **4L:0T:0P** | **4 credits** | **4Hrs/Week** |

## MODERN PHARMACEUTICS (MPH 103T)

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

**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

**THEORY** 60 Hrs

| | | |
|---|---|---|
| 1 | a. Preformation Concepts – Drug Excipient interactions - different methods, kinetics of stability, Stability testing. Theories of dispersion and pharmaceutical Dispersion (Emulsion and Suspension, SMEDDS) preparation and stability Large and small volume parental – physiological and formulation consideration, Manufacturing and evaluation.<br>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 | 10 Hrs |
| 2 | Validation: Introduction to Pharmaceutical Validation, Scope & merits of 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<br>Process Model, URS, DQ, IQ, OQ & P.Q. of facilities. | 10 Hrs |
| 3 | cGMP & Industrial Management: Objectives and policies of current good manufacturing practices, 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. | 10 Hrs |
| 4 | Compression and compaction: Physics of tablet compression, compression, consolidation, effect of friction, distribution of forces, compaction profiles. Solubility | 10 Hrs |

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| 5 | 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. | 10 Hrs |

**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.

# DEPARTMENT OF PHARMACY

## SRI SATYA SAI UNIVERSITY OF TECHNOLOGY AND MEDICAL SCIENCES

**Outcome based Curriculum for**

**Postgraduate Degree Courses in Pharmacy**

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| **MPH 104T** | **Regulatory Affairs** | **4L:0T:0P** | **4 credits** | **4Hrs/Week** |

## REGULATORY AFFAIRS (MPH 104T)

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

- To know the approval process of
- To know the chemistry, manufacturing controls and their regulatory importance
- To learn the documentation requirements for
- To learn the importance and

**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
- Pharmacovigilence and process of monitoring in clinical trials.

**THEORY** 60 Hrs

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|---|---|---|
| 1 | a. 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) ,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.<br>b. Regulatory requirement for product approval: API, biologics, novel, therapies obtaining<br>NDA, ANDA for generic drugs ways and means of US registration for foreign drugs | 12 Hrs |
| 2 | 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. Regulatory requirements of EU, MHRA, TGA and ROW countries. | 12 Hrs |
| 3 | Non clinical drug development: Global submission of IND, NDA, ANDA. Investigation of medicinal products dossier, dossier (IMPD) and investigator brochure (IB). | 12 Hrs |

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| 4 | 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. | 12 Hrs |

**REFERENCES**


1. Generic Drug Product Development, Solid Oral Dosage forms, Leon Shargel and IsaderKaufer,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.

# DEPARTMENT OF PHARMACY

## SRI SATYA SAI UNIVERSITY OF TECHNOLOGY AND MEDICAL SCIENCES

**Outcome based Curriculum for**

**Postgraduate Degree Courses in Pharmacy**

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| **MPH 105P** | **Pharmaceutics** | **0L:0T:12P** | **6 credits** | **12Hrs/Week** |

## PHARMACEUTICS PRACTICALS - I (MPH 105P)

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 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 Muco adhesive 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.

# DEPARTMENT OF PHARMACY

## SRI SATYA SAI UNIVERSITY OF TECHNOLOGY AND MEDICAL SCIENCES

**Outcome based Curriculum for**
**Postgraduate Degree Courses in Pharmacy**

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| **MPH 201T** | **Molecular Pharmaceutics (Nano Technology & Targeted DDS) (NTDS)** | **4L:0T:0P** | **4 credits** | **4Hrs/Week** |

## MOLECULAR PHARMACEUTICS (NANO TECHNOLOGY & TARGETED DDS) (NTDS) MPH 201T

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

**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.

**THEORY** **60 Hrs**

**1. Targeted Drug Delivery Systems:** **12 hrs**

Concepts, Events and biological process involved in drug targeting. Tumor targeting and Brain specific delivery.

**2. Targeting Methods:** **12 hrs**

Introduction preparation and evaluation. Nano Particles & Liposomes: Types, preparation and evaluation

**3. Micro Capsules / Micro Spheres:** **12 Hrs**

Types, preparation and evaluation, Monoclonal Antibodies; preparation and application, preparation and application of Niosomes, Aquasomes, Phytosomes, Electrosomes.

**4. Pulmonary Drug Delivery Systems :** **12 Hrs**

Aerosols, propellants, Containers Types, preparation and evaluation, Intra Nasal Route Delivery systems; Types, preparation and evaluation.

**5. Nucleic Acid Based Therapeutic Delivery System:** **12 Hrs**

Gene therapy, introduction (ex-vivo & in-*vivo* gene therapy). Potential target diseases for gene therapy (inherited disorder and cancer). Gene expression systems (viral and non-viral gene transfer). Liposomal gene delivery systems. Bio-distribution 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, 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).

# DEPARTMENT OF PHARMACY

## SRI SATYA SAI UNIVERSITY OF TECHNOLOGY AND MEDICAL SCIENCES

**Outcome based Curriculum for**

**Postgraduate Degree Courses in Pharmacy**

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| **MPH 202T** | **Advanced Biopharmaceutics & Pharmacokinetics** | **4L:0T:0P** | **4 credits** | **4Hrs/Week** |

## ADVANCED BIOPHARMACEUTICS & PHARMACOKINETICS MPH 202T

**Scope: -** This course is designed to impart knowledge and skills necessary for dose calculations, dose adjustments and to apply bio-pharmaceutics theories in practical problem solving. Basic theoretical discussions of the principles of bio-pharmaceutics and pharmacokinetics are provided to help the students" to clarify the concepts.

**Objectives: -** Upon completion of this course it is expected that students will be able understand.

1. The basic concepts in bio-pharmaceutics 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

**THEORY** **60 Hrs**

1. **Drug Absorption from the Gastrointestinal Tract:** **12Hrs**

   Gastrointestinal tract, Mechanism of drug absorption, 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.

2. **Biopharmaceutic considerations in drug product design and In vitro Drug Product Performance:** **12 Hrs**

   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. In vitro–in vivo correlation, dissolution profile comparisons, drug product stability, considerations in the design of a drug product.

**3. Pharmacokinetics: 12 Hrs**

Basic considerations, pharmacokinetic models, compartment modeling: 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 $k_{max}$ and $v_{max}$. 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.

**4. Drug Product Performance, *In Vivo*: 12Hrs**

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, 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.

**5. Application of Pharmacokinetics: 12hrs**

Modified-Release Drug Products, Targeted Drug Delivery Systems and Biotechnological Products. Introduction to Pharmacokinetics and pharmacodynamic, drug interactions. Pharmacokinetics and pharmacodynamics of biotechnology drugs. Introduction, Proteins and peptides, Monoclonal antibodies, Oligonucleotides, Vaccines (immunotherapy), Gene therapies.

**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. Jaiswal., Vallabh Prakashan, Pitampura, Delhi.
3. Applied Biopharmaceutics and Pharmacokinetics by Shargel. Land YuABC, 2nd edition, Connecticut Appleton Century Crofts, 1985.
4. Textbook of Biopharmaceutics and Pharmacokinetics, Dr. Shobha Rani R. Hiremath, Prism Book Pharmacokinetics by Milo Gibaldi and D. Perrier, 2nd edition, Marcel Dekker Inc., New York, 1982
5. Current Concepts in Pharmaceutical Sciences: Biopharmaceutics, Swarbrick. J, Leaand Febiger, Philadelphia, 1970.
6. Clinical Pharmacokinetics, Concepts and Applications 3rd edition by Malcolm Rowland and Thom~ N. Tozer, Lea and Febiger, Philadelphia, 1995.
7. Dissolution, Bioavailability and Bioequivalence, Abdou. H.M, Mack Publishing Company, Pennsylvania 1989.
8. Biopharmaceutics and Clinical Pharmacokinetics, An Introduction, 4th edition, revised and expande by Robert. E. Notari, Marcel Dekker Inc, New York and Basel, 1987.
9. Biopharmaceutics and Relevant Pharmacokinetics by John. G Wagner and M. Pemarowski, 1st edition, Drug Intelligence Publications, Hamilton, Illinois, 1971.
10. Encyclopedia of Pharmaceutical Technology, Vol 13, James Swarbrick, James. G.Boylan, Marcel Dekker Inc, New York, 1996.
11. Basic Pharmacokinetics, 1st edition,Sunil S JambhekarandPhilip J Breen,pharmaceutical press, RPS Publishing, 2009.
12. Absorption and Drug Development- Solubility, Permeability, and Charge State, Alex Avdeef, John Wiley & Sons, Inc, 2003.

# DEPARTMENT OF PHARMACY

## SRI SATYA SAI UNIVERSITY OF TECHNOLOGY AND MEDICAL SCIENCES

**Outcome based Curriculum for**

**Postgraduate Degree Courses in Pharmacy**

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| **MPH 203T** | **Computer Aided Drug Development** | **4L:0T:0P** | **4 credits** | **4Hrs/Week** |

## COMPUTER AIDED DRUG DEVELOPMENT

**Scope:** 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:** Upon completion of this course it is expected that students will be able to Understand.

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. Computers in Clinical Development
7. Artificial Intelligence (AI) and Robotics
8. Computational fluid dynamics(CFD)

**THEORY** **60 Hrs**

1. **a. Computers in Pharmaceutical Research and Development:** **12 hrs**

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 $Q_8$ guideline, Regulatory and industry views on $Q_bD$, Scientifically based $Q_bD$-examples of application.]

2. **Computational Modeling of Drug Disposition: Introduction, Modeling Techniques:** **12 hrs**

Drug Absorption, Solubility, Intestinal Permeation, Drug Distribution ,Drug Excretion, Active Transport; P-gp, BCRP, Nucleoside Transporters, hPEPT1, ASBT, OCT, OATP, BBB- Choline Transporter.

**3. Computer-Aided Formulation Developments: 12Hrs**

Concept of optimization, Optimization parameters, Factorial design, Optimization technology & Screening design. Computers in Pharmaceutical Formulation: Development of pharmaceutical emulsions, micro emulsion drug carriers Legal Protection of Innovative Uses of Computers in R&D, The Ethics of Computing in Pharmaceutical Research, Computers in Market analysis**.**

**a) Computer-aided biopharmaceutical characterization: 12Hrs**

Gastrointestinal absorption simulation. Introduction, Theoretical background, Model construction, Parameter sensitivity analysis, Virtual trial, Fed vs. fasted state, In vitro dissolutionand in vitro in vivo correlation, Bio waiver 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.

**4. Artificial Intelligence (AI), Robotics and Computational fluid dynamics:**

**12**Hrs

General overview, Pharmaceutical Automation, Pharmaceutical applications, Advantages and Disadvantages. Current Challenges and Future Directions.

**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.

# DEPARTMENT OF PHARMACY

## SRI SATYA SAI UNIVERSITY OF TECHNOLOGY AND MEDICAL SCIENCES

**Outcome based Curriculum for**
**Postgraduate Degree Courses in Pharmacy**

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| **MPH 204T** | **Cosmetics and Cosmeceuticals** | **4L:0T:0P** | **4 credits** | **4Hrs/Week** |

## COSMETICS AND COSMECEUTICALS

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

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

**a.** Key ingredients used in cosmetics and cosmeceuticals.

**b.** Key building blocks for various formulations.

**c.** Current technologies in the market

**d.** Various key ingredients and basic science to develop cosmetics and cosmeceuticals

**e.** Scientific knowledge to develop cosmetics and cosmeceuticals with desired Safety, stability, and efficacy.

**THEORY** **60 Hrs**

**1. Cosmetics-Regulatory:** **12 Hrs**

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.

**2. Cosmetics -Biological aspects:** **12 Hrs**

**3.** 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.

**4. Formulation Building blocks:** **12 Hrs**

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 syndetbars.

Perfumes; Classification of perfumes. Perfume ingredients listed as allergens in EU regulation.

**Controversial ingredients:** Parabens, formaldehyde liberators, dioxane.

**5. Design of Cosmeceutical products: 12 Hrs**

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.

**6. Herbal Cosmetics: 12 Hrs**

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‟s perfume cosmetics and Soaps, 10th edition.
3. Cosmetics - Formulation, Manufacture and quality control, PP.Sharma,4th edition.
4. Handbook of cosmetic science and Technology A.O.Barel, M.Paye and H.I. Maibach. 3 rd edition
5. Cosmetic and Toiletries recent suppliers‟ catalogue.
6. CTFA directory.

# DEPARTMENT OF PHARMACY

## SRI SATYA SAI UNIVERSITY OF TECHNOLOGY AND MEDICAL SCIENCES

**Outcome based Curriculum for**

**Postgraduate Degree Courses in Pharmacy**

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| **MPH 205P** | **PharmaceuticS Practicals** | **0L:0T:12P** | **6 credits** | **12Hrs/Week** |

## PHARMACEUTICS PRACTICALS

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.

# MASTER OF PHARMACY

## SRI SATYA SAI UNIVERSITY OF TECHNOLOGY AND MEDICAL SCIENCES

**Outcome based Curriculum**

**for Postgraduate Degree Courses in Pharmacy**

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| **MPH301T** | **Research Methodology & Biostatistics** | **4L:0T:0P** | **4 credits** | **4Hrs/Week** |

### MPH301T/MPL301T - Research Methodology & Biostatistics

**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.