# SCHEME OF INSTRUCTION, EXAMINATION AND EVALUATION

**Program Code: 886**  
**M. Pharm. (Pharmaceutics)**  
**2015 – 16**

## SEMESTER - I

<table>
<thead>
<tr>
<th>Course Code</th>
<th>Course Title</th>
<th>Hours /Week</th>
<th>Credits</th>
<th>Marks</th>
<th>Duration of Exam</th>
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<tr>
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<td>Pharmaceutical Analytical Techniques</td>
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<td>Pharmaceutical Product Development</td>
<td>4 L 0 T 4 P</td>
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* *Discipline Centric – Cosmetic Technology/Drug Polymer Technology; Open – Pharmaceutical Biotechnology*

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|                |                              | 510         | 24      | 300   | 17                |
PHARMACEUTICAL ANALYTICAL TECHNIQUES

Scheme of Instruction

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Course Objectives:
To familiarize students in conventional and modern techniques of analysis used in different areas of pharmacy.
To understand the experimental concepts, the procedures and safety considerations in a quality control lab.
To give training in use of the technique and its applications in day to day practice.
To build on the basics learned at UG level and give latest advances in the area.

Course Outcomes:
By pursuing this course students are prepared for:
- Research and Development
- Food, Bio and Pharma Industries
- Clinical Research and Quality Control Administration

Unit - I:


Unit - II:

Mass Spectrometry: Basic principles Mass Spectrometry. Ionization techniques (EI and CI), Mass spectrum and its characteristics, molecular ion, metastable ions, fragment ions; fragmentation processes, Nitrogen Rules, Relative abundances of isotopes and their contribution to characteristic peaks and molecular formula determination.

Unit - III:
Chromatographic Techniques: General Principles, Classification of Chromatographic Methods Thin Layer Chromatography, Paper Chromatography and Column Chromatography and Methods based on Mechanism.

Gas Chromatography: Instrumentation, Column efficiency parameters, derivatization methods, applications in pharmaceutical analysis.

Unit - IV :

Electrophoresis: Principles, Instrumentation and Applications of Moving Boundary Electrophoresis Zone Electrophoresis (ZE), Isoelectric Focusing (IEF), Continuous Electrophoresis (Preparative) and Capillary Electrophoresis. SDS Gel Electrophoresis and Blotting Techniques.

Radio Immunoassay and ELISA: Principle, Instrumentation, Applications and Limitations.

Unit - V :

X-Ray Spectroscopy: Origin of X-rays, basic aspects of crystals, X-ray crystallography, miller indices, rotating crystal technique, single crystal diffraction, powder diffraction, structural elucidation and applications.

Thermal Analytical Techniques: Principles, Theory and Application of Thermal Analysis (DSC, DTA and TGA)

Books and References:

PHARMACEUTICAL PRODUCT DEVELOPMENT

Course Objectives:
This subject imparts overall theoretical knowledge on formulation development of dosage forms and its stability. The student learn about various physical and pharmaceutical parameter/properties of raw materials, drug substances and excipients to be studied and optimized in the pharmaceutical product development.

Course Outcomes:
The students after undergoing their course work shall become thorough in understanding the influence of various physical and pharmaceutical properties of drug substance, raw material and excipients. They shall become aware of various parameters to be studied and number of experiments to be conducted to develop the optimized formulation of drugs and pharmaceuticals.

Unit - I :
Pre-formulation (API): Influence of melting point, dissociation constant, pharmaceutical salts and hygroscopicity, physical forms of drugs, Methods of preparation and characterization.
Product Design and Specifications: Design, Laying Down and Optimization of Materials and Products Specifications, Process and In-Process Controls;

Unit - II :
Pre-formulation (Excipients Science): Tablet excipients, factors influencing selection of excipients, directly compressible excipients, co-processing of excipients, determination of functionality tests of excipients, flow properties, compression properties, drug-excipient compatibility, methods of evaluations;
Formulation Additives: Study of different types of additives e.g. antioxidants and preservatives, coloring and flavoring agents, emulsifying and suspending agents, basic materials for ointment bases, diluents and pharmaceutical solvents,

Unit - III :
Solubility: Importance, experimental determination, aqueous solubility aspects in pre-formulation, intrinsic solubility, phase-solubility analysis, pH solubility profile, Solubility Improvement; Solubility Techniques, Co-Solvency, Salt-Formation, Complexation, Solid Dispersion;

Unit - IV :
Unit - V :


**Novel Products Development:** Nano-Pharmaceuticals - Generation and Significance of Nano-suspensions, Nano-gels, Nano-carrier Systems;

**Books and References:**

PHARMACEUTICAL PRODUCTION TECHNOLOGY

Scheme of Instruction

| Total Duration | 60 Hrs. |
| Hours/Week     | 4 Hrs.  |
| Credits        | 4       |
| Instruction Mode | Lecture |
| Course Code   | PY.09.886.13.T |

Scheme of Examination

| Max. Marks | 100 |
| Mid Semester | 20 |
| Quiz       | 05  |
| End Semester | 75 |
| Exam Duration | 3 Hrs. |

Course Objectives:
The students are given the emphasis on the production activities of pharmaceutical industry with general requirements and special emphasis on the equipment, process problems, including safety and environment concerns.

Course Outcomes:
The students should be able to explain the commercial production activities of different dosage forms of tablets, capsules, disperse systems, describe special requirements for the parenteral products, evaluate the status of safety and pollution, presenting them with specific programs in pharmaceutical industry.

Unit - I:
Improved Tablet Production: Tablet production process, unit operation improvements, granulation and palletization equipment, continuous and batch mixing, rapid mixing granulators, rota granulators, spheronizers and marumerisers, and other specialized granulation and drying equipment. Problems encountered.

Coating Technology: Process, equipment, particle coating, fluidized bed coating, application techniques. Problems encountered.

Unit - II:
Parenteral Production: Area planning & environmental control, wall and floor treatment, fixtures and machineries, change rooms, personnel flow, utilities & utilities equipment location, engineering and maintenance.


Unit - III:
Capsule Production: Production process, improved capsule manufacturing and filling machines for hard and soft gelatin capsules. Layout and problems encountered.

Disperse Systems Production: Production processes, applications of mixers, mills, disperse equipment including fine solids dispersion, Problems Encountered.

Unit - IV:
Packaging Technology: The packaging function, types of packaging materials, paper and board based, glass, plastics, metals, films, foils and laminations. Closures and closure system, packaging machinery including blister strips and sachet packaging, labeling of pharmaceutical packages, package printing and decoration, regulatory aspects of packaging.

Unit - V:
Air Handling Systems: Study of AHUs, humidity & temperature control, air filtration systems, dust collectors.

Pharmaceutical Water Systems: Sources, pretreatment, techniques and maintenance; types of waters; water treatment-ion exchange, reverse osmosis (RO), distillation, ultrafiltration, quality control, storage & distribution.

Books and References:
1. The theory & Practice of Industrial Pharmacy, L. Lachman, Varghese Publ, Bombay.
2. Modern Pharmaceutics by Banker, Vol 72, Marcel Dekker, NY.
3. Pharmaceutical Dosage Forms, Vol 1, 2, 3 by Lachman, Lieberman, Marcel Dekker, NY.
4. Pharmaceutical Dosage Forms, Parenteral Medications, Vol 1, 2 by K.E. Avis, Marcel Dekker, NY.
6. Dispersed System Vol 1, 2, 3 by Lachman, Lieberman, Marcel Dekker, NY.
10. Quality Control of Packaging Materials in Pharmaceutical Industry, Kharburn, Marcel Dekker, NY.
12. Tablet Machine Instrumentation in Pharmaceuticals, PR Watt, Ellis Harwood’s, UK.
ADVANCED PHYSICAL PHARMACEUTICS

Course Objectives:
The students are given the training on the physical and chemical properties of drugs and polymers, for their judicious application in the design of product and development, which facilitates the effective release of drugs in order to contribute to the development of drugs.

Course Outcomes:
The students should be able to explain the principles and methods for evaluation of particle size including nanoparticles and viscoelastic behavior of raw materials and products. The students should describe the factors and processes involved in compression; explain the physicochemical properties of polymer and their utility in the design, evaluation, and the efficient release of drugs from the novel drug delivery systems.

Unit - I:
Viscoelasticity: Oscillatory testing and behavior analysis, creep testing and behavior analysis, mechanical modeling of viscoelasticity, psycho-rheology
Advanced Methods of Particle Size Distribution: Particle characterization by size, shape and surface of individual particle and for contacted particle.
Drug Delivery Gels: Synthetic hydrogels— their preparation. Diffusion properties of swollen hydrogels;

Unit - II:
Physics of Tableting: General principles, compression, consolidation, decompression compaction at High Loads Forces Distribution during Compression, compaction profiles, forces in compression – measurement, energy involved in compaction, properties of granules for compression, properties related to machinery for compression, influence of compression force on the properties of tablets

Unit - III:
Surfactant System: Phase behavior of surfactant in binary and ternary systems. Factors affecting phase behavior; Micellization, micelle structure, shape, size factors affecting CMC and micelle size, thermodynamics and kinetics of micelle formation. Pharmaceutical aspects of Solubilization, Solubilization in non-aqueous system, interactions with polymers and oppositely charged species. Hydro trophy in pharmaceuticals, surfactants in emulsions and suspensions. Biological Implications; Effect on: dissolution of drugs, permeability of membranes, drug absorption, antibacterial activity, Cyclodextrin inclusion complexes and co-solvents

Unit - IV:
Unit - V


Books and References:
1. A. Kitahard and A. Watanabe; Electrical Phenomena at Interfaces; Marcel Dekker.
2. A. Martin, P. Bustamante and A. H. Chun; Physical Pharmacy; Waverly.
3. D. M. Parikh; Handbook of Pharmaceutical Granulation Technology; Marcel Dekker.
4. G. Alderborn and C. Nystrom; Pharmaceutical Powder Compaction Technology; Marcel Dekker.
5. H. G. Brittain; Physical Characterization of Pharmaceutical solids; Marcel Dekker.
6. J. T. Cartensen; Drug Stability; Marcel Dekker.
7. James J. Wells; Pharmaceutical Preformulation, Ellis Harwood Ltd.
8. Lieberman, Rieser and Banker; Pharmaceutical Dosage Forms; Disperse system; Marcel Dekker.
11. N. G. Stanley – Wooed; Enlargement and compaction of particle solids; Butterworths.
13. P. J. Tarcha; Polymer for Controlled Drug Delivery, CRC Press.
QUALITY ASSURANCE

Scheme of Instruction

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<th>Total Duration</th>
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Scheme of Examination

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<td>75</td>
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<tr>
<td>Exam Duration</td>
<td>3 Hrs.</td>
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Course Objectives:
Achieve comprehensive understanding and acquiring professional competency in global quality standards systems and regulatory requirements in the pharmaceutical industry.
Develop and implement a robust quality assurance system in an organization towards quality excellence.

Course Outcomes:
This subject is aimed at giving knowledge about concepts of quality assurance,
- Acquire knowledge on various quality assurance systems, processes and current regulatory guidelines related to manufacturing and distribution.
- Address quality issues and provide solutions needed to attain Quality leadership in an environment of continual improvement.
- Understand the importance of effective documentation and formula for various operating procedures in Pharmaceutical industry.

Unit - I :
Basic Quality Assurance Systems: Basic concept of quality control & quality assurance, functions, sources of variation, quality assurance for raw materials, APIs, packing materials & finished products (specifications, receipt, testing, sampling and certificate of analysis), production (change control, aseptic process control, temperature, pressure & humidity control tests, tests for air flow pattern, microbiological monitoring) buildings & facilities (design and construction features, construction materials, lighting, air handling systems, sanitation & maintenance) equipments (construction, cleaning and maintenance, calibration & handling).

Unit - II :
In-Process Quality Control: Importance, inspection, IPQC tests for tablets (weight variation, hardness, thickness, friability, disintegration tests and content uniformity), suspensions and emulsions (appearance and feel, volume check, viscosity, particle size distribution, electrical conductivity and content uniformity) and parenterals (pH, volume check, clarity, content uniformity, integrity of seals and particulate matter). Problems encountered and trouble shooting.

Unit - III :
Audits: GMP compliance audit, Definition summary, Audit policy, Internal and External Audits, Second Party Audits, External third party audits.

Unit - IV :
Documentation - Good Documentation Practices, Route Cause Analysis, Corrective Action Preventive Action (CAPA), Out of Specifications (OOS) and Out of Trend (OOT)
Unit - V:

Impurity Profile: Sources of impurities, their effect on drug stability and therapeutic action. Determination of impurities in bulk drugs and formulation - isolation, characterization, analytical methods and guidelines as per ICH and WHO for impurity and related substances, concept of purity angle, threshold and flag.

Study of Compendia: Evolution, study of parts of compendia like: policies, general notices, monographs, comparative picture of IP, USP and BP.

Books and References:
7. Mehra ML. Good Manufacturing Practices (GMP), University Book Agency.
9. Statistical Design and Analysis in Pharmaceutical Sciences, Marcel Dekker, NY.
10. D.A. Berry, Statistical Methodology in Pharmaceutical Science, Marcel Dekker, NY.
PHARMACEUTICAL ANALYTICAL TECHNIQUES

Course Objectives:
To make students familiar with the principles of modern analytical techniques and application of analytical instruments in pharmacy.

Course Outcomes:
At the end of the course, the student will be able to understand the fundamental concept of modern analytical techniques, which is important for qualitative as well as quantitative analysis of drug substances and drug product.

List of Experiments:
1. UV/Visible spectrum scanning of a few organic compounds for UV- absorption and correlations of structures (5 compounds) and isosbestic point in case of mixtures.
2. Effect of solvents and pH on UV spectrum of drugs (2 experiments).
3. Estimation of multicomponent formulation by UV- Spectrophotometer in formulations. (2 experiments).
4. Experiments based on the application of derivative spectroscopy. (2 experiments).
5. Experiments based on HPLC (Isocratic and Gradient elution) techniques. (2 experiments).
6. Interpretation of drugs by IR spectra.
7. Workshop of spectroscopy: (UV, IR, NMR, MASS) structural elucidation of at least 5 compounds (4 experiments).
9. Any other relevant experiments based on theory.

Books and References:
PHARMACEUTICAL PRODUCT DEVELOPMENT

Scheme of Instruction

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<td>75</td>
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<td>Exam Duration</td>
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Course Objectives:
To acquaint in analyzing the physical parameters required in pharmaceutical product development.

Course Outcomes:
To develop capacity to explain the differential principles applies to solve the physical parameters associated with product development.

List of Experiments:
1. Effect of surfactants on the solubility of drugs.
2. Effect of pH on the solubility of drugs.
3. Dissolution methods of transdermal drug delivery systems.
4. Dissolution studies of drug in three different bio-relevant dissolution media (2 experiments).
5. Effect of solid dispersion and hydrotropy on the dissolution.
6. Test for degradation of compounds using TLC for any two drugs.
7. Stability testing of solution and solid dosage forms for photo degradation (2 experiments).
8. Effect of hydrogen peroxide, hydrochloric acid and sodium hydroxide solutions on the stability of drugs in solution at elevated temperatures and room temperature. (2 experiments).
9. Stability studies of drugs in dosage forms at 25°C, 60% RH and 40°C, 75% RH.
10. Compatibility evaluation of drugs and excipients.
11. Product development and protocol preparation using preformulation data for tablets and capsules.
12. Dissolution of drugs in different pH media for comparison of performance with innovator.

Books and References:
INTELLECTUAL PROPERTY RIGHTS & REGULATORY AFFAIRS

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Course Objectives:

To make students familiar with the fundamental principles of IPR and Drug Regulatory Affairs

Course Outcomes:

On completion of the course the student would understand the principle and importance of IPR and Drug Regulatory Affairs in the Competitive World.

Further to familiarize with Safety and Pollution Control Regulations in addition to Other Product Regulations and Sustainable Development Principles.

Unit - I:


Unit - II:
International Patent Filing Procedures – Requirements for patenting, utility, novelty non-obviousness, patent specification & claims, patent infringement and doctrine of equivalents, federal circuit and patent system.


Unit - III:
ICH – Guidelines: Harmonization Efforts, Basic Principles (Quality, Safety and Efficacy), ICH Q11 (Quality Management Systems); Common Technical Document (CTD) and Generic Drug Products.

WHO – Guidelines: Sampling Operations

PICS Guidelines: Basic Requirements of Medicinal Products and API's

OECD Guidelines: Clinical Studies


Unit - IV:
Regulatory Affairs: Indian Context- Drugs and Cosmetics Act 1940 and Rules 1945 with reference to Schedule M, U and Y. Drug Regulatory Controls and Authorities;

Important Regulations: Import and Export of Drugs; Preparation and Submission of Marketing Application of India, US and Europe; Approval and Appeals Present and Issues of Confidentiality.
Unit - V

Industrial Safety Regulations: Industrial Development & Regulation Act 1951, Industrial Hazards – Mechanical, Electrical, Chemical and Pharmaceutical (MSDS Preparation), Industrial Safety - Plant, Gas, Dust, Fire and Explosion, Safety Management. Monitoring & Prevention Systems,

Pollution Control Regulations: Pollution Control Act; Industrial Effluent Testing & Treatment. Control of Environmental Pollution, Water and Solid Waste in Formulation, Synthetic and Fermentation Plants.

Other Product Regulations: Prevention of Food Adulteration Act 1954; Consumer Protection Act

Sustainable Development: 10 Principles Bench Marked against leading International Standards;

Books and References:

8. Original Laws Published by Government of India.
9. Hussain. Law of Drugs in India.
10. Regulatory Guidelines Related to GMP by
    b. 21 Code of Federal Regulation, parts 210, 211 & 58. (US-FDA Guidelines)
    c. MHRA, UK Guidelines on GMP
    d. GMP Guidelines by Medicines Control Council of South Africa
    e. Schedule M of D & C Act
13. PICS Guidelines (Website: http://www.picscheme.org/)
15. Relevant OECD Guidelines (Website: http://www.ingentaconnect.com/content/oecd/16073/2001/00000001/00000004)
**BIOPHARMACEUTICS AND PHARMACOKINETICS**

### Scheme of Instruction

- **Total Duration**: 60 Hrs.
- **Hours/Week**: 4 Hrs.
- **Credits**: 4
- **Instruction Mode**: Lecture
- **Course Code**: PY.09.886.22.T

### Scheme of Examination

- **Max. Marks**: 100
- **Mid Semester**: 20
- **Quiz**: 05
- **End Semester**: 75
- **Exam Duration**: 3 Hrs.

### Course Objectives:

To make students familiar with the fundamental principles of drug absorption, distribution, metabolism and excretion of drugs.

To emphasize on bioavailability study and application of biopharmaceuticals.

### Course Outcomes:

On completion of the course the student would understand the

- Drug absorption, distribution, metabolism, and elimination.
- Basic mechanisms and concepts of absorption, distribution, metabolism, and elimination.
- How to predict the fate of drugs in the body given all the physiological, chemical and physical parameters of the drug and the patient

### Unit - I: Bioavailability and Bioequivalence

- Objectives, bioavailability & variations, measurements of bioavailability, enhancing bioavailability, concepts of equivalents, official bioequivalence protocols & therapeutic equivalence.
- Methods of determining absorption-in-vitro, in-situ, and in-vivo methods.

### Unit - II: Pharmacokinetics

- Parameters & determination, pharmacokinetic models – one compartment, multi compartment in IV bolus, IV infusion & extra vascular, drug & metabolites levels in blood, urine and other biological fluids.
- Integration of kinetics; Application of pharmacokinetics in new drug development, design of dosage forms and novel drug delivery systems. Physiological basis for in-vitro modeling.

### Unit - III: Pharmacokinetics of Multiple Dosing

- Various terminology, determination, adjustment of dosage in renal & hepatic impairment, individualization of therapy, therapeutic drug monitoring.

### Unit - IV: Non-linear kinetics


### Unit - V: Drug Disposition and Excretion

- Factors affecting biotransformation, Phase I & Phase-II reactions.
- Clearance: Concept, renal, non-renal clearance, mechanism, determination, % drug metabolized, different volume of distribution.

### Books and References:


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Chairperson, BoS
Head of the Department
Dean of the Faculty
3. Theory & Practice of Industrial Pharmacy, L.Lachman, Varghese Publ, Bombay.
ADVANCES IN DRUG DELIVERY SYSTEMS

Course Objectives:
To get acquainted with applications of New Drug Delivery Systems.

Course Outcomes:
Students can select research based project in subsequent semesters for specific type of delivery systems. The knowledge gained by the students during the study of this course can also help them in research projects and in Pharma industry.

Unit - I :
Concept & Models for NDDS: Classification of rate controlled drug delivery systems (DDS), rate programmed release, activation modulated & feedback regulated DDS, effect of system parameters in controlled drug delivery, computation of desired release rate and dose for controlled release DDS, pharmacokinetic design for DDS – intermittent, zero order & first order release.

Unit - II :
Study of Various DDS: Concepts, design, formulation & evaluation of controlled release oral DDS, Muco-adhesive DDS (buccal, nasal, pulmonary).

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

Advances in Drug Delivery: Pulsatile, colon specific, liquid sustained release systems.

Unit - IV :

Unit - V :
Protein/Peptide Drug Delivery Systems: Concepts, delivery techniques, formulation, stability testing, causes of protein destabilization, stability and destabilization.

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

Books and References:
3. Transdermal Controlled Systemic Medications, YW Chein, Vol 31, Marcel Dekker, NY.
PROCESS SCALE UP AND VALIDATION

Scheme of Instruction

Total Duration : 60 Hrs.
Hours/Week : 4 Hrs.
Credits : 4
Instruction Mode : Lecture
Course Code : PY.09.886.24.T

Course Objectives:
To enable the students acquaint with the scale up techniques, pilot plant design and validation

Course Outcomes:
To apply their knowledge of process scale up and validation for reproducibility

Unit – I
Scale Up Techniques: Importance and strategies, principles of similarity, dimensional analysis, microspheres (emulsification method) – Dimensional analysis, scale up techniques involved in tablets- mixing, granulation, size reduction, compression, film coating, scale up techniques involved in filling in hard gelatin capsules,

Unit – II

Unit – III
Validation: General concepts, types, procedures & protocols, documentation, validation master file (VMF).
Analytical Method Validation: General principles, HPLC and dissolution test apparatus.

Unit – IV
Equipment Qualification: Importance, IQ, OQ, PQ for equipment – autoclave, DHS, membrane filter, rapid mixer granulator, cone blender, FBD, tablet compression machine, liquid filling and sealing machine.
Utilities Validation: Validation of Pharmaceutical Water system, HVAC system, Cleaning Validation.

Unit – V
Process Validation: Importance, validation of mixing, granulation, drying, compression, tablet coating, liquid filling and sealing, sterilization, water process systems, environmental control.

Inventory Control: Different Systems of inventory control; Import and Export regulations laws and methods to obtain I & E licenses; I and E regulations USA, EU and Japanese perspectives and Vendor Qualification.

Books and References:
1. JR Berry, Nash, Pharmaceutical Process Validation, Vol 57, Marcel Dekker, NY.
5. PR Watt, Tablet Machine Instruments in Pharmaceuticals, John Wiley.
6. L. Lachman, H.A. Lieberman, Pharmaceutical Dosage Forms, Tablets, Vol 1, 2, 3 by Marcel Dekker, NY.
7. K.E. Axs, Pharmaceutical dosage forms, Parenteral Medications, Vol 1, 2 Marcel Dekker, NY.
8. L. Lachman, H.A. Lieberman, Dispersed System Vol 1, 2, 3 Marcel Dekker, NY.
ELECTIVE
COSMETIC TECHNOLOGY

Scheme of Instruction

<table>
<thead>
<tr>
<th>Total Duration</th>
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<td>Credits</td>
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<td>Instruction Mode</td>
<td>Lecture</td>
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<td>Course Code</td>
<td>PY.09.886.25.T</td>
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Scheme of Examination

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<tr>
<th>Max. Marks</th>
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<td>Mid Semester</td>
<td>20</td>
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<td>Quiz</td>
<td>05</td>
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<td>End Semester</td>
<td>75</td>
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<td>Exam Duration</td>
<td>3 Hrs.</td>
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Course Objectives:

To provide the concepts of various parameters involved in the formulation and development of Cosmetics

Course Outcomes:

Understand the formulation concepts and factors influencing the development of various Cosmetics

Unit – I :
General Raw Materials in Cosmetic Formulations: Overview of raw materials - Water, natural & synthetic oils, fats & waxes, inorganic solids, emulsifiers, thickeners, hydrocolloids, polymers, surfactants, antioxidants, humectants, poly-siloxanes, preservatives; Coloring agents used in cosmetics. Quality evaluation of colors, safety, toxicity and regulatory aspects of colors w.r.t. cosmetic products;

Perfumes in cosmetics: Raw materials in perfumery, developing a perfume composition, current trends including emulsified and solid perfumery, analytical and separation techniques of perfumes, sensory analysis, safety and toxicological evaluation of perfumes, manufacturing and packaging of perfumes, legislation and regulations for perfumes in cosmetics.

Unit – II :
Novel Approaches in Cosmetic Formulations: Concepts of micro-emulsions, liposomes, niosomes, nanoparticles, iontophoresis, to enhance functional attributes & delivery of cosmeceuticals.

Therapeutic Ingredients in various Cosmetics: Skin Products, Dentifrices, Hair care and Nail preparations, and performance evaluation of these activities.

Herbal Cosmetics: Current trends in use of herbal materials in cosmetics such as aloe Vera, henna, tea tree oil, neem in various cosmetic products

Unit – III :
Physiological Consideration: Skin, Hair, Nail and Eye- in relation to Cosmetic Application.

Rheology of Cosmetics: Rheological additives in cosmetics, rheology of nail products, antiperspirants, deodorants, hair products, creams and lotions.

Manufacturing Techniques: Cosmetic creams, powders, compacts, sticks, liquids, foam and aerosols.

Packaging: Package development and design for cosmetics including aerosol packs.

Unit – IV :
Quality Standards of Cosmetic Products: Quality Control, BIS guidelines for quality of finished products for cosmetics, Microbiological Quality of Cosmetic Products

Evaluation of Cosmetics: Textural Analysis, Performance, Physicochemical, Microbiological and Psychometric evaluation of various cosmetic products such as creams, gels, powders, lipstick, nail lacquer, shampoo, sunscreen products, dentifrices. Design and Assessment of preservative systems for cosmetics, evaluation of preservatives in cosmetic products and factors affecting activity of preservatives.
Osmania University

Unit – V :

Clinical Safety Testing: Safety and toxicity evaluation of cosmetic products; Irritation, sensitization, photoirritation, photoallergy, ocular irritation and protocols for the same. Testing of moisturizers, deodorants, antiperspirants, sunscreen and anti-aging products.

Regulatory Requirements: Manufacturing and Sale of Cosmetics.

Books and References:

5. J. Knowlton and S. Rarce; Handbook of Cosmetic Sciences and Technology Elsevier Science Publisher.
7. S. N. Katju’s; Law of Drugs; Law Publishers (India) Pvt. Ltd.
8. E. G. Thomssen; Modern Cosmetics; Universal Publishing Corporation.
10. R. L. Elder; Cosmetic Ingredients, their Safety Assessment; Pathotox.
11. H. R. Moskowitz; Cosmetic Product Testing; Marcel Dekker.
12. W. C. Waggoner; Clinical Safety and Efficacy Testing of Cosmetics; Marcel Dekker.
14. L. Appell; The Formulation and Preparation of Cosmetics, Fragrances and Flavors; Micelle Press.
15. W. A. Poucher; Poucher’s Perfumes, Cosmetics and Soaps; vol. 3 Chapman and Hall
16. Dr. Laba; ‘Rheological Properties of Cosmetics and Toiletries; Marcel Dekker
17. Drugs & Cosmetics Act & Rules, 1940 (with latest amendments).
ELECTIVE

PHARMACEUTICAL BIOTECHNOLOGY

<table>
<thead>
<tr>
<th>Scheme of Instruction</th>
<th>Scheme of Examination</th>
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<tbody>
<tr>
<td>Total Duration</td>
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<td>Hours/Week</td>
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<td>Course Code</td>
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<td>Lecture</td>
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<td>PY.09.886.25.T</td>
<td>3 Hrs.</td>
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Course Objectives:
To understand the basics of biotechnology in production of drugs and pharmaceuticals

Course Outcomes:
To apply the knowledge of biotechnology in development of Biopharmaceuticals

Unit - I :
Status and Scope of Biotechnology in Pharmacy Enzyme immobilization - Principles and Pharmaceutical applications. Immobilization of enzymes, proteins and their applications – biosensors, enzyme electrodes, immune-sensors, optical sensors
Biotransformation principles and industrial applications in the production of chemicals and drugs;

Unit - II :
Biotechnology based pharmaceutical using recombinant DNA Technology, interferons and reverse transcriptase.
Production and Control of Biotech derived products: Recombinant DNA products – insulin, growth hormone, erythropoietin, cytokines; Vaccines – attenuated virus, genetic alterations of live virus as a vector of other pathogens (recombinant virus or recombinant vaccinia virus); Diagnostic proteins – protein A, protein G, antibodies; Quality control testing of biotech products – determining impurities, contamination - viral, bacterial endotoxin, rabbit pyrogen test, sterility, protein identification, finger prints by electrophoresis, isoelectric focusing, immunogenicity, partial sequence analysis

Unit - III :
Biotech products through fermentation: Fermentation – batch, continuous fermentation; Role of bioengineering in fermentation – geometry of fermentation tanks, design of impellers, agitation systems and environmental conditions of fermentation; Fermentative production of important secondary metabolites – penicillins, amino glycosides polyene macrolides, macrolides, anthracyclines; Principles of downstream processing of fermentation products; Unit operations and techniques employed in downstream processing of fermentation; products, microbial strain selection and preservation methods; Genotype and phenotype variation of characters of microbes;

Unit - IV :
Plant biotech products: Substances produced by plant cell culture; Transgenic plants and their application; Biotransformations with plant cell culture;
Bio-technology & GMP- Formulation approaches to protein stabilization. Regulatory aspects of Biotechnology based pharmaceuticals.
Osmania University

Unit - V  :
Introduction to Bio-informatics. Information theory and biology, redundancy networking, network access, Internet & E-mail services, use of data base in biology, sequence data base for comparisons. Applications of predictive pharmaceutics, chemico-pharmaceutics, cheminformatics, bioinformatics and data mining.

Books and References:

10. C. Clark, Genetic Engineering Fundamentals, Karl Kammer, Meyer Virginia.,
12. Bernard R Glick, John E Thompson, Methods in Plant Molecular Biology and Biotechnology, CRC Press.
BIOPHARMACEUTICS AND PHARMACOKINETICS

<table>
<thead>
<tr>
<th>Course Objective</th>
<th>Detail</th>
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<tbody>
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<table>
<thead>
<tr>
<th>Course Outcomes</th>
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<td>Understands the basic mechanisms and concepts of absorption, distribution, metabolism, and elimination.</td>
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<table>
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<tr>
<th>List of Experiments</th>
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<tbody>
<tr>
<td>1. Comparative dissolution studies on different dosage forms for drugs.</td>
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<td>2. Effect of pH / particle size on dissolution studies.</td>
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<tr>
<td>3. Plasma protein binding studies on different drugs.</td>
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<tr>
<td>5. Estimation of creatinine clearance.</td>
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<tr>
<td>6. Estimation of pharmacokinetic parameters for the given urinary excretion data.</td>
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<tr>
<td>7. Estimation of pharmacokinetic parameters for the given oral absorption data.</td>
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<tr>
<td>8. Introduction to Biopharmaceutics. - G.P. - Shrivastav.</td>
</tr>
<tr>
<td>11. Biopharmaceutics and Clinical Pharmacokinetics by Milo Gibaldi.</td>
</tr>
</tbody>
</table>
ADVANCED DRUG DELIVERY SYSTEMS

Scheme of Instruction

| Total Duration | 60 Hrs. |
| Hours/Week     | 4 Hrs.  |
| Credits        | 2       |
| Instruction Mode | Practical |
| Course Code    | PY.09.886.23.P |

Scheme of Examination

| Max. Marks | 100 |
| Mid Semester | 20 |
| Quiz        | 05 |
| End Semester | 75 |
| Exam Duration | 6 Hrs. |

Course Objectives:
To understand the factors influencing the preparation of formulation of advanced drug delivery systems.

Course Outcomes:
Comprehend various classes of excipients involved in formulation of advanced drug delivery systems.

List of Experiments:
1. Preparation and evaluation of albumin microspheres (1 expt)
2. Preparation and evaluation of matrix tablets using various polymers (1 expt)
3. Preparation and in vitro evaluation of buccal mucoadhesive formulations (tablets/films) (2 expts)
4. Preparation and evaluation of hydrodynamically balanced tablets (1 expt)
5. Preparation and evaluation of ocular films (1 expt)

Books and References: