## DEPARTMENT: PHARMACEUTICS

## FIRST YEAR

| Subject Code | Subject | Teaching Scheme | | | Marking System | | | |
|---|---|---|---|---|---|---|---|---|
| | | Theory (Hrs) | Practical (Hrs) | Total Hours | Theory | | Practical | |
| | | | | | Internal | External | Internal | External |
| 08200101 | Modern Analytical Techniques (Common for all Stream) | 3 | 4 | 7 | 50 | 100 | 50 | 100 |
| 08202101 | Research Methodology and Industrial Regulations | 4 | - | 4 | 50 | 100 | - | - |
| 08202102 | Advanced Pharmaceutics | 3 | 6 | 9 | 50 | 100 | 50 | 100 |
| 08202103 | Novel Drug Delivery Systems | 3 | 6 | 9 | 50 | 100 | 50 | 100 |
| **Total Hour** | | **13 +** | **16** | **= 29** | **Total Marks 600 +** | | **300** | **= 900** |

**08200101: MODERN ANALYTICAL TECHNIQUES**

**Objective of the course:**

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

**Students learning outcomes/objectives:**

**A] Knowledge:**

1) Students will able to analysis of various drugs in single and combination dosage forms
2) 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
3) Illuminate relevance & significance of Advance analytical techniques to Pharmaceutical Sciences.
4) Understand the basic principles of chromatographic, spectroscopic and scattering methods.
5) Apply spectroscopic methods for analysis of Raw materials and Formulation.
6) Develop an in-depth knowledge and critical awareness of the application of modern analytical methods.
7) Understand and apply different spectroscopic and separation on raw materials
8) Explain types, instrumentation and applications of spectroscopic, chromatographic and separation techniques
9) Define and compare the terms used in spectroscopic methods like UV-VIS Spectroscopy, IR Spectroscopy, NMR andMass Spectroscopy.
10) Understand & apply the theory and operational principles of UV-VIS Spectroscopy, IR Spectroscopy etc .
11) Understand the basic concepts and applications of Mass Spectroscopy.
12) Elucidate structure of organic compounds by various spectroscopic methods.

**B. Skills:**

1. Clarify and understand the correct use of laboratory instruments like UV-Visbile spectrophotometer, High Performance Liquid Chromatography , Flame Photometer with calibration of various instruments used in pharmaceutical analysis laboratory together with safety measures to be followed.
2. Develop practical hand in analytical methods by estimation of analyte concentration in pure form and in formulation with thorough understanding of principle and procedures used in different analytical techniques.
3. Develop UV and HPLC method for simultaneous estimation of Drugs.
4. Various advanced analytical instrumental techniques for identification, characterization and quantification of drugs using IR, HPLC and TLC

**DETAIL SYLLABUS** **THEORY (3 HOURS/WEEK)**

| Chapter No. | Topics | Hours Allotted |
|---|---|---|
| 1 | **UV-VISIBLE SPECTROSCOPY**<br><br>Theory of UV-Spectroscopy, absorption law and limitations, choice of solvent and solvent effects. Applications of UV-Visible spectroscopy, Woodward–Fischer rules for calculating absorption maximum, interpretation of spectra, multi-component assay, difference spectra and derivative spectra. | **06** |
| 2 | **INFRARED SPECTROPHOTOMETRY:**<br><br>Introduction, basic principles, and sampling techniques, interpretation of spectra, applications in Pharmacy. FT-IR, Attenuated Total Reflectance (ATR), near infrared Spectroscopy (NIR) -theory and applications,. | **06** |
| 3 | **NUCLEAR MAGNETIC RESONANCE SPECTROSCOPY:** Fundamental Principle and Theory, Instrumentation, solvents, chemical shift, and factors affecting chemical shift, spin-spin coupling, coupling constant, and factors influencing the value of coupling constant, spin-spin decoupling, proton exchange reactions, simplification of complex spectra, FT-NMR, 2D -NMR and applications in Pharmacy, interpretation ofspectra. C13 NMR-Introduction, Natural abundance, C13 NMR Spectra and its structuralapplications. | **08** |
| 4 | **MASS SPECTROMETRY**<br><br>Principle, Theory, Instrumentation of Mass Spectroscopy, Different types of ionization like electron impact, chemical, field, FAB and MALDI, Analyzers of Quadrupole and Time of Flight, Mass fragmentation and its rules, Fragmentation of important functional groups like alcohols, amines, carbonyl groups and alkanes, Meta stable ions, Mc Lafferty rearrangement, Ring rule, Isotopic peaks, Tandem Mass Instruments, Interpretation and Applications of Mass spectroscopy | **08** |
| 5 | **ATOMIC ABSORPTION AND PLASMA EMISSION SPECTROSCOPY:**<br><br>Principle, instrumentation, interferences and applications in Pharmacy. | **04** |

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| **6** | **X-RAY DIFFRACTION METHODS:**<br><br>Introduction, generation of X-rays, X-ray diffraction, Bragg's law, X-ray powder diffraction, interpretation of diffraction patterns and applications | **04** |
| **7** | **OPTICAL ROTARY DISPERSION:**<br><br>Principle, Plain curves, curves with cotton effect, octant rule and its applications with example, circular dichroism and its relation to ORD. | **03** |
| **8** | **THERMAL METHODS OF ANALYSIS:**<br><br>Theory, instrumentation and applications of Thermo Gravimetric Analysis (TGA), Differential Thermal Analysis (DTA), Differential Scanning Calorimetry (DSC). And Thermo Mechanical Analysis (TMA). | **04** |
| **9** | **CHROMATOGRAPHIC TECHNIQUES:**<br><br>a) Classification of chromatographic methods based on mechanism of separation. Theories of chromatographic separation.<br><br>b) Principles, elution techniques, instrumentation, derivatization and applications of gas chromatography, HPLC and HPTLC.<br><br>c)Principles, elution techniques, applications of ion exchange and ion pair chromatography, affinity chromatography, size exclusion chromatography, and chiral chromatography, super fluid chromatography (SFC), GC-MS, UPLC and LC-MS-stability studies and its applications. | **15** |
| **10** | **ELECTROPHORESIS:**<br><br>Principle, Instrumentation, Working conditions, factors affecting separation and applications of the following:<br><br>a) Paper electrophoresis b) Gel electrophoresis c) Capillary electrophoresis d) Zone electrophoresis e) Moving boundary electrophoresis f) Iso electric focusing | **03** |
| **11** | **RADIO IMMUNO ASSAY:**<br><br>Introduction, Principle, Theory and Methods in Radio Immuno Assay, Related Immuno Assay procedures and applications of RIA Techniques. Enzyme immuno assay- ELISA and EMIT | **03** |
| **12** | **REFERENCE STANDARDS** | **02** |

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| | Source, preparation, characterization, usage, storage , records and Concept of Working standard. | |
| **13** | **ELECTRON MICROSCOPY:**<br><br>Introduction to Scanning Electron Microscopy and Travelling Electron Microscopy. | **02** |
| **14** | **PREFORMULATION**<br><br>(a) Physical, Chemical and Pharmaceutical factors influencing formulation (b) Solid-state characterization: Crystallinity, hygroscopicity, Particle size and particle size distribution, compaction properties (c) Crystalline and polymorphism and its evaluation. Rationale for selecting the preferred polymorph/crystalline form (d) General principles and applications of various characterization techniques viz: Differential thermal analysis Differential scanning calorimetry, X-Ray diffraction, FTIR in Preformulation study. (e) Drug-excipient compatibility study (f) Traces of organic volatile impurities (OVIs) and their regulatory limits (residual solvents). (g) Preformulation studies of Biotechnological derived products and reference guidelines. | **07** |

**PRACTICAL (4 HOURS/WEEK)**

1. Find out the wavelength maxima of drugs.
2. Study of effect of solvent on wavelength maxima of drugs.
3. Find Beer's law limit of drugs in suitable solvent(linearity-range).
4. Find out the isobestic point for (any one) combined drug
5. Multicomponent analysis by UV-Spectrophotometry
    a)Absorbance corrected for interference method
    b)Simultaneous equation method
    c)Absorbance ratio method
    d)Area under curve method
    e)First derivative spectrophotometric method
6. Assay of drugs official in various pharmacopoeias (Any five). This should cover UV-spectrophotometry, titrimetric, HPLC methods. The titrimetric method should include potentiometric end point determination.
7. Interpretation of some unknown intermediates and drugs.
    a. Interpretation of UV spectra (At least two exercise),
    b. Interpretation of IRspectra (At least two exercise),
    c. Interpretation of NMRspectra (At least two exercise) and
    d. Interpretation of Mass spectra(At least two exercise)

    [Note: For interpretation NMR and Mass spectral data, the spectra can be obtained from available literature]
8. Experiment on Flame Photometer.
9. Experiment on Fluorimetry.

**Reference Books:**


1. M. Orchin and H.H. Jaffe – Theory and applications of Ultraviole spectroscopy. (John Wiley and Sons. N.Y).
2. Silverstein, Basseler, Morril- Spectrometric identification of organic compounds (John Wiley and Sons. N.Y).
3. Willard, Merritt, Dean – Instrumental methods of analysis (CBS Publishers and Distributors, Delhi).
4. J.R. Dyer – Application of absorption Spectroscopy of Organic Compounds (Prentice Hall,London).
5. C.N.R. Rao – Chemical Applications of Infrared spectroscopy. (Academic Press, N.Y.).
6. L.M. Jackmann and B.D. Sternhell – Application of NMR spectroscopy in organic chemistry(Pergamon Press, London.).
7. F.W. McLafferty and F. Turecek- Interpretation of Mass Spectra.
8. R.J. Hamilton and P. A. Sewell- Introduction to High Performance Liquid Chromatography.(Chapman and Hall, London ).
9. J.W. Munson- Pharmaceutical Analysis: Modern methods –Part A and Part B (MarcelDekker, Inc., New York).
10. Introduction to Spectroscopy, 3rd edition, Pavia, Lampman, Kriz, Thomson Publisher.
11. Analytical chemistry: A Modern Approach to Analytical Science, 2nd edition by Kellner,Mermet, Otto, Valcarcel Wiley ECH.
12. Ewing's Analytical Instrumentation Handbook, 3rdedition, edited by Jack, Cazes, Marcel Dekker.
13. P.D. Sethi – Quantitative Analysis of Drugs in Pharmaceutical Formulations (VBS Publishers, Delhi).
14. Pharmacopoeia of India (latest edition).
15. United State Pharmacopoeia (latest edition).
16. British Pharmacopoeia (latest edition).
17. A.H. Beckett, J.B. Stenlake – Practical Pharmaceutical Chemistry, Part I and Part II (CBSPublishers Delhi)
18. F. D. Snell and C. T. Snell- Colorimetric Methods of analysis (Van Nostrand Reinhold Company, N.Y.).

**SUBJECT NAME (08202101): RESEARCH METHODOLOGY AND INDUSTRIAL REGULATIONS**

**Learning objectives:**

The objective of the course is to introduce the basic methods of conducting research, explore ideas in formulating research objectives / hypotheses and guiding the researchers to take up research studies in a structured manner. Research activities start with search of prior arts including articles and patents, followed by writing research proposals, actual conduct, data analysis, interpretation and presentation of reports in different forms. With this subject, the students will become familiar to all these steps involved in a good research work.

The ultimate goal of every pharmaceutical research is the large scale production and marketing of the developed formulation to serve the mankind. This course is also designed to give insights of regulations and requirements for setting up and operations within a Pharmaceutical Industry. Students will be made familiar with the global pharmaceutical market by exposing them to different regulatory bodies, regulations essential for registration & post-approval necessities of pharmaceutical products in different markets.

**DETAIL SYLLABUS (THEORY) (4 HOURS/WEEK)**

| S. No. | Topics | Hours Allotted |
|---|---|---|
| 1. | **INTRODUCTION TO RESEARCH** Introduction to research and research methodology: Meaning of research, Objectives of research, Motivations in research, different types of research, research approaches, steps involved in research process, Significance of research. | 2 |
| 2. | **LITERATURE SURVEY & RESEARCH PROBLEM FORMULATION**<br>Purpose, Methods and Use of literature survey, locating relevant information, use of library & electronic databases, patent data base, preparation & presentation of literature review, research article reviews, identification of gaps in research, selecting the problem, formulation of | 8 |

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| | research problem, definition of research objectives, preparing research proposals | |
| **3.** | **SCIENTIFIC WRITING & PRESENTATION**<br>Research report and thesis writing (Title, abstract, key words, introduction, methodology, results, discussion, conclusion, acknowledgement, references), types of research paper (research articles, review article, short communications), instructions to Authors, steps involved in the process of publications (registration, new article submission, submitting articles electronically, review process, tracking the process, submitting revised articles), importance of publishing a research paper, Citations, Citation index, Quality indices, Impact factor, etc.<br>Importance, types, content, posters, oral presentation, importance of body language -posture, gestures, eye contact, facial expressions, stage, fright, volume, pitch, speed, pause & language, visual aids & seating, questionnaire. | **9** |
| **4.** | **PROJECT PROPOSALS**<br>a) **COST MANAGEMENT:** Different types of cost, Cost analysis of the project- cost incurred on raw materials, procedure, instrumentations & clinical trials.<br>b) **RESEARCH GRANTS**: Introduction to various research funding organization and their funding schemes (AICTE, UGC, CSIR, ICMR, DST, DBT, GUJCOST, etc.)<br>c) **INDUSTRY- INSTITUTION COLLABORATION:** Industrial-institution interaction, Industrial projects, significance, feasibility reports.<br>d) **MORALS:** Issues related to plagiarism, collaborative models and ethics, acknowledgements. | **8** |
| **5.** | **Introduction to Experimental Design** | **7** |

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| | Basic Biostatistics used in experimental design: Study of F Test, t test, Chi Square Test, ANOVA and Normal Distribution in Pharmacy. Numerical Problems related to above. Introduction to Design of Experiments, Terminologies used in Experimental Design such as factors, levels, confounding, Response, Screening, Optimization, etc. Application of Experimental Design in various pharmaceutical fields. Methods of selection of different designs. Screening studies using Placket and Burman Design and Taguchi Design. | |
| **6.** | **Factorial Design, Response Surface Methodology & Applications**<br>Full and fractional factorial designs, Design layout, How to implement the Design in Pharmaceutical Research. Evolution of full and reduced mathematical models in experimental design. Application of Factorial Designs. Introduction to Central Composite Design, axial points prediction, Contour Plots, 3D Plots, Box Behnken Design and Validation of optimized model. Application of Response Surface Methodology. Parallel, Crossover Designs and clusters designs used in clinical trials and their applications. Pharmacoinformatics, Methodology, Tools and Application in Pharmacy field. | **8** |
| **7.** | **Introduction to Patents, Patent Claims & Patent Websites**<br>Patents Definition, Need for patenting, Types of Patents, Condition to be satisfied by an invention to be patentable, Introduction to patent search, The essential elements of patents, Guidelines for preparations of laboratory notebook, non-obviousness in patents, Introduction to Patent Claims, Drafting of patent claims, important patent related websites. How to search Patents in different websites. | **5** |
| **8.** | **Trademark protection and WO patents**<br>Brief introduction to trademark protection and WO patents, Introduction to “The Patents Act 1970” and “The Patents Rule 2003”, with special emphasis on the forms to be submitted along with a patent application. | **3** |

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| **9.** | **Pharmaceutical factory**<br><br>• Location: Selection, layout and planning<br>• Utility services, HVAC and personnel facilities.<br>• Detailed study of the equipments required in the manufacture of different dosage forms as per Schedule-M.<br>• General considerations for Scale-up<br>• Contract manufacture. | **12** |
| **10.** | **Documentation and Validation:**<br><br>• Master Formula Card, Batch manufacturing record, batch packing record, Protocols and Reports, Standard operative procedure for equipments and manufacturing or processing steps, STPs and Specifications<br>• Validation of Pharmaceutical Processes, equipments/apparatus and Computer System. | **12** |
| **11.** | **Regulatory Agencies**<br><br>• Organization, responsibilities and function of various regulatory agencies: USFDA, CDSCO, EMEA, MCA, TGA, MHRA, ANVISA, WHO, ICH, MCC etc. | **8** |
| **12.** | **Basics in Drug approval process and Database**<br><br>• IND, IB, NDA, ANDA, Concept of para I to IV, Exclusivity.<br>• Regulatory submission procedures in European Union.<br>• Orange book, Freedom of information, IIG,<br>• DMF, CTD, Material Safety Data Sheet | **12** |
| **13.** | **Guidelines** | **6** |

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| | • BA/BE guidelines<br>• Guidelines for Post Approval Changes: **S**UPAC, CBE, Post-NOC, etc. with respect to different dosage forms | |

**SUGGESTED BOOKS:**


1. Research Methodology : Methods & Techniques, C.R. Kothari, Viswa Prakashan,
2. Research Methods- A Process of Inquiry, Graziano, A.M., Raulin, M.L, Pearson Publications.
3. Pharmaceutical Statistics: Practical and Clinical Applications, Sanford Bolton and Charles Bon.
4. Thesis projects in Science & Engineering – Richard M. Davis.
5. Thesis & Assignment – Jonathan Anderson
6. Writing a technical paper- Donald Menzel
7. How to Write a Thesis: Murray, R. Tata McGraw Hill
8. Writing For Academic Journals, Murray, R., McGraw Hill International.
9. A Handbook of Academic Writing, Murray, R. and Moore, S., Tata McGraw Hill International
10. Writing for Publication, Henson, K.T., Allyn & Bacon.
11. Effective Business Report Writing –Leland Brown
12. Manual for evaluation of industrial projects-United Nations
13. Manual for the preparation of industrial feasibility studies
14. Presentation skills - Michael Hallon- Indian Society for Institute education
15. Protection of industrial Property rights- P. Das & Gokul Das
16. Practical Introduction to copyright.- Gavin Mcfarlane
17. Operational research by Dr. S.D.Sharma, Kedarath, Ramnath & Co.
18. Bolten, Pharmaceutical Statistics , 2010, Informa Healthcare
19. Lewis, Pharmaceutical Experimental Design, 2008, Informa Healthcare

20. Anderson, M, DOE simplified, CRC Press

21. Anderson, M, RSM simplified, CRC Press

22. Box, GEP, Hunter, WG, and Hunter, JS, 1978, Statistics for Experimenters, Wiley.

23. Cochran, WG and Cox, GM, 1957, Experimental Designs, Wiley.

24. Fisher, RA, 1966, The Design of Experiments, 8th ed., Hafner.

25. Hinkelmann, K and Kempthorne, O, 1994, Design and Analysis of Experiments (Vol I), Wiley.

26. Pukelsheim, F, 1993, Optimal Design of Experiments,Wiley.

27. Winer, BJ, 1962, Statistical Principles in Experimental Design, 2nd ed., McGraw-Hill.

28. Wu, C.F. Jeff and Michael Hamada, 2000, Experiments: Planning, Analysis , and Parameter Design Optimization, Wiley.

29. Lachman "The theory and Practice of Industrial Pharmacy

30. Bentley's Pharmaceutics.

31. Pilot plants model and scale-up methods, by Johnstone and Thring.

32. GMP practices for pharmaceutical –James Swarbrick.

33. How to practice GMPs by P.P. Sharma.

34. Pharmaceutical Process Validation by Loftus and Nash.

35. Various websites for patent related search

36. Instruction to Authors of journals of repute in the respective field.

37. The websites of the respective Government.

**SUBJECT NAME : (08202103) ADVANCED PHARMACEUTICS**

**Learning objectives:**

The learning objective of course is to study the basics involved in the development of safe and effective dosage forms. This subject also discusses recent advances of conventional dosage forms and advances in pharmaceutical technologies.

**DETAIL SYLLABUS (THEORY) THEORY (3 HOURS/WEEK)**

| Chapter No. | Topics | Hours Allotted |
|---|---|---|
| 1. | **Polymers in pharmaceutical formulations:** Classification, General methods of synthesis, properties, characterization and evaluation. Biodegradable polymers: Classification, Mechanism of biodegradation in the body. Polymer processing with respect to novel formulation design, Applications of polymers in novel drug delivery systems, Medical prosthetics and packaging. | 5 |
| 2. | **Solubilization and solubilized system** (a) Theoretical aspects and applications. (b) Techniques for improvement in drug solubilization for development of various dosage forms. | 5 |
| 3. | **Dissolution study:** (a) Importance, objectives, equipments, (b) Biological classification system (BCS); its significance on dissolution study and application in dosage form development. (c) Selection of dissolution media and conditions. (d) Comparison of dissolution profile by model independent (similarity and dissimilarity factor) and dependent methods. (e) Concept of IVIVC, Methods of establishing IVIVC, Factors affecting IVIVC. Numericals and Case studies. Application of IVIVC | 12 |
| 4. | **Drug Absorption** (a) Factors affecting drug absorption; i.e. Physicochemical, Physiological and Pharmaceutical. | 8 |

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| | (b) Method of studying bioavailability and bioequivalence.<br>(c) Transport across CACO 2 monolayers, Other Cell-lines to predict- Biological, Pharmaceutical and Analytical considerations | |
| **5.** | **Pharmacokinetic parameters**<br>(a) Basic concept and importance of biological half-life, volume of distribution, renal clearance, total body clearance, plasma protein binding, and absorption rate constant, elimination rate constant.<br>(b) Analysis of blood and urine data, compartment models, kinetics of one and two compartment model. | **8** |
| **6.** | Recent Innovations in conventional dosage forms –<br>a) Tablets: including site specific and time release modulation. e.g.: Osmotic, Colon target, Gastro-retentive, Buccal, and Sublingual.<br>b) Capsules: Modified release capsules<br>c) Semi-solids: In situ gels, Hydrogel, Organogels, Lipogels, emulgel, nanogel.<br>d) Parenteral: Implants, Ophthalmic, lyophilized injectables.<br>e) Liquids: Self emulsifying/microemulsifying drug delivery systems, microemulsion, nanoemulsion, nanosuspension. | **20** |
| **7.** | Recent advances in powders: Particle coating, Taste-masking, Spherical crystallization, Super and sub-critical fluids, Meter dose Inhaler, pelletization, Extrusion-spheronization, Spray drying. | **12** |
| **8.** | Miscellaneous advance drug delivery systems: Strips, Disketts, film/patches, Nanofibres | **5** |

**Practical: 6 hrs. /week**

Laboratory experiments including oral and practical examination in general course illustrative of theory section in the syllabus.

**Reference Books:**


1. Theory & Practice of Industrial Pharmacy, L. Lachman, Varghese Publication, Bombay.
2. Modern Pharmaceutics, G.S. Banker and C.T. Rhodes, Marcel Dekker, NY.
3. Physical Pharmacy, A. Martin, Lea and Febiger, Philadelphia.
4. Pharmaceutical dissolution testing, U.V. Banker, Marcel Dekker, Inc., New York.
5. Pharmaceutical Dosage Forms: Parenteral Medications, Avis K. E., Leon Lachman and H. Lieberman, Marcel Dekker, New York
6. Pharmaceutical Dosage Forms: Tablets, Lierberman H. A. and Leon Lachman, Marcel Dekker, New York
7. Biopharmaceutics and Clinical Pharmacokinetics- An introduction; Robert. E. Notari, Marcel Dekker Inc, New York
8. Applied Biopharmaceutics and pharmacokinetics, Leon Shargel, Mc Graw Hill.
9. Controlled Drug Delivery: J. R. Robinson and V. H. Lee, Marcel Dekker, Inc., New York.
10. Progress in Controlled and Novel Delivery Systems, edited by N.K. Jain, CBS Publishers & Distributors, New Delhi.
11. Pharmaceutical Dosage Forms: Disperse system, Vol. I, II &III, Lierberman H. A. and Leon Lachman, Marcel Dekker, New York
12. Protein Formulation & Delivery, edited by E. J. Manally and J. E. Hastedt, Informa Healthcare, New York
13. Encyclopedia of Pharmaceutical Technology, Jasmes Swarbrick and James C. Boylan, Marcel Dekker Inc., New York.
14. Handbook of Pharmaceutical Controlled Release Technology, Donald L. Wise, Marcel Dekker, USA.
15. Supercritical fluid technology for drug product development edited by Peter York, Uday B. Kompella, and Boris Y. Shekunov, Drug and the Pharmaceutical Sciences. Vol. 138.

**SUBJECT NAME: (08202104) NOVEL DRUG DELIVERY SYSTEMS**

**Learning objectives:**

The learning objective of course is to study different novel strategies, routes and carrier systems for drug delivery in order to achieve increased efficacy and reduced toxicity.

**DETAIL SYLLABUS (THEORY) (3 HOURS/WEEK)**

| Chapter No. | Topics | Hours Allotted |
|---|---|---|
| 1 | **Drug targeting:** Basic Concepts of Molecular Pharmaceutics, Rationale of targeted drug delivery system; importance in therapeutics; Biological processes & events involved in drug targeting; 1st order, 2nd order & 3rd order targeting, Active & Passive targeting, Organ specific targeting. Principles of Molecular biology - Cell recognition and signaling - signal transduction – cell surface receptors. | **15** |
| 2 | **Basic Techniques for development of NDDS**: Nanotechnology, bioadhesive systems, intelligent drug delivery, and tailor made medicines, Ionto and sonophoretic systems. | **10** |
| 3 | **Nasal Drug delivery:** Anatomy, physiology and histology of nose, mechanisms of drug transport across nasal mucosa and related tissues, factors affecting nasal drug absorption, strategies to increase the nasal drug absorption, in vitro and in vivo models of the nasal drug delivery, Promising strategies/devices and applications of intranasal drug delivery Local delivery, Systemic delivery, Nasal vaccines. | **08** |
| 4 | **Pulmonary Drug Delivery:** Delivery to and Through the Lung Introduction, Anatomy and physiology of lung, physicochemical characteristics of particles influencing the delivery of drugs into different regions of the lungs, Mechanism of drug clearance & pharmacokinetics of disposition, Drug absorption via the lung Formulations for metered dose inhalers, Nebulizers, Dry powder inhalers and other inhalation products In vitro particle size analysis and deposition measurements In vitro and in vivo deposition efficacy of inhalation systems Targeting drugs to the lungs via the bloodstream. | **08** |

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| **5** | **Transdermal Drug Delivery Systems:** The structure & function of skin Fundamental of skin permeation, kinetic evaluation, formulation design & optimization, Permeation enhancement techniques viz. Electrical, Chemical and Mechanical methods of permeation enhancements, recent advancements in skin delivery systems, Evaluation, Merits & Demerits | **08** |
| **6** | **CNS targeting:** Physiology of CNS, Different routes and formulation approaches for CNS delivery | **06** |
| **7** | **Drug Delivery Systems**: Structure, stability, composition, methods of preparation, evaluation, applications in drug delivery, drug targeting and commercial aspects of: Particulate Carriers, Vesicular carriers. | **10** |
| **8** | PEGylation and prodrug approach.<br>Biotech based products, Proteins and peptides, immunomodulated molecules. | **10** |

**Practical: 6 hrs. /week**

Laboratory experiments reflecting the theory section of the syllabus.

**Reference Books:**


1. Oral-Lipid Based Formulations: Enhancing the Bioavailability of Poorly Water-soluble Drugs, edited by David J. Hauss.
2. Biodegradable polymers as drug delivery systems, edited by M. Chasin, R. Langer, Marcel Dekker, New York.
3. Bioadhesive Drug Delivery Systems, E. Mathiowitz, Vol 98, Marcel Dekker, NY.
4. Novel Drug Delivery Systems, Y.W. Chien, Marcel Dekker, Inc., New York.
5. Targeted & Controlled Drug Delivery, S. P. Vyas and R. K. Khar, CBS Publishers & Distributors, New Delhi.
6. Nasal Systemic Drug Delivery, Y. W. Chien and K.S.E. Su, Vol 39, Marcel Dekker, NY.