Master of Pharmacy

M.Pharm. Pharmaceutics
M.Pharm. Pharmacology

J.N. Medical College-Belgaum

2007

K L E UNIVERSITY

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BELGAUM (Karnataka, India

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Mission Statement

Our mission is to contribute to the national programme of providing graduate trained pharmaceutical manpower through prescribed training programme of M.Pharm, with Professional Pharmaceutical education and effective competency to undertake the national task of meeting social and pharmaceutical needs in Industrial pharmacy, Medicare program, pharmaceutical education and research.

Section-I

1. Aim and Objective

To produce a competent Industrial pharmacist/ Research pharmacologist with ackground knowledge of various modern analytical techniques.

1.1 Pharmaceutics

Upon completion of the course, the candidate shall have Knowledge and understanding of the concept and design of various pharmaceutical dosage forms. The ability to formulate and evaluate various dosage forms

1.2 Pharmacology

Upon completion of the course, the candidate shall have Knowledge of understanding the concept of drug action and its mechanism involved. The ability to screen new molecules for their potential pharmacological effects and toxicity.

Section-II

Regulations Governing M.Pharm Course

1. Eligibility:

A candidate who has passed B.Pharm degree examination of any recognized Indian University established by law in India or any other degree courses in pharmacy recognized as equivalent by KLE UNIVERSITY and recognized by Pharmacy council of India or All India Council of Technical Education for this purpose and who has secured not less than 55% of the maximum marks (aggregate of four years) prescribed for the qualifying examination shall be eligible for the admission to the M.Pharm course.

Further, pharmacy teachers having recognized B.Pharm qualification and with minimum of five years of teaching experience in an institution approved by A.I.C.T.E. and PCI will be eligible provided they have scored not less than 50% of the maximum marks (aggregate of four years in B.Pharm).

For SC / ST candidates the prescribed percentage of Marks will be 50% of the maximum marks in the qualifying examination.

2. Duration:

The course of study including submission of dissertation on the topic registered shall be of 24 months(Two years) duration from the commencement of academic term.

3. Course of study:

The study of M.Pharm course shall be of annual system that includes M.Pharm Part-I, extending for twelve months from the commencement of academic term and M.Pharm Part-II of twelve months duration. At the end of M.Pharm Part-I, there shall be an university examination of M.Pharm Part-I. At the end of M.Pharm Part-II, the candidate shall submit a dissertation on the topic approved by the university.

Subjects to be studied in different branches of M.Pharm course.

Sl.No	Branch Specialization	Paper	Name of the subject
1	**Pharmaceutics**	I	Modern Pharmaceutical Analysis
		II	Preformulation & Production Management
		III	Biopharmaceutics & Pharmacokinetics
		IV	Advances In Drug Delivery Systems

Sl.No	Branch Specialization	Paper	Name of the subject
1	**Pharmacology**	I	Modern Pharmaceutical Analysis
		II	Advanced Pharmacotherapeutics and Toxicology
		III	Pharmacological Screening methods and clinical Evaluation
		IV	Molecular Biology & Pharmacology

4. Attendance and progress of studies:

4.1. A candidate pursuing M.Pharm Course shall study in the concerned department of the institution for the entire period as full time student. No candidate is permitted to work in any laboratory/college/industries/pharmacy etc., while studying post graduate course. No candidate should join any other course of study or appear for any other examination conducted by this university or any other university in India or abroad during the period of registration.

4.2.Each year shall be taken as a unit for the purpose of calculating attendance.

4.3. Every student shall attend symposia, seminars, conferences, journal review meetings and lectures during each year as prescribed by the department/college/university and not absent himself/herself without valid reasons.

4.4. Candidate who has put in a minimum of 80% of attendance in the theory and practical assignments separately shall be permitted to appear for M.Pharm part-I examination.

4.5 Candidate who has put in a minimum of 80% of attendance in M.Pharm part-II shall only be eligible to submit the dissertation.

4.6 Any student who fails to complete the course in the manner stated above shall not be permitted to appear for the University examinations.

Every candidate shall maintain a work diary and record of his/her participation in the training programmes conducted by the department such as journal reviews, seminars, etc. The work diary shall be scrutinized and certified by the Head of the Department and Head of the Institution, and presented in the university practical examination if called for. Special mention may be made of the presentations by the candidate as well as details of experiments or laboratory procedures conducted by the candidate. The presentations will be assessed by the faculty members and peers.

5. **EXAMINATION:**

There shall be an examination for M.Pharm part-I at the end of one academic year. For M.Pharm Part-II, the examination shall be an evaluation of dissertation and Viva-Voce at the end of twelve months (one year) after the commencement of M.Pharm Part-II course.

5.1 Sessional Examination:

There shall be minimum of two sessional examinations in each subject of specialization conducted by the colleges at regular interval at the end of First term and Second term respectively both in theory and in practical which include seminars.

The sessional marks shall be awarded out of a maximum of 50 for theory and practical for each subject as follows:

Theory		**Practical**	
Written examination	30 marks (average of two)	Practical examination	30 marks (average of two)
Seminar	20 marks	Lab work	20 marks
Total	**50 marks**		**50 marks**

5.2 University Examination (M.Pharm part-I):

There shall be two university examinations annually, conducted at an interval of not less than four months. There shall be four theory papers in the university examination. Each theory paper shall be of 3 hours duration carrying 100 marks each. In each paper, there shall be two long essay questions of 20 marks each, five short essay questions of ten marks each and two short notes of five marks each. One of the short note questions would be on Pharmacy Ethics in Paper I.

There shall be four practical examinations in all the respective branches. The duration of each practical examination is of six hours which carries 100 marks each.

5.3 Criteria for Pass

5.3.1 M. Pharm Part-I

A candidate who secures 50% of marks in each subject in theory and practical separately including Sessional marks and university examination marks together shall be declared to have passed in M.Pharm part-I examination, provided the candidate secures a minimum of 40% marks (excluding Sessional) in theory & Practical separately. Candidate, who fails in theory or practical exam in a subject, shall appear for both theory and practical in the subsequent examination in that subject. Those candidates who fail in one or more subjects shall have to appear only in the subjects so failed, in the subsequent examinations.

Re-sessional examination:

Candidates who want to improve their sessional marks may be permitted to take re-sessional examination after the announcement of results only once in one or more subjects (theory/practical). In respect of practical resessionals however, the Sessional for laboratory work(Out of 20marks) remain unchanged.

Candidates who fail in M.Pharm part-I examination shall be permitted to continue M.Pharm part-II course. However, such candidate shall not be permitted to submit the dissertation unless the candidate completes M.Pharm part-I examination and passes both theory and practical.

5.3.2 M.Pharm. Part-lI

Dissertation

i. Every candidate pursuing M. Pharm course is required to carry out work on a selected research project under the guidance of a recognized postgraduate teacher. The results of such a work shall be submitted in the form of a dissertation.

ii. The dissertation is aimed to train a postgraduate student in research methods and techniques. It includes identification of the problem, formulation of a hypothesis, review of literature, getting acquainted with recent advances, designing of a research study, collection of data, critical analysis, and comparison of results and drawing conclusions.

iii. The dissertation should be written under the following headings

1. Introduction
2. Aims or Objectives of study
3. Review of literature
4. Material and Methods
5. Results
6. Discussion
7. Conclusion
8. Summary
9. References
10. Tables
11. Annexure

iv. The written text of dissertation shall be not less than 50 pages and shall not exceed 150 pages excluding references, tables, questionnaires and other annexure. It should be neatly typed with double line spacing on one side of the bond paper (A4 size, 8.27" x 11.69") and bound properly. Spiral binding should be avoided. The dissertation shall be certified by the guide and co-guide if any, Head of the Department and Head of the Institution. The dissertation shall be submitted at least two month before the end of M. Pharm Part II term.

v. A guide shall be a full time post graduate teacher of an institution affiliated to KLE University and recognized by KLE University as a guide for supervision of dissertation work. However a Co-guide can be opted wherever required. The Co-Guide shall also be a postgraduate teacher recognized by KLE University as guide.

vi. Synopsis: A candidate shall submit synopsis duly approved by IAEC (Institutional Animal Ethical Committee) to the Registrar, KLE University of the intended project work through the guide, HOD and Head of the institution, not later than nine months from the date of admission to M.Pharm Part I on or before the date specified by KLE University

5.4 Submission Of Dissertation:

Three copies of the dissertation duly certified by the Guide, Head of the Department and the Principal shall be submitted to the Registrar Evaluation, KLE University, through the Head of the department one months before the final examination notified by KLE University, Belgaum.

5.5 Viva-Voce Examination:

The Viva-Voce examination shall aim at assessing the depth of knowledge, logical reasoning, confidence and oral communication skills.

The Viva-Voce examination shall be held after the submission of dissertation. If any candidate fails to submit the dissertation on or before the date prescribed, his/her Viva-Voce shall be conducted during the subsequent examination, which shall not be earlier than six months from the date fixed in the first instance.

Examiners: There shall be at least two examiners in each branch/specialization, out of them one shall be external examiner and the other one shall be the internal examiner. The internal examiner ordinarily be the guide.

5.6 DISTRIBUTION OF MARKS FOR M. PHARM PART-II EXAMINATION:

Total- 200 marks, Dissertation- 150 marks, Viva-Voce-50 marks. The dissertation and viva-voce shall be valued, by the examiners together appointed by the university.

Scheme of evaluation of M. Pharm. Dissertation	
Literature Review	30 marks
Materials and Methods	60 marks
Result, Discussion and Conclusion	60 marks
Total	**150 marks**

5.7 MINIMUM MARKS FOR PASSING M.PHARM PART-II:

The minimum marks for pass in M.Pharm Part II shall be 50% of the marks of dissertation and viva voce and an aggregate of 100 marks out of 200 marks.

6. AWARD OF DEGREE

Class shall be declared on the basis of the aggregate of marks scored in M.Pharm part-I and part-II:

(1)	75 % & above	at first attempt	Distinction.
(2)	60% & above but less than 75%	at first attempt	First class.
(3)	50% & above but less than 60%		Second class.

The candidate shall not take more than double the number of years prescribed for the course (i.e. 4 years) for passing. Otherwise, the candidate should seek readmission.

M.PHARM PART-I EXAMINATION

Scheme of Examination for all Branches

Consolidated marks for Part-I & Part-II

Scheme of Examination for all branches

		THEORY				PRACTICAL			
Subjects	**No of Papers**	**Duration of Papers [hours]**	**Sessional Max Marks**	**Maximum Marks for Written Exam**	**Total**	**Duration of Practical**	**Sessional Max Marks [Hours]**	**Maximum Marks**	**Total**
Paper – I MPA	1	3	50	100	150	6	50	100	150
Paper – II	1	3	50	100	150	6	50	100	150
Paper – III	1	3	50	100	150	6	50	100	150
Paper – IV	1	3	50	100	150	6	50	100	150
Total					600				600

Part-I	Part-II	Grand Total
1200	200	1400

MODERN PHARMACEUTICAL ANALYSIS

[Common Paper]

GOALS: The important goals of this subject is to give thorough understanding of the spectroscopy, Mass and chromatographic techniques so that the postgraduate students can work in the pharmaceutical companies and research laboratories. Goal of this course is also to train the student's Structural elucidation of organic compounds.

OBJECTIVES: On completion of the course, the student shall be able to

1. Know the fundamental principles, instrumentation and applications of UV-Visible, IR, NMR, Mass spectroscopy, ORD and chromatographic techniques.
2. Know ORD, Electrophoresis and statistical analysis.
3. Shall be able to analyze drugs and pharmaceuticals using the above instruments.
4. Shall be able to interpret the structure of the organic compounds with the given spectral data.
5. Shall be able to appreciate the importance of modern instruments in the quality control and research.

COURSE CONTENTS

THEORY **75 Hours (3Hrs/wk)**

1.UV-VISUALSPECTROSCOPY: Brief review of electromagnetic spectrum, UV-Visual range, energy, wavelength and color relationships. Interaction of electromagnetic radiation with matter and its effects. Chromophores and their interaction with E.M.R. Absorption spectra of organic compounds and complexes illustrating the phenomenon and its utilization in qualitative and quantitative studies of drugs, shifts and their interpretation (including solvent effects). Empirical correlation of structure with absorption phenomena (Woodward's rules etc), quantitative estimations.

Modern instrumentation of single ,double and split beam U-V spectrophotometer.

6 Hours

2. INFRARED SPECTROSCOPY: Nature of Infra-red radiation, Interaction of I.R. radiation with organic molecules and effects on bonds, Molecular Infrared spectra, Brief outline of classical I.R. instrumentation and particle details of obtaining spectra, Including sample preparation for spectroscopy, qualitative interpretation of I.R. spectroscopy including FT-IR. 5 Hours

3. OPTICAL ROTATORY DISPERSION: Fundamental principles of ORD. Cotton effect curves- their characteristics and interpretation, Octant rule and its application with examples, Circular dichroism and its relation to ORD

3 Hours

4. NUCLEAR MAGNETIC RESONANCE SPECTROSCOPY: Fundamental principles of NMR (Magnetic properties of nuclei; applied field and precession; absorption and transition; frequency). Chemical shifts concept: Isotopic nuclei, Reference standards: Proton Magnetic spectra, their characteristics, presentation terms used in describing spectra and their interpretation (Signal No., Position, Intensity). Brief outline of instrumental arrangements and some practical details. Signal multiplicity phenomenon in high resolution PMR, Spin-spin coupling. Application of Signal Split and coupling constant data for interpretation of spectra. De-coupling and shift reagent methods. Brief outline of principles of FT-NMR with reference to ^{13}CNMR: Spin-spin and spin-lattice relaxation phenomenon. Free induction decay (FID) proton noise de-coupling signal, average time domain and frequency domain,signals, nuclear overhauser enhancement, ^{13}C NMR spectra-their presentation, characteristics, interpretation, examples and applications. Brief indication for application of magnetic resonance spectral data of other nuclei by modem NMR instruments, Introduction to 2-D NMR techniques.

14Hours

5. MASS SPECTROMETRY: Basic principles and brief outline of instrumentation. Ion formation and types; molecular ion, meta stable ions, fragmentation processes. Fragmentation patterns and fragmentation characteristics in relation to parent structure and functional groups. Relative abudances of isotopes and their contribution to characteristic peaks. Mass spectrum, its characteristics, presentation and interpretation. Chemical ionization, Mass spectrometry. GC-MS, other recent advances in MS, Fast atom bombardment mass spectrometry. 9 Hours

6. CHROMATOGRAPHIC TECHNIQUES: Classification of chromatographic methods based on mechanism of separation. Paper chromatography- techniques and applications. Thin Layer chromatography, comparison to paper chromatography and HPLC, adsorbents for TLC. Preparation techniques, mobile phase selection, reversed phase TLC, High performance TLC detection methods, quantitative methods in TLC, programmed multiple development techniques.

5 Hours

7. GAS CHROMATOGRAPHY: Instrumentation, packed and open tubular column, Column efficiency parameters, the Vandeemeter equation, Resolution, liquid stationary phases, derivatization methods of GC including acylation, perfluoroacylation, alkylation and esterification. Detectors; FID, ECD, TCD, NPDA critical comparison of sensitivity, selectivity and fields of application of these detectors, examples of GC applications in pharmaceutical analysis. 6 Hours

8. LIQUID CHROMATOGRAPHY: Comparison of GC and HPLC, instrumentation in HPLC, Analytical, preparative and micro bore columns, normal and reversed-phase packing materials, Reverse phase HPLC, column selection, mobile phase selection, efficiency parameters, resolution, detectors in HPLC refractive index, Photometric and electrochemical. Comparison of sensitivity, selectivity and fields of application of these detectors. HPTLC - instrumentation and applications. 10 Hours

9.ELECTROPHORESIS: Moving boundary electrophoresis, zone electrophoresis, Isotachophoresis, Isoelectric focusing and immunoelectrophores, continuous electrophoresis (preparative) and their applications. 2 Hours

10. X-RAY DIFFRACTION METHODS: Introduction, Generation of X-rays, Elementary crystallography, Miller Indices, X-ray diffraction, Bragg's law, X-ray powder diffraction, X-ray powder diffractometer, obtaining and interpretation of X-ray powder diffraction data. 4 Hours

11. STATISTICAL ANALYSIS: Introduction, significance of statistical methods, Normal distribution, probability, Degrees of freedom, measures of variation-standard deviation, variance, standard error, tests for statistical significance - students 'T' test. chi-square test. 5 Hours

12. TEACHING SKILLS, RESEARCH METHODOLOGY AND LITERATURE SOURCES: Fundamentals of teaching and learning; art and science of teaching. Thesis writing and presentation of the work. Citation of references 3 Hours

13. ETHICS IN PHARMACY 3 Hours

PRACTICALS **150 Hours (6 Hrs/wk)**

Minimum of 15 experiments to be performed :

Major Experiments

1 - 4 Simultaneous estimation of Paracetamol and Ibuprofen; Aspirin and Caffeine; Rifampicin and Isoniazid other combination formulation (4 expts).

5. U.V. Visible spectrum scanning of certain organic compounds- absorption and correlation of structures. Comparison e.g.
   a) Chloramphenicol
   b) Analgin
   c) Sulphadiazine

d) Ibuprofen

6. Comparison of three different analytical methods for Salbutamol or other drugs.

7-8. Experiments based on HPLC & G.C. (2 expt).

9-13 Workshop on spectroscopy structural elucidation of at least 5 unknown compounds.

14 IR, NMR & Mass spectroscopy (! compound each).

15. Effect of pH and solvent on U.V. Spectrum of certain drugs.

16. Separation by electrophoresis.

17. Any other relevant exercises based on theory.

Minor Experiments

18. Case studies on quality control lab planning & analytical reporting of raw materials, In-process and finished goods.

19. Two dimensional paper chromatography and TLC

20. Gradient elution and other techniques in column chromatography

Teaching / learning activities:

1. Journal Club: Minimum of one presentation per term per student.

2. Seminars: Minimum of one seminar per term per student.

3. Field visits / Industrial visits: Minimum of one visit during first year.

4. Conferences / workshops: The students and teaching staff shall be encouraged to attend at least one conference/meetings in their respective discipline.

Scheme of the examination:

Subjects	Sessional Marks	Seminar / Record marks	Annual Examination marks	Total marks
Theory	30	20	100 (3 hours)	**150**
Practical	30	20	100 (6 hours)	**150**

Practical Examination

1. Synopsis 20 marks
2. Major Experiment 35 marks
3. Minor Experiment 25 marks
4. Viva- voce 20 marks

Total 100 marks

Journals:

1. At least one international journal is to be subscribed
2. Journal of Chromatography
3. The Analyst

Recommended books (Latest Edition)

Sl.No	Name of the book	Author	Publisher
01	Fundamentals of applied statistics	S.C. Gupta and C.K'. Kapoor.	Sultan Chaond & Sons.
02	Spectrophotometric identification of organic compounds	Silverstein et.al	John Wiley & Sonc, INC.

Reference books(Latest Edition

Sl.No	Name of the book	Author	Publisher
01	X-ray methods	Clive Whoston	published by John Wiley & Sons
02	Principles of Instrumental analysis	Skoog.D.A; Holler.F.J.	Harcourt Asia Pte Ltd.,
03	Instrumental Method of analysis - Modern methods part-B, vo1-2 pages 11 to 154	Editor - James W. Munson,.	Drug & Pharm. Sciences Marcel Dekker

M.PHARM PHARMACEUTICS

TITLE OF PAPERS

Paper-I Modern Pharmaceutical Analysis

Paper-II Preformulation And Production Management

Paper-III Bio-pharmaceutics and Pharmacokinetics

PaperIV Advances in Drug delivery Systems

PAPER-II PREFORMULATION AND PRODUCTION MANAGEMENT

GOAL: To train the students to work at managerial level in pharmaceutical industries in formulation, production, QC & QA, Research and Development departments.

OBJECTIVES:

Upon completion of the course, the candidate shall be able to

-Manage the production of large batches of pharmaceutical formulations.

-Work in F & D department for Preformulation studies

-Optimize and validate various techniques in pharmaceutical formulation & processing

-To establish safety guidelines, which prevent industrial hazards.

COURSE DESCRIPTION

THEORY **50 Hours (T: 2 Hrs/wk)**

1. **PREFORMULATION:** Introduction. Organoleptic properties, purity, particle size, shape, and surface area, Solubilization, surfactants and its importance, temperature, pH, cosolvancy, solid dispersion, b-cyclodextrin drug dispersion system, techniques for the studies of crystal; properties and polymorphism. Preformulation stability studies. A consideration of physico-chemical characteristics of new drug molecules with respect to different dosage forms. 10 Hours

2. COMPACTION AND COMPRESSION: Compaction of product with their particular reference to distribution and measurement of forces within the powder mass and undergoing compression. Effect of particle size, moisture content, lubrication etc. on the strength of tablets. A brief study on formulation aspect of tablet such as sublingual, Buccal, chewable and medicated lozenges. 4 Hours

3. PRODUCTION MANAGEMENT AND DOCUMENTATION: ISO 9000 series, Total quality management, guide to pharmaceutical manufacturing facilities, productivity, GMP considerations, Quality assurance and process control stress on documentation practices, validation for tablets and parenterals, validation aspects. 8 Hours

4.INVENTORY MANAGEMENT: Costs in inventory, inventory categories-special considerations, selective inventory control, reorder quantity methods and EOQ, inventory models, safety stock-stock out, lead time-reorder time methods, modern inventory management systems, inventory evaluation. 3 Hours

5. MATERIAL MANAGEMENT AND HUMAN RESOURCE DEVEMOPMENT: Materials-quality and quantity, value analysis, purchasing-centralized and decentralized, vendor development, buying techniques, purchasing cycle and procedures, stores management salvaging and disposal of scrap an d surplus, Selection of material handling systems, maintenance of material handling equipment, unit load, pelletization and containerization, types of material handling systems. Human resource development- Personnel training, job specification. Job enlargement and enrichment, blue and white-collar jobs. Labor welfare. 8 Hours

6. OPTIMIZATION TECHNIQUES IN PHARMACEUTICAL FORMULATION AND PROCESSING: Concept of optimization, optimization parameters, classical optimization, statistical design, and optimization methods.

3 Hours

7. PILOT PLANT SCALE UP TECHNIQUES: Significance of pilot plant scale up phase to effect an orderly set up from laboratory procedures and formulations to routine production procedures. Pilot study of some important dosage forms such as tablets, capsules, injections and liquid orals and discussion on important parameters such as formula and equipment, product uniformity and stability. Raw materials and process, physical layouts, personal requirements and reporting responsibilities. Inputs specifications and in process and finished product specifications.

8 Hours

8. INDUSTRIAL SAFETY: Industrial hazards due to fire accidents, mechanical and electrical equipments, chemical and pharmaceutical. Monitoring and prevention systems. Industrial effluent testing and treatment. Discussion on industrial accident case studies, environment and pollution acts.

4 Hours

9 PATENT, INTELLECTUAL PROPERTY AND REGULATORY AFFAIRS: Definitions, procedures for applying, Indian scenario, GATT, TRIPS, TRIMS & WTO Legal aspects. 2 Hours

PRACTICALS: **150 Hrs (6Hours/wk)**

Suggested practical exercises: (at least 15 experiments to be conducted)

1. Preformulation study of tablets. - 3 experiments

2. Study of effect of various experiments on the properties of tablets -4 experiments

3. Preparation and evaluation of Diclofenac sodium gels containing two different gel bases. - 2 experiments

4. Preparation and comparative evaluation with marketed product for efficiency of neutralizing property of antacid suspensions. - 1 experiment

5. Formulation and evaluation of stability of reconstituted dry syrup of Amoxycillin, Ampicillin etc. - 2 experiments

6. Product development and protocol preparation for :
   I. Liquid antacid preparation.
   II. Multivitamin tablet/capsule
   III. Skin ointments.
   IV. Injection containing antibiotics -4 experiments
7. Validation of any equipment -2experiments

8. Solid dispersion-formulation and evaluation. - 2experiments

9. Industrial visit and submission of report on safety, pilot plant, effluent treatment and documentation.

Scheme of examination:

1. Synopsis 20marks
2. Experimental
    a. Formulation 35 marks
    b. Evaluation 25 marks
3. Viva-voce 20 marks

Total 100 marks

Journals:

1. Drug Development and Industrial Pharmacy, Publisher-Dekker, www.dekker.com
2. Indian Journal of Pharmaceutical sciences, Publisher-Indian Pharmaceutical Association. www.indianpharma.org
3. Indian Drugs, Publisher-IDMA.

Recommended books (Latest Edition)

Sl.No	Name of the book	Author	Publisher
01	The theory and practice of industrial pharmacy	Leon Lachman, Herbert. A. Lieberman, Joseph. L. Kanig,	Varghese Publishing House, Hind Rajasthan Building, Dadar, Bombay-400014.
02	Modern Pharmaceutics	Gilbert. S. Banker, Christopher. T. Rhodes,	Marcel Decker, Inc., 270 Madison Avenue, New York.
03	Textbook of Pharmaceutics by E. A. Rawlins,	Bently's	Baillere Tindall, London

Reference books(Latest Edition)

Sl.No	Name of the book	Author	Publisher
01	Physical Pharmacy	Alfred Martin, James Swarbrick, Arthur Cammarata,	Varghese Publishing House, Bombay.
02	Pharmaceutical Dosage Forms-Tablets, Volumes 1, 2, 3	Herbert. A. Lieberman, Leon Lachman, Joseph. B. Schwartz,	Marcel Decker, Inc., 270 Madison Avenue, New York.
03	Pharmaceutical Dosage Forms-Parenteral Medications, Volumes 1 & 2	Kenneth, E. Avis, Leon Lachman, Herbert. A. Lieberman,	Marcel Dekker, Inc., 270 Madison Avenue, New York.
04	Drug Formulation Manual	D. P. S. Kohli, D. H. Shah	Eastern Publishers, New Delhi.
05	How to practice GMPs	P. P. Sharma,	Publications, Kamla Nagar, Agra.
06	Pharmaceutical process validation,	Edited by Fra. R. Berry and Robert. A. Nash.	Marcel Dekker. INC.
07	Good Manufacturing Practices for Pharmaceuticals, A Plan for Total Quality Control,	Edited by Sydney. H. Willing & James. R. Shoher.	Marcel Dekker. INC.
08	Applied production and operations management	Evans, Anderson, Sweemey and Williams	West publishing company Ltd.St.Paul.
09	Management (task, responsibility and practices)	Peter F. Drucker	Allied publication, Bangalore.

PAPER-III BIOPHARMACEUTICS AND PHARMACOKINETICS

GOALS: To train the students in the area of biopharmaceutics and pharmacokinetics to work efficiently in the R & D department of industry, to take part in clinical research (clinical trials).

OBJECTIVES: Upon completion of the course, the candidate shall have the ability to

- calculate Pharmacokinetic parameters from the given data.
- Apply the principles of Pharmacokinetcs in new drug drug development as well as in the design of new formulation.
- Conduct Bioavailability and Bioequivalence studies.

COURSE CONTENTS N

THEORY **50 Hours (T: 2Hrs/wk)**

ABSORPTION OF DRUGS: Structure of cell membrane, Gastro-intestinal absorption of drugs, mechanisms of drug absorption, Factors affecting drug absorption; Biological, Physiological, Physiochemical, Pharmaceutical, Absorption of drug from non-per oral routes. Methods determining absorption; In-vitro, In situ and In-vivo methods. 8 hours

BIOAVAILABILITY: Objective and considerations in bioavailability studies, concept of equivalents, Measurement of bioavailability, Determination of the rate of absorption. Bioequivalence and its importance, Bioequivalence studies.

7 hours

DISSOLUTION: Noyes-Whitney's Dissolution rate law, Study of various approaches to improve dissolution of poorly soluble drugs, In-Vitro dissolution testing models, In-Vitro In-Vivo correlation. 3 hours

PHARMACOKINETICS: Basic considerations, Pharmacokinetic models, Compartment modeling; One compartment model-IV Bolus, IV Infusion, Extra-vascular; Multi compartment models; Two compartment model-IV Bolus, IV Infusion, Extra-vascular, Three compartment model in brief, Application of pharmacokinetics in new drug development under designing of dosage forms and novel drug delivery systems. 11 hours

NONLINEAR PHARMACOKINETICS: Cause of nonlinerity, Michaelis-Menten equation, Estimation of K_m and $V_{max.}$ 4 hours

DRUG DISTRIBUTION: Factors affecting drug distribution, volume of distribution, protein binding-factors affecting, significance and kinetics of protein binding. 4 hours

BIOTRANSFORMATION: Phase I (oxidative, reductive and hydrolytic reactions) and Phase II reactions (Conjugation), Factors affecting biotransformation. 3 hours

EXCRETION OF DRUGS: Renal and non-renal excretion, Concept of clearance-Renal clearance, Organ clearance & Hepatic clearance 3 hours

DOSAGE REGIMEN: Multiple dosing with respect to I.V. and oral route, Concept of loading dose, maintenance dose, Accumulation index, (Adjustment of dosage in renal and hepatic impairment, individualization of therapy, Therapeutic Drug Monitoring.) 7 hours

PRACTICALS: **150 Hrs (6Hrs/wk)**

Suggested Practical Exercises: (At least 15 experiments to be conducted)

1.Improvement of dissolution characteristics of slightly soluble drugs by various solid dispersion techniques and solvent deposition systems.

-4 experiments

2. Comparison of dissolution of two different marketed products/brands.

-2 experiments

3. Influence of polymorphism on solubility and dissolution.

-2 experiments

4. Protein binding studies of a highly protein bond drug and poorly protein bond drug.

-2 experiments

5. Bioavailibility studies of Paracetamol by salivary data.

-1 experiments

6. Calculation of Ka, Ke, $T_{1/2}$, C_{max} and T_{max} for two sets of data.

-2 experiments

7. Calculation of Bioavailibility from the given urinary excretion data for two drugs.

2 experiments

8. Calculation of AUC and bioequivalance from the given data for two drugs.

-2 experiments

Scheme of examination:

1. Synopsis 20marks
2. Experiment 40 marks
3. Calculation 20 marks
4. Viva-voce 20 marks

Total 100 marks

Journals:

1. European Journal of Biopharmaceutics and Pharmacokinetics, Publisher- Elsevier Science, www.elsevier.com
2. Indian drugs
3. Indian journal of pharmaceutical sciences.

Recommended books (Latest Edition)

Sl.No	Name of the book	Author	Publisher
01	Biopharmaceutics and clinical pharmacokinetics	Milo Gibaldi.	Philadelphia, Lea and Febiger,
02	Biopharmaceutics and pharmacokinetics,	A. Treatise, D. M. Brahmankar amd Sunil B. Jaiswal.,	Vallabh Prakashan, Pitampura, Delhi.
03	Applied Biopharmaceutics and pharmacokinetics	Shargel. L. and Yu ABC.	Connecticut, Appleton Century Crofts, 1985.
04	Textbook of Biopharmaceutics and pharmacokinetics	Dr. Shobha Rani R. Hiremath,	Prism Books Pvt Ltd, Bangalore,

Reference books (Latest Edition)

Sl.No	Name of the book	Author	Publisher
01	Pharmacokinetics.	GIBALDI.M; PERRIER.D.	**Marcel Dekker. INC.**
02	Current concept in Pharmaceutical sciences; Biopharmaceutics,	Swarbrick. J.	Lea And Febiger, Philadelphia,
03	Clinical pharmacokinetics, concepts and applications	Malcolm Rowland and Thomas N. Tozer,	Lea And Febiger, Philadelphia,
04	Dissolution, Bioavailibility and Bioequivalence,	Abdou. H. M,	Mack Publishing company, Pensylvania,
05	Biopharmaceutics and clinical pharmacokinetics, An introduction,	Robert. E. Notari,	Marcel Dekker Inc., New York and Basel,
06	Biopharmaceutics and relevant pharmacokinetics	John G. Wagner and M.pernarowski,	Drug Intelligence Publications, Hamilton, Illinois,
07	Encyclopedia of Pharmaceutical Technology,	James Swarbrick, James.C. Boylam	Marcel Dekker Inc., Publication New York,

PAPER IV ADVANCES DRUG DELIVERY SYSTEMS

GOAL: To train the students in the area of new drug delivery systems.

OBJECTIVE: Upon the completion of the course, the student shall have an understanding of the concept, design and evaluation of various sustained and controlled release dosage forms.

COURSE DESCRIPTION

THEORY **50Hrs (2Hrs/wk)**

1. Sustained release formulations: Introduction, concept advantages and disadvantages, physicochemical and biological properties of drugs relevant to sustained release formulations. 4 Hours

2. **Polymer science:** Introduction, Polymer classification, Application of polymers in formulation of controlled drug delivery systems, Biodegradable and natural polymers. 4 Hours

3. **Concept and System Design for Rate-Controlled Drug Delivery:** Classification of rate controlled drug delivery systems, Rate programmed release, activation-modulated and feedback-regulated drug delivery systems, effect of system parameters on controlled release drug delivery. 5 Hours

4. **Controlled Release Oral Drug Delivery systems:** Dissolution, Diffusion, Combination of Dissolution and Diffusion Controlled, Osmotic pressure controlled, Hydrodynamically balanced systems, pH controlled, and Ion Exchange controlled systems. 6 Hours

5. **Buccal Drug Delivery systems:** Concepts, advantages and disadvantages structure of oral mucosa, transmucosal permeability, mimosa membrane models, and Permeability en hankers, *In-Vitro, In-Vivo* methods for buccal absorption. Nasal and pulmonary drug delivery systems and its applications. 6 Hours
6. **Ocular Drug Delivery System:** Formulation and evaluation of ocular controlled drug delivery systems. Pilocarpine delivery system, ophthalmic inserts. 3 Hours
7. **Transdermal Drug Delivery system:** Permeation through skin, Factors affecting permeation, Basic components of TDDS, Formulation approaches used in development of TDDS in their evaluation, Permeation enhancers. 6 Hours

8. **Parentral controlled release drug delivery systems:** Approaches for injectable controlled release formulations and development of implantable drug delivery systems. 5 Hours

9. **Intrauterine Drug Delivery systems:** Development of intrauterine devices (IUDs), copper IUDs, hormone-releasing IUDs. 4 Hours

10. **Targeted Drug Delivery Systems:** Concept, advantages and disadvantages, Biological processes and event involved in drug targeting, nanoparticals, liposomes, released erythrocytes, micro spheres, magnetic micro spheres and monoclonal antibodies. 7 Hours

PRACTICALS **150Hrs (6Hrs/wk)**

Suggested practical experiments (at least 15 experiments to be conducted)

- Preparation and evaluation of albumin microspheres. (2 experiments)
- Preparation and evaluation of microcapsules by different microencapsulation techniques.
- Preparation and evaluation of matrix tablets by using various polymers
- Study on diffusion of drugs through various polymeric membranes.

  (2 experiments)
- Preparation and In-Vitro evaluation of Buccal mucoadhesives

  (2 experiments)
- Preparation and evaluation of hydrodynemically balanced tablets

  (1 experiments)
- Preparation and evaluation of transdermal films

  (2 experiments)
- Study of In-Vitro dissolution of various sustained release formulations of marketed products.

  (2 experiments)

Scheme of examination:

1. Synopsis 20marks
2. Experimental
   a. Formulation 35 marks
   b. Evaluation 25 marks
3. Viva-voce

   Total 100 marks

Journals:

1. The Indian journal of pharmaceutical sciences (IPA)
2. Indian Drugs (IDMA)
3. Journal of controlled release (Elsevier sciences) desirable
4. Drug Development and Industrial Pharmacy (Marcel and Decker) desirable.

Recommended books(Latest Edition)

Sl.No	Name of the book	Author	Publisher
01	Novel Drug Delivery systems ,	Y.W. Chien,	Revised and expanded, Marcel Dekkar, Inc., New York
02	Controlled Drug Delivery systems,	Robinson, J. R. Lee V. H. L	Marcel Dekker, Inc., New York,

Reference books (Latest Edition)

Sl.No	Name of the book	Author	Publisher
01	Encyclopedia of controlled delivery,	Editor-Edith Mathiowitz,	Published by Wiley Interscience Publication, John Wiley and Sons, Inc., New York/ Chichester/ Weinheim.
02	Controlled and Novel Drug Delivery,	N. K. Jain,	CBS Publishers & Distributors, New Delhi,
03	Controlled Drug Delivery-concept and advances,	S. P. Vyas and R. K. Khar,	Vallabh Prakashan, New Delhi,

M.PHARM PHARMACOLOGY

TITLE OF PAPERS

Paper I Modern Pharmaceutical Analysis

Paper II Advanced Pharmacotherapeutics and Toxicology

Paper III Pharmacological Screening Methods and Clinical Evaluation

Paper IV Molecular Biology and Pharmacology

PAPER II. ADVANCED PHARMACOTHERAPEUTICS AND TOXICOLOGY

GOAL: To understand the mechanism of drug action in detail and toxicity of drugs.

OBJECTIVES: Upon completion of the course, the candidate shall be able to Know the chemical mediators and mechanisms by which the Drugs act. Know the drug therapy of certain disorders Understand gene therapy, different types of toxicities.

COURSE CONTENT

THEORY: **50 Hours (2Hrs/wk)**

1. Neurotransmitter receptor mechanisms, ion channel and G-protein linked receptors, second messenger systems.

8 Hours

Receptor expression and regulation with specific emphasis on adrenergic, dopaminergic, cholinergic, serotoninergic, histaminergic, GABA/BZ and excitatory aminoacid receptors, opioid receptors, purinoceptors and their subtypes with agonists and antagonists. Isolation and characterization of receptors.

2. Mediators of inflammation and allergy Autocoids 7 Hours

(Histamine, Bradykinins, PAF, Eicosanoids: prostaglandins, thromboxanes, leukotrienes and related compounds), nitric oxide / EDRF and vascular substances, oxygen free radicals and their scavengers. Cytokines and their actions, Cox- I, Cox-2 inhibitors and their role in inflammatory process, anti-inflammatory agents, asthma and COPD.

3. Immunomodulators, AIDS & Rheumatoid arthritis 3 Hours.

4. Drugs acting on 21 Hours

- CNS -- general anaesthetics, anxiolytics & hypnotics, antipsychotics, antidepressants, antiepileptics, analgesics, anti migraine agents and anti parkinsonism agents.
- ANS -- sympathomimetics, sympatholytics, parasympathomimetics, parasympatholytics and Neuromuscular Junction blockers.
- CVS -- antihypertensives, cardiotonics, antiarrhythmics, antianginal hypolipidemics and antiatherosclerotic agents.
- Hormones -- pituitary, thyroid, parathyroid, pancreatic, adrenal, male and female sex hormones and Diabetes mellitus.
- GIT -GERD and antiulcer agents, emetics and antiemetics
- Kidney-diuretics and anti-diuretics.

5. Recent developments in chemotherapeutic agents 6 Hours

Mechanism of multidrug resistance (MDR), antibacterial, antiviral, antiprotozoal and anthelmintics, Cancer chemotherapy.

6. Toxicology: 5 Hours

Definition, scope and general principles of toxicology, Dose-response relationships, Factors influencing toxicity, Evaluation of safety, Biotransformation and toxicokinetics, Target organ toxicity: Neuronal and Behavioural toxicity, kidney, pulmonary, hepatic, Cutaneous, Ototoxicity. Haematotoxicity, Mutagenecity, Carcinogenecity, reproductive toxicity, Environmental and industrial toxicology. Management of toxicity reactions in humans.

PRACTICALS **150 Hrs (6 Hrs/wk)**

1. Common laboratory animals: breeding, maintenance, handling and CPCSEA regulations
2. Effect of various drugs on isolated mammalian heart preparation using Langendorff's setup.
3. Effect of various drugs on rat / rabbit thoracic aorta (with and without endothelium).
4. Effect of various autonomic drugs on rat phrenic nerve diaphragm preparation.
5. Anti-dysrrhythmic activity in rats using ECG
6. Effect of various autonomic drugs on rat blood pressure.
7. Effect of various drugs on rabbit jejunum preparation.

Each Experiment needs to be repeated

Note:

virtual / Simulated experiments are permitted

Scheme of Examination:

Synopsis	20 marks
Major experiment	35 marks
Minor experiment	25 marks
Viva-voce	20 marks
Total	**100 marks**

Journals:

1. Trends in Pharmacological Sciences. [Essential]
2. Indian Journal of Pharmacology [Essential]
3. Indian Journal of Physiology and Pharmacology.(Desirable)
4. Annual Reviews of Pharmacology and Toxicology.[Desirable]
5. Pharmacological Reviews. [Desirable]
6. Journal of Pharmacy & pharmacology

Recommended books (Latest Edition)

Sl.No	Name of the book	Author	Publisher
01	Basic and Clinical Pharmacology	Bertram.G Katzung	(International Edition) Lange Medical Book/ McGraw-Hill, U.S.A.
02	Pharmacology	Rang HE Dale MM and Ritter JM	Churchill Livingstone, London,
03	Pharmacological Basis of Therapeutics.	Goodman and Gilman's	(International Edition) McGraw Hill, New York

Reference books(Latest Edition)

Sl.No	Name of the book	Author	Publisher
01	General and applied toxicology	B.B allantyne, T. Man-s, P.	Turner (Eds) The Macmillan Press Ltd.London.
02	Clinical Pharmacy	D.R. Laurence, P.N. Bennett & M.J. Brown,	8th Edition Churchill Livingstone
03	Harrison's Principles of Internal Medicine.	Braunwald, Fauci, Kasper, Hauser, Longo Jameson,	McGraw Hill, New York,

PAPER III. PHARMACOLOGICAL SCREENING METHODS & CLINICAL EVALUATION

GOALS:

To understand the process of drug development and estimation of drugs using bioassays.

To understand and apply pharmacokinetics to rational drug therapy.

OBJECTIVES:

Upon completion of the course, the candidate is expected to know

- The regulations and ethics concerning animal studies and experiments on human beings.
- Carry out screening of new drugs, Participate in drug development process.
- Know alternatives to animal screening procedures / techniques
- To perform Bioassays official in IP/BP/USP,
- Concepts of kinetics and various pharmacokinetic models.

COURSE CONTENTS

THEORY **50 Hours (2 Hrs/wk)**

1. Study of laboratory animals, Regulations and ethics requirements. 8 Hour

Transgenic animals and other genetically prone animal models (Viz Nude Mice, SH rats). Bioassays: Basic principles of bioassay, official bioassay, experimental models and statistical designs employed in biological standardization. Intra cerebro-ventricular and other newer techniques of drug administration.

2. **Preclinical models employed in the screening of new drugs belonging to following categories:** 20 Hours

Antipsychotic agent; Antianxiety agents; Nootropic drugs; Antidepressant drugs; Antiparkinsonian agents; Analgesics; Antiepileptics and models for status epilepticus; Antiinflammatory agents; Antiulcer agents; Antianginals; Antiarrythmics; Antiatherosclerotic drugs; Antimalarials; Anthelmintics; Antidiabetics; Drugsfor myocardial infarction; Antihypertensives.

3. **Definition and Scope of Pharmacokinetics.** 2 Hour

Physiological concepts and kinetics, Movement of the drugs through biological membranes, Absorption, Distribution, Metabolism / Biotransformation, Elimination Integration with kinetics 7 Hour

Individualization:

Variability, genetics, age and weight, disease., interacting drugs, and monitoring of the same. 2 Hour

Pharmacokinetic models: 4 Hour

Compartmental models, noncompartmental models and physiologic model Nonlinear pharmacokinetics, multiple dosing and dosage regimen.

4. `Drug development process: 2 Hour

Clinical trials, safety evaluation, preparation of IND/NDAs, statistical design in clinical trials, data analysis techniques and presentation skills. International guidelines (ICH recommendations) GLP including GCP. ICMR guidelines.

5. Alternatives to animal: 5 Hour

Screening procedures, cell-line, patch-clamp technique, in-vitro models, molecular biology techniques.

PRACTICALS **150Hrs (6 Hrs/wk)**

1. Bioass.ay of acetylcholine/Nstamine using guinea pig ileum preparation.
2. Bioassay of oxytocin using rat uterine preparation.
3. Bioassay of 5-HT using rat fundus preparation.
4. PA2 values of various antagonists using suitable isolated tissue preparations.
5. Monitoring of concentration of drugs in saliva/urine
6. Monitoring of concentration of drugs in blood.
7. Screening of anxiolytic drugs
8. Screening of antidepressant drugs Screening of antiulcer drugs

Virtual / Simulated experiments are permitted Scheme of examination

Synopsis	20 marks
Major experiment	35 marks
Minor experiment	25 marks
Viva-voce	20 marks
Total	**100 marks**

Journals:

1. Indian Journal of Pharmacology [Essential]
2. British Journal of Pharmacology.

Recommended books(Latest Edition)

Sl.No	Name of the book	Author	Publisher
01	Drug Discovery and Evaluation-PharmacologicalAssays2nd Edition	H.Gerhard.Vogel.	Springer-Verlag. Berlin Heidelberg.
02	Fundamentals of Experimental Pharmacology	M.N.Ghosh.	Scientific Book Agency, Calcutta
03	Clinical Pharmacokinetics	Malcolm Rowland and Thomas M. Tozer	A Lea and Febiger Book
04	Biopharmaceutics and Pharmacokinetics	Leon Shargel,	Williams and Wilkins
05	Biopharmaceutics and Pharmacokinetics	Madan.	Jaypee Brothers.

Reference books(Latest Edition)

Sl.No	**Name of the book**	**Author**	**Publisher**
01	Pharmacological Experiments in Intact preparations,	McLEOD.L.J.	Churchill Livingstone.
02	Pharmacological Experiments On Isolated Preparations	Perry.W.L.M.	Churchill Livingstone.
03	Screening Methods in Pharmacology,	Turner.r.A; Herborn.P.	Academic Press New York
04	Biopharmaceutics and Clinical Pharmacokinetics	Milo Gibaldi.	Lea & Febiger.

Paper IV. Molecular Biology and Pharmacology

GOALS :
To understand the cell biology & genetics that forms the basis for new drug discovery.

OBJECTIVES:
Upon completion of the course, the candidate is expected to know basic cell biology. Recombinant DNA technology, transfer of genes to mammalian cells.

COURSE CONTENT

THEORY **50Hrs (2 Hrs/wk)**

1. Introduction
2. The cell, cell cycle, cellular Aging and Death, Animal cell culture.
3. Structure and functions of plasma membrane. 2 Hours
4. Cell signaling: Communication between cells and their environment, ion-channels, Organization of signal transduction pathways, third messengers, Biosensors. 6 hours
5. Role of genes within cells, DNA- the primary genetic material, Elucidation of genetic code, Gene expression, Genetic elements that control gene expression. 6 Hours
6. Recombinant DNATechnology: Principles, process and applications. Gene cloning: Isolation,cloning vectors, enzymes used in molecular cloning, PCR (Polymerase chain reaction), LCR (Ligation chain reaction) and their applications. The formation and uses of RFLP's (Restriction Fragment Length Polymorphism). 8 Hours
7. Recombinant DNA and Human Genetics: DNA sequencing, Mapping and cloning of Human disease genes, DNA-Based diagnosis of genetic diseases, Gene therapy and Antisense technology, Human genome project. 9 Hours
8. Biotechnology related techniques: Protein engineering, Peptide chemistry and peptidornimetics, Nucleic acid technologies, catalytic antibodies, glycobiology. 7 Hours

9. Recombinant products in medicine with special reference to : Insulin, GH, Vaccines, Monoclonal antibodies, FSH, t-PA (tissue plasminogen activator), Biotechnology products in the pipeline. 7 Hours

10. Pharmacokinetics and pharmacodynamics of Peptide and protein drugs: Elimination, distribution, pharmacodynamics and immunogenicity of protein therapeutics. 3 Hours

11. Bio Ethics 2 Hours

PRACTICALS (6 Hrs/wk)

1. Drug mutagenicity study using mice bone-marrow chromosomal aberration test.
2. Drug mutagenicity study using mice bone-marrow micronucleus test.
3. Isolation and estimation of DNA and RNA.
4. Restriction digestion of DNA.
5. Ligation of DNA.
6. Isolation of plasmids.
7. Transformation of bacteria.

Virtual / Simulated experiments are permitted Scheme of examination:

Synopsis	20 marks
Major experiment	35 marks
Minor experiment	25 marks
Viva-voce	20 marks
Total	**100 marks**

Journals:

1. Gene therapy (Essential)
2. Cell (Desirable)
3. Nature (Desirable)
4. Molecular biology and Medicine (Desirable)

Recommended books(Latest Edition)

Sl.No	Name of the book	Author	Publisher
01	Pharmaceutical Biotechnology, Harward Academic	Crommelin, DJA and Sindelar, RD. (Eds).	Publishers, Australia, UK.
02	Molecular biology of the CELL.	Alberts, B.et.al-	Garlound Publishing Inc. New York andLondon.
03	Goodman and Gilman's Pharmacological basis of therapeutics.	Brurence.L.L.;Lazo.J.S.	McGraw-Hill Book Company.

Reference books(Latest Edition)

Sl.No	Name of the book	Author	Publisher
01	Biopharmaceuticals: Biochemistry & Biotechnology	Gary Walsh.	John Wiley and Sons.
02	Recombinant DNA,	James D. Watson, Michael Gilman, Jan Witowski,	Mark Zollet Scientific American Books, New York