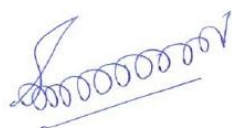


**Pt. Ravishankar Shukla University,
Raipur (C.G.) 492 010**

Master of Pharmacy
(Pharmaceutics)
(A Two Year Post-Graduate Degree Program
W.E.F. Academic Session 2006-2007)

**Ordinance
&
Syllabus**
(W. E. F. Academic Session **2015-2016**)

University Institute of Pharmacy
Faculty of Technology.



Pt. Ravi Shankar Shukla University, Raipur C.G.

Ordinance No.

Ordinance of Master of Pharmacy 2 Years Post Graduate Degree Course

1.0 The Master Degree in Pharmacy of 2 years (4 Semesters) Duration hereafter shall be designated in short **M. Pharm.**

1.1 The duration of M. pharm. course shall extend over a period of two years consisting of four semesters named below:

- (i) M. Pharm. I Semester
- (ii) M. Pharm. II Semester
- (iii) M. Pharm. III Semester
- (iv) M. Pharm. IV Semester

1.2 Each semester shall be spread over for not less than sixteen weeks.

2.0 Academic Qualifications for Admission

2.1 The minimum qualification for admission to first semester of master of pharmacy two years (four semesters) course will be as under:

The candidate who has passed the B. Pharm. examination from AICTE approved institutes with at least 60% marks (55% for reserved category) will be eligible for admission to M. Pharmacy.

3.0 Admission and Fee Structure

As decided by Pt. Ravishankar Shukla university from time to time.

4.0 Sessional

4.1 Twenty five percent of the marks for each theory and practical subject/paper shall be allotted for sessionals of M. Pharm. I semester and II semester.

4.1.1 **Theory:** Two sessional examinations shall be held during each semester for each theory paper/subject from which one best answered by the candidate shall be considered for the award of sessional marks.

4.1.2 **Practical:** Marks shall be awarded on the basis of the experiments performed by the students, prior preparation for the experiment for the experiment, conduct inside the laboratory, results of the experiments, day to day completion of the records and viva-voce.

4.1.3 No improvement will be allowed in sessional marks by reappearing in the sessional examinations.

5.0 Examinations:

5.1 There shall be one university examination at the end of each semester. These examinations will be designated as follows:

M. Pharm. I Semester

M. Pharm. II Semester

M. Pharm. III Semester (Mini Project & Major Research Project),

M. Pharm. IV Semester (Major Research Project).

5.2 There will be a full examination at the end of each semester consisting of theory papers and the laboratory practicals.

5.3 A candidate who fails to secure the minimum marks will be permitted to appear in the failed subject.

5.4 The examination of major research project shall be conducted in the fourth semester.

5.5 There will be no supplementary examination.

5.6 The candidate has to complete the M. Pharm. course in maximum 4 years.

5.7 A.T.K.T. / Backlog:

5.7.1 A candidate can proceed from M. Pharm. first semester to M. Pharm. second semester, irrespective of the number of subjects in which he/she has failed.

5.7.2 A candidate is allowed to proceed from M. Pharm second semester to M. Pharm third semester, irrespective of number of subjects in which he / she has failed in second semester but he/ she has to cleared/passed M. Pharm first semester examination in all subjects.

5.7.3 A candidate is allowed to continue his/her project work and submit the dissertation in accordance with the relevant regulation, but the result of the M.Pharm fourth semester will not be declared until he / she has cleared the M. Pharm. first, second and third semester examinations.

6.0 Standard of Passing:

6.1 In each subject (theory and practical)

6.1.1 Minimum 50% in sessional and semester examination taken together.

6.1.2 Each theory paper & practical will be treated as separate subject for passing.

7.0 Division and Merit List

7.1 The division shall be awarded only after IV semester examination and shall be based on the aggregate marks obtained at his/her successful attempts at the I, II, III and iv semester examinations i.e. full examination of M. Pharm. there will be only four divisions as follows:

| S. No. | Block of Grand Total Marks | Division |
|--------|---------------------------------|------------------------------|
| 1. | 75% and above | First class with distinction |
| 2. | 65% and above but less than 75% | First class |
| 3. | 60% and above but less than 65% | Second class |
| 4. | Below 60% marks | Pass class |

7.2 The university shall declare the merit after the main examination of the fourth semester of M. Pharm. on the basis of the integrated performance of all the 2 years (four semesters). The merit list shall include the first five candidates securing at least first class and passing all the semester examinations in single attempt.

8.0 Medium of Instruction and Examination:

8.1 The medium of instruction and examination shall be English throughout the course of study.

8.2 The subjects to be studied in different semester of M. Pharm. shall be as per the scheme & syllabus approved by the board of studies from time to time in different discipline of pharmaceutical sciences.

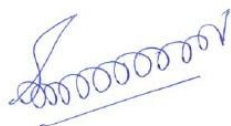
9.0 Project Work:

For M. Pharm. III (mini project) and IV (major research project) semester students a project work shall be compulsory. The project shall be undertaken in any of the areas of pharmacy in respective discipline. The project work shall be done under the supervision of faculty member/s. The candidate shall be required to submit the project report in triplicate. The candidate shall present a seminar on his / her mini project there shall be thesis seminar, examination & viva voce of the major research project at the end of IV semester.

10.0 Attendance

Candidate appearing as regular student for any semester examination are required to attend 75 percent of the lectures delivered and of the practical classes held separately in each subject of the course of study, provided that a short fall in attendance up to 10% and a further 5% can be condoned by the principal of the college and vice-chancellor of the university respectively for satisfactory reasons.

If a candidate has passed a semester examination in full he/she shall not be permitted to reappear in the examination for improvement of division/ marks or any other purpose.



Appendix-A
Course of Study and Scheme of Examination
M. Pharm. (Pharmaceutics)
First Semester

| Code No. | Subject | Teaching (Hours Per Week) | | | Distribution of Marks | | | | |
|----------|-------------------------------------|---------------------------|-----------|-------|-----------------------|-------|----------------------|-------|------------|
| | | Theory | Practical | Total | Theory Marks (I) | | Practical Exam. (II) | | Total I+II |
| | | | | | Sessional | Exam. | Sessional | Exam. | |
| 01. | DRA, IPR and Quality Assurance | 04 | --- | 04 | 25 | 75 | -- | -- | 100 |
| 02. | Biotechnology & Herbal Technology | 04 | 04 | 08 | 25 | 75 | 25 | 75 | 200 |
| 03. | Modern Analytical Techniques | 04 | 06 | 10 | 25 | 75 | 25 | 75 | 200 |
| 04. | Product Development and Formulation | 04 | 06 | 10 | 25 | 75 | 25 | 75 | 200 |
| | Total | 16 | 16 | 32 | 100 | 300 | 75 | 225 | 700 |

M. Pharm. Second Semester

| Code No. | Subject | Teaching (Hours Per Week) | | | Distribution of Marks | | | | Total I + II |
|----------|--|---------------------------|-----------|-------|-----------------------|------|----------------------|------|--------------|
| | | Theory | Practical | Total | Theory Marks (I) | | Practical Exam. (II) | | |
| | | | | | Sessional | Exam | Sessional I | Exam | |
| 01. | Biopharmaceutics, Pharmacokinetics and Clinical Kinetics | 04 | - | 04 | 25 | 75 | -- | -- | 100 |
| 02. | Controlled Drug Delivery Systems | 04 | - | 04 | 25 | 75 | -- | -- | 100 |
| 03. | Novel Drug Delivery Systems | 04 | - | 04 | 25 | 75 | - | - | 100 |
| 04 | Pharmaceutical Packaging Technology | 04 | - | 04 | 25 | 75 | - | - | 100 |
| 05 | *Lab (Practical) | - | 16 | 16 | - | - | 100 | 200 | 300 |
| | Total | 16 | 16 | 32 | 100 | 300 | 100 | 200 | 700 |

*Practical based on theory paper 1 To 4.

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In second year i.e. third and fourth semester, a minor and a major research project shall be undertaken by the candidate respectively. A minor research project has to be undertaken by the candidate in the third semester and evaluation of the same shall be done at the end of the third semester as per the scheme.

M. Pharm. Third Semester

| Seminar / Viva | . Project report | Total |
|----------------|------------------|-------|
| 100 | 200 | 300 |
| - | | |

There will be thesis/ project work seminar/ presentation, examination and viva voce of major research project at the end of fourth semester.

M. Pharm. Fourth Semester

| Sessional work | . Thesis examination Viva- Voce | Presentation of thesis work in the institute | Total |
|----------------|------------------------------------|---|-------|
| 200 | 400 | 100 | 700 |
| | | | |

Grand Total of M. Pharm. Marks

| First Year (First Sem) | + | First Year (Second Sem) | + | Second Year (Third Sem) | + | Second Year (Fourth Sem) | = | Grand Total |
|---------------------------|---|----------------------------|---|----------------------------|---|-----------------------------|---|-------------|
| 700 | | 700 | | 300 | | 700 | | 2400 |
| | | | | | | | | |

M. Pharm. Semester- I

DRA Intellectual Property Rights and Quality Assurance

1. Requirements of GMP, CGMP, GLP, USFDA, WHO guidelines and ISO 9000 series.
2. Drugs and cosmetics acts and rules, Drug regulatory affairs.
3. Documentation-Protocols, forms and maintenance of records in pharmaceutical industry.
4. Preparation of documents for new drug approval and export registration.
5. Processing and its application, intellectual property rights (Patent, Copyright and Trade marks).
6. Sewage disposal and pollution control.
7. Concepts in validation, validation of manufacturing, analytical and process validation and its application.
8. 8. Basic concepts of quality control and quality assurance systems, source and control of quality variation of raw materials: Containers, closures, personnel, environmental, etc. .
9. In-process quality control tests, IPQC problems in pharmaceutical industries. ICH guidelines.
10. Sampling plans sampling and characteristic curves.
11. Master formula generation and maintenance, standard operating procedure (SOP) for different dosage forms.

Books and References Recommended

1. Willing, S.H., " Good Manufacturing Practices for Pharmaceuticals" Marcel Dekker, Inc., New York.
 - a. Dekker, Inc., New York.
2. Drugs and Cosmetic Acts and Rules.
3. Bharathi, Drugs and Pharmacy Laws in India.
4. Patel, A .H." Industrial Microbiology", Macmillan India Ltd., Delhi.
5. Nash R. A. and Wachter, A .H." Pharmaceutical Process Validation", Marcel Dekker, Inc., New York.
6. Bolton, S., Pharmaceutical Statistics.
7. Banker, G. S. And Rhodes, Ct., "Modern Pharmaceutics", Marcel Dekker, Lnc., New York.
8. OPPI, Quality Assurance.
9. Carleton, Fj. And Agallow, J.P., " Validation of Aseptic Pharmaceutical Processes", Marcel Dekker, Inc., New York.
10. Garfield, Quality Assurance Principles of Analytical Laboratories.
11. Indian Pharmacopoeia. The Controller of Publications, Govt. Of India, Delhi



Biotechnology and Herbal Technology

1. Introduction

Advent of biotechnology and herbal technology, Pharmaceutical biotechnology and its applications.

2. Genetics And Genetic Engineering

Genetics: Structure of DNA as genetic material, Replication, repair, gene rearrangements, recombination and transposition, RNA synthesis and splicing. Protein synthesis and targeting. Control of gene expression in prokaryotes, Eukaryotic chromosomes and genetic defects.

Genetic Engineering: Introduction, mutagenesis, cutting and rejoining. Polymerase chain reaction, Isolation and amplification of genes, gene expression and general introduction to genomics. Principal of Genetic recombination, vectors for gene delivery, Gene cloning, Pharmacogenomics, genetic pharmaceutical products.

3. Immunology And Its Preparations

A brief introduction to immunology, Monoclonal antibodies and Hybridoma technology, Formation and selection of hybrid cells, principles and productions of monoclonal antibodies, commercial production, characterization, quality control and storage of monoclonal antibodies, Advantages and applications of monoclonal antibodies.

4. Introduction To Bioinformatics & Biostatistics:

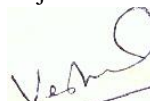
Biological Data base, sequence analysis, protein structure, Genetic and physical mapping, Application of bioinformatics in pharmaceutical industries.

5. Tissue Culture

Introduction, historical background, preparation of culture media, types of culture, modification through transformative cell culture, Regeneration of plants. Micro propagation, protoplast microinjection, Methods of gene transfer in plants, pharmaceutical applications of plant tissue culture.

6. Fermentation:

Introduction, Enzyme technology process: Chemically and genetically modified enzyme, Isolation, purification and modification in enzymes. Enzymes as therapeutics, enzymes in drug delivery design.



Biotransformation, techniques of fermentation, design of fermentors and bioreactors, fermentation products.

7. Immobilization

Various techniques of immobilization, immobilization of cells and enzymes. Applications of Immobilization enzyme and cell immobilization and its therapeutic applications.

8. Herbal Drug Standardization

Definitions of a range of medicinal plant materials as noted in Ayurvedic Pharmacopoeia of India(API), United States Pharmacopoeia(USP), European Pharmacopoeia(EP) and documents of European Medicines Evaluation Agency (EMA) and World Health Organization (WHO) and factors affecting quality of plant drugs. Significance of important techniques in establishing identity, purity and quality of plant drugs as described in different pharmacopoeias.

9. Nutraceuticals

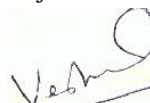
Approach for health management. Overview of internationally marketed nutraceuticals and functional Foods. Issues of quality control of nutraceuticals, various approaches for quality control and standardization of raw materials, extracts and formulation.

10. Herbal Technology

Herbal technology techniques, Manufacturing techniques of traditional herbals formulation and Formulation development of novel herbals formulation.

Books and References Recommended

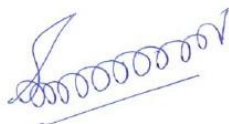
1. Nelson, D.L. and Coy, M.M., "Lehninger's Principles of Biochemistry", Worth Publishers, New York.
2. Karp, G., Cell & Molecular Biology.
3. Crommelin, D. J., A, And Sindelar Rd., Pharmaceutical Biotechnology.
4. Templeton N. S., And Lasic. D. D., Gene Therapy.
5. Benjamin Lewin, Genes.
6. Watson and Trooze, Recombinant DNA Techniques
7. Lesk, A.M., "Introduction To Bioinformatics", Oxford University Press(Indian Edition), New Delhi.
8. Watson, Molecular Biology of Cell.
9. Watson, J.D., Gilman, M, Recombinant DNA Technology
10. Baxevanis, A.D., Frana, Duelette, B.F., Bioinformatics
11. Alberts, B., Johnson, A, Lewin, J., Raff, M., Roberts, K, Walter, P., Molecular Biology of the Cell.



M. Pharm. Semester - I

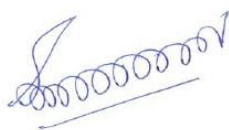
Modern Analytical Techniques

1. Theory, Instrumentation, Methods and applications of UV spectrophotometer.
2. Theory and Instrumentation of IR, FTIR, their advantages and applications in structural elucidation.
3. NMR, C-13 NMR, Origin of Spectra, Chemical Shifts, Spin-Spin Coupling, Coupling Constant, Instrumentation and application for structural elucidation.
4. Mass spectra, Instrumentation, Fragmentation pattern and application for structural elucidation. .
5. Theory, Instrumentation and application of the following:
 - a. Fluorescence
 - b. X- ray
 - c. Atomic spectroscopy
 - d. Ultra centrifugation
 - e. ESR
 - f. Liquid scintillation spectrometry
 - g. Auto radiography
6. Separation techniques: Fundamental principles, basic instrumentation, qualitative and quantitative pharmaceutical applications of gas-liquid chromatography, HPLC HPTLC, gel chromatography, electrophoresis and ion-pair chromatography.
7. Principles, instrumentation and application of GC-Mass, HPLC-Mass for complex mixtures.
8. Immunoassay Technique: Enzymes and radioimmunoassay techniques. Theory, methods and applications.
9. Thermal Methods: Thermo gravimetry (Tg), Differential scanning calorimetry (DSC). Differential thermal analysis (DTA)
10. Principles and application of light, phase contrast, scanning and transmission electron microscopy, cytometry and flow cytometry.



Books and References Recommended

1. Fiorey, Analytical Profiles of Drugs, Vol.1-16.
2. Sinder, Text Book of HPLC
3. Mclafferty, Mass Spectrometry.
4. Rao, C. N., Ultraviolet Spectroscopy for Chemical Application.
5. Silverstein, R.M. And Webster, F., " Spectrophotometric Identification Of Organic Compounds", John Wiley & Sons, Ltd., USA
6. Rao, C. N., Chemical Application of Infrared Spectroscopy
7. Weissberger, Physical Methods in Organic Chemistry.
8. Kienicz, B. And Dierasi, C., Interpretation of Mass Spectra of Organic Compounds.
9. Jackmann, Application of NMR Spectra to Organic Compounds.
10. Willard, H ,And Merrit L., " Instrumental Methods Of Analysis", CBS Publisher & Distributors, New Delhi.
11. Eliel, E. L., "Stereochemistry of Carbon Compounds", Tata Mcgraw Hill Publishing Co. Ltd., New Delhi.
12. Naahod, P., Physical Method of Structure Determination.
13. Stahl, Thin Layer Chromatography.
14. Ewing, G.W., " Instrumental Methods of Chemical Analysis", Mcgraw Hill Book Company, New York
15. Block and Durrum, Paper Chromatography and Electrophoresis.
16. Gennaro, A.R., "Remington- The Science And Practice Of Pharmacy", Lippincot, Williams And Wilkins, Philadelphia.
17. Sirmer, Spectroscopic Analysis.



Product Development and Formulation

1. Preformulation Studies

Perspective and Concepts: Detailed study of parameters like solubility, partition coefficient, dissolution influencing formulation and bioavailability of drugs. Methodology, solid state properties and purity studies, drug excipient compatibility study.

2. Formulation additives

Study of different formulation additives, drug-excipients, excipient–excipient interactions and incompatibilities.

3. Solubilization

Theory of solubilization, methods of solubility enhancement, factors influencing solubility.

4. Recent advances in parenteral and solid dosage form technology and automation in manufacturing process.

5. Dissolution Technology

Design of dissolution apparatus (forced convection devices, non-sink devices, and continuous flow through methods), dissolution media, dissolution testing of different types of dosage formulations, effect of environmental factors in dissolution testing; data interpretation, in-vitro and in-vivo correlation.

6. Polymers

Classification, general methods of synthesis, properties, characterization and application in pharmacy. biodegradable polymers, classification, mechanism of biodegradation in the body, safety and applications in pharmaceuticals and biomedical engineering.

7. Drug Stability

Solid state drug stability, kinetics stability study programme for formulations, stability indicating assays and ICH guidelines for stability.

8. Optimization Techniques in Pharmaceutical Formulation and Processing

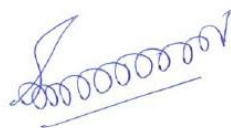
Optimization parameters, statistical design and their applications.

9. Cosmeceuticals: Advances in cosmetic technology



Books and References Recommended

1. Swarbrick,J. and Boynin,J.C., "Encyclopedia Of Pharmaceutical Technology", Vol. 1-3, Marcel Dekkar ,Inc., New York.
2. Gennaro,A.R.,Remington - The Science & Practice Of Pharmacy, Lippincot Wiliams and Wilkins, Philadelphia
3. Aulton,M.E., Pharmaceuticals -The Science Of Dosage Form Design", Churchill Livingstone,London
4. Carstensen, J. T., "Drug Stability: Principles & Practice", Marcel Dekker,Inc.,Ny
5. Banker,G.S. and Rhodes,C., "Modern Pharmaceutics",Marcel Dekker,Inc.,Ny
6. Ilium,L. and Davis,S.S., "Polymers In Controlled Drug Delivery ",Wright Bristol.
7. Kibbe, Handbook of Pharmaceutical Excipients "Pharmaceutical Press", London.
8. Lachman, L. & Lieberman, H.A., "Theory and Practice of Industrial Pharmacy". Verghese Publishing House, Bombay
9. Martin, Physical Pharmacy
10. Lieberman,H.A. And Lachman,L., "Pharmaceutical Dosage Forms - Dispersed Systems" Vol. 1 – 3, Marcel Dekker, Inc.,Ny
11. Avis,K.E.. And Lachman,L., "Pharmaceutical Dosage Forms - Parenteral Medications" Vol. 1 - 3, Marcel Dekker, Inc.,Ny
12. Lieberman, H. A. and Lachman, L., "Pharmaceutical Dosage Forms - Tablets" Vol. 1 - 3, Marcel Dekker, Inc.,Ny
13. Yalkowsky;S.H., "Techniques of Solubilization of Drugs",Marcell Dekker, Inc.,Ny



Biopharmaceutics, Pharmacokinetics and Clinical Kinetics

1. Transport of Drugs through Biological Membranes:

Drug Absorption: Gastrointestinal absorption of drugs, mechanism of drug absorption, physico-chemical, and biological factors influencing absorption. Buccal absorption, salivary excretion of drugs, excretion of drugs via. sweat, excretion of drugs into milk, penetration of drugs into eye, transfer across placenta, passage of drug into and out of cerebrospinal and brain. Transport across caco 2 monolayers, Other Cell-lines to predict- biological, pharmaceutical and analytical considerations

2. Bio-Availability and Bio-Equivalence

Bioequivalence its importance and determination, Objectives and consideration in bio-availability studies, Concept of Equivalents, study design for the assessment of bioavailability and bio-equivalence, factors influencing bio-availability and bio-equivalence, Regulatory aspects of bio-availability and bioequivalence studies for conventional dosage forms and controlled drug delivery systems, In-vitro in-vivo data correlation, Methods of establishing IVIVC and Factors affecting IVIVC.

3. Pharmacokinetics

Basic consideration, Pharmacokinetic models, Consideration of one, two and multiple compartment models on intravenous administration, intravenous infusion and oral dosage forms.

Kinetics of multiple dosing: Dosage regimens, loading and maintenance doses, one and two compartment models on intravenous administration, and first order absorption in multiple dosing. Kinetics of reversible pharmacological effects – direct and indirect effects.

4. Clinical Pharmacokinetics

Introduction to clinical pharmacokinetics: Concepts, absorption, distribution and renal excretion, hepatic clearance and elimination, disposition and absorption kinetics, intravenous dose, constant I.V. infusion, extra-vascular dose, metabolite kinetics. Pharmacokinetic drug interactions, Inhibition and induction of drug

metabolism, Inhibition of biliary excretion, Therapeutic regimens: Therapeutic response and toxicity, dosage regimens, clinical trial studies, Therapeutic drug monitoring (TDM).

5. Physiologic Pharmacokinetic Models

Concepts, physiologic pharmacokinetic model with binding, blood flow limited versus diffusion limited model, applications and limitation of physiologic pharmacokinetic models, mean residence time (MRT), statistical moments theory, mean absorption time (MAT), mean dissolution time (MDT).

6. Non-Linear Pharmacokinetic

Definition, significance and applications with literature examples, recognition of non-linearity, computation of nonlinear pharmacokinetic parameters (V_m , K_m , AUC, etc.) by single Michaelis Menten kinetics. Non –Linear Tissue Binding Constants.

7. Software used for Bio-Pharmaceutics and pharmacokinetics study and their significance

Books and References Recommended

1. Notari R.E., "Biopharmaceutics and Clinical Pharmacokinetics - An Introduction", Marcel Dekker, Inc., New York.
2. Gibaldi, M., "Biopharmaceutics and Clinical Pharmacokinetics", Marcel Dekker, Inc., New York
3. Shargel, L. and Andrew, B.C., "Applied Biopharmaceutics and Pharmacokinetics", Prentice-Hall International, Inc.,
4. Smith,R. and Steward,J., "Text Book Of Biopharmaceutical Analysis", Lea and Febiger,Philadelphia,
5. Rowland,M. and Tozer.T.N.,"Clinical Pharmacokinetics-Concepts and Applications",B.I. Wavery Pvt. Ltd.(Lea & Febiger),New Delhi
6. Swarbrick,J.," Current Concept In The Pharm. Sci., Dosage Form Design and bioavailability, Marcell Dekker .Lnc.,Ny
7. Gibaldi,M. and Perrier,D.: ' Pharmacokinetics",MarccI Dekker,Lnc.,Ny
8. Banker,G.S. and Rhodes,C.,Modem Pharmaceutics,Marcel Dekker,Lnc.,Ny
9. Aulton,M.E.,Pharmaceutics-The Science of Dosage Form Design",Marcel Dekker, Inc.,Ny
10. Tozer, N., Malcolm Rowland Thomas; Clinical Pharmacokinetics: Concepts and Applications.

Controlled Drug Delivery System

1. Concepts & Models of Controlled Drug Delivery System

Theoretical concepts, influence of drug properties and routes of drug administration on the design of sustained and controlled release systems. Classification of rate controlled drug delivery systems, with special reference to rate programmed release, activation modulated & feedback regulated. Computation of desired release rate for CDDS, pharmacokinetic design-intermittent, zero order, first order release.

2. Oral Controlled Release Drug Delivery Systems

Fabrication and evaluation of various drug delivery systems including gastro-retentive, colon-targeted and pulsatile drug delivery.

3. Transdermal Therapeutic Systems

Permeation enhancers, technologies for developing transdermal drug delivery system & evaluations, current innovations in skin delivery systems including iontophoresis

4. Parenteral Products

General considerations, various approaches and factors influencing the design and performance

5. Chemical Drug Delivery Systems

Prodrug and chemical delivery systems. Soft drug approach

6. Brain Drug Delivery

Physiological and physicochemical factors affecting drug delivery to brain, strategies for brain drug delivery.

7. Mucosal Drug Delivery Models

Buccal, Rectal, Nasal, Vaginal, Bioadhesive and Mucoadhesive drug delivery, formulation development, In-Vitro, Ex-Vivo and In-Vivo Methods of Evaluation (For Each Route).

8. Pulmonary Drug Delivery

Factors affecting absorption and metabolism of drug in airways, current and new technologies to pulmonary drug delivery.

9. Ophthalmic Drug Delivery

Development performance evaluation for topical and intraocular drug delivery.



Books and References Recommended

1. Mathiowitz, E., "Encyclopedia of Controlled Drug Delivery", Vol-1 & II John Wiley & Sons, Canada
2. Swarbrick, J. and Boylston, J. ; "Encyclopedia Of Pharmaceutical Technology" Vol. I - III, Marcel Dekker, Lnc., New York.
3. Jones, D.A., "Transdermal & Related Drug Delivery System.", Marcel Dekker, Lnc., Ny
4. Robinson, J.R and Lee, H., "Controlled Drug Delivery Fundamentals & Applications Marcel Dekker , Inc., New York.
5. Chein, Y.W., "Transdermal Controlled Systemic Medications" , Marcel Dekker , Inc., New York
6. Hillery, A. and Lloyd, A.W., "Drug Delivery & Targetting", Taylor & Francis, London
7. Deasy, P.B., "Microencapsulation & Related Drug Processes" Marcel Dekker, Lnc., New York

Novel Drug Delivery System

1. Targeted Drug Delivery

Definition, concept, importance in therapeutics principles of molecular biology - cell recognition and signalling, signal transduction, cell surface receptors, methods in drug targeting delivery systems, appreciation of Aquasomes, Pharmacosomes.

2. General Considerations, Biochemical and Molecular Biology Approaches, Characterization & Commercial Concept of following Drug Delivery Systems

- a. Liposomes
- b. Resealed Erythrocytes
- c. Nanoparticles
- d. Monoclonal Antibodies
- e. Microparticulate Carriers

3. Peptide and Protein Drug Delivery: Concepts, delivery techniques, formulation, stability testing, causes of protein destabilization, stability and destabilization

4. An Overview and Applications of following Drug Delivery Systems:

- a. Liquid crystals
- b. Magnetically modulated drug delivery
- c. Dendrimers
- d. Submicron emulsions
- e. Hydrogel system
- f. Transfersomes

Books and References Recommended

1. Mathiowitz, E., "Encyclopedia of Controlled Drug Delivery", Vol- I & II, John Wiley & Sons, Canada
2. Swarbrick, J. and Boyl, J., "Encyclopedia of Pharmaceutical Technology" Vol. I-III, Marcel Dekker, Lnc., New York.
3. Jones, D.A., "Transdermal & Related Drug Delivery System. Marcel Dekker, Lnc., New York.
4. Robinson, J.R. and Lec, "Controlled Drug Delivery Fundamentals & Applications Marcel Dekker, Lnc., New York.
5. Chein, Y.W., "Transdermal Controlled Systemic Medications", Marcel Dekker, Lnc., New York
6. Hillery, A., and Liyod, A.W., "Drug Delivery & Targeting", Taylor & Francis, London
7. Deasy, P.B., "Microencapsulation & Related Drug Processes" Marcel Dekker, Lnc., New York

M. Pharm. Semester – II

Pharmaceutical Packaging Technology

1. Concepts in pharmaceutical packaging
2. The packaging function
3. Regulatory aspects of pharmaceutical packaging. Package system, package design research.
4. Packaging materials with special reference to: Glass, Plastics, Metals & Polymers
5. Control of Packaging Materials
6. Ancillary materials used in packaging
7. Types and testing of containers and closures, closure systems
8. Pharmacopoeial Tests and Specifications.
9. Types of packaging with special reference to: Blister, strip, sachet, child resistant and tamper evident packaging, Packaging of parenteral, ophthalmics and aerosols
10. Stability of packages and packaging materials
11. Sterilization of packaging materials
12. Printing and decoration of labels and packages
13. Package testing
14. Defects in packaging

Books and References Recommended

1. Swarbrick, L. and Bolyl, J.C., Encyclopedia of Pharmaceutical Technology Vol. 1 - 3, Marcel Dekker, Inc., New York.
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