REGULATIONS2017

Syllabus

Kerala University of Health Sciences

Thrissur - 680596

POST GRADUATE COURSE IN PHARMACY

Master of Pharmacy

(M.Pharm. – Pharmaceutics)

Course code: 276

(2017-18 Academic year onwards)

2017

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2. COURSE CONTENT

2.1 Title of course

These regulations shall be called as "Master of Pharmacy (M.Pharm. – Pharmaceutics) Degree Program - Credit Based Semester System (CBSS) of the Kerala University of Health sciences. They shall come into effect from the Academic Year 2017-18 onwards. The regulations framed are subject to modifications from time to time by the authorities of the University.

2.2 Objectives of course

To generate Pharmacy Post Graduates with profound knowledge in various branches of Pharmaceutical Sciences to meet with the rapidly increasing demands put forward by-

- Pharmaceutical Manufacturing
- Pharmaceutical Research & Development
- Pharmacological research including preclinical & clinical studies.
- Herbal Drug Research
- Pharmaceutical & Herbal Drug Analysis
- Clinical Toxicology & Toxicological Analysis

To discover the potential to become faculty in Pharmaceutical Sciences with unmatched quality and excellence, so as to educate the future pharmacy generation (Undergraduate, Post graduate, and Doctoral).

2.3 Medium of Instruction

Medium of instruction and examination shall be in English.

2.4 Course Outline

The specialization in M.Pharm. Program is given in Table 1.

Table – 1: M.Pharm. Specialization and their code

S.No	Specialization	Code
1.	Pharmaceutics	MPH

The course of study for M. Pharm Pharmaceutics shall include Semester wise Theory & Practical as given in Table – 2 & 3. The number of hours to be devoted to each theory and practical course in any semester shall not be less than that shown in Table – 2 & 3.

Table – 2: Course of study for M.Pharm. I & II Semester

Course Code	Course	Credit Hours	Credit Points	Hrs./wk	Marks
Semester I					
MPH 101T	Modern Pharmaceutical Analytical Techniques	4	4	4	100
MPH 102T	Drug Delivery System	4	4	4	100
MPH 103T	Modern Pharmaceutics	4	4	4	100
MPH 104T	Regulatory Affair	4	4	4	100
MPH 105P	Pharmaceutics Practical I	12	6	12	150
-	Seminar/Assignment	7	4	7	100
Total		35	26	35	650
Semester II					
MPH 201T	Molecular Pharmaceutics (Nano Tech and Targeted DDS)	4	4	4	100
MPH 202T	Advanced Biopharmaceutics & Pharmacokinetics	4	4	4	100
MPH 203T	Computer Aided Drug Delivery System	4	4	4	100
MPH 204T	Cosmetics and Cosmeceuticals	4	4	4	100
MPH 205P	Pharmaceutics Practical II	12	6	12	150
-	Seminar /Assignment	7	4	7	100
Total		35	26	35	650

Table – 3: Course of study for M. Pharm. III & IV Semester

Course Code	Course	Credit Hours	Credit Points
Semester III			
MRM 301T	Research Methodology and Biostatistics*	4	4
-	Journal Club	1	1
-	Discussion / Presentation (proposal presentation)	2	2
-	Research Work*	28	14
Total		35	21
Semester IV			
-	Journal Club	1	1
-	Research Work	31	16
-	Discussion / Final Presentation	3	3
Total		35	20

*Non University Exam

Program/Course credit structure

As per the philosophy of Credit Based Semester System, certain quantum of academic work viz. theory classes, practical classes, seminars, assignments, etc. are measured in terms of credits. On satisfactory completion of the courses, a candidate earns credits. The amount of credit associated with a course is dependent upon the number of hours of instruction per week in that course. Similarly the credit associated with any of the other academic, co/extracurricular activities is dependent upon the quantum of work expected to be put in for each of these activities per week/per activity.

Credit assignment

a) Theory and Laboratory courses

Courses are broadly classified as Theory and Practical. Theory courses consist of lecture (L) and Practical (P) courses consist of hours spent in the laboratory. Credits (C) for a course is dependent on the number of hours of instruction per week in that course, and is obtained by using a multiplier of one (1) for lecture and a multiplier of half (1/2) for practical (laboratory) hours. Thus, for example, a theory course having four lectures per week throughout the semester carries a credit of 4. Similarly, a practical having four laboratory hours per week throughout semester carries a credit of 2. The contact hours of seminars, assignments and research work shall be treated as that of practical courses for the purpose of calculating credits. i.e., the contact hours shall be multiplied by 1/2. Similarly, the contact hours of journal club, research work presentations and discussions with the supervisor shall be considered as theory course and multiplied by 1.

b) Minimum credit requirements

The minimum credit points required for the award of M. Pharm. degree is 95. However based on the credit points earned by the students under the head of co-curricular activities, a student shall earn a maximum of 100 credit points. These credits are divided into Theory courses, Practical, Seminars, Assignments, Research work, Discussions with the supervisor, Journal club and Co-Curricular activities over the duration of four semesters. The credits are distributed semester-wise as shown in Table 4. Courses generally progress in sequence, building competencies and their positioning indicates certain academic maturity on the part of the learners. Learners are expected to follow the semester-wise schedule of courses given in the syllabus.

Table – 4: Semester wise credits distribution

Semester	Credit Points
I	26
II	26
III	21
IV	20
Co-curricular Activities (attending Conference, Scientific Presentations and other scholarly Activities)	Minimum = 02 Maximum = 07*
Total Credit Points	Minimum = 95 Maximum = 100

*Credit points for Co-curricular Activities

Table – 5: Guidelines for Awarding Credit Points for Co-Curricular Activities

Name of the Activity	Maximum Credit Points Eligible / Activity
Participation in National Level Seminar/ Conference/ Workshop / Symposium / Training Programs (related to the specialization of the student)	01
Participation in international Level Seminar/ Conference/ Workshop/ Symposium/ Training Programs (related to the specialization of the student)	02
Academic Award/Research Award from State Level/ National Agencies	01
Academic Award/Research Award from International Agencies	02
Research / Review Publication in National Journals (Indexed in Scopus / Web of Science)	01
Research / Review Publication in International Journals (Indexed in Scopus / Web of Science)	02

Note: International Conference: Held outside India

International Journal: The Editorial Board outside India

*The credit points assigned for extracurricular and or co-curricular activities shall be given by the Principals of the colleges and the same shall be submitted to the University. The criteria to acquire this credit point shall be defined by the colleges from time to time.

Program Committee

1. The M. Pharm. programme shall have a Programme Committee constituted by the Head of the institution in consultation with all the Heads of the departments.
2. The composition of the Programme Committee shall be as follows:
   A teacher at the cadre of Professor shall be the Chairperson; One Teacher from each M. Pharm specialization and four student representatives (two from each academic year), nominated by the Head of the institution.
3. Duties of the Programme Committee:
   i. Periodically reviewing the progress of the classes.
   ii. Discussing the problems concerning curriculum, syllabus and the conduct of classes.
   iii. Discussing with the course teachers on the nature and scope of assessment for the course and the same shall be announced to the students at the beginning of respective semesters.
   iv. Communicating its recommendation to the Head of the institution on academic matters.
   v. The Programme Committee shall meet at least twice in a semester preferably at the end of each sessional exam and before the end semester exam.

2.5 Duration

The program of study for M.Pharm. shall extend over a period of four semesters (two academic years). The curricula and syllabi for the program shall be prescribed from time to time by the Kerala University of Health sciences.

The duration for the completion of the program shall be fixed as double the actual duration of the program and the students have to pass within the said period, otherwise they have to get fresh Registration.

2.6 Syllabus

PHARMACEUTICS (MPH)

MODERN PHARMACEUTICAL ANALYTICAL TECHNIQUES

(MPH 101T)

Scope

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

Objectives

After completion of course student is able to know,

- Chemicals and Excipients
- The analysis of various drugs in single and combination dosage forms
- Theoretical and practical skills of the instruments

THEORY **60 HOURS**

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

   b. IR spectroscopy: Theory, Modes of Molecular vibrations, Sample handling, Instrumentation of Dispersive and Fourier - Transform IR Spectrometer, Factors affecting vibrational frequencies and Applications of IR spectroscopy

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

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

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

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

4. Chromatography: Principle, apparatus, instrumentation, chromatographic parameters, factors affecting resolution and applications of the following: — 11 Hrs

   a) Paper chromatography b) Thin Layer chromatography
   c) Ion exchange chromatography d) Column chromatography
   e) Gas chromatography f) High Performance Liquid chromatography
   g) Affinity chromatography

5. a. Electrophoresis: Principle, Instrumentation, Working — 11 Hrs

   conditions, factors affecting separation and applications of the following:

   a) Paper electrophoresis b) Gel electrophoresis c) Capillary electrophoresis d) Zone electrophoresis e) Moving boundary electrophoresis f) Iso electric focusing

   b. X ray Crystallography: Production of X rays, Different X ray diffraction methods, Bragg's law, Rotating crystal technique, Xray powder technique, Types of crystals and applications of X-ray diffraction.

6. Immunological assays: RIA (Radio immuno assay), ELISA, Bioluminescence assays. — 5Hrs

REFERENCES

1. Spectrometric Identification of Organic compounds - Robert M Silverstein, Sixth edition, John Wiley & Sons, 2004.
2. Principles of Instrumental Analysis - Doglas A Skoog, F. James Holler, Timothy A. Nieman, 5th edition, Eastern press, Bangalore, 1998.
3. Instrumental methods of analysis – Willards, 7th edition, CBS publishers.
4. Practical Pharmaceutical Chemistry – Beckett and Stenlake, Vol II, 4th edition, CBS Publishers, New Delhi, 1997.
5. Organic Spectroscopy - William Kemp, 3rd edition, ELBS, 1991.
6. Quantitative Analysis of Drugs in Pharmaceutical formulation - P D Sethi, 3rd Edition, CBS Publishers, New Delhi, 1997.
7. Pharmaceutical Analysis- Modern methods – Part B - J W Munson, Volume 11, Marcel Dekker Series

DRUG DELIVERY SYSTEMS

(MPH 102T)

SCOPE

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

OBJECTIVES

Upon completion of the course, student shall be able to understand

- The various approaches for development of novel drug delivery systems.
- The criteria for selection of drugs and polymers for the development of delivering system
- The formulation and evaluation of Novel drug delivery systems..

THEORY **60 Hrs**

1.	Sustained Release (SR) and Controlled Release (CR) formulations: Introduction & basic concepts, advantages/ disadvantages, factors influencing, Physicochemical & biological approaches for SR/CR formulation, Mechanism of Drug Delivery from SR/CR formulation. Polymers: introduction, definition, classification, properties and application Dosage Forms for Personalized Medicine: Introduction, Definition, Pharmacogenetics, Categories of Patients for Personalized Medicines: Customized drug delivery systems, Bioelectronic Medicines, 3D printing of pharmaceuticals, Telepharmacy.	10 Hrs
2.	Rate Controlled Drug Delivery Systems: Principles & Fundamentals, Types, Activation; Modulated Drug Delivery Systems;Mechanically activated, pH activated, Enzyme activated, and Osmotic activated Drug Delivery Systems Feedback regulated Drug Delivery Systems; Principles & Fundamentals.	10 Hrs
3.	Gastro-Retentive Drug Delivery Systems: Principle, concepts advantages and disadvantages, Modulation of GI transit time approaches to extend GI transit. Buccal Drug Delivery Systems:Principle of muco adhesion, advantages and disadvantages, Mechanism of drug permeation, Methods of formulation and its evaluations.	10 Hrs
4.	Occular Drug Delivery Systems: Barriers of drug permeation, Methods to overcome barriers.	06 Hrs
5.	Transdermal Drug Delivery Systems: Structure of skin and barriers, Penetration	10

enhancers, Transdermal Drug Delivery Systems, Formulation and evaluation. Hrs

6. Protein and Peptide Delivery: Barriers for protein delivery. Formulation and Evaluation of delivery systems of proteins and other macromolecules. 08 Hrs

7. Vaccine delivery systems: Vaccines, uptake of antigens, single shot vaccines, mucosal and transdermal delivery of vaccines. 06 Hrs

REFERENCES

1. Y W. Chien, Novel Drug Delivery Systems, 2nd edition, revised and expanded, Marcel Dekker, Inc., New York, 1992.
2. Robinson, J. R., Lee V. H. L, Controlled Drug Delivery Systems, Marcel Dekker,Inc., New York, 1992.
3. Encyclopedia of controlled delivery, Editor- Edith Mathiowitz, Published by WileyInterscience Publication, John Wiley and Sons, Inc, New York!Chichester/Weinheim
4. N.K. Jain, Controlled and Novel Drug Delivery, CBS Publishers & Distributors, New Delhi, First edition 1997 (reprint in 2001).
5. S.P.Vyas and R.K.Khar, Controlled Drug Delivery - concepts and advances, Vallabh Prakashan, New Delhi, First edition 2002

JOURNALS

1. Indian Journal of Pharmaceutical Sciences (IPA)
2. Indian drugs (IDMA)
3. Journal of controlled release (Elsevier Sciences) desirable
4. Drug Development and Industrial Pharmacy (Marcel & Decker) desirable

MODERN PHARMACEUTICS

(MPH 103T)

Scope

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

Objectives

Upon completion of the course, student shall be able to understand

- The elements of preformulation studies.
- The Active Pharmaceutical Ingredients and Generic drug Product development
- Industrial Management and GMP Considerations.
- Optimization Techniques & Pilot Plant Scale Up Techniques
- Stability Testing, sterilization process & packaging of dosage forms.

THEORY **60 HRS**

1.	a. Preformation Concepts – Drug Excipient interactions - different methods, kinetics of stability, Stability testing. Theories of dispersion and pharmaceutical Dispersion (Emulsion and Suspension, SMEDDS) preparation and stability Large and small volume parental – physiological and formulation consideration, Manufacturing and evaluation.	10 Hrs
	b. Optimization techniques in Pharmaceutical Formulation:Concept and parameters of optimization, Optimization techniques in pharmaceutical formulation and processing. Statistical design, Response surface method, Contour designs, Factorial designs and application in formulation	10 Hrs
2.	Validation: Introduction to Pharmaceutical Validation, Scope & merits of Validation, Validation and calibration of Master plan, ICH & WHO guidelines for calibration and validation of equipments, Validation of specific dosage form, Types of validation. Government regulation, Manufacturing Process Model, URS, DQ, IQ, OQ & P.Q. of facilities.	10 Hrs
3.	cGMP & Industrial Management: Objectives and policies of current good manufacturing practices, layout of buildings, services, equipments and their maintenance Production management: Production organization, , materials management, handling and transportation, inventory management and control,	10 Hrs

production and planning control, Sales forecasting, budget and cost control, industrial and personal relationship. Concept of Total Quality Management.

4. Compression and compaction: Physics of tablet compression, compression, consolidation, effect of friction, distribution of forces, compaction profiles. Solubility. 10 Hrs

5. Study of consolidation parameters; Diffusion parameters, Dissolution parameters and Pharmacokinetic parameters, Heckel plots, Similarity factors – f2 and f1, Higuchi and Peppas plot, Linearity Concept of significance, Standard deviation , Chi square test, students T-test , ANOVA test. 10 Hrs

REFERENCES

1. Theory and Practice of Industrial Pharmacy By Lachmann and Libermann
2. Pharmaceutical dosage forms: Tablets Vol. 1-3 by Leon Lachmann.
3. Pharmaceutical Dosage forms: Disperse systems, Vol, 1-2; By Leon Lachmann.
4. Pharmaceutical Dosage forms: Parenteral medications Vol. 1-2; By Leon Lachmann.
5. Modern Pharmaceutics; By Gillbert and S. Banker.
6. Remington's Pharmaceutical Sciences.
7. Advances in Pharmaceutical Sciences Vol. 1-5; By H.S. Bean & A.H.Beckett.
8. Physical Pharmacy; By Alfred martin
9. Bentley's Textbook of Pharmaceutics – by Rawlins.
10. Good manufacturing practices for Pharmaceuticals: A plan for total quality control, Second edition; By Sidney H. Willig.
11. Quality Assurance Guide; By Organization of Pharmaceutical producers of India.
12. Drug formulation manual; By D.P.S. Kohli and D.H.Shah. Eastern publishers, New Delhi.
13. How to practice GMPs; By P.P.Sharma. Vandhana Publications, Agra.
14. Pharmaceutical Process Validation; By Fra. R. Berry and Robert A. Nash.
15. Pharmaceutical Preformulations; By J.J. Wells.
16. Applied production and operations management; By Evans, Anderson, Sweeney and Williams.
17. Encyclopaedia of Pharmaceutical technology, Vol I – III.

REGULATORY AFFAIRS

(MPH 104T)

Scope

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

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

Objectives:

Upon completion of the course, it is expected that the students will be able to understand

- The Concepts of innovator and generic drugs, drug development process
- The Regulatory guidance's and guidelines for filing and approval process
- Preparation of Dossiers and their submission to regulatory agencies in different countries
- Post approval regulatory requirements for actives and drug products
- Submission of global documents in CTD/ eCTD formats
- Clinical trials requirements for approvals for conducting clinical trials
- Pharmacovigilence and process of monitoring in clinical trials.

THEORY **60 Hrs**

1. a. Documentation in Pharmaceutical industry: Master formula record, DMF (Drug Master File), distribution records. Generic drugs product development Introduction , Hatch- Waxman act and amendments, CFR (CODE OF FEDERAL REGULATION) ,drug product performance, in-vitro, ANDA regulatory approval process, NDA approval process, BE and drug product assessment, in –vivo, scale up process approval changes, post marketing surveillance, outsourcing BA and BE to CRO. 12 Hrs

   b. Regulatory requirement for product approval: API, biologics, novel, therapies obtaining NDA, ANDA for generic drugs ways and means of US registration for foreign drugs 12 Hrs

2.	CMC, post approval regulatory affairs. Regulation for combination products and medical devices.CTD and ECTD format, industry and FDA liaison. ICH - Guidelines of ICH-Q, S E, M. Regulatory requirements of EU, MHRA, TGA and ROW countries.	12 Hrs
3.	Non clinical drug development: Global submission of IND, NDA, ANDA. Investigation of medicinal products dossier, dossier (IMPD) and investigator brochure (IB).	12 Hrs
4.	Clinical trials: Developing clinical trial protocols. Institutional review board/ independent ethics committee Formulation and working procedures informed Consent process and procedures. HIPAA- new, requirement to clinical study process, pharmacovigilance safety monitoring in clinical trials	12 Hrs

REFERENCES

1. Generic Drug Product Development, Solid Oral Dosage forms, Leon Shargel and IsaderKaufer,Marcel Dekker series, Vol.143
2. The Pharmaceutical Regulatory Process, Second Edition Edited by Ira R. Berry and Robert P.Martin, Drugs and the Pharmaceutical Sciences,Vol.185, Informa Health care Publishers.
3. New Drug Approval Process: Accelerating Global Registrations By Richard A Guarino, MD,5th edition, Drugs and the Pharmaceutical Sciences,Vol.190.
4. Guidebook for drug regulatory submissions / Sandy Weinberg. By John Wiley & Sons.Inc.
5. FDA regulatory affairs: a guide for prescription drugs, medical devices, and biologics/edited By Douglas J. Pisano, David Mantus.
6. Clinical Trials and Human Research: A Practical Guide to Regulatory Compliance By Fay A.Rozovsky and Rodney K. Adams
7. www.ich.org/
8. www.fda.gov/
9. europa.eu/index_en.htm
10. https://www.tga.gov.au/tga-basics

PHARMACEUTICS PRACTICALS - I

(MPH 105P)

1. Analysis of pharmacopoeial compounds and their formulations by UV Vis spectrophotometer
2. Simultaneous estimation of multi component containing formulations by UV spectrophotometry
3. Experiments based on HPLC
4. Experiments based on Gas Chromatography
5. Estimation of riboflavin/quinine sulphate by fluorimetry
6. Estimation of sodium/potassium by flame photometry
7. To perform In-vitro dissolution profile of CR/ SR marketed formulation
8. Formulation and evaluation of sustained release matrix tablets
9. Formulation and evaluation osmotically controlled DDS
10. Preparation and evaluation of Floating DDS- hydro dynamically balanced DDS
11. Formulation and evaluation of Muco adhesive tablets.
12. Formulation and evaluation of trans dermal patches.
13. To carry out preformulation studies of tablets.
14. To study the effect of compressional force on tablets disintegration time.
15. To study Micromeritic properties of powders and granulation.
16. To study the effect of particle size on dissolution of a tablet.
17. To study the effect of binders on dissolution of a tablet.
18. To plot Heckal plot, Higuchi and peppas plot and determine similarity factors.

MOLECULAR PHARMACEUTICS (NANO TECHNOLOGY & TARGETED DDS) (NTDS)

(MPH 201T)

Scope

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

Objectives

Upon completion of the course student shall be able to understand

- The various approaches for development of novel drug delivery systems.
- The criteria for selection of drugs and polymers for the development of NTDS
- The formulation and evaluation of novel drug delivery systems.

THEORY **60 Hrs**

1.	Targeted Drug Delivery Systems: Concepts, Events and biological process involved in drug targeting. Tumor targeting and Brain specific delivery.	12 Hrs
2.	Targeting Methods: introduction preparation and evaluation. Nano Particles & Liposomes: Types, preparation and evaluation.	12 Hrs
3.	Micro Capsules / Micro Spheres: Types, preparation and evaluation , Monoclonal Antibodies ; preparation and application, preparation and application of Niosomes, Aquasomes, Phytosomes, Electrosomes.	12 Hrs
4.	Pulmonary Drug Delivery Systems : Aerosols, propellents, ContainersTypes, preparation and evaluation, Intra Nasal Route Delivery systems; Types, preparation and evaluation.	12 Hrs
5.	Nucleic acid based therapeutic delivery system : Gene therapy, introduction (ex-vivo & in-vivo gene therapy). Potential target diseases for gene therapy (inherited disorder and cancer). Gene expression systems (viral and nonviral gene transfer). Liposomal gene delivery systems. Biodistribution and Pharmacokinetics. knowledge of therapeutic antisense molecules and aptamers as drugs of future.	12 Hrs

REFERENCES

1. Y W. Chien, Novel Drug Delivery Systems, 2nd edition, revised and expanded,Marcel Dekker, Inc., New York, 1992.
2. S.P.Vyas and R.K.Khar, Controlled Drug Delivery - concepts and advances VallabhPrakashan New Delhi First edition 2002.
3. N.K. Jain, Controlled and Novel Drug Delivery, CBS Publishers & Distributors, NewDelhi, First edition 1997 (reprint in 2001).

ADVANCED BIOPHARMACEUTICS & PHARMACOKINETICS

(MPH 202T)

Scope

This course is designed to impart knowledge and skills necessary for dose calculations, dose adjustments and to apply biopharmaceutics theories in practical problem solving. Basic theoretical discussions of the principles of biopharmaceutics and pharmacokinetics are provided to help the students' to clarify the concepts.

Objectives

Upon completion of this course it is expected that students will be able understand,

- The basic concepts in biopharmaceutics and pharmacokinetics.
- The use raw data and derive the pharmacokinetic models and parameters the best describe the process of drug absorption, distribution, metabolism and elimination.
- The critical evaluation of biopharmaceutic studies involving drug product equivalency.
- The design and evaluation of dosage regimens of the drugs using pharmacokinetic and biopharmaceutic parameters.
- The potential clinical pharmacokinetic problems and application of basics of pharmacokinetic

THEORY **60 Hrs**

1. Drug Absorption from the Gastrointestinal Tract: 12 Hrs

   Gastrointestinal tract, Mechanism of drug absorption, Factors affecting drug absorption, pH–partition theory of drug absorption. Formuulation and physicochemical factors: Dissolution rate, Dissolution process, Noyes–Whitney equation and drug dissolution, Factors affecting the dissolution rate. Gastrointestinal absorption: role of the dosage form: Solution (elixir, syrup and solution) as a dosage form ,Suspension as a dosage form, Capsule as a dosage form, Tablet as a dosage form ,Dissolution methods ,Formulation and processing factors, Correlation of in vivo data with in vitro dissolution data.Transport model:Permeability-Solubility-Charge State and the pH Partition Hypothesis, Properties of the Gastrointestinal Tract (GIT), pH Microclimate Intracellular pH Environment, Tight-Junction Complex.

2. Biopharmaceutic considerations in drug product design and In Vitro Drug Product Performance: Introduction, biopharmaceutic factors affecting drug 12 Hrs

bioavailability, rate-limiting steps in drug absorption, physicochemical nature of the drug formulation factors affecting drug product performance, in vitro:dissolution and drug release testing, compendial methods of dissolution, alternative methods of dissolution testing,meeting dissolution requirements,problems of variable control in dissolution testingperformance of drug products. In vitro–in vivo correlation, dissolution profile comparisons, drug product stability,considerations in the design of a drug product.

3. Pharmacokinetics: Basic considerations, pharmacokinetic models, compartment modeling: one compartment model- IV bolus, IV infusion, extra-vascular. Multi compartment model:two compartment - model in brief, non-linear pharmacokinetics: cause of non-linearity, Michaelis – Menten equation, estimation of kmax and vmax. Drug interactions: introduction, the effect of protein- binding interactions,the effect of tissue-binding interactions,cytochrome p450-based drug interactions,drug interactions linked to transporters. 12 Hrs

4. Drug Product Performance, In Vivo: Bioavailability and Bioequivalence: drug product performance, purpose of bioavailability studies, relative and absolute availability. methods for assessing bioavailability, bioequivalence studies, design and evaluation of bioequivalence studies, study designs, crossover study designs, evaluation of the data, bioequivalence example, study submission and drug review process. biopharmaceutics classification system, methods. Permeability: In-vitro, in-situ and In-vivo methods.generic biologics (biosimilar drug products),clinical significance of bioequivalence studies, special concerns in bioavailability and bioequivalence studies, generic substitution. 12 Hrs

5. Application of Pharmacokinetics: Modified-Release Drug Products, Targeted Drug Delivery Systems and Biotechnological Products. Introduction to Pharmacokinetics and pharmacodynamic, drug interactions. Pharmacokinetics and pharmacodynamics of biotechnology drugs. Introduction, Proteins and peptides, Monoclonal antibodies, Oligonucleotides, Vaccines (immunotherapy), Gene therapies. 12 Hrs

REFERENCES

1. Biopharmaceutics and Clinical Pharmacokinetics by Milo Gibaldi, 4th edition,Philadelphia, Lea and Febiger, 1991

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

COMPUTER AIDED DRUG DEVELOPMENT

(MPH 203T)

Scope

This course is designed to impart knowledge and skills necessary for computer Applications in pharmaceutical research and development who want to understand the application of computers across the entire drug research and development process. Basic theoretical discussions of the principles of more integrated and coherent use of computerized information (informatics) in the drug development process are provided to help the students to clarify the concepts.

Objectives

Upon completion of this course it is expected that students will be able to understand,

- History of Computers in Pharmaceutical Research and Development
- Computational Modeling of Drug Disposition
- Computers in Preclinical Development
- Optimization Techniques in Pharmaceutical Formulation
- Computers in Market Analysis
- Computers in Clinical Development
- Artificial Intelligence (AI) and Robotics
- Computational fluid dynamics(CFD)

THEORY **60 Hrs**

1. a. Computers in Pharmaceutical Research and Development: A General Overview: History of Computers in Pharmaceutical Research and Development. Statistical modeling in Pharmaceutical research and development: Descriptive versus Mechanistic Modeling, Statistical Parameters, Estimation, Confidence Regions, Nonlinearity at the Optimum, Sensitivity Analysis, Optimal Design, Population Modeling — 12 Hrs

   b. Quality-by-Design In Pharmaceutical Development: Introduction, ICH Q8 guideline, Regulatory and industry views on QbD, Scientifically based QbD - examples of application.

2. Computational Modeling Of Drug Disposition: Introduction ,Modeling Techniques: Drug Absorption, Solubility, Intestinal Permeation, Drug Distribution ,Drug Excretion, Active Transport;P-gp, BCRP, Nucleoside Transporters, hPEPT1, — 12 Hrs

ASBT, OCT, OATP, BBB-Choline Transporter.

3. Computer-aided formulation development:: Concept of optimization, Optimization parameters, Factorial design, Optimization technology & Screening design. Computers in Pharmaceutical Formulation: Development of pharmaceutical emulsions, microemulsion drug carriers Legal Protection of Innovative Uses of Computers in R&D, The Ethics of Computing in Pharmaceutical Research, Computers in Market analysis — 12 Hrs

4. a. Computer-aided biopharmaceutical characterization: Gastrointestinal absorption simulation. Introduction, Theoretical background, Model construction, Parameter sensitivity analysis, Virtual trial, Fed vs. fasted state, In vitro dissolution and in vitro- in vivo correlation, Biowaiver considerations — 12 Hrs

   b. Computer Simulations in Pharmacokinetics and Pharmacodynamics: Introduction, Computer Simulation: Whole Organism, Isolated Tissues, Organs, Cell, Proteins and Genes.

   c. Computers in Clinical Development: Clinical Data Collection and Management, Regulation of Computer Systems

5. Artificial Intelligence (AI), Robotics and Computational fluid dynamics: General overview, Pharmaceutical Automation, Pharmaceutical applications, Advantages and Disadvantages. Current Challenges and Future Directions. — 12 Hrs

REFERENCES

1. Computer Applications in Pharmaceutical Research and Development, Sean Ekins, 2006, John Wiley & Sons.
2. Computer-Aided Applications in Pharmaceutical Technology, 1st Edition, Jelena Djuris, Woodhead Publishing
3. Encyclopedia of Pharmaceutical Technology, Vol 13, James Swarbrick, James. G.Boylan, Marcel Dekker Inc, New York, 1996.

COSMETICS AND COSMECEUTICALS

(MPH 204T)

Scope

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

Objectives

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

- Key ingredients used in cosmetics and cosmeceuticals.
- Key building blocks for various formulations.
- Current technologies in the market
- Various key ingredients and basic science to develop cosmetics and cosmeceuticals
- Scientific knowledge to develop cosmetics and cosmeceuticals with desired Safety, stability, and efficacy.

THEORY **60 Hrs**

1. Cosmetics – Regulatory : Definition of cosmetic products as per Indian regulation. Indian regulatory requirements for labeling of cosmetics Regulatory provisions relating to import of cosmetics., Misbranded and spurious cosmetics. Regulatory provisions relating to manufacture of cosmetics – Conditions for obtaining license, prohibition of manufacture and sale of certain cosmetics, loan license, offences and penalties. 12 Hrs

2. Cosmetics - Biological aspects : Structure of skin relating to problems like dry skin, acne, pigmentation, prickly heat, wrinkles and body odor. Structure of hair and hair growth cycle. Common problems associated with oral cavity. Cleansing and care needs for face, eye lids, lips, hands, feet, nail, scalp, neck, body and under-arm. 12 Hrs

3. Formulation Building blocks: Building blocks for different product formulations of cosmetics/cosmeceuticals. Surfactants – Classification and application. Emollients, rheological additives:classification and application. Antimicrobial used as preservatives, their merits and demerits. Factors affecting microbial preservative efficacy. Building blocks for formulation of a moisturizing cream, vanishing cream, cold cream, shampoo and toothpaste. Soaps and syndetbars. 12 Hrs

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

Controversial ingredients: Parabens, formaldehyde liberators, dioxane.

4. Design of cosmeceutical products: Sun protection, sunscreens classification and regulatory aspects. Addressing dry skin, acne, sun-protection, pigmentation, prickly heat, wrinkles, body odor., dandruff, dental cavities, bleeding gums, mouth odor and sensitive teeth through cosmeceutical formulations. 12 Hrs

5. Herbal Cosmetics : Herbal ingredients used in Hair care, skin care and oral care. Review of guidelines for herbal cosmetics by private bodies like cosmos with respect to preservatives, emollients, foaming agents, emulsifiers and rheology modifiers. Challenges in formulating herbal cosmetics. 12 Hrs

REFERENCES

1. Harry's Cosmeticology. 8th edition.
2. Poucher'sperfumecosmeticsandSoaps,10th edition.
3. Cosmetics - Formulation, Manufacture and quality control, PP.Sharma,4th edition
4. Handbook of cosmetic science and Technology A.O.Barel, M.Paye and H.I. Maibach. 3rd edition
5. Cosmetic and Toiletries recent suppliers catalogue.
6. CTFA directory.

PHARMACEUTICS PRACTICALS - II

(MPH 205P)

1. To study the effect of temperature change , non solvent addition, incompatible polymer addition in microcapsules preparation
2. Preparation and evaluation of Alginate beads
3. Formulation and evaluation of gelatin /albumin microspheres
4. Formulation and evaluation of liposomes/niosomes
5. Formulation and evaluation of spherules
6. Improvement of dissolution characteristics of slightly soluble drug by Solid dispersion technique.
7. Comparison of dissolution of two different marketed products /brands
8. Protein binding studies of a highly protein bound drug & poorly protein bound drug
9. Bioavailability studies of Paracetamol in animals.
10. Pharmacokinetic and IVIVC data analysis by Winnoline^{R} software
11. In vitro cell studies for permeability and metabolism
12. DoE Using Design Expert® Software
13. Formulation data analysis Using Design Expert® Software
14. Quality-by-Design in Pharmaceutical Development
15. Computer Simulations in Pharmacokinetics and Pharmacodynamics
16. Computational Modeling of Drug Disposition
17. To develop Clinical Data Collection manual
18. To carry out Sensitivity Analysis, and Population Modeling.
19. Development and evaluation of Creams
20. Development and evaluation of Shampoo and Toothpaste base
21. To incorporate herbal and chemical actives to develop products
22. To address Dry skin, acne, blemish, Wrinkles, bleeding gums and dandruff

Semester III

MRM 301T - Research Methodology & Biostatistics

UNIT – I

General Research Methodology: Research, objective, requirements, practical difficulties, review of literature, study design, types of studies, strategies to eliminate errors/bias, controls, randomization, crossover design, placebo, blinding techniques.

UNIT – II

Biostatistics: Definition, application, sample size, importance of sample size, factors influencing sample size, dropouts, statistical tests of significance, type of significance tests, parametric tests(students "t" test, ANOVA, Correlation coefficient, regression), non-parametric tests (wilcoxan rank tests, analysis of variance, correlation, chi square test), null hypothesis, P values, degree of freedom, interpretation of P values.

UNIT – III

Medical Research: History, values in medical ethics, autonomy, beneficence, non-maleficence, double effect, conflicts between autonomy and beneficence/non-maleficence, euthanasia, informed consent, confidentiality, criticisms of orthodox medical ethics, importance of communication, control resolution, guidelines, ethics committees, cultural concerns, truth telling, online business practices, conflicts of interest, referral, vendor relationships, treatment of family members, sexual relationships, fatality.

UNIT – IV

CPCSEA guidelines for laboratory animal facility: Goals, veterinary care, quarantine, surveillance, diagnosis, treatment and control of disease, personal hygiene, location of animal facilities to laboratories, anesthesia, euthanasia, physical facilities, environment, animal husbandry, record keeping, SOPs, personnel and training, transport of lab animals.

UNIT – V

Declaration of Helsinki: History, introduction, basic principles for all medical research, and additional principles for medical research combined with medical care.

2.7 Total number of hour

As mentioned in Course outline (clause 2.4)

2.8 Branches if any, with definition

As mentioned in Syllabus (clause 2.6)

2.9 Teaching Learning methods

A regular record of attendance both in Theory, Practical, Seminar, Assignment, Journal club, Discussion with the supervisor, Research work presentation and Dissertation shall be maintained by the department / teaching staff of respective courses.

2.10 Content of each subject in each year

As mentioned in Syllabus (clause 2.6)

2.11 No: of hours per subject

As mentioned in Syllabus (clause 2.6)

2.12 Practical Training

As mentioned in Course outline (clause 2.4)

2.13 Records

To be maintained for all Practical Work

2.14 Dissertation

As mentioned in Project work to be done (clause 2.16)

2.15 Speciality Training if ANY

As mentioned in Syllabus (clause 2.6)

2.16 Project work to be done if any

All the students shall undertake a project under the supervision of a teacher in Semester III to IV and submit a report. 4 copies of the project report shall be submitted (typed & bound copy not less than 75 pages).

The internal and external examiner appointed by the University shall evaluate the project at the time of the Practical examinations of other semester(s). The projects shall be evaluated as per the criteria given below.

Evaluation of Dissertation Book:

Objective(s) of the work done	50 Marks
Methodology adopted	150 Marks
Results and Discussions	250 Marks
Conclusions and Outcomes	50 Marks
Total	500 Marks

Evaluation of Presentation:

Presentation of work	100 Marks
Communication skills	50 Marks
Question and answer skills	100 Marks
Total	250 Marks

2.17 Any other Requirements [CME, Paper Publishing, etc,.]

As mentioned in Course outline (clause 2.4)

2.18 Prescribed/Recommended textbooks for each subject

As mentioned in Syllabus (clause 2.6)

2.19 Reference books

As mentioned in Syllabus (clause 2.6)

2.20 Journals

All Pharmacy and related Medical Journals

2.21 Logbook

Registers to be maintained

3. EXAMINATION

3.1 Eligibility to appear for exams

A candidate is required to put in at least 80% attendance in individual courses considering theory and practical separately. The candidate shall complete the prescribed course satisfactorily to be eligible to appear for the respective examinations.

3.2 Schedule of Regular / Supplementary exams

Semester examinations will be conducted once in every six months after fulfilling 100 working days.

Table: 6 - Question paper pattern for end semester theory & practical examinations

Question paper pattern for end semester theory examinations			
I.	Long Answers	3 X 10	30 Marks
II.	Short Answers	9 X 5	45 Marks
		Total	75 Marks
Question paper pattern for end semester practical examinations			
I.		Synopsis	15 Marks
II.		Experiment - I	40 Marks
III.		Experiment – II	30 Marks
IV.		Viva voce	15 Marks
		Total	100 Marks

3.3 Scheme of examination showing maximum marks and minimum marks

The End Semester Examinations for each theory and practical Course through semesters I to IV shall be conducted by the respective university except for the subject with asterisk symbol (*) in table – 8 for which examinations shall be conducted by the subject experts at college level and the marks/grades shall be submitted to the university.

Schemes for internal assessments and end semester examinations are given in table below

Table – 7: Schemes for internal assessments and end semester examination

Course code	Course	Internal Assessment				End Semester Exams		Total Marks
		Continuous Mode	Sessional Exams		Total	Marks	Duration	
			Marks	Duration				
SEMESTER I								
MPH 101T	Modern Pharmaceutical Analytical Techniques	10	15	1 Hr	25	75	3 Hrs	100
MPH 102T	Drug Delivery System	10	15	1 Hr	25	75	3 Hrs	100
MPH 103T	Modern Pharmaceuics	10	15	1 Hr	25	75	3 Hrs	100
MPH 104T	Regulatory Affair	10	15	1 Hr	25	75	3 Hrs	100
MPH 105P	Pharmaceutics Practical I	20	30	6 Hrs	50	100	6 Hrs	150
-	Seminar /Assignment	-	-	-	-	-	-	100
Total								
SEMESTER II								
MPH 201T	Molecular Pharmaceutics (Nano Tech and Targeted DDS)	10	15	1 Hr	25	75	3 Hrs	100
MPH 202T	Advanced Biopharmaceutics & Pharmacokinetics	10	15	1 Hr	25	75	3 Hrs	100
MPH 203T	Computer Aided Drug Delivery System	10	15	1 Hr	25	75	3 Hrs	100
MPH 204T	Cosmetics and Cosmeceuticals	10	15	1 Hr	25	75	3 Hrs	100
MPH 205P	Pharmaceutics Practical II	20	30	6 Hrs	50	100	6 Hrs	150
-	Seminar /Assignment	-	-	-	-	-	-	100
Total								650

Table – 8: Schemes for internal assessments and end semester examinations (Semester III& IV)

Course code	Course	Internal Assessment				End Semester Exams		Total Marks
		Continuous Mode	Sessional Exams		Total	Marks	Duration	
			Marks	Duration				
SEMESTER III								
MRM 301T	Research Methodology and Biostatistics*	10	15	1 Hr	25	75	3 Hrs	100
-	Journal Club	-	-	-	25	-	-	25
-	Discussion / Presentation (proposal presentation)	-	-	-	50	-	-	50
-	Research Work*	-	-	-	-	350	1 Hr	350
Total								525
SEMESTER IV								
-	Journal club	-	-	-	25	-	-	25
-	Discussion / Presentation (proposal presentation)	-	-	-	75	-	-	75
-	Research Work and Colloquium	-	-	-	-	400	1 Hr	400
Total								500

*Non University Examination

Table – 9: Scheme for awarding internal assessment

Theory	
Criteria	**Maximum Marks**
Attendance (Refer Table – 10)	8
Student – Teacher interaction	2
Total	10
Practical	
Attendance (Refer Table – 10)	10
Based on Practical Records, Regular viva voce, etc.	10
Total	20

Table – 10: Guidelines for the allotment of marks for attendance

Percentage of Attendance	Theory	Practical
95 – 100	8	10
90 – 94	6	7.5
85 – 89	4	5
80 – 84	2	2.5
Less than 80	0	0

Allowed to keep terms (ATKT):

No student shall be admitted to any examination unless he/she fulfills the norms given in clause 3.1. ATKT rules are applicable as follows:

A student shall be eligible to carry forward all the courses of I and II semesters till the III semester examinations. However, he/she shall not be eligible to attend the courses of IV semester until all the courses of I, II and III semesters are successfully completed.

A student shall be eligible to get his/her CGPA upon successful completion of the courses of I to IV semesters within the stipulated time period as per the norms.

Note: Grade AB should be considered as failed and treated as one head for deciding ATKT. Such rules are also applicable for those students who fail to register for examination(s) of any course in any semester.

Grading of performances

a) Letter grades and grade points allocations:

Based on the performances, each student shall be awarded a final letter grade at the end of the semester for each course. The letter grades and their corresponding grade points are given in Table – 11.

Table – 11: Letter grades and grade points equivalent to Percentage of marks and performances

Percentage of Marks obtained	Letter Grade	Grade point	Performance
90.00 – 100	O	10	Outstanding
80.00 – 89.99	A	9	Excellent
70.00 – 79.99	B	8	Good
60.00 – 69.99	C	7	Fair
50.00 – 59.99	D	6	Average
Less than 50	F	0	Fail
Absent	AB	0	Fail

A learner who remains absent for any end semester examination shall be assigned a letter grade of AB and a corresponding grade point of zero. He/she should reappear for the said evaluation/examination in due course.

b) The Semester grade point average (SGPA)

The performance of a student in a semester is indicated by a number called 'Semester Grade Point Average' (SGPA). The SGPA is the weighted average of the grade points obtained in all the courses by the student during the semester. For example, if a student takes five courses (Theory/Practical) in a semester with credits C1, C2, C3 and C4 and the student's grade points in these courses are G1, G2, G3 and G4, respectively, and then students' SGPA is equal to:

$$SGPA = \frac{C_1G_1 + C_2G_2 + C_3G_3 + C_4G_4}{C_1 + C_2 + C_3 + C_4}$$

The SGPA is calculated to two decimal points. It should be noted that, the SGPA for any semester shall take into consideration the F and ABS grade awarded in that semester. For example if a learner has a F or ABS grade in course 4, the SGPA shall then be computed as:

$$SGPA = \frac{C_1G_1 + C_2G_2 + C_3G_3 + C_4*ZER0}{C_1 + C_2 + C_3 + C_4}$$

c) Cumulative Grade Point Average (CGPA)

The CGPA is calculated with the SGPA of all the IV semesters to two decimal points and is indicated in final grade report card/final transcript showing the grades of all IV semesters and their courses. The CGPA shall reflect the failed status in case of F grade(s), till the course(s) is/are passed. When the course(s) is/are passed by obtaining a pass grade on subsequent examination(s) the CGPA shall only reflect the new grade and not the fail grades earned earlier.The CGPA is calculated as:

$$CGPA = \frac{C_1S_1 + C_2S_2 + C_3S_3 + C_4S_4}{C_1 + C_2 + C_3 + C_4}$$

where C_1, C_2, C_3,…. is the total number of credits for semester I,II,III,…. And S_1, S_2, S_3… is the SGPA of semester I, II, III…. .

3.4 Papers in each year

As mentioned in Course outline (clause 2.4)

3.5 Details of theory exams

As mentioned in Schedule of regular / Supplementary Exams (clause 3.2)

3.6 Model question paper for each subject with question paper pattern

As mentioned in Schedule of regular / Supplementary Exams (clause 3.2) See Annexure

3.7 Internal assessment component

As mentioned in Scheme of examination. (Clause 3.3)

- Two sessional exams shall be conducted for each theory / practical course as per the schedule fixed by the college(s). The average marks of two sessional exams shall be computed for internal assessment as per the requirements
- A student shall have the opportunity to improve his/her performance only once in the sessional exam component of the internal assessment. The re-conduct of the sessional exam shall be completed before the commencement of next end semester theory examinations.

3.8 Details of practical / clinical practicum exams.

As mentioned in Schedule of regular / Supplementary Exams (clause 3.2) Scheme of examination. (Clause 3.3)

3.9 Number of examiners (Internal & External) and their qualifications

- A post graduate (PG) degree in M. Pharm shall be eligible as teacher.
- A post graduate degree in M. Pharm with 5 years Post PG experience is eligible as internal examiner.
- A post graduate degree in M. Pharm with 10 years Post PG is eligible as external examiner.
- A post graduate degree in M. Pharm with 5 years Post PG is eligible to guide maximum of 5 candidates for M. Pharm dissertation.

For the conduct of practical examination of I semester one external examiner and 2 internal examiners (one faculty dealing with the respective speciality and one faculty dealing Modern Analytical and Research methods) shall be appointed by the University. For the evaluation of Practical Examination of II semester one internal and one external examiner shall be appointed by the university.

3.10 Details of viva:

As mentioned in Schedule of regular / Supplementary Exams (clause 3.2) Scheme of examination. (Clause 3.3)

4. INTERNSHIP

Not applicable

5. ANNEXURES

5.1 Check Lists for Monitoring:

Log Book, Seminar Assessment etc. to be formulated by the curriculum committee of the concerned Institution.

QP Code: Reg No:----------

Model Question Paper (M.PHARM PHARMACEUTICS)

Ist Semester M.Pharm Degree Examination

Paper -1 Modern pharmaceutical Analysis (MPA 101T)

Time: 3hrs Max marks:75

- Answer all questions

Essays (3 x10 =30)

1. Briefly describe the molecular vibrations, sample handling and instrumentation of IR spectroscopy ?
2. Explain the principle, instrumentation and applications of Flame emission and Atomic absorption spectroscopy?
3. Explain column chromatography with theory of separations of individual components ? Write a note on HPLC ?

Short notes **(5 x9 =45)**

1. Explain the theory of T.L.C?
2. Describe application of I.R spectroscopy?
3. Explain fluorescence and factors affecting fluorescence
4. Factors influencing chemical shift in NMR spectroscopy?
5. Different ions produced in Mass spectroscopy?
6. Principles of X-ray diffraction techniques?
7. Explain one method of identification of a compound using paper chromatography ?
8. Principles of electrophoresis?
9. Principles of radio immunoassays ?

QP Code: **Reg No:----------**

First Semester M Pharm Degree examinations
Model question paper
Paper –II Drug Delivery System (MPH101T)

Time 3hrs **Max marks: 75**

Answer all questions

Essay **(3x10=30)**

1. Write a note on Transdermal drug delivery systems. Explain in detail about its classification and formulation development.
2. Write briefly on the concept of Controlled drug delivery. Explain about the mechanisms of drug release from controlled release systems.
3. What are Gastro retentive drug delivery systems? Write its advantages and disadvantages. Explain various approaches to enhance gastric retention.

Short notes: **(9x5=45)**

4. Describe the design and manufacture of an osmotic pump
5. Write a short note on biodegradable polymers
6. Discuss about the 3D printing of Pharmaceuticals
7. Explain the applications of Pharmacogenetics.
8. Give a brief description on the formulation of Ocuserts
9. Explain about various techniques to overcome the barriers in the oral delivery of proteins and peptides
10. Discuss on various vesicular systems for vaccine delivery
11. Write briefly on feedback regulated drug delivery systems
12. Explain the evaluation of mucoadhesive drug delivery systems

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QP Code: **Reg No:----------**

First Semester M Pharm Degree examinations
Model question paper
Paper- III Modern Pharmaceutics (MPH102T)

Time 3hrs **Max marks: 75**

Answer all questions

Essay **(3x10=30)**

13. Define small and large volume parenterals. Explain the evaluation tests for parenteral preparations.
14. What you mean by pharmaceutical validation? Which are the different types of validation methods? Briefly describe the process validation of tablets.
15. Discuss the various optimization techniques used in pharmaceutical formulation.

Short notes: **(9x5=45)**

16. Give the general formulation development and stability studies of SMEDDS
17. Briefly discuss the principles of TQM in pharmaceutical industry.
18. Write a note on chi square test.
19. Describe Heckel's plot and its significance.
20. Discuss drug-excipient compatibility evaluation in pharmaceutical preformulation studies.
21. Explain different systems of inventory management in pharmaceutical industry.
22. Write on different approaches used for sales forecasting.
23. Describe the protocol for stability testing as per ICH guidelines.
24. Write on different properties of tablets influenced by compression

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QP Code: **Reg No:----------**

First Semester M Pharm Degree examinations
Model question paper
Paper – IV Regulatory Affairs (MPH103T)

Time 3hrs **Max marks: 75**

Answer all questions

Essay **(3x10=30)**

1. What are Clinical Trials? Explain the clinical study design with respect to various phases involved in Clinical Trial.
2. Explain the regulatory requirements for IND submission, format and content of IND.
3. Write a note on Bioequivalence and Drug Product Assessment. Write briefly on the outsourcing of BA and BE to CRO

Short notes: **(9x5=45)**

4. Discuss the Format and Process of NDA for US registration
5. Explain the importance of Hatch-Waxman Act
6. Discuss on Drug Master File records for pharmaceutical industries in India
7. Explain the benefits and structure of CTD.
8. Write the regulatory requirements for medical devices
9. Discuss on the significance of HIPAA
10. Explain the constitutions and functions of Independent Ethics Committee
11. Write a note on Investigation Medicinal products Dossier
12. Write briefly on the Pharmacovigilance safety monitoring in clinical trials

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REGULATIONS2017

Syllabus

Kerala University of Health Sciences

Thrissur - 680596

POST GRADUATE COURSE IN PHARMACY

Master of Pharmacy

(M.Pharm. Pharmaceutical Chemistry)

Course code: 277

(2017-18 Academic year onwards)

2017

2. COURSE CONTENT

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2. COURSE CONTENT

2.1 Title of course

These regulations shall be called as "Master of Pharmacy (M.Pharm. – Pharmaceutical Chemistry) Degree Program - Credit Based Semester System (CBSS) of the Kerala University of Health sciences. They shall come into effect from the Academic Year 2017-18 onwards. The regulations framed are subject to modifications from time to time by the authorities of the University.

2.2 Objectives of course

To generate Pharmacy Post Graduates with profound knowledge in various branches of Pharmaceutical Sciences to meet with the rapidly increasing demands put forward by-

- Pharmaceutical Manufacturing
- Pharmaceutical Research & Development
- Pharmacological research including preclinical & clinical studies.
- Herbal Drug Research
- Pharmaceutical & Herbal Drug Analysis
- Clinical Toxicology & Toxicological Analysis

To discover the potential to become faculty in Pharmaceutical Sciences with unmatched quality and excellence, so as to educate the future pharmacy generation (Undergraduate, Post graduate, and Doctoral).

2.3 Medium of Instruction

Medium of instruction and examination shall be in English.

2.4 Course Outline

The specialization in M.Pharm. Program is given in Table 1.

Table – 1: M.Pharm. Specialization and its code

S.No	Specialization	Code
1.	Pharmaceutical Chemistry	MPC

The course of study for M.Pharm Pharmaceutical Chemistry shall include Semester wise Theory & Practical as given in Table – 2 & 3. The number of hours to be devoted to each theory and practical course in any semester shall not be less than that shown in Table – 2 & 3.

Table – 2: Course of study for M.Pharm. I & II Semester

Course Code	Course	Credit Hours	Credit Points	Hrs./wk	Marks
Semester I					
MPC 101T	Modern Pharmaceutical Analytical Techniques	4	4	4	100
MPC 102T	Advanced Organic Chemistry –I	4	4	4	100
MPC 103T	Advanced Medicinal Chemistry	4	4	4	100
MPC 104T	Chemistry of Natural Products	4	4	4	100
MPC 105P	Pharmaceutical Chemistry Practical – I	12	6	12	150
-	Seminar /Assignment	7	4	7	100
Total		35	26	35	650
Semester II					
MPC 201T	Advanced Spectral Analysis	4	4	4	100
MPC 202T	Advanced Organic Chemistry –II	4	4	4	100
MPC 203T	Computer Aided Drug Design	4	4	4	100
MPC 204T	Pharmaceutical Process Chemistry	4	4	4	100
MPC 205P	Pharmaceutical Chemistry Practical II	12	6	12	150
-	Seminar /Assignment	7	4	7	100
Total		35	26	35	650

Table – 3: Course of study for M. Pharm. III & IV Semester

Course Code	Course	Credit Hours	Credit Points
Semester III			
MRM 301T	Research Methodology and Biostatistics*	4	4
-	Journal Club	1	1
-	Discussion / Presentation (proposal presentation)	2	2
-	Research Work*	28	14
Total		35	21
Semester IV			
-	Journal Club	1	1
-	Research Work	31	16
-	Discussion / Final Presentation	3	3
Total		35	20

*Non University Exam

Program/Course credit structure

As per the philosophy of Credit Based Semester System, certain quantum of academic work viz. theory classes, practical classes, seminars, assignments, etc. are measured in terms of credits. On satisfactory completion of the courses, a candidate earns credits. The amount of credit associated with a course is dependent upon the number of hours of instruction per week in that course. Similarly the credit associated with any of the other academic, co/extracurricular activities is dependent upon the quantum of work expected to be put in for each of these activities per week/per activity.

Credit assignment

a) Theory and Laboratory courses

Courses are broadly classified as Theory and Practical. Theory courses consist of lecture (L) and Practical (P) courses consist of hours spent in the laboratory. Credits (C) for a course is dependent on the number of hours of instruction per week in that course, and is obtained by using a multiplier of one (1) for lecture and a multiplier of half (1/2) for practical (laboratory) hours. Thus, for example, a theory course having four lectures per week throughout the semester carries a credit of 4. Similarly, a practical having four laboratory hours per week throughout semester carries a credit of 2. The contact hours of seminars, assignments and research work shall be treated as that of practical courses for the purpose of calculating credits. i.e., the contact hours shall be multiplied by 1/2. Similarly, the contact hours of journal club, research work presentations and discussions with the supervisor shall be considered as theory course and multiplied by 1.

b) Minimum credit requirements

The minimum credit points required for the award of M. Pharm. degree is 95. However based on the credit points earned by the students under the head of co-curricular activities, a student shall earn a maximum of 100 credit points. These credits are divided into Theory courses, Practical, Seminars, Assignments, Research work, Discussions with the supervisor, Journal club and Co-Curricular activities over the duration of four semesters. The credits are distributed semester-wise as shown in Table 4. Courses generally progress in sequence, building competencies and their positioning indicates certain academic maturity on the part of the learners. Learners are expected to follow the semester-wise schedule of courses given in the syllabus.

Table – 4: Semester wise credits distribution

Semester	Credit Points
I	26
II	26
III	21
IV	20
Co-curricular Activities (attending Conference, Scientific Presentations and other scholarly Activities)	Minimum = 02 Maximum = 07*
Total Credit Points	Minimum = 95 Maximum = 100

*Credit points for Co-curricular Activities

Table – 5: Guidelines for Awarding Credit Points for Co-curricular Activities

Name of the Activity	MaximumCredit Points Eligible / Activity
Participation in National Level Seminar/ Conference/ Workshop / Symposium / Training Programs (related to the specialization of the student)	01
Participation in international Level Seminar/ Conference/ Workshop/ Symposium/ Training Programs (related to the specialization of the student)	02
Academic Award/Research Award from State Level/ National Agencies	01
Academic Award/Research Award from International Agencies	02
Research / Review Publication in National Journals (Indexed in Scopus / Web of Science)	01
Research / Review Publication in International Journals (Indexed in Scopus / Web of Science)	02

Note: International Conference: Held outside India

International Journal: The Editorial Board outside India

*The credit points assigned for extracurricular and or co-curricular activities shall be given by the Principals of the colleges and the same shall be submitted to the University. The criteria to acquire this credit point shall be defined by the colleges from time to time.

Program Committee

1. The M. Pharm. programme shall have a Programme Committee constituted by the Head of the institution in consultation with all the Heads of the departments.
2. The composition of the Programme Committee shall be as follows:
   A teacher at the cadre of Professor shall be the Chairperson; One Teacher from each M.Pharm specialization and four student representatives (two from each academic year), nominated by the Head of the institution.
3. Duties of the Programme Committee:
   i. Periodically reviewing the progress of the classes.
   ii. Discussing the problems concerning curriculum, syllabus and the conduct of classes.
   iii. Discussing with the course teachers on the nature and scope of assessment for the course and the same shall be announced to the students at the beginning of respective semesters.
   iv. Communicating its recommendation to the Head of the institution on academic matters.
   v. The Programme Committee shall meet at least twice in a semester preferably at the end of each sessional exam and before the end semester exam.

2.5 Duration

The program of study for M.Pharm. shall extend over a period of four semesters (two academic years). The curricula and syllabi for the program shall be prescribed from time to time by the Kerala University of Health sciences.

The duration for the completion of the program shall be fixed as double the actual duration of the program and the students have to pass within the said period, otherwise they have to get fresh Registration.

2.6 Syllabus

PHARMACEUTICAL CHEMISTRY (MPC)

MODERN PHARMACEUTICAL ANALYTICAL TECHNIQUES

(MPC 101T)

Scope

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

Objectives

After completion of course student is able to know about chemicals and excipients

- The analysis of various drugs in single and combination dosage forms
- Theoretical and practical skills of the instruments

THEORY **60 Hrs**

1. a. UV-Visible spectroscopy: Introduction, Theory, Laws, Instrumentation associated with UV-Visible spectroscopy, Choice of solvents and solvent effect and Applications of UV-Visible spectroscopy, Difference/ Derivative spectroscopy. 10 Hrs

   b. IR spectroscopy: Theory, Modes of Molecular vibrations, Sample handling, Instrumentation of Dispersive and Fourier - Transform IR Spectrometer, Factors affecting vibrational frequencies and Applications of IR spectroscopy, Data Interpretation.

   c. Spectroflourimetry: Theory of Fluorescence, Factors affecting fluorescence (Characterestics of drugs that can be analysed by flourimetry), Quenchers, Instrumentation and Applications of fluorescence spectrophotometer.

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

2. NMR spectroscopy: Quantum numbers and their role in NMR, Principle, Instrumentation, Solvent requirement in NMR, Relaxation process, NMR signals in various compounds, Chemical shift, Factors influencing chemical shift, Spin-Spin coupling, Coupling constant, Nuclear magnetic double resonance, Brief 10 Hrs

outline of principles of FT-NMR and 13C NMR. Applications of NMR spectroscopy.

3. Mass Spectroscopy: Principle, Theory, Instrumentation of Mass Spectroscopy, Different types of ionization like electron impact, chemical, field, FAB and MALDI, APCI, ESI, APPI Analyzers of Quadrupole and Time of Flight, Mass fragmentation and its rules, Meta stable ions, Isotopic peaks and Applications of Mass spectroscopy. 10 Hrs

4. Chromatography: Principle, apparatus, instrumentation, chromatographic parameters, factors affecting resolution, isolation of drug from excipients, data interpretation and applications of the following: 10 Hrs

   a) Thin Layer chromatography

   b) High Performance Thin Layer Chromatography

   c) Ion exchange chromatography

   d) Column chromatography

   e) Gas chromatography

   f) High Performance Liquid chromatography

   g) Ultra High Performance Liquid chromatography

   h) Affinity chromatography

   i) i) Gel Chromatography

5. a.Electrophoresis: Principle, Instrumentation, Working conditions, factors affecting separation and applications of the following: 10 Hrs

   a) Paper electrophoresis b) Gel electrophoresis c) Capillary electrophoresis d) Zone electrophoresis e) Moving boundary electrophoresis f) Iso electric focusing

   b.X ray Crystallography: Production of X rays, Different X ray methods, Bragg's law, Rotating crystal technique, X ray powder technique, Types of crystals and applications of X-ray diffraction.

6. a. Potentiometry: Principle, working, Ion selective Electrodes and Application of potentiometry. 10 Hrs

   b. Thermal Techniques: Principle, thermal transitions and Instrumentation (Heat flux and power-compensation and designs), Modulated DSC, Hyper DSC,

experimental parameters (sample preparation, experimental conditions, calibration, heating and cooling rates, resolution, source of errors) and their influence, advantage and disadvantages, pharmaceutical applications.

Differential Thermal Analysis (DTA): Principle, instrumentation and advantage and disadvantages, pharmaceutical applications, derivative differential thermal analysis (DDTA). TGA: Principle, instrumentation, factors affecting results, advantage and disadvantages, pharmaceutical applications.

REFERENCES

1. Spectrometric Identification of Organic compounds - Robert M Silverstein, Sixth edition, John Wiley & Sons, 2004.
2. Principles of Instrumental Analysis - Doglas A Skoog, F. James Holler, Timothy A. Nieman, 5th edition, Eastern press, Bangalore, 1998.
3. Instrumental methods of analysis – Willards, 7th edition, CBS publishers.
4. Practical Pharmaceutical Chemistry – Beckett and Stenlake, Vol II, 4th edition, CBS Publishers, New Delhi, 1997.
5. Organic Spectroscopy - William Kemp, 3rd edition, ELBS, 1991.
6. Quantitative Analysis of Drugs in Pharmaceutical formulation - P D Sethi, 3rd Edition, CBS Publishers, New Delhi, 1997.
7. Pharmaceutical Analysis - Modern Methods – Part B - J W Munson, Vol 11, Marcel. Dekker Series
8. Spectroscopy of Organic Compounds, 2nd edn., P.S/Kalsi, Wiley estern Ltd Delhi., .
9. Textbook of Pharmaceutical Analysis, KA.Connors, 3rd Edition, John Wiley & Sons, 1982.

ADVANCED ORGANIC CHEMISTRY - I

(MPC 102T)

Scope

The subject is designed to provide in-depth knowledge about advances in organic chemistry, different techniques of organic synthesis and their applications to process chemistry as well as drug discovery.

Objectives

Upon completion of course, the student shall be to understand

- The principles and applications of reterosynthesis
- The mechanism & applications of various named reactions
- The concept of disconnection to develop synthetic routes for small target molecule.
- The various catalysts used in organic reactions
- The chemistry of heterocyclic compounds

THEORY **60 Hrs**

1. Basic Aspects of Organic Chemistry: 12 Hrs

    1. Organic intermediates: Carbocations, carbanions, free radicals, carbenes and nitrenes. Their method of formation, stability and synthetic applications.
    2. Types of reaction mechanisms and methods of determining them,
    3. Detailed knowledge regarding the reactions, mechanisms and their relative reactivity and orientations.

    Addition reactions

    a) Nucleophilic uni- and bimolecular reactions (SN1 and SN2)

    b) Elimination reactions (E1 & E2; Hoffman & Saytzeff's rule)

    c) Rearrangement reaction

2. Study of mechanism and synthetic applications of following named Reactions: 12 Hrs

    Ugi reaction, Brook rearrangement, Ullmann coupling reactions, Dieckmann Reaction, Doebner-Miller Reaction, Sandmeyer Reaction, Mitsunobu reaction,

Mannich reaction, Vilsmeyer-Haack Reaction, Sharpless asymmetric epoxidation, Baeyer-Villiger oxidation, Shapiro & Suzuki reaction, Ozonolysis and Michael addition reaction

3. Synthetic Reagents & Applications: 12 Hrs

Aluminiumisopropoxide, N-bromosuccinamide, diazomethane, dicyclohexylcarbodimide, Wilkinson reagent, Witting reagent. Osmium tetroxide, titanium chloride, diazopropane, diethyl azodicarboxylate, Triphenylphosphine, Benzotriazol-1-yloxy) tris (dimethylamino) phosphonium hexafluoro-phosphate (BOP).

Protecting groups

a. Role of protection in organic synthesis
b. Protection for the hydroxyl group, including 1,2-and1,3-diols: ethers, esters, carbonates, cyclic acetals & ketals
c. Protection for the Carbonyl Group: Acetals and Ketals
d. Protection for the Carboxyl Group: amides and hydrazides, esters
e. Protection for the Amino Group and Amino acids: carbamates and amides

4. Heterocyclic Chemistry: 12 Hrs

Organic Name reactions with their respective mechanism and application involved in synthesis of drugs containing five, six membered and fused hetrocyclics such as Debus-Radziszewski imidazole synthesis, Knorr Pyrazole Synthesis Pinner Pyrimidine Synthesis, Combes Quinoline Synthesis, Bernthsen Acridine Synthesis, Smiles rearrangement and Traube purine synthesis.

Synthesis of few representative drugs containing these hetrocyclic nucleus such as Ketoconazole, Metronidazole, Miconazole, celecoxib, antipyrin, Metamizole sodium, Terconazole, Alprazolam, Triamterene, Sulfamerazine, Trimethoprim, Hydroxychloroquine, Quinine, Chloroquine, Quinacrine, Amsacrine, Prochlorpherazine, Promazine, Chlorpromazine,Theophylline , Mercaptopurine and Thioguanine.

5. Synthon approach and retrosynthesis applications 12 Hrs

i. Basic principles, terminologies and advantages of retrosynthesis; guidelines for dissection of molecules. Functional group interconvertion

and addition (FGI and FGA)

ii. C-X disconnections; C-C disconnections – alcohols and carbonyl compounds; 1,2-, 1,3-,1,4-, 1,5-, 1,6-difunctionalized compounds

iii. Strategies for synthesis of three, four, five and six-membered ring.

REFERENCES

1. "Advanced Organic chemistry, Reaction, Mechanisms and Structure", J March, John Wiley and Sons, New York.
2. "Mechanism and Structure in Organic Chemistry", ES Gould, Hold Rinchart and Winston, New York.
3. "Organic Chemistry" Clayden, Greeves, Warren and Woihers., Oxford University Press 2001.
4. "Organic Chemistry" Vol I and II. I.L. Finar. ELBS, Pearson Education Lts, Dorling Kindersley 9India) Pvt. Ltd.,.
5. A guide to mechanisms in Organic Chemistry, Peter Skyes (Orient Longman, New Delhi).
6. Reactive Intermediates in Organic Chemistry, Tandom and Gowel, Oxford & IBH Publishers.
7. Combinational Chemistry – Synthesis and applications – Stephen R Wilson & Anthony W Czarnik, Wiley – Blackwell.
8. Carey, Organic Chemistry, 5th Edition (Viva Books Pvt. Ltd.)
9. Organic Synthesis - The Disconnection Approach, S. Warren, Wily India
10. Principles of Organic Synthesis, ROC Norman and JM Coxan, Nelson Thorns.
11. Organic Synthesis - Special Techniques. VK Ahluwalia and R Agarwal, Narosa Publishers.
12. Organic Reaction Mechanisms IV Edtn, VK Ahluwalia and RK Parashar, Narosa Publishers.

ADVANCED MEDICINAL CHEMISTRY

(MPC 103T)

Scope

The subject is designed to impart knowledge about recent advances in the field of medicinal chemistry at the molecular level including different techniques for the rational drug design.

Objectives

At completion of this course it is expected that students will be able to understand

- Different stages of drug discovery
- Role of medicinal chemistry in drug research
- Different techniques for drug discovery
- Various strategies to design and develop new drug like molecules for biological targets
- Peptidomimetics

THEORY **60 Hrs**

1. Drug discovery: Stages of drug discovery, lead discovery; identification, validation and diversity of drug targets. 12 Hrs

   Biological drug targets: Receptors, types, binding and activation, theories of drug receptor interaction, drug receptor interactions, agonists vs antagonists, artificial enzymes.

2. Prodrug Design and Analog design: 12 Hrs

   a) Prodrug design: Basic concept, Carrier linked prodrugs / Bioprecursors, Prodrugs of functional group, Prodrugs to improve patient acceptability, Drug solubility, Drug absorption and distribution, site specific drug delivery and sustained drug action. Rationale of prodrug design and practical consideration of prodrug design.

   b) Combating drug resistance: Causes for drug resistance, strategies to combat drug resistance in antibiotics and anticancer therapy, Genetic principles of drug resistance.

   c) Analog Design: Introduction, Classical & Non classical, Bioisosteric replacement strategies, rigid analogs, alteration of chain branching, changes in ring size, ring position isomers, design of stereo isomers and geometric isomers, fragments of a lead molecule, variation in inter

atomic distance.

3. Medicinal chemistry aspects of the following class of drugs: 12 Hrs

Systematic study, SAR, Mechanism of action and synthesis of new generation molecules of following class of drugs:

a) Anti-hypertensive drugs, Psychoactive drugs, Anticonvulsant drugs, H1 & H2 receptor antagonist, COX1 & COX2 inhibitors, Adrenergic & Cholinergic agents, Antineoplastic and Antiviral agents.

b) Stereochemistry and Drug action: Realization that stereo selectivity is a pre-requisite for evolution. Role of chirality in selective and specific therapeutic agents. Case studies, Enantio selectivity in drug adsorption, metabolism, distribution and elimination.

4. Rational Design of Enzyme Inhibitors 12 Hrs

Enzyme kinetics & Principles of Enzyme inhibitors, Enzyme inhibitors in medicine, Enzyme inhibitors in basic research, rational design of non-covalently and covalently binding enzyme inhibitors.

5. Peptidomimetics 12 Hrs

Therapeutic values of Peptidomimetics, design of peptidomimetics by manipulation of the amino acids, modification of the peptide backbone, incorporating conformational constraints locally or globally. Chemistry of prostaglandins, leukotrienes and thromboxones.

REFERENCES

1. Medicinal Chemistry by Burger, Vol I –VI.
2. Wilson and Gisvold's Text book of Organic Medicinal and Pharmaceutical Chemistry, 12th Edition, Lppincott Williams & Wilkins, Woltess Kluwer (India) Pvt.Ltd, New Delhi.
3. Comprehensive Medicinal Chemistry – Corwin and Hansch.
4. Computational and structural approaches to drug design edited by Robert M Stroud and Janet. F Moore
5. Introduction to Quantitative Drug Design by Y.C. Martin.
6. Principles of Medicinal Chemistry by William Foye, 7th Edition, Ippincott Williams & Wilkins, Woltess Kluwer (India) Pvt.Ltd, New Delhi.
7. Drug Design Volumes by Arienes, Academic Press, Elsevier Publishers, Noida, Uttar Pradesh.

8. Principles of Drug Design by Smith.
9. The Organic Chemistry of the Drug Design and Drug action by Richard B.Silverman, II Edition, Elsevier Publishers, New Delhi.
10. An Introduction to Medicinal Chemistry, Graham L.Patrick, III Edition, Oxford University Press, USA.
11. Biopharmaceutics and pharmacokinetics, DM.Brahmankar, Sunil B. Jaiswal II Edition, 2014, Vallabh Prakashan, New Delhi.
12. Peptidomimetics in Organic and Medicinal Chemistry by Antonio Guarna and Andrea Trabocchi, First edition, Wiley publishers.

CHEMISTRY OF NATURAL PRODUCTS

(MPC 104T)

Scope

The subject is designed to provide detail knowledge about chemistry of medicinal compounds from natural origin and general methods of structural elucidation of such compounds. It also emphasizes on isolation, purification and characterization of medicinal compounds from natural origin.

Objectives

At completion of this course it is expected that students will be able to understand-

- Different types of natural compounds and their chemistry and medicinal importance
- The importance of natural compounds as lead molecules for new drug discovery
- The concept of rDNA technology tool for new drug discovery
- General methods of structural elucidation of compounds of natural origin
- Isolation, purification and characterization of simple chemical constituents from natural source

THEORY **60 Hrs**

1. Study of Natural products as leads for new pharmaceuticals for the following class of drugs — 12 Hrs

   a) Drugs Affecting the Central Nervous System: Morphine Alkaloids

   b) Anticancer Drugs: Paclitaxel and Docetaxel, Etoposide, and Teniposide

   c) Cardiovascular Drugs: Lovastatin, Teprotide and Dicoumarol

   d) Neuromuscular Blocking Drugs: Curare alkaloids

   e) Anti-malarial drugs and Analogues

   f) Chemistry of macrolid antibiotics (Erythromycin, Azithromycin, Roxithromycin, and Clarithromycin) and β - Lactam antibiotics (Cephalosporins and Carbapenem)

2. a) Alkaloids — 12 Hrs

   General introduction, classification, isolation, purification, molecular modification and biological activity of alkaloids, general methods of structural

determination of alkaloids, structural elucidation and stereochemistry of ephedrine, morphine, ergot, emetine and reserpine.

b) Flavonoids

Introduction, isolation and purification of flavonoids, General methods of structural determination of flavonoids; Structural elucidation of quercetin.

c) Steroids

General introduction, chemistry of sterols, sapogenin and cardiac glycosides. Stereochemistry and nomenclature of steroids, chemistry of contraceptive agents male & female sex hormones (Testosterone, Estradiol, Progesterone), adrenocorticoids (Cortisone), contraceptive agents and steroids (Vit – D).

3. a) Terpenoids — 12 Hrs

Classification, isolation, isoprene rule and general methods of structural elucidation of Terpenoids; Structural elucidation of drugs belonging to mono (citral, menthol, camphor), di(retinol, Phytol, taxol) and tri terpenoids (Squalene,Ginsenoside) carotinoids (β carotene).

b) Vitamins

Chemistry and Physiological significance of Vitamin A, B1, B2, B12, C, E, Folic acid and Niacin.

4. a). Recombinant DNA technology and drug discovery — 12 Hrs

rDNA technology, hybridoma technology, New pharmaceuticals derived from biotechnology; Oligonucleotide therapy. Gene therapy: Introduction, Clinical application and recent advances in gene therapy, principles of RNA & DNA estimation

b). Active constituent of certain crude drugs used in Indigenous system Diabetic therapy – Gymnema sylvestre, Salacia reticulate, Pterocarpus marsupiam, Swertia chirata, Trigonella foenum graccum; Liver dysfunction – Phyllanthus niruri;Antitumor – Curcuma longa Linn.

5. Structural Characterization of natural compounds — 12 Hrs

Structural characterization of natural compounds using IR, 1HNMR, 13CNMR and MS Spectroscopy of specific drugs e.g., Penicillin, Morphine, Camphor, Vit-D, Quercetin and Digitalis glycosides.

REFERENCES

1. Modern Methods of Plant Analysis, Peech and M.V.Tracey, Springer – Verlag, Berlin, Heidelberg.
2. Phytochemistry Vol. I and II by Miller, Jan Nostrant Rein Hld.
3. Recent advances in Phytochemistry Vol. I to IV – Scikel Runeckles, Springer Science & Business Media.
4. Chemistry of natural products Vol I onwards IWPAC.
5. Natural Product Chemistry Nakanishi Gggolo, University Science Books, California.
6. Natural Product Chemistry "A laboratory guide" – Rapheal Khan.
7. The Alkaloid Chemistry and Physiology by RHF Manske, Academic Press. 8. Introduction to molecular Phytochemistry – CHJ Wells, Chapmannstall.
8. Organic Chemistry of Natural Products Vol I and II by Gurdeep and Chatwall, Himalaya Publishing House.
9. Organic Chemistry of Natural Products Vol I and II by O.P. Agarwal, Krishan Prakashan.
10. Organic Chemistry Vol I and II by I.L. Finar, Pearson education.
11. Elements of Biotechnology by P.K. Gupta, Rastogi Publishers.
12. Pharmaceutical Biotechnology by S.P.Vyas and V.K.Dixit, CBS Publishers.
13. Biotechnology by Purohit and Mathur, Agro-Bios, 13th edition.
14. Phytochemical methods of Harborne, Springer, Netherlands.
15. Burger's Medicinal Chemistry.

PHARMACEUTICAL CHEMISTRY PRACTICAL - I

(MPC 105P)

1. Analysis of Pharmacopoeial compounds and their formulations by UV Vis spectrophotometer, RNA & DNA estimation
2. Simultaneous estimation of multi component containing formulations by UV spectrophotometry
3. Experiments based on Column chromatography
4. Experiments based on HPLC
5. Experiments based on Gas Chromatography
6. Estimation of riboflavin/quinine sulphate by fluorimetry
7. Estimation of sodium/potassium by flame photometry

To perform the following reactions of synthetic importance

1. Purification of organic solvents, column chromatography
2. Claisen-schimidt reaction.
3. Benzyllic acid rearrangement.
4. Beckmann rearrangement.
5. Hoffmann rearrangement
6. Mannich reaction
7. Synthesis of medicinally important compounds involving more than one step along with purification and Characterization using TLC, melting point and IR spectroscopy (4 experiments)
8. Estimation of elements and functional groups in organic natural compounds
9. Isolation, characterization like melting point, mixed melting point, molecular weight determination, functional group analysis, co-chromatographic technique for identification of isolated compounds and interpretation of UV and IR data.
10. Some typical degradation reactions to be carried on selected plant constituents

ADVANCED SPECTRAL ANALYSIS

(MPC 201T)

Scope

This subject deals with various hyphenated analytical instrumental techniques for identification, characterization and quantification of drugs. Instruments dealt are LC-MS, GC-MS, ATR-IR, DSC etc.

Objectives

At completion of this course it is expected that students will be able to understand-

- Interpretation of the NMR, Mass and IR spectra of various organic compounds
- Theoretical and practical skills of the hyphenated instruments
- Identification of organic compounds

THEORY **60Hrs**

1.	UV and IR spectroscopy: Wood ward – Fieser rule for 1,3- butadienes, cyclic dienes and α, β-carbonyl compounds and interpretation compounds of enones. ATR-IR, IR Interpretation of organic compounds.	12 Hrs
2.	NMR spectroscopy: 1-D and 2-D NMR, NOESY and COSY, HECTOR, INADEQUATE techniques, Interpretation of organic compounds.	12 Hrs
3.	Mass Spectroscopy 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, Interpretation of organic compounds.	12 Hrs
4.	Chromatography: Principle, Instrumentation and Applications of the following : a) GC-MS b) GC-AAS c) LC-MS d) LC-FTIR e) LC-NMR f) CE- MS g) High Performance Thin Layer chromatography h) Super critical fluid chromatography i) Ion Chromatography j) I-EC (Ion- Exclusion Chromatography) k) Flash chromatography	12 Hrs

5. a). Thermal methods of analysis 12 Hrs

Introduction, principle, instrumentation and application of DSC, DTA and TGA.

b). Raman Spectroscopy

Introduction, Principle, Instrumentation and Applications.

c). Radio immuno assay

Biological standardization, bioassay, ELISA, Radioimmuno assay of digitalis and insulin.

REFERENCES

1. Spectrometric Identification of Organic compounds - Robert M Silverstein, Sixth edition, John Wiley & Sons, 2004.
2. Principles of Instrumental Analysis - Doglas A Skoog, F. James Holler, Timothy A. Nieman, 5th edition, Eastern press, Bangalore, 1998.
3. Instrumental methods of analysis – Willards, 7th edition, CBS publishers.
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5. Quantitative analysis of Pharmaceutical formulations by HPTLC - P D Sethi, CBS Publishers, New Delhi.
6. Quantitative Analysis of Drugs in Pharmaceutical formulation - P D Sethi, 3rd Edition, CBS Publishers, New Delhi, 1997.
7. Pharmaceutical Analysis- Modern methods – Part B - J W Munson, Volume 11 Marcel Dekker Series

ADVANCED ORGANIC CHEMISTRY - II

(MPC 202T)

Scope

The subject is designed to provide in-depth knowledge about advances in organic chemistry, different techniques of organic synthesis and their applications to process chemistry as well as drug discovery.

Objectives

Upon completion of course, the student shall able to understand

- The principles and applications of Green chemistry
- The concept of peptide chemistry.
- The various catalysts used in organic reactions
- The concept of stereochemistry and asymmetric synthesis.

THEORY **60 Hrs**

1. Green Chemistry: 12 Hrs

    a) Introduction, principles of green chemistry

    b) Microwave assisted reactions: Merit and demerits of its use, increased reaction rates, mechanism, superheating effects of microwave, effects of solvents in microwave assisted synthesis, microwave technology in process optimization, its applications in various organic reactions and heterocycles synthesis

    c) Ultrasound assisted reactions: Types of sonochemical reactions, homogenous, heterogeneous liquid-liquid and liquid-solid reactions, synthetic applications

    d) Continuous flow reactors: Working principle, advantages and synthetic applications.

2. Chemistry of peptides 12 Hrs

    a) Coupling reactions in peptide synthesis

    b) Principles of solid phase peptide synthesis, t-BOC and FMOC protocols, various solid supports and linkers: Activation procedures, peptide bond

formation, deprotection and cleavage from resin, low and high HF cleavage protocols, formation of free peptides and peptide amides, purification and case studies, site-specific chemical modifications of peptides

c) Segment and sequential strategies for solution phase peptide synthesis with any two case studies

d) Side reactions in peptide synthesis: Deletion peptides, side reactions initiated by proton abstraction, protonation, over- activation and side reactions of individual amino acids.

3. Photochemical Reactions 12 Hrs

Basic principles of photochemical reactions. Photo-oxidation, photo-addition and photo-fragmentation.

Pericyclic reactions

Mechanism, Types of pericyclic reactions such as cyclo addition, electrocyclic reaction and sigmatrophic rearrangement reactions with examples

4. Catalysis: 12 Hrs

a) Types of catalysis, heterogeneous and homogenous catalysis, advantages and disadvantages

b) Heterogeneous catalysis – preparation, characterization, kinetics, supported catalysts, catalyst deactivation and regeneration, some examples of heterogeneous catalysis used in synthesis of drugs.

c) Homogenous catalysis, hydrogenation, hydroformylation, hydrocyanation, Wilkinson catalysts, chiral ligands and chiral induction, Ziegler-Natta catalysts, some examples of homogenous catalysis used in synthesis of drugs

d) Transition-metal and Organo-catalysis in organic synthesis: Metal-catalyzed reactions

e) Biocatalysis: Use of enzymes in organic synthesis, immobilized enzymes/cells in organic reaction.

f) Phase transfer catalysis - theory and applications

5. Stereochemistry & Asymmetric Synthesis 12

a) Basic concepts in stereochemistry – optical activity, specific rotation, racemates and resolution of racemates, the Cahn, Ingold, Prelog (CIP) sequence rule, meso compounds, pseudo asymmetric centres, axes of symmetry, Fischers D and L notation, cis-trans isomerism, E and Z notation. Hrs

b) Methods of asymmetric synthesis using chiral pool, chiral auxiliaries and catalytic asymmetric synthesis, enantiopure separation and Stereo selective synthesis with examples.

REFERENCES

1. "Advanced Organic chemistry, Reaction, mechanisms and structure", J March, John Wiley and sons, New York.
2. "Mechanism and structure in organic chemistry", ES Gould, Hold Rinchart and Winston,NewYork.
3. "Organic Chemistry" Clayden, Greeves, Warren and Woihers., Oxford University Press 2001.
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7. Principles of organic synthesis, ROCNorman and JMCoxan, Nelson thorns
8. Organic synthesis- Special techniques VK Ahluwalia and R Aggarwal, Narosa Publishers.
9. Organic reaction mechanisms IV edtn, VK Ahluwalia and RK Parashar, Narosa Publishers.

COMPUTER AIDED DRUG DESIGN

(MPC 203T)

Scope

The subject is designed to impart knowledge on the current state of the art techniques involved in computer assisted drug design.

Objectives

At completion of this course it is expected that students will be able to understand

- Role of CADD in drug discovery
- Different CADD techniques and their applications
- Various strategies to design and develop new drug like molecules.
- Working with molecular modeling softwares to design new drug molecules
- The in silico virtual screening protocols

Theory **60 Hrs**

1. Introduction to Computer Aided Drug Design (CADD) — 12 Hrs

   History, different techniques and applications.

   Quantitative Structure Activity Relationships: Basics History and development of QSAR: Physicochemical parameters and methods to calculate physicochemical parameters: Hammett equation and electronic parameters (sigma), lipophilicity effects and parameters (log P, pi-substituent constant), steric effects (Taft steric and MR parameters) Experimental and theoretical approaches for the determination of these physicochemical parameters.

2. Quantitative Structure Activity Relationships: Applications Hansch analysis, Free Wilson analysis and relationship between them, Advantages and disadvantages; Deriving 2D-QSAR equations. — 12 Hrs

   3D-QSAR approaches and contour map analysis.

   Statistical methods used in QSAR analysis and importance of statistical parameters.

3. Molecular Modeling and Docking — 12 Hrs

   a) Molecular and Quantum Mechanics in drug design.

   b) Energy Minimization Methods: comparison between global minimum

conformation and bioactive conformation

c) Molecular docking and drug receptor interactions: Rigid docking, flexible docking and extra-precision docking. Agents acting on enzymes such as DHFR, HMG-CoA reductase and HIV protease, choline esterase (AchE & BchE)

4. Molecular Properties and Drug Design — 12 Hrs

a) Prediction and analysis of ADMET properties of new molecules and its importance in drug design.

b) De novo drug design: Receptor/enzyme-interaction and its analysis, Receptor/enzyme cavity size prediction, predicting the functional components of cavities, Fragment based drug design.

c) Homology modeling and generation of 3D-structure of protein.

5. Pharmacophore Mapping and Virtual Screening — 12 Hrs

Concept of pharmacophore, pharmacophore mapping, identification of Pharmacophore features and Pharmacophore modeling; Conformational search used in pharmacophore mapping.

In Silico Drug Design and Virtual Screening TechniquesSimilarity based methods and Pharmacophore based screening, structure based In-silico virtual screening protocols.

REFERENCES

1. Computational and structural approaches to drug discovery, Robert M Stroud and Janet. F Moore, RCS Publishers.
2. Introduction to Quantitative Drug Design by Y.C. Martin, CRC Press, Taylor & Francis group..
3. Drug Design by Ariens Volume 1 to 10, Academic Press, 1975, Elsevier Publishers.
4. Principles of Drug Design by Smith and Williams, CRC Press, Taylor & Francis.
5. The Organic Chemistry of the Drug Design and Drug action by Richard B. Silverman, Elsevier Publishers.
6. Medicinal Chemistry by Burger, Wiley Publishing Co.
7. An Introduction to Medicinal Chemistry –Graham L. Patrick, Oxford University Press.
8. Wilson and Gisvold's Text book of Organic Medicinal and Pharmaceutical Chemistry, Ippincott Williams & Wilkins.

9. Comprehensive Medicinal Chemistry – Corwin and Hansch, Pergamon Publishers.
10. Computational and structural approaches to drug design edited by Robert M Stroud and Janet. F Moore

PHARMACEUTICAL PROCESS CHEMISTRY

(MPC 204T)

Scope

Process chemistry is often described as scale up reactions, taking them from small quantities created in the research lab to the larger quantities that are needed for further testing and then to even larger quantities required for commercial production. The goal of a process chemist is to develop synthetic routes that are safe, cost-effective, environmentally friendly, and efficient. The subject is designed to impart knowledge on the development and optimization of a synthetic route/s and the pilot plant procedure for the manufacture of Active Pharmaceutical Ingredients (APIs) and new chemical entities (NCEs) for the drug development phase.

Objectives

At completion of this course it is expected that students will be able to understand

- The strategies of scale up process of apis and intermediates
- The various unit operations and various reactions in process chemistry

THEORY **60 Hrs**

1. Process chemistry — 12 Hrs

   Introduction, Synthetic strategy

   Stages of scale up process: Bench, pilot and large scale process. In-process control and validation of large scale process.Case studies of some scale up process of APIs.

   Impurities in API, types and their sources including genotoxic impurities

2. Unit operations — 12 Hrs

   a) Extraction: Liquid equilibria, extraction with reflux, extraction with agitation, counter current extraction.

   b) Filtration: Theory of filtration, pressure and vacuum filtration, centrifugal filtration,

   c) Distillation: azeotropic and steam distillation

   d) Evaporation: Types of evaporators, factors affecting evaporation.

   e) Crystallization: Crystallization from aqueous, non- aqueous solutions factors affecting crystallization, nucleation. Principle and general

methods of Preparation of polymorphs, hydrates, solvates and amorphous APIs.

3. Unit Processes - I — 12 Hrs

a) Nitration: Nitrating agents, Aromatic nitration, kinetics and mechanism of aromatic nitration, process equipment for technical nitration, mixed acid for nitration,

b) Halogenation: Kinetics of halogenations, types of halogenations, catalytic halogenations. Case study on industrial halogenation process.

c) Oxidation: Introduction, types of oxidative reactions, Liquid phase oxidation with oxidizing agents. Nonmetallic Oxidizing agents such as H2O2, sodium hypochlorite, Oxygen gas, ozonolysis.

4. Unit Processes - II — 12 Hrs

a) Reduction: Catalytic hydrogenation, Heterogeneous and homogeneous catalyst; Hydrogen transfer reactions, Metal hydrides. Case study on industrial reduction process.

b) Fermentation: Aerobic and anaerobic fermentation. Production of

   i. Antibiotics; Penicillin and Streptomycin,

   ii. Vitamins: B2 and B12

   iii. Statins: Lovastatin, Simvastatin

c) Reaction progress kinetic analysis

   i. Streamlining reaction steps, route selection,

   ii. Characteristics of expedient routes, characteristics of cost-effective routes, reagent selection, families of reagents useful for scale-up.

5. Industrial Safety — 12 Hrs

a) MSDS (Material Safety Data Sheet), hazard labels of chemicals and Personal Protection Equipment (PPE)

b) Fire hazards, types of fire & fire extinguishers

c) Occupational Health & Safety Assessment Series 1800 (OHSAS-1800) and ISO-14001(Environmental Management System), Effluents and its

management

REFERENCES

1. Process Chemistry in the Pharmaceutical Industry: Challenges in an Ever- Changing Climate-An Overview; K. Gadamasetti, CRC Press.
2. Pharmaceutical Manufacturing Encyclopedia, 3rd edition, Volume 2.
3. Medicinal Chemistry by Burger, 6th edition, Volume 1-8.
4. W.L. McCabe, J.C Smith, Peter Harriott. Unit operations of chemical engineering, 7th edition, McGraw Hill
5. Polymorphism in Pharmaceutical Solids .Dekker Series Volume 95 Ed: H G Brittain (1999)
6. Regina M. Murphy: Introduction to Chemical Processes: Principles, Analysis, Synthesis
7. Peter J. Harrington: Pharmaceutical Process Chemistry for Synthesis: Rethinking the Routes to Scale-Up
8. P.H.Groggins: Unit processes in organic synthesis (MGH)
9. F.A.Henglein: Chemical Technology (Pergamon)
10. M.Gopal: Dryden's Outlines of Chemical Technology, WEP East-West Press
11. Clausen,Mattson: Principle of Industrial Chemistry, Wiley Publishing Co.,
12. Lowenheim & M.K. Moran: Industrial Chemicals
13. S.D. Shukla & G.N. Pandey: A text book of Chemical Technology Vol. II, Vikas Publishing House
14. J.K. Stille: Industrial Organic Chemistry (PH)
15. Shreve: Chemical Process Mc Grawhill, .
16. B.K.Sharma: Industrial Chemistry, Goel Publishing House
17. ICH Guidelines
18. United States Food and Drug Administration official website www.fda.gov

PHARMACEUTICAL CHEMISTRY PRACTICALS – II

(MPC 205P)

1. Synthesis of organic compounds by adapting different approaches involving (3 experiments)
    a) Oxidation
    b) Reduction/hydrogenation
    c) Nitration
2. Comparative study of synthesis of APIs/intermediates by different synthetic routes (2 experiments)
3. Assignments on regulatory requirements in API (2 experiments)
4. Comparison of absorption spectra by UV and Wood ward – Fieser rule
5. Interpretation of organic compounds by FT-IR
6. Interpretation of organic compounds by NMR
7. Interpretation of organic compounds by MS
8. Determination of purity by DSC in pharmaceuticals
9. Identification of organic compounds using FT-IR, NMR, CNMR and Mass spectra
10. To carry out the preparation of following organic compounds
11. Preparation of 4-chlorobenzhydrylpiperazine. (an intermediate for cetirizine HCl).
12. Preparation of 4-iodotolene from p-toluidine.
13. NaBH4 reduction of vanillin to vanillyl alcohol
14. Preparation of umbelliferone by Pechhman reaction
15. Preparation of triphenyl imidazole
16. To perform the Microwave irradiated reactions of synthetic importance (Any two)
17. Determination of log P, MR, hydrogen bond donors and acceptors of selected drugs using softwares
18. Calculation of ADMET properties of drug molecules and its analysis using softwares Pharmacophore modeling
19. 2D-QSAR based experiments
20. 3D-QSAR based experiments
21. Docking study based experiment
22. Virtual screening based experiment

Semester III

MRM 301T - Research Methodology & Biostatistics

UNIT – I

General Research Methodology: Research, objective, requirements, practical difficulties, review of literature, study design, types of studies, strategies to eliminate errors/bias, controls, randomization, crossover design, placebo, blinding techniques.

UNIT – II

Biostatistics: Definition, application, sample size, importance of sample size, factors influencing sample size, dropouts, statistical tests of significance, type of significance tests, parametric tests(students "t" test, ANOVA, Correlation coefficient, regression), non-parametric tests (wilcoxan rank tests, analysis of variance, correlation, chi square test), null hypothesis, P values, degree of freedom, interpretation of P values.

UNIT – III

Medical Research: History, values in medical ethics, autonomy, beneficence, non-maleficence, double effect, conflicts between autonomy and beneficence/non-maleficence, euthanasia, informed consent, confidentiality, criticisms of orthodox medical ethics, importance of communication, control resolution, guidelines, ethics committees, cultural concerns, truth telling, online business practices, conflicts of interest, referral, vendor relationships, treatment of family members, sexual relationships, fatality.

UNIT – IV

CPCSEA guidelines for laboratory animal facility: Goals, veterinary care, quarantine, surveillance, diagnosis, treatment and control of disease, personal hygiene, location of animal facilities to laboratories, anesthesia, euthanasia, physical facilities, environment, animal husbandry, record keeping, SOPs, personnel and training, transport of lab animals.

UNIT – V

Declaration of Helsinki: History, introduction, basic principles for all medical research, and additional principles for medical research combined with medical care.

2.7 Total number of hour

As mentioned in Course outline (clause 2.4)

2.8 Branches if any, with definition

As mentioned in Syllabus (clause 2.6)

2.9 Teaching Learning methods

A regular record of attendance both in Theory, Practical, Seminar, Assignment, Journal club, Discussion with the supervisor, Research work presentation and Dissertation shall be maintained by the department / teaching staff of respective courses.

2.10 Content of each subject in each year

As mentioned in Syllabus (clause 2.6)

2.11 No: of hours per subject

As mentioned in Syllabus (clause 2.6)

2.12 Practical Training

As mentioned in Course outline (clause 2.4)

2.13 Records

To be maintained for all Practical Work

2.14 Dissertation

As mentioned in Project work to be done (clause 2.16)

2.15 Speciality Training if ANY

As mentioned in Syllabus (clause 2.6)

2.16 Project work to be done if any

All the students shall undertake a project under the supervision of a teacher in Semester III to IV and submit a report. 4 copies of the project report shall be submitted (typed & bound copy not less than 75 pages).

The internal and external examiner appointed by the University shall evaluate the project at the time of the Practical examinations of other semester(s). The projects shall be evaluated as per the criteria given below.

Evaluation of Dissertation Book:

Objective(s) of the work done	50 Marks
Methodology adopted	150 Marks
Results and Discussions	250 Marks
Conclusions and Outcomes	50 Marks
Total	500 Marks

Evaluation of Presentation:

Presentation of work	100 Marks
Communication skills	50 Marks
Question and answer skills	100 Marks
Total	250 Marks

2.17 Any other Requirements [CME, Paper Publishing, etc,.]

As mentioned in Course outline (clause 2.4)

2.18 Prescribed/Recommended textbooks for each subject

As mentioned in Syllabus (clause 2.6)

2.19 Reference books

As mentioned in Syllabus (clause 2.6)

2.20 Journals

All Pharmacy and related Medical Journals

2.21 Logbook

Registers to be maintained

3. EXAMINATION

3.1 Eligibility to appear for examinations

A candidate is required to put in at least 80% attendance in individual courses considering theory and practical separately. The candidate shall complete the prescribed course satisfactorily to be eligible to appear for the respective examinations.

3.2 Schedule of Regular / Supplementary exams

Semester examinations will be conducted once in every six months after fulfilling 100 working days.

Table: 6 - Question paper pattern for end semester theory & practical examinations

Question paper pattern for end semester theory examinations			
I.	Long Answers	3 X 10	30 Marks
II.	Short Answers	9 X 5	45 Marks
		Total	**75 Marks**
Question paper pattern for end semester practical examinations			
I.	Synopsis		15 Marks
II.	Experiment - I		40 Marks
III.	Experiment – II		30 Marks
IV.	Viva voce		15 Marks
		Total	**100 Marks**

3.3 Scheme of examination showing maximum marks and minimum marks

The End Semester Examinations for each theory and practical Course through semesters I to IV shall be conducted by the respective university except for the subject with asterisk symbol (*) in table – 8 for which examinations shall be conducted by the subject experts at college level and the marks/grades shall be submitted to the university.

Schemes for internal assessments and end semester examinations are given in table below

Table – 7: Schemes for internal assessments and end semester examination

Course code	Course	Internal Assessment				End Semester Exams		Total Marks
		Continuous Mode	Sessional Exams		Total	Marks	Duration	
			Marks	Duration				
SEMESTER I								
MPC 101T	Modern Pharmaceutical Analytical Techniques	10	15	1 Hr	25	75	3 Hrs	100
MPC 102T	Advanced Organic Chemistry –I	10	15	1 Hr	25	75	3 Hrs	100
MPC 103T	Advanced Medicinal Chemistry	10	15	1 Hr	25	75	3 Hrs	100
MPC 104T	Chemistry of Natural Products	10	15	1 Hr	25	75	3 Hrs	100
MPC 105P	Pharmaceutical Chemistry Practical – I	20	30	6 Hrs	50	100	6 Hrs	150
-	Seminar /Assignment	-	-	-	-	-	-	100
Total								650
SEMESTER II								
MPC 201T	Advanced Spectral Analysis	10	15	1 Hr	25	75	3 Hrs	100
MPC 202T	Advanced Organic Chemistry –II	10	15	1 Hr	25	75	3 Hrs	100
MPC 203T	Computer Aided Drug Design	10	15	1 Hr	25	75	3 Hrs	100
MPC 204T	Pharmaceutical Process Chemistry	10	15	1 Hr	25	75	3 Hrs	100
MPC 205P	Pharmaceutical Chemistry Practical II	20	30	6 Hrs	50	100	6 Hrs	150
-	Seminar /Assignment	-	-	-	-	-	-	100
Total								650

Table – 8: Schemes for internal assessments and end semester examinations

(Semester III& IV)

Course code	Course	Internal Assessment				End Semester Exams		Total Marks
		Continuous Mode	Sessional Exams		Total	Marks	Duration	
			Marks	Duration				
SEMESTER III								
MRM 301T	Research Methodology and Biostatistics*	10	15	1 Hr	25	75	3 Hrs	100
-	Journal Club	-	-	-	25	-	-	25
-	Discussion / Presentation (proposal presentation)	-	-	-	50	-	-	50
-	Research Work*	-	-	-	-	350	1 Hr	350
Total								525
SEMESTER IV								
-	Journal club	-	-	-	25	-	-	25
-	Discussion / Presentation (proposal presentation)	-	-	-	75	-	-	75
-	Research Work and Colloquium	-	-	-	-	400	1 Hr	400
Total								500

*Non University Examination

Table – 9: Scheme for awarding internal assessment

Theory	
Criteria	**Maximum Marks**
Attendance (Refer Table – 10)	8
Student – Teacher interaction	2
Total	10
Practical	
Attendance (Refer Table – 10)	10
Based on Practical Records, Regular viva voce, etc.	10
Total	20

Table – 10: Guidelines for the allotment of marks for attendance

Percentage of Attendance	Theory	Practical
95 – 100	8	10
90 – 94	6	7.5
85 – 89	4	5
80 – 84	2	2.5
Less than 80	0	0

Allowed to keep terms (ATKT):

No student shall be admitted to any examination unless he/she fulfills the norms given in clause 3.1. ATKT rules are applicable as follows:

A student shall be eligible to carry forward all the courses of I and II semesters till the III semester examinations. However, he/she shall not be eligible to attend the courses of IV semester until all the courses of I, II and III semesters are successfully completed.

A student shall be eligible to get his/her CGPA upon successful completion of the courses of I to IV semesters within the stipulated time period as per the norms.

Note: Grade AB should be considered as failed and treated as one head for deciding ATKT. Such rules are also applicable for those students who fail to register for examination(s) of any course in any semester.

Grading of performances

a) Letter grades and grade points allocations:

Based on the performances, each student shall be awarded a final letter grade at the end of the semester for each course. The letter grades and their corresponding grade points are given in Table – 11.

Table – 11: Letter grades and grade points equivalent to Percentage of marks and performances

Percentage of Marks obtained	Letter Grade	Grade point	Performance
90.00 – 100	O	10	Outstanding
80.00 – 89.99	A	9	Excellent
70.00 – 79.99	B	8	Good
60.00 – 69.99	C	7	Fair
50.00 – 59.99	D	6	Average
Less than 50	F	0	Fail
Absent	AB	0	Fail

A learner who remains absent for any end semester examination shall be assigned a letter grade of AB and a corresponding grade point of zero. He/she should reappear for the said evaluation/examination in due course.

b) The Semester grade point average (SGPA)

The performance of a student in a semester is indicated by a number called 'Semester Grade Point Average' (SGPA). The SGPA is the weighted average of the grade points obtained in all the courses by the student during the semester. For example, if a student takes five courses (Theory/Practical) in a semester with credits C1, C2, C3 and C4 and the student's grade points in these courses are G1, G2, G3 and G4, respectively, and then students' SGPA is equal to:

$$SGPA = \frac{C_1G_1 + C_2G_2 + C_3G_3 + C_4G_4}{C_1 + C_2 + C_3 + C_4}$$

The SGPA is calculated to two decimal points. It should be noted that, the SGPA for any semester shall take into consideration the F and ABS grade awarded in that semester. For example if a learner has a F or ABS grade in course 4, the SGPA shall then be computed as:

$$SGPA = \frac{C_1G_1 + C_2G_2 + C_3G_3 + C_4*ZER0}{C_1 + C_2 + C_3 + C_4}$$

c) Cumulative Grade Point Average (CGPA)

The CGPA is calculated with the SGPA of all the IV semesters to two decimal points and is indicated in final grade report card/final transcript showing the grades of all IV semesters and their courses. The CGPA shall reflect the failed status in case of F grade(s), till the course(s) is/are passed. When the course(s) is/are passed by obtaining a pass grade on subsequent examination(s) the CGPA shall only reflect the new grade and not the fail grades earned earlier.The CGPA is calculated as:

$$CGPA = \frac{C_1S_1 + C_2S_2 + C_3S_3 + C_4S_4}{C_1 + C_2 + C_3 + C_4}$$

where C_1, C_2, C_3,…. is the total number of credits for semester I,II,III,…. And S_1, S_2, S_3… is the SGPA of semester I, II, III…. .

3.4 Papers in each year

As mentioned in Course outline (clause 2.4)

3.5 Details of theory exams

As mentioned in Schedule of regular / Supplementary Exams (clause 3.2)

3.6 Model question paper for each subject with question paper pattern

As mentioned in Schedule of regular / Supplementary Exams (clause 3.2)See Annexure

3.7 Internal assessment component

As mentioned in Scheme of examination. (Clause 3.3)

- Two sessional exams shall be conducted for each theory / practical course as per the schedule fixed by the college(s). The average marks of two sessional exams shall be computed for internal assessment as per the requirements
- A student shall have the opportunity to improve his/her performance only once in the sessional exam component of the internal assessment. The re-conduct of the sessional exam shall be completed before the commencement of next end semester theory examinations.

3.8 Details of practical / clinical practicum exams.

As mentioned in Schedule of regular / Supplementary Exams (clause 3.2) Scheme of examination. (Clause 3.3)

3.9 Number of examiners (Internal & External) and their qualifications

- A post graduate (PG) degree in M. Pharm shall be eligible as teacher.
- A post graduate degree in M. Pharm with 5 years Post PG experience is eligible as internal examiner.
- A post graduate degree in M. Pharm with 10 years Post PG is eligible as external examiner.
- A post graduate degree in M. Pharm with 5 years Post PG is eligible to guide maximum of 5 candidates for M. Pharm dissertation.

For the conduct of practical examination of I semester one external examiner and 2 internal examiners (one faculty dealing with the respective speciality and one faculty dealing Modern Analytical and Research methods) shall be appointed by the University. For the evaluation of Practical Examination of II semester one internal and one external examiner shall be appointed by the university.

3.10 Details of viva:

As mentioned in Schedule of regular / Supplementary Exams (clause 3.2) Scheme of examination. (Clause 3.3)

4. INTERNSHIP

Not applicable

5. ANNEXURES

5.1 Check Lists for Monitoring:

Log Book, Seminar Assessment etc. to be formulated by the curriculum committee of the concerned Institution.

QP Code: Reg No:----------

Model Question Paper (M.Pharm Pharmaceutical Chemistry)

I Semester M.Pharm Degree Examination

PAPER – I – MODERN PHARMACEUTICAL ANALYTICAL TECHNIQUES (MPA 101T)

- **Answer all Questions**

Time: 3 hours Maximum: 75 Marks

Essays (3x10=30)

1. Explain the theory of fluorescence. What are the factors affecting fluorescence ?
2. Classify chromatographic methods based on mechanism of separation and add a note on column chromatography
3. What is the principle of NMR spectroscopy? What are its applications.

Short notes (9x5=45)

4. Compare flame emission and atomic absorption spectroscopy.
5. Discuss about gel electrophoresis
6. What is Bragg's law? Describe rotating crystal technique in x-ray crystallography.
7. Write a note on ion selective electrodes
8. Discuss about the principle and instrumentation of differential thermal analysis
9. Briefly explain the principle and working of potentiometer
10. Write about MALDI. Explain principle and applications of MALDI
11. Sample handing techniques in IR spectroscopy
12. Write briefly on derivative UV spectroscopy

QP Code: Reg No:----------

Model Question Paper (M.Pharm Pharmaceutical Chemistry)

I Semester M.Pharm Degree Examination

PAPER – II – ADVANCED ORGANIC CHEMISTRY I (MPC 101T)

- **Answer all Questions**

Time: 3 hours Maximum: 75 Marks

Essay Questions (3x10=30)

1. Explain the detailed mechanism of the following reactions
   (a) Sandmeyer reaction
   (b) Michaele addition reactions
2. Discuss about SN1 and SN2 reactions
3. Describe with suitable examples the synthesis of carbanions and carbocations.

Write notes on (9x5=45)

4. Outline the synthesis and medicinal uses of Alprazolam and Metronidazole.
5. Discuss about the role of protection in organic synthesis
6. What are the applications of Wilkinson reagent?
7. Write about Combes Quinoline synthesis
8. What is the mechanism of brook rearrangement?
9. Outline the synthesis and medicinal uses of Chlorpromazine and Antipyrin
10. What are the protecting groups for carbonyl group? Explain briefly
11. Discuss about Traube purine synthesis
12. What are the application of BOP?

QP Code: Reg No:----------

Model Question Paper (M.Pharm Pharmaceutical Chemistry)

I Semester M.Pharm Degree Examination

PAPER – III – ADVANCED MEDICINAL CHEMISTRY (MPC 102T)

- **Answer all Questions**

Time: 3 hours Maximum: 75 Marks

Essays (3x10=30)

1. Explain the design and medicinal aspects of peptidomimetics
2. What are the theories of drug receptor interactions?
3. What are the causes for drug resistance and what are the strategies to combat drug resistance in antimicrobial therapy?

Short notes (9x5=45)

4. Briefly explain the types of bio isoters and bioisosteric replacement approach
5. Write a note on cholinergic agents
6. Discuss about enzyme inhibitors in medicine
7. Write a detailed note on the role of stereo selectivity in therapeutic agents
8. What are the practical considerations in prodrug design?
9. Discuss about site specific drug delivery
10. Write a note on H1 and H2 receptor antagonists
11. Explain role of stereochemistry drug action
12. Discuss about artificial enzymes.

QP Code: Reg No:----------

Model Question Paper (M.Pharm Pharmaceutical Chemistry)

I Semester M.Pharm Degree Examination

PAPER – IV – CHEMISTRY OF NATURAL PRODUCTS (MPC 103T)

Answer all Questions

- **Answer all Questions**

Time: 3 hours Maximum: 75 Marks

Essays (3x10=30)

1. Write briefly the classification, isolation and isoprene rule of Terpenoids
2. Discuss the chemistry of male contraceptive agents
3. Classify alkaloids with examples. What are the general methods of structural determination of alkaloids?

Short notes (9x5=45)

4. Chemistry and significance of folic acid
5. Chemical constituents of Cururma longa
6. Give the chemistry and physiological significance of adenocorticoids
7. What are the clinical applications of gene therapy?
8. Explain how the structure of morphine can be elucidated using spectroscopic methods?
9. Explain how Curare alkaloids were developed as neuromuscular blocking drugs
10. Explain the concept of & DNA technology tool for new drug discovery
11. What are methods of isolation of chemical constituents from natural source?
12. How is the structure of quercetin elucidated?

REGULATIONS2017

Syllabus

Kerala University of Health Sciences

Thrissur - 680596

POST GRADUATE COURSE IN PHARMACY

Master of Pharmacy

(M.Pharm. -“ Pharmacognosy")

Course code: 278

(2017-18 Academic year onwards)

2017

2. COURSE CONTENT

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2.7	**Total number of hour**	28
2.8	**Branches if any with definition**	
2.9	**Teaching learning methods**	
2.10	**Content of each subject in each year**	
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2. COURSE CONTENT

2.1 Title of course

These regulations shall be called as "Master of Pharmacy (M.Pharm. – Pharmacognosy) Degree Program - Credit Based Semester System (CBSS) of the Kerala University of Health sciences. They shall come into effect from the Academic Year 2017-18 onwards. The regulations framed are subject to modifications from time to time by the authorities of the University.

2.2 Objectives of course

To generate Pharmacy Post Graduates with profound knowledge in various branches of Pharmaceutical Sciences to meet with the rapidly increasing demands put forward by-

- Pharmaceutical Manufacturing
- Pharmaceutical Research & Development
- Pharmacological research including preclinical & clinical studies.
- Herbal Drug Research
- Pharmaceutical & Herbal Drug Analysis
- Clinical Toxicology & Toxicological Analysis

To discover the potential to become faculty in Pharmaceutical Sciences with unmatched quality and excellence, so as to educate the future pharmacy generation (Undergraduate, Post graduate, and Doctoral).

2.3 Medium of Instruction

Medium of instruction and examination shall be in English.

2.4 Course Outline

The specialization in M.Pharm. Program is given in Table 1.

Table – 1: M.Pharm. Specialization and its code

S.No	Specialization	Code
1.	Pharmacognosy	MPG

The course of study for M.Pharm Pharmacognosy shall include Semester wise Theory & Practical as given in Table – 2 & 3. The number of hours to be devoted to each theory and practical course in any semester shall not be less than that shown in Table – 2 & 3.

Table – 2: Course of study for M.Pharm. I & II Semester

Course Code	Course	Credit Hours	Credit Points	Hrs./wk	Marks
Semester I					
MPG 101T	Modern Pharmaceutical Analytical Techniques	4	4	4	100
MPG 102T	Advanced Pharmacognosy	4	4	4	100
MPG 103T	Phytochemistry	4	4	4	100
MPG 104T	Industrial Pharmacognostical Technology	4	4	4	100
MPG105P	Pharmacognosy Practical – I	12	6	12	150
-	Seminar /Assignment	7	4	7	100
Total		35	26	35	650
Semester II					
MPG 201T	Medicinal Plant Biotechnology	4	4	4	100
MPG 202T	Advanced Pharmacognosy -II	4	4	4	100
MPG 203T	Indian System of Medicine	4	4	4	100
MPG 204T	Herbal Cosmetics	4	4	4	100
MPG 205P	Pharmacognosy Practical II	12	6	12	150
-	Seminar /Assignment	7	4	7	100
Total		35	26	35	650

Table – 3: Course of study for M. Pharm. III & IV Semester

Course Code	Course	Credit Hours	Credit Points
Semester III			
MRM 301T	Research Methodology and Biostatistics*	4	4
-	Journal Club	1	1
-	Discussion / Presentation (proposal presentation)	2	2
-	Research Work*	28	14
Total		35	21
Semester IV			
-	Journal Club	1	1
-	Research Work	31	16
-	Discussion / Final Presentation	3	3
Total		35	20

*Non University Exam

Program/Course credit structure

As per the philosophy of Credit Based Semester System, certain quantum of academic work viz. theory classes, practical classes, seminars, assignments, etc. are measured in terms of credits. On satisfactory completion of the courses, a candidate earns credits. The amount of credit associated with a course is dependent upon the number of hours of instruction per week in that course. Similarly the credit associated with any of the other academic, co/extracurricular activities is dependent upon the quantum of work expected to be put in for each of these activities per week/per activity.

Credit assignment

a) Theory and Laboratory courses

Courses are broadly classified as Theory and Practical. Theory courses consist of lecture (L) and Practical (P) courses consist of hours spent in the laboratory. Credits (C) for a course is dependent on the number of hours of instruction per week in that course, and is obtained by using a multiplier of one (1) for lecture and a multiplier of half (1/2) for practical (laboratory) hours. Thus, for example, a theory course having four lectures per week throughout the semester carries a credit of 4. Similarly, a practical having four laboratory hours per week throughout semester carries a credit of 2. The contact hours of seminars, assignments and research work shall be treated as that of practical courses for the purpose of calculating credits. i.e., the contact hours shall be multiplied by 1/2. Similarly, the contact hours of journal club, research work presentations and discussions with the supervisor shall be considered as theory course and multiplied by 1.

b) Minimum credit requirements

The minimum credit points required for the award of M. Pharm. degree is 95. However based on the credit points earned by the students under the head of co-curricular activities, a student shall earn a maximum of 100 credit points. These credits are divided into Theory courses, Practical, Seminars, Assignments, Research work, Discussions with the supervisor, Journal club and Co-Curricular activities over the duration of four semesters. The credits are distributed semester-wise as shown in Table 4. Courses generally progress in sequence, building competencies and their positioning indicates certain academic maturity on the part of the learners. Learners are expected to follow the semester-wise schedule of courses given in the syllabus.

Table – 4: Semester wise credits distribution

Semester	Credit Points
I	26
II	26
III	21
IV	20
Co-curricular Activities (attending Conference, Scientific Presentations and other scholarly Activities)	Minimum = 02 Maximum = 07*
Total Credit Points	Minimum = 95 Maximum = 100

*Credit points for Co-curricular Activities

Table – 5: Guidelines for Awarding Credit Points for Co-curricular Activities

Name of the Activity	MaximumCredit Points Eligible / Activity
Participation in National Level Seminar/ Conference/ Workshop / Symposium / Training Programs (related to the specialization of the student)	01
Participation in international Level Seminar/ Conference/ Workshop/ Symposium/ Training Programs (related to the specialization of the student)	02
Academic Award/Research Award from State Level/ National Agencies	01
Academic Award/Research Award from International Agencies	02
Research / Review Publication in National Journals (Indexed in Scopus / Web of Science)	01
Research / Review Publication in International Journals (Indexed in Scopus / Web of Science)	02

Note: International Conference: Held outside India

International Journal: The Editorial Board outside India

*The credit points assigned for extracurricular and or co-curricular activities shall be given by the Principals of the colleges and the same shall be submitted to the University. The criteria to acquire this credit point shall be defined by the colleges from time to time.

Program Committee

1. The M. Pharm. programme shall have a Programme Committee constituted by the Head of the institution in consultation with all the Heads of the departments.
2. The composition of the Programme Committee shall be as follows:
   A teacher at the cadre of Professor shall be the Chairperson; One Teacher from each M.Pharm specialization and four student representatives (two from each academic year), nominated by the Head of the institution.
3. Duties of the Programme Committee:
   i. Periodically reviewing the progress of the classes.
   ii. Discussing the problems concerning curriculum, syllabus and the conduct of classes.
   iii. Discussing with the course teachers on the nature and scope of assessment for the course and the same shall be announced to the students at the beginning of respective semesters.
   iv. Communicating its recommendation to the Head of the institution on academic matters.
   v. The Programme Committee shall meet at least twice in a semester preferably at the end of each sessional exam and before the end semester exam.

2.5 Duration

The program of study for M.Pharm. shall extend over a period of four semesters (two academic years). The curricula and syllabi for the program shall be prescribed from time to time by the Kerala University of Health sciences.

The duration for the completion of the program shall be fixed as double the actual duration of the program and the students have to pass within the said period, otherwise they have to get fresh Registration.

2.6 Syllabus

PHARMACOGNOSY (MPG)

MODERN PHARMACEUTICAL ANALYTICAL TECHNIQUES

(MPG 101T)

Scope

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

Objectives

After completion of course student is able to know,

- The analysis of various drugs in single and combination dosage forms
- Theoretical and practical skills of the instruments

THEORY **60 Hrs**

1. UV-Visible spectroscopy: Introduction, Theory, Laws, Instrumentation associated with UV-Visible spectroscopy, Choice of solvents and solvent effect and Applications of UV-Visible spectroscopy. (10 Hrs)

   IR spectroscopy: Theory, Modes of Molecular vibrations, Sample handling, Instrumentation of Dispersive and Fourier - TransformIR Spectrometer, Factors affecting vibrational frequencies and Applications of IR spectroscopy

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

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

2. NMR spectroscopy: Quantum numbers and their role in NMR, Principle, Instrumentation, Solvent requirement in NMR, Relaxation process, NMR signals in various compounds, Chemical shift, Factors influencing chemical shift, Spin-Spin coupling, Coupling constant, Nuclear magnetic double resonance, Brief outline of principles of FT-NMR and 13C NMR. Applications of NMR (10 Hrs)

spectroscopy.

3. Mass Spectroscopy: Principle, Theory, Instrumentation of Mass Spectroscopy, Different types of ionization like electron impact, chemical, field, FAB and MALDI, APCI, ESI, APPI Analyzers of Quadrupole and Time of Flight, Mass fragmentation and its rules, Meta stable ions, Isotopic peaks and Applications of Mass spectroscopy. 10 Hrs

4. Chromatography: Principle, apparatus, instrumentation, chromatographic parameters, factors affecting resolution, isolation of drug from excipients, data interpretation and applications of the following: 10 Hrs

    a) Thin Layer chromatography
    b) High Performance Thin Layer Chromatography
    c) Ion exchange chromatography
    d) Column chromatography
    e) Gas chromatography
    f) High Performance Liquid chromatography
    g) Ultra High Performance Liquid chromatography
    h) Affinity chromatography
    i) Gel Chromatography

5. Electrophoresis: Principle, Instrumentation, Working conditions, factors affecting separation and applications of the following: 10 Hrs

    a) Paper electrophoresis
    b) Gel electrophoresis
    c) Capillary electrophoresis
    d) Zone electrophoresis
    e) Moving boundary electrophoresis
    f) Iso electric focusing

X ray Crystallography: Production of X rays, Different X ray methods, Bragg's law, Rotating crystal technique, X ray powder technique, Types of crystals and

applications of X-ray diffraction.

6. a. Potentiometry: Principle, working, Ion selective Electrodes and Application of potentiometry. 10 Hrs

b. Thermal Techniques: Principle, thermal transitions and Instrumentation (Heat flux and power-compensation and designs), Modulated DSC, Hyper DSC, experimental parameters (sample preparation, experimental conditions, calibration, heating and cooling rates, resolution, source of errors) and their influence, advantage and disadvantages, pharmaceutical applications.

Differential Thermal Analysis (DTA): Principle, instrumentation and advantage and disadvantages, pharmaceutical applications, derivative differential thermal analysis (DDTA). TGA: Principle, instrumentation, factors affecting results, advantage and disadvantages, pharmaceutical applications.

REFERENCES

1. Spectrometric Identification of Organic compounds - Robert M Silverstein, Sixth edition, John Wiley & Sons, 2004.
2. Principles of Instrumental Analysis - Doglas A Skoog, F. James Holler, Timothy A. Nieman, 5th edition, Eastern press, Bangalore, 1998.
3. Instrumental methods of analysis – Willards, 7th edition, CBS publishers.
4. Practical Pharmaceutical Chemistry – Beckett and Stenlake, Vol II, 4th edition, CBS Publishers, New Delhi, 1997.
5. Organic Spectroscopy - William Kemp, 3rd edition, ELBS, 1991.
6. Quantitative Analysis of Drugs in Pharmaceutical formulation - P D Sethi, 3rd Edition, CBS Publishers, New Delhi, 1997.
7. Pharmaceutical Analysis - Modern Methods – Part B - J W Munson, Vol 11, Marcel. Dekker Series
8. Spectroscopy of Organic Compounds, 2nd edn., P.S/Kalsi, Wiley estern Ltd Delhi., .

ADVANCED PHARMACOGNOSY - I

(MPG 102T)

SCOPE

To learn and understand the advances in the field of cultivation and isolation of drugs of natural origin, various phytopharmaceuticals, nutraceuticals and their medicinal use and health benefits.

OBJECTIVES

Upon completion of the course, the student shall be able to know the,

- advances in the cultivation and production of drugs
- Various phyto-pharmaceuticals and their source, its utilization and medicinal value.
- various nutraceuticals/herbs and their health benefits
- Drugs of marine origin
- Pharmacovigilance of drugs of natural origin

THEORY **60 Hrs**

1.	Plant drug cultivation: General introduction to the importance of Pharmacognosy in herbal drug industry, Indian Council of Agricultural Research, Current Good Agricultural Practices, Current Good Cultivation Practices, Current Good Collection Practices, Conservation of medicinal plants- Ex-situ and In- situ conservation of medicinal plants.	12 Hrs
2.	Marine natural products: General methods of isolation and purification, Study of Marine toxins, Recent advances in research in marine drugs, Problems faced in research on marine drugs such as taxonomical identification, chemical screening and their solution.	12 Hrs
3.	Nutraceuticals: Current trends and future scope, Inorganic mineral supplements, Vitamin supplements, Digestive enzymes, Dietary fibres, Cereals and grains, Health drinks of natural origin, Antioxidants, Polyunsaturated fatty acids, Herbs as functional foods, Formulation and standardization of neutraceuticals, Regulatory aspects, FSSAI guidelines, Sources, name of marker compounds and their chemical nature, medicinal uses and health benefits of following i) Spirulina ii) Soya bean iii) Ginseng iv) Garlic v) Broccoli vi) Green and Herbal Tea vii) Flax seeds viii) Black cohosh ix) Turmeric.	12 Hrs

4. Phytopharmaceuticals: Occurrence, isolation and characteristic features (Chemical nature, uses in pharmacy, medicinal and health benefits) of following. 12 Hrs

   a. Carotenoids – i) α and β - Carotene ii) Xanthophyll (Lutein)

   b. Limonoids – i) d-Limonene ii) α – Terpineol

   c. Saponins – i) Shatavarins

   d. Flavonoids – i) Resveratrol ii) Rutin iii) Hesperidin iv) Naringin v) Quercetin

   e. Phenolic acids- Ellagic acid

   f. Vitamins

   g. Tocotrienols and Tocopherols

   h. Andrographolide, Glycolipids, Gugulipids, Withanolides, Vascine, Taxol

   i. Miscellaneous

5. Pharmacovigilance of drugs of natural origin: WHO and AYUSH guidelines for safety monitoring of natural medicine, Spontaneous reporting schemes for biodrug adverse reactions, bio drug-drug and bio drug-food interactions with suitable examples. 12 Hrs

REFERENCES (Latest Editions of)

1. Pharmacognosy - G. E. Trease and W.C. Evans. Saunders Edinburgh, New York.
2. Pharmacognosy-Tyler, Brady, Robbers
3. Modem Methods of Plant Analysis- Peach & M.V. Tracey, Vol. I&II
4. Text Book of Pharmacognosy by T.E. Wallis
5. Marine Natural Products-Vol.I to IV.
6. Natural products: A lab guide by Raphael Ikan , Academic Press 1991.
7. Glimpses of Indian Ethano Pharmacology, P. Pushpangadam. Ulf Nyman. V.George Tropical Botanic Garden & Research Institute, 1995.
8. Medicinal natural products (a biosynthetic approach), Paul M. Dewick, John Wiley & Sons Ltd., England, 1998.
9. Chemistry of Marine Natural Products- Paul J. Schewer 1973.
10. Herbal Drug Industry by RD. Choudhary, Eastern Publisher, New Delhi, 1996.
11. Cultivation of Medicinal Plants by C.K. Atal & B.M. Kapoor.
12. Cultivation and Utilization of Aromatic Plants, C.K. Atal & B.M. Kapoor

13. Cultivation of medicinal and aromatic crops, AA Farooqui and B.S. Sreeramu. University Press, 2001.
14. Natural Products from Plants, 1st edition, by Peter B. Kaufman, CRC Press, New York, 1998
15. Recent Advances in Phytochemistry- Vol. 1&4: Scikel Runeckles- Appleton Century crofts.
16. Text book of Pharmacognosy, C.K.Kokate, Purohit, Ghokhale, Nirali Prakasshan, 1996.
17. Pharmacognosy and Pharmacobiotechnology, Ashutoshkar, New Age Publications, New Delhi.

PHYTOCHEMISTRY

(MPG 103T)

SCOPE

Students shall be equipped with the knowledge of natural product drug discovery and will be able to isolate, identify and extract and the phyto- constituents

OBJECTIVES

Upon completion of the course, the student shall be able to know the,

- different classes of phytoconstituents, their biosynthetic pathways, their properties, extraction and general process of natural product drug discovery
- phytochemical fingerprinting and structure elucidation of phytoconstituents.

THEORY **60 Hrs**

1. Biosynthetic pathways and Radio tracing techniques: 12 Hrs

   Constituents & their Biosynthesis, Isolation, Characterization and purification with a special reference to their importance in herbal industries of following phyto-pharmaceuticals containing drugs:

   a. Alkaloids: Ephedrine, Quinine, Strychynine, Piperine, Berberine, Taxol, Vinca alkoloids.

   b. Glycosides: Digitoxin, Glycyrrhizin, Sennosides, Bacosides, Quercitin.

   c. Steroids: Hecogenin, guggulosterone and withanolides

   d. Coumarin: Umbelliferone.

e. Terpenoids: Cucurbitacins

2. Drug discovery and development: History of herbs as source of drugs and drug discovery, the lead structure selection process, structure development, product discovery process and drug registration, Selection and optimization of lead compounds with suitable examples from the following source : artemesin, andrographolides. Clinical studies emphasising on phases of clinical trials, protocol design for lead molecules. 12 Hrs

3. Extraction and Phytochemical studies: Recent advances in extractions with emphasis on selection of method and choice of solvent for extraction, successive and exhaustive extraction and other methods of extraction commonly used like microwave assisted extraction, Methods of fractionation. Separation of phytoconstituents by latest CCCET, SCFE techniques including preparative HPLC and Flash column chromatography. 12 Hrs

4. Phytochemical finger printing: HPTLC and LCMS/GCMS applications in the characterization of herbal extracts. Structure elucidation of phytoconstituents. 12 Hrs

5. Structure elucidation of the following compounds by spectroscopic techniques like UV, IR, MS, NMR (1H, 13C) 12 Hrs

   a. Carvone, Citral, Menthol

   b. Luteolin, Kaempferol

   c. Nicotine, Caffeine iv) Glycyrrhizin.

REFERENCES (Latest Editions of)

1. Organic chemistry by I.L. Finar Vol.II
2. Pharmacognosy by Trease and Evans, ELBS.
3. Pharmacognosy by Tylor and Brady.
4. Text book of Pharmacognosy by Wallis.
5. Clark's isolation and Identification of drugs by A.C. Mottal.
6. Plant Drug Analysis by Wagner & Bladt.
7. Wilson and Gisvolds text book of Organic Medicinnal and Pharmaceutical Chemistry by Deorge. R.F.
8. The Chemistry of Natural Products, Edited by R.H. Thomson, Springer International Edn. 1994.
9. Natural Products Chemistry Practical Manual by Anees A Siddiqui and SeemiSiddiqui
10. Organic Chemistry of Natural Products, Vol. 1&2. Gurdeep R Chatwal.
11. Chemistry of Natural Products- Vol. 1 onwards IWPAC.

12. Modem Methods of Plant Analysis- Peach & M.V. Tracey, Vol. I&II
13. Medicinal Natural products – a biosynthetic approach, Dewick PM, John Wiley & Sons, Toronto, 1998.
14. Chemistry of Natural Products, Bhat SV, Nagasampagi BA, Meenakshi S, Narosa Publishing House, New Delhi.
15. Pharmacognosy & Phytochemistry of Medicinal Plants, 2nd edition, Bruneton J, Interceptt Ltd., New York, 1999.

INDUSTRIAL PHARMACOGNOSTICAL TECHNOLOGY

(MPG 104T)

SCOPE

To understand the Industrial and commercial potential of drugs of natural origin, integrate traditional Indian systems of medicine with modern medicine and also to know regulatory and quality policy for the trade of herbals and drugs of natural origin.

OBJECTIVES

By the end of the course the student shall be able to know,

- the requirements for setting up the herbal/natural drug industry.
- the guidelines for quality of herbal/natural medicines and regulatory issues.
- the patenting/IPR of herbals/natural drugs and trade of raw and finished materials.

THEORY **60 Hrs**

1.	Herbal drug industry: Infrastructure of herbal drug industry involved in production of standardized extracts and various dosage forms. Current challenges in upgrading and modernization of herbal formulations. Entrepreneurship Development, Project selection, project report, technical knowledge, Capital venture, plant design, layout and construction. Pilot plant scale –up techniques, case studies of herbal extracts. Formulation and production management of herbals.	12 Hrs
2.	Regulatory requirements for setting herbal drug industry: Global marketing management. Indian and international patent law as applicable herbal drugs and natural products. Export - Import (EXIM) policy, TRIPS. Quality assurance in herbal/natural drug products.Concepts of TQM, GMP, GLP, ISO-9000.	12 Hrs
3.	Monographs of herbal drugs: General parameters of monographs of herbal drugs and comparative study in IP, USP, Ayurvedic Pharmacopoeia, Siddha and Unani Pharmacopoeia, American herbal pharmacopoeia, British herbal pharmacopoeia, WHO guidelines in quality assessment of herbal drugs.	12 Hrs
4.	Testing of natural products and drugs: Herbal medicines - clinical laboratory	12

testing. Stability testing of natural products, protocols. Hrs

5. Patents: Indian and international patent laws, proposed amendments as applicable to herbal/natural products and process. Geographical indication, Copyright, Patentable subject maters, novelty, non obviousness, utility, enablement and best mode, procedure for Indian patent filing, patent processing, grant of patents, rights of patents, cases of patents, opposition and revocation of patents, patent search and literature, Controllers of patents. 12 Hrs

REFERENCES (Latest Editions of)

1. Herbal drug industry by R.D. Choudhary (1996), Eastern Publisher, New Delhi.
2. GMP for Botanicals - Regulatory and Quality issues on Phytomedicine by Pulok K Mukharjee (2003), Ist Edition, Business horizons Robert Verpoorte, New Delhi.
3. Quality control of herbal drugs by Pulok K Mukarjee (2002), Business Horizons Pharmaceutical Publisher, New Delhi.
4. PDR for Herbal Medicines (2000), Medicinal Economic Company, New Jersey.
5. Indian Herbal Pharmacopoeia (2002), IDMA, Mumbai.
6. Text book of Pharmacognosy by C.K. Kokate, Purohit, Gokhlae (1996), Nirali Prakashan, New Delhi.
7. Text book of Pharmacognosy and Phytochemistry by Vinod D. RangarI (2002), Part I & II, Career Publication, Nasik, India.
8. Plant drug analysis by H.Wagner and S.Bladt, Springer, Berlin.
9. Standardization of Botanicals. Testing and extraction methods of medicinal herbs by V. Rajpal (2004), Vol.I, Eastern Publisher, New Delhi.
10. Phytochemical Dictionary. Handbook of Bioactive Compounds from Plants by J.B.Harborne, (1999), IInd Edition, Taylor and Francis Ltd, UK.
11. Herbal Medicine. Expanded Commission E Monographs by M.Blumenthal, (2004), IST Edition,
12. Drug Formulation Manual by D.P.S.Kohli and D.H.Shah (1998), Eastern Publisher, New Delhi.

PHARMACOGNOSY PRACTICAL - I

(MPG I05P)

1. Analysis of Pharmacopoeial compounds of natural origin and their formulations by UV Vis spectrophotometer
2. Analysis of recorded spectra of simple phytoconstituents
3. Experiments based on Gas Chromatography
4. Estimation of sodium/potassium by flame photometry
5. Development of fingerprint of selected medicinal plant extracts commonly used in herbal drug industry viz. Ashwagandha, Tulsi, Bael, Amla, Ginger, Aloe, Vidang, Senna, Lawsonia by TLC/HPTLC method.
6. Methods of extraction
7. Phytochemical screening
8. Demonstration of HPLC- estimation of glycerrhizin
9. Monograph analysis of clove oil
10. Monograph analysis of castor oil.
11. Identification of bioactive constituents from plant extracts
12. Formulation of different dosage forms and their standardisation.

MEDICINAL PLANT BIOTECHNOLOGY

(MPG 201T)

SCOPE

To explore the knowledge of Biotechnology and its application in the improvement of quality of medicinal plants

OBJECTIVES

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

- Know the process like genetic engineering in medicinal plants for higher yield of Phytopharmaceuticals.
- Use the biotechnological techniques for obtaining and improving the quality of natural products/medicinal plants

THEORY **60 Hrs**

1.	Introduction to Plant biotechnology: Historical perspectives, prospects for development of plant biotechnology as a source of medicinal agents. Applications in pharmacy and allied fields. Genetic and molecular biology as applied to pharmacognosy, study of DNA, RNA and protein replication, genetic code, regulation of gene expression, structure and complicity of genome, cell signaling, DNA recombinant technology.	12 Hrs
2.	Different tissue culture techniques: Organogenesis and embryogenesis, synthetic seed and monoclonal variation, Protoplast fusion, Hairy root multiple shoot cultures and their applications. Micro propagation of medicinal and aromatic plants. Sterilization methods involved in tissue culture, gene transfer in plants and their applications.	15 Hrs
3.	Immobilisation techniques & Secondary Metabolite Production: Immobilization techniques of plant cell and its application on secondary metabolite Production. Cloning of plant cell: Different methods of cloning and its applications. Advantages and disadvantages of plant cell cloning. Secondary metabolism in tissue cultures with emphasis on production of medicinal agents. Precursors and elicitors on production of secondary metabolites.	15 Hrs
4.	Biotransformation and Transgenesis: Biotransformation, bioreactors for pilot and large scale cultures of plant cells and retention of biosynthetic potential in	13 Hrs

cell culture. Transgenic plants, methods used in gene identification, localization and sequencing of genes. Application of PCR in plant genome analysis.

5. Fermentation technology: Application of Fermentation technology, Production of ergot alkaloids, single cell proteins, enzymes of pharmaceutical interest. 05 Hrs

REFERENCES (Latest Editions of)

1. Plant tissue culture, Bhagwani, vol 5, Elsevier Publishers.
2. Plant cell and Tissue Culture (Lab. Manual), JRMM. Yeoman.
3. Elements in biotechnology by PK. Gupta, Rastogi Publications, New Delhi.
4. An introduction to plant tissue culture by MK. Razdan, Science Publishers.
5. Experiments in plant tissue culture by John HD and Lorin WR., Cambridge University Press.
6. Pharmaceutical biotechnology by SP. Vyas and VK. Dixit, CBS Publishers.
7. Plant cell and tissue culture by Jeffrey W. Pollard and John M Walker, Humana press.
8. Plant tissue culture by Dixon, Oxford Press, Washington DC, 1985
9. Plant tissue culture by Street.
10. Pharmacognosy by G. E. Trease and WC. Evans, Elsevier.
11. Biotechnology by Purohit and Mathur, Agro-Bio, 3rd revised edition.
12. Biotechnological applications to tissue culture by Shargool, Peter D, Shargoal, CKC Press.
13. Pharmacognosy by Varo E. Tyler, Lynn R. Brady and James E. Robberrt, That Tjen, NGO.
14. Plant Biotechnology, Ciddi Veerasham.

ADVANCED PHARMACOGNOSY - II

(MPG 202T)

SCOPE

To know and understand the Adulteration and Deterioration that occurs in herbal/natural drugs and methods of detection of the same. Study of herbal remedies and their validations, including methods of screening

OBJECTIVES

Upon completion of the course, the student shall be able to know the,

- validation of herbal remedies
- methods of detection of adulteration and evaluation techniques for the herbal drugs
- methods of screening of herbals for various biological properties

THEORY **60 Hrs**

1.	Herbal remedies – Toxicity and Regulations: Herbals vs Conventional drugs, Efficacy of Herbal medicine products, Validation of herbal therapies, Pharmacodynamic and Pharmacokinetic issues.	12 Hrs
2.	Adulteration and Deterioration: Introduction, Types of Adulteration/ Substitution of Herbal drugs, Causes and Measures of Adulteration, Sampling Procedures, Determination of Foreign Matter, DNA Finger printing techniques in identification of drugs of natural origin, detection of heavy metals, pesticide residues, phytotoxin, microbial contamination in herbs and their formulations.	12 Hrs
3.	Ethnobotany and Ethnopharmacology: Ethnobotany in herbal drug evaluation, Impact of Ethnobotany in traditional medicine, New development in herbals, Bio-prospecting tools for drug discovery, Role of Ethnopharmacology in drug evaluation, Reverse Pharmacology.	12 Hrs
4.	Analytical Profiles of herbal drugs: Andrographis paniculata, Boswellia serata, Coleus forskholii, Curcuma longa, Embelica officinalis, Psoralea corylifolia.	12 Hrs
5.	Biological screening of herbal drugs: Introduction and Need for Phyto-Pharmacological Screening, New Strategies for evaluating Natural Products, In vitro evaluation techniques for Antioxidants, Antimicrobial and Anticancer drugs. In vivo evaluation techniquesfor Anti-inflammatory, Antiulcer, Anticancer, Wound healing, Antidiabetic, Hepatoprotective, Cardio protective, Diuretics and	12 Hrs

Antifertility, Toxicity studies as per OECD guidelines.

REFERENCES (Latest Editions of)

1. Glimpses of Indian Ethano Pharmacology by P. Pushpangadam. Ulf Nyman. V.George Tropical Botanic Garden & Research Institute.
2. Natural products: A lab guide by Raphael Ikan, Academic Press.
3. Pharmacognosy - G. E. Trease and W.C. Evans. WB. Saunders Edinburgh, New York.
4. Pharmacognosy-Tyler, Brady, Robbers, Lee & Fetiger.
5. Modem Methods of Plant Analysis- Peach & M.V. Tracey, Vol. I & II, Springer Publishers.
6. Herbal Drug Industry by RD. Choudhary, Eastern Publishers, New Delhi.
7. Text book of Pharmacognosy by C.K.Kokate, Purohit, Ghokhale, Nirali Prakashan.
8. Text Book of Pharmacognosy by T.E. Wallis, J & A Churchill Ltd., London.
9. Quality control of herbal drugs by Pulok K Mukherjee, Business Horizons Pharmaceutical Publishers, New Delhi.
10. Indian Herbal Pharmacopoeia, IDMA, Mumbai.
11. Text book of Pharmacognosy and Phytochemistry by Vinod D. RangarI, Part I & II Career Publication Nasik, India.
12. Plant drug analysis by H.Wagner and S.Bladt, 2nd edition, Springer, Berlin.
13. Standardization of Botanicals. Testing and extraction methods of medicinal herbs by V. Rajpal (2004), Vol.I, Eastern PublisherS, New Delhi.
14. Herbal Medicine. Expanded Commission E Monographs, M.Blumenthal.

INDIAN SYSTEMS OF MEDICINE

(MPG 203T)

SCOPE

To make the students understand thoroughly the principles, preparations of medicines of various Indian systems of medicine like Ayurveda, Siddha, Homeopathy and Unani. Also focusing on clinical research of traditional medicines, quality assurance and challenges in monitoring the safety of herbal medicines.

OBJECTIVES

After completion of the course, student is able to

- To understand the basic principles of various Indian systems of medicine
- To know the clinical research of traditional medicines, Current Good Manufacturing Practice of Indian systems of medicine and their formulations.

THEORY **60 Hrs**

1.	Fundamental concepts of Ayurveda, Siddha, Unani and Homoeopathy systems of medicine Different dosage forms of the ISM. Ayurveda: Ayurvedic Pharmacopoeia, Analysis of formulations and bio crude drugs with references to: Identity, purity and quality. Siddha: Gunapadam (Siddha Pharmacology), raw drugs/Dhatu/Jeevam in Siddha system of medicine, Purification process (Suddhi).	12 Hrs
2.	Naturopathy, Yoga and Aromatherapy practices a) Naturopathy - Introduction, basic principles and treatment modalities. b) Yoga - Introduction and Streams of Yoga. Asanas, Pranayama, Meditations and Relaxation techniques. c) Aromatherapy – Introduction, aroma oils for common problems, carrier oils.	12 Hrs
3.	Formulation development of various systems of medicine Salient features of the techniques of preparation of some of the important class of Formulations as per Ayurveda, Siddha, Homeopathy and Unani Pharmacopoeia and texts. Standardization,	12 Hrs

Shelf life and Stability studies of ISM formulations.

4. Schedule T – Good Manufacturing Practice of Indian systems of medicine — 12 Hrs

Components of GMP (Schedule – T) and its objectives, Infrastructural requirements, working space, storage area, machinery and equipments, standard operating procedures, health and hygiene, documentation and records.

Quality assurance in ISM formulation industry - GAP, GMP and GLP. Preparation of documents for new drug application and export registration.

Challenges in monitoring the safety of herbal medicines:Regulation, quality assurance and control, National/Regional Pharmacopoeias.

5. TKDL, Geographical indication Bill, Government bills in AYUSH, — 12 Hrs

ISM, CCRAS, CCRS, CCRH, CCRU

REFERENCES (Latest Editions of)

1. Ayurvedic Pharmacopoeia, The Controller of Publications, Civil Lines, Govt. of India, New Delhi.
2. Hand Book on Ayurvedic Medicines, H. Panda, National Institute of Industrial Research, New Delhi.
3. Ayurvedic System of Medicine, Kaviraj Nagendranath Sengupata, Sri Satguru Publications, New Delhi.
4. Ayurvedic Pharmacopoeia. Formulary of Ayurvedic Medicines, IMCOPS, Chennai.
5. Homeopathic Pharmacopoeia. Formulary of Homeopathic Medicines, IMCOPS, Chennai.
6. Homeopathic Pharmacy : An introduction & Hand book, Steven B. Kayne, Churchill Livingstone, New York.
7. Indian Herbal Pharmacopoeia, IDMA, Mumbai.
8. British Herbal Pharmacopoeia, bRITISH Herbal Medicine Association, UK.
9. GMP for Botanicals - Regulatory and Quality issues on Phytomedicine, Pulok K Mukharjee, Business Horizons, New Delhi.
10. Indian System of Medicine and Homeopathy in India, Planning and Evaluation Cell, Govt. of India, New Delhi.
11. Essential of Food and Nutrition, Swaminathan, Bappco, Bangalore.
12. Clinical Dietitics and Nutrition, F.P. Antia, Oxford University Press, Delhi.13. Yoga - The Science of Holistic Living by V.K.Yoga, Vivekananda Yoga Prakashna Publishing, Bangalore.

HERBAL COSMETICS

(MPG 204T)

SCOPE

This subject deals with the study of preparation and standardization of herbal/natural cosmetics. This subject gives emphasis to various national and international standards prescribed regarding herbal cosmeceuticals.

OBJECTIVES

After completion of the course, student shall be able to,

- understand the basic principles of various herbal/natural cosmetic preparations
- current Good Manufacturing Practices of herbal/natural cosmetics as per the regulatory authorities

THEORY **60 Hrs**

1.	Introduction: Herbal/natural cosmetics, Classification & Economic aspects. Regulatory Provisions relation to manufacture of cosmetics: - License, GMP, offences & Penalties, Import & Export of Herbal/natural cosmetics, Industries involved in the production of Herbal/natural cosmetics.	12 Hrs
2.	Commonly used herbal cosmetics, raw materials, preservatives, surfactants, humectants, oils, colors, and some functional herbs, preformulation studies, compatibility studies, possible interactions between chemicals and herbs, design of herbal cosmetic formulation.	12 Hrs
3.	Herbal Cosmetics : Physiology and chemistry of skin and pigmentation, hairs, scalp, lips and nail, Cleansing cream, Lotions, Face powders, Face packs, Lipsticks, Bath products, soaps and baby product, Preparation and standardisation of the following : Tonic, Bleaches, Dentifrices and Mouth washes & Tooth Pastes, Cosmetics for Nails.	12 Hrs
4.	Cosmeceuticals of herbal and natural origin: Hair growth formulations, Shampoos, Conditioners, Colorants & hair oils, Fairness formulations, vanishing & foundation creams, anti-sun burn preparations, moisturizing creams, deodorants.	12 Hrs

5. Analysis of Cosmetics, Toxicity screening and test methods: Quality control and toxicity studies as per Drug and Cosmetics Act. 12 Hrs

REFERENCES (Latest Editions of)

1. Panda H. Herbal Cosmetics (Hand book), Asia Pacific Business Press Inc, New Delhi.
2. Thomson EG. Modern Cosmetics, Universal Publishing Corporation, Mumbai.
3. P.P.Sharma. Cosmetics - Formulation, Manufacturing & Quality Control, Vandana Publications, New Delhi.
4. Supriya K B. Handbook of Aromatic Plants, Pointer Publishers, Jaipur.
5. Skaria P. Aromatic Plants (Horticulture Science Series), New India Publishing Agency, New Delhi.
6. Kathi Keville and Mindy Green. Aromatheraphy (A Complete Guide to the Healing Art), Sri Satguru Publications, New Delhi.
7. Chattopadhyay PK. Herbal Cosmetics & Ayurvedic Medicines (EOU), National Institute of Industrial Research, Delhi.
8. Balsam MS & Edward Sagarin. Cosmetics Science and Technology, Wiley Interscience, New York.

HERBAL COSMETICS PRACTICALS

(MPG 205P)

1. Isolation of nucleic acid from cauliflower heads
2. Isolation of RNA from yeast
3. Quantitative estimation of DNA
4. Immobilization technique
5. Establishment of callus culture
6. Establishment of suspension culture
7. Estimation of aldehyde contents of volatile oils
8. Estimation of total phenolic content in herbal raw materials
9. Estimation of total alkaloid content in herbal raw materials
10. Estimation of total flavonoid content in herbal raw materials
11. Preparation and standardization of various simple dosage forms from Ayurveda, Siddha, Homoeopathy and Unani formulary
12. Preparation of certain Aromatherapy formulations
13. Preparation of herbal cosmetic formulation such as lip balm, lipstick, facial cream, herbal hair and nail care products
14. Evaluation of herbal tablets and capsules
15. Preparation of sunscreen, UV protection cream, skin care formulations.
16. Formulation & standardization of herbal cough syrup.

Semester III

MRM 301T - Research Methodology & Biostatistics

UNIT – I

General Research Methodology: Research, objective, requirements, practical difficulties, review of literature, study design, types of studies, strategies to eliminate errors/bias, controls, randomization, crossover design, placebo, blinding techniques.

UNIT – II

Biostatistics: Definition, application, sample size, importance of sample size, factors influencing sample size, dropouts, statistical tests of significance, type of significance tests, parametric tests (students "t" test, ANOVA, Correlation coefficient, regression), non-parametric tests (Wilcoxon rank tests, analysis of variance, correlation, chi square test), null hypothesis, P values, degree of freedom, interpretation of P values.

UNIT – III

Medical Research: History, values in medical ethics, autonomy, beneficence, non-maleficence, double effect, conflicts between autonomy and beneficence/non-maleficence, euthanasia, informed consent, confidentiality, criticisms of orthodox medical ethics, importance of communication, control resolution, guidelines, ethics committees, cultural concerns, truth telling, online business practices, conflicts of interest, referral, vendor relationships, treatment of family members, sexual relationships, fatality.

UNIT – IV

CPCSEA guidelines for laboratory animal facility: Goals, veterinary care, quarantine, surveillance, diagnosis, treatment and control of disease, personal hygiene, location of animal facilities to laboratories, anesthesia, euthanasia, physical facilities, environment, animal husbandry, record keeping, SOPs, personnel and training, transport of lab animals.

UNIT – V

Declaration of Helsinki: History, introduction, basic principles for all medical research, and additional principles for medical research combined with medical care.

2.7 Total number of hour

As mentioned in Course outline (clause 2.4)

2.8 Branches if any, with definition

As mentioned in Syllabus (clause 2.6)

2.9 Teaching Learning methods

A regular record of attendance both in Theory, Practical, Seminar, Assignment, Journal club, Discussion with the supervisor, Research work presentation and Dissertation shall be maintained by the department / teaching staff of respective courses.

2.10 Content of each subject in each year

As mentioned in Syllabus (clause 2.6)

2.11 No: of hours per subject

As mentioned in Syllabus (clause 2.6)

2.12 Practical Training

As mentioned in Course outline (clause 2.4)

2.13 Records

To be maintained for all Practical Work

2.14 Dissertation

As mentioned in Project work to be done (clause 2.16)

2.15 Specialty Training if ANY

As mentioned in Syllabus (clause 2.6)

2.16 Project work to be done if any

All the students shall undertake a project under the supervision of a teacher in Semester III to IV and submit a report. 4 copies of the project report shall be submitted (typed & bound copy not less than 75 pages).

The internal and external examiner appointed by the University shall evaluate the project at the time of the Practical examinations of other semester(s). The projects shall be evaluated as per the criteria given below.

Evaluation of Dissertation Book:

Objective(s) of the work done	50 Marks
Methodology adopted	150 Marks
Results and Discussions	250 Marks
Conclusions and Outcomes	50 Marks
Total	500 Marks

Evaluation of Presentation:

Presentation of work	100 Marks
Communication skills	50 Marks
Question and answer skills	100 Marks
Total	250 Marks

2.17 Any other Requirements [CME, Paper Publishing, etc,.]

As mentioned in Course outline (clause 2.4)

2.18 Prescribed/Recommended textbooks for each subject

As mentioned in Syllabus (clause 2.6)

2.19 Reference books

As mentioned in Syllabus (clause 2.6)

2.20 Journals

All Pharmacy and related Medical Journals

2.21 Logbook

Registers to be maintained

3. EXAMINATION

3.1 Eligibility to appear for examinations

A candidate is required to put in at least 80% attendance in individual courses considering theory and practical separately. The candidate shall complete the prescribed course satisfactorily to be eligible to appear for the respective examinations.

3.2 Schedule of Regular / Supplementary exams

Semester examinations will be conducted once in every six months after fulfilling 100 working days.

Table: 6 - Question paper pattern for end semester theory & practical examinations

Question paper pattern for end semester theory examinations			
I.	Long Answers	3 X 10	30 Marks
II.	Short Answers	9 X 5	45 Marks
		Total	**75 Marks**
Question paper pattern for end semester practical examinations			
I.	Synopsis		15 Marks
II.	Experiment - I		40 Marks
III.	Experiment – II		30 Marks
IV.	Viva voce		15 Marks
		Total	**100 Marks**

3.3 Scheme of examination showing maximum marks and minimum marks

The End Semester Examinations for each theory and practical Course through semesters I to IV shall be conducted by the respective university except for the subject with asterisk symbol (*) in table – 8 for which examinations shall be conducted by the subject experts at college level and the marks/grades shall be submitted to the university.

Schemes for internal assessments and end semester examinations are given in table below

Table – 7: Schemes for internal assessments and end semester examinations

Course code	Course	Internal Assessment				End Semester Exams		Total Marks
		Continuous Mode	Sessional Exams		Total	Marks	Duration	
			Marks	Duration				
SEMESTER I								
MPG 101T	Modern Pharmaceutical Analytical Techniques	10	15	1 Hr	25	75	3 Hrs	100
MPG 102T	Advanced Pharmacognosy - I	10	15	1 Hr	25	75	3 Hrs	100
MPG 103T	Phytochemistry	10	15	1 Hr	25	75	3 Hrs	100
MPG 104T	Industrial Pharmacognostical Technology	10	15	1 Hr	25	75	3 Hrs	100
MPG 105P	Pharmacognosy Practical – I	20	30	6 Hrs	50	100	6 Hrs	150
-	Seminar /Assignment	-	-	-	-	-	-	100
Total								
SEMESTER II								
MPG 201T	Medicinal Plant Biotechnology	10	15	1 Hr	25	75	3 Hrs	100
MPG 202T	Advanced Pharmacognosy -II	10	15	1 Hr	25	75	3 Hrs	100
MPG 203T	Indian System of Medicine	10	15	1 Hr	25	75	3 Hrs	100
MPG 204T	Herbal Cosmetics	10	15	1 Hr	25	75	3 Hrs	100
MPG 205P	Pharmacognosy Practical II	20	30	6 Hrs	50	100	6 Hrs	150
-	Seminar /Assignment	-	-	-	-	-	-	100
Total								650

Table – 8: Schemes for internal assessments and end semester examinations

(Semester III& IV)

Course code	Course	Internal Assessment				End Semester Exams		Total Marks
		Continuous Mode	Sessional Exams		Total	Marks	Duration	
			Marks	Duration				
SEMESTER III								
MRM 301T	Research Methodology and Biostatistics*	10	15	1 Hr	25	75	3 Hrs	100
-	Journal Club	-	-	-	25	-	-	25
-	Discussion / Presentation (proposal presentation)	-	-	-	50	-	-	50
-	Research Work*	-	-	-	-	350	1 Hr	350
Total								525
SEMESTER IV								
-	Journal club	-	-	-	25	-	-	25
-	Discussion / Presentation (proposal presentation)	-	-	-	75	-	-	75
-	Research Work and Colloquium	-	-	-	-	400	1 Hr	400
Total								500

*Non University Examination

Table – 9: Scheme for awarding internal assessment

Theory	
Criteria	**Maximum Marks**
Attendance (Refer Table – 10)	8
Student – Teacher interaction	2
Total	10
Practical	
Attendance (Refer Table – 10)	10
Based on Practical Records, Regular viva voce, etc.	10
Total	20

Table – 10: Guidelines for the allotment of marks for attendance

Percentage of Attendance	Theory	Practical
95 – 100	8	10
90 – 94	6	7.5
85 – 89	4	5
80 – 84	2	2.5
Less than 80	0	0

Allowed to keep terms (ATKT):

No student shall be admitted to any examination unless he/she fulfills the norms given in clause 3.1. ATKT rules are applicable as follows:

A student shall be eligible to carry forward all the courses of I and II semesters till the III semester examinations. However, he/she shall not be eligible to attend the courses of IV semester until all the courses of I, II and III semesters are successfully completed.

A student shall be eligible to get his/her CGPA upon successful completion of the courses of I to IV semesters within the stipulated time period as per the norms.

Note: Grade AB should be considered as failed and treated as one head for deciding ATKT. Such rules are also applicable for those students who fail to register for examination(s) of any course in any semester.

Grading of performances

a) Letter grades and grade points allocations:

Based on the performances, each student shall be awarded a final letter grade at the end of the semester for each course. The letter grades and their corresponding grade points are given in Table – 11.

Table – 11: Letter grades and grade points equivalent to Percentage of marks and performances

Percentage of Marks obtained	Letter Grade	Grade point	Performance
90.00 – 100	O	10	Outstanding
80.00 – 89.99	A	9	Excellent
70.00 – 79.99	B	8	Good
60.00 – 69.99	C	7	Fair
50.00 – 59.99	D	6	Average
Less than 50	F	0	Fail
Absent	AB	0	Fail

A learner who remains absent for any end semester examination shall be assigned a letter grade of AB and a corresponding grade point of zero. He/she should reappear for the said evaluation/examination in due course.

b) The Semester grade point average (SGPA)

The performance of a student in a semester is indicated by a number called 'Semester Grade Point Average' (SGPA). The SGPA is the weighted average of the grade points obtained in all the courses by the student during the semester. For example, if a student takes five courses (Theory/Practical) in a semester with credits C1, C2, C3 and C4 and the student's grade points in these courses are G1, G2, G3 and G4, respectively, and then students' SGPA is equal to:

$$SGPA = \frac{C_1G_1 + C_2G_2 + C_3G_3 + C_4G_4}{C_1 + C_2 + C_3 + C_4}$$

The SGPA is calculated to two decimal points. It should be noted that, the SGPA for any semester shall take into consideration the F and ABS grade awarded in that semester. For example if a learner has a F or ABS grade in course 4, the SGPA shall then be computed as:

$$SGPA = \frac{C_1G_1 + C_2G_2 + C_3G_3 + C_4*ZER0}{C_1 + C_2 + C_3 + C_4}$$

c) Cumulative Grade Point Average (CGPA)

The CGPA is calculated with the SGPA of all the IV semesters to two decimal points and is indicated in final grade report card/final transcript showing the grades of all IV semesters and their courses. The CGPA shall reflect the failed status in case of F grade(s), till the course(s) is/are passed. When the course(s) is/are passed by obtaining a pass grade on subsequent examination(s) the CGPA shall only reflect the new grade and not the fail grades earned earlier. The CGPA is calculated as:

$$CGPA = \frac{C_1S_1 + C_2S_2 + C_3S_3 + C_4S_4}{C_1 + C_2 + C_3 + C_4}$$

where C_1, C_2, C_3,…. is the total number of credits for semester I,II,III,…. And S_1, S_2, S_3… is the SGPA of semester I, II, III…. .

3.4 Papers in each year

As mentioned in Course outline (clause 2.4)

3.5 Details of theory exams

As mentioned in Schedule of regular / Supplementary Exams (clause 3.2)

3.6 Model question paper for each subject with question paper pattern

As mentioned in Schedule of regular / Supplementary Exams (clause 3.2)See Annexure

3.7 Internal assessment component

As mentioned in Scheme of examination. (Clause 3.3)

- Two sessional exams shall be conducted for each theory / practical course as per the schedule fixed by the college(s). The average marks of two sessional exams shall be computed for internal assessment as per the requirements
- A student shall have the opportunity to improve his/her performance only once in the sessional exam component of the internal assessment. The re-conduct of the sessional exam shall be completed before the commencement of next end semester theory examinations.

3.8 Details of practical / clinical practicum exams.

As mentioned in Schedule of regular / Supplementary Exams (clause 3.2) Scheme of examination. (Clause 3.3)

3.9 Number of examiners (Internal & External) and their qualifications

- A post graduate (PG) degree in M. Pharm shall be eligible as teacher.
- A post graduate degree in M. Pharm with 5 years Post PG experience is eligible as internal examiner.
- A post graduate degree in M. Pharm with 10 years Post PG is eligible as external examiner.
- A post graduate degree in M. Pharm with 5 years Post PG is eligible to guide maximum of 5 candidates for M. Pharm dissertation.

For the conduct of practical examination of I semester one external examiner and 2 internal examiners (one faculty dealing with the respective speciality and one faculty dealing Modern Analytical and Research methods) shall be appointed by the University. For the evaluation of Practical Examination of II semester one internal and one external examiner shall be appointed by the university.

3.10 Details of viva:

As mentioned in Schedule of regular / Supplementary Exams (clause 3.2) Scheme of examination. (Clause 3.3)

4. INTERNSHIP

Not applicable

5. ANNEXURES

5.1 Check Lists for Monitoring:

Log Book, Seminar Assessment etc. to be formulated by the curriculum committee of the concerned Institution.

Q P CODE REG NO

MODEL QUESTION PAPER
M.PHARM PHARMACOGNOSY

FIRST SEMESTER M'PHARM DEGREE EXAMINATIONS

PAPER – I – MODERN PHARMACEUTICAL ANALYTICAL TECHNIQUES (MPA 101T)

- answer all questions

Time: 3 hours Maximum: Marks: 75

Essay s (3x10=30)

1. Explain the sample handling and instrumentation of Dispersive and FTIR spectroscopy.
2. Classify chromatographic methods based on mechanism of separation and add a note on column chromatography
3. Explain the theory and instrumentation of NMR spectroscopy.

Short notes (9x5=45)

4. Write note on X-ray powder diffraction technique
5. Discuss about gel electrophoresis
6. Instrumentation associated with UV spectroscopy
7. Write a note on ion selective electrodes
8. Discuss about the principle and instrumentation of differential thermal analysis
9. Briefly explain the moving boundary meter electrophoresis
10. Write about MALDI Explain principle and applications of MALDI
11. Sample handing techniques in IR spectroscopy
12. Write briefly on the principle of 13CNMR

Q P CODE REG NO

MODEL QUESTION PAPER
M.PHARM PHARMACOGNOSY

FIRST SEMESTER M'PHARM DEGREE EXAMINATIONS

PAPER – II – ADVANCED PHARMACOGNOSY – I (MPG 101T)

- answer all questions

Time: 3 hours Maximum: Marks: 75

Essay (3x10=30)

1. Elaborate on the WHO guidelines for safety monitoring of natural medicine
2. Describe the standardisation of neutraceuticals
3. Describe current good cultivation practices

Short notes (9x5=45)

4. Marine toxins
5. Source and health benefits of Garlic and Soya bean
6. Chemical nature and medicinal uses of Resveratrol
7. Isolation of Andrographolides
8. Problems faced in research on marine drugs
9. Ex-site conservation of medicinal plants
10. Bio-drug-food inter actions
11. Write a note on chemistry and uses of PUFA
12. Chemical nature occurance and isolation of Taxol

Q P CODE REG NO

MODEL QUESTION PAPER
M.PHARM PHARMACOGNOSY

FIRST SEMESTER M'PHARM DEGREE EXAMINATIONS

PAPER – III – PHYTOCHEMISTRY (MPG 102T)

- answer all questions

Time: 3 hours Maximum: Marks: 75

Essay (3x10=30)

1. What is the principle and advantages of microwave assisted techniques
2. What are the clinical trial protocols for lead molecules?
3. Write about radio tracer techniques for elucidation of biosynthetic pathways

Short notes (9x5=45)

4. Structure elucidation of menthol
5. Applications of HPTLC in the characterization of herbal extracts
6. Advantages of SCFE method
7. Spectroscopic identification of Glycyrrhizin
8. Methods of fractionation of phytoconstituents
9. Write a note on lead structure selection process
10. Isolation and characterization of sennosides
11. Applications of LCMS in phytochemical finger printing
12. What are the technique and advantages of preparative HPLC for separation of phyto constituents?

Q P CODE REG NO

MODEL QUESTION PAPER
M.PHARM PHARMACOGNOSY

FIRST SEMESTER M'PHARM DEGREE EXAMINATIONS

PAPER – IV – INDUSTRIAL PHARMACOGNOSTICAL TECHNOLOGY (MPG 103T)

- answer all questions

Time: 3 hours Maximum: Marks: 75

Essay (3x10=30)

1. Discuss about basic concepts of quality management relating to ISO – 9000
2. Write about procedures for Indian patents for herbal drugs
3. What are the pilot plant scale – up techniques for herbal formulations?

Short notes (9x5=45)

4. Stability testing of herbal drugs
5. Write a note on Geographical Indication
6. Concept of GMP in herbal manufacturing units
7. Current challenges in modernization of herbal formulations
8. Write a note on Ayurvedic pharmacopoeia
9. What are WHO guide lines in quality assessment of crude drugs?
10. Write a note on TRIPS
11. Discuss about copyright as applicable to patents
12. Global marketing management of herbal drugs

REGULATIONS2017

Syllabus

Kerala University of Health Sciences

Thrissur - 680596

POST GRADUATE COURSE IN PHARMACY

Master of Pharmacy

(M.Pharm. - " Pharmaceutical Analysis")

Course code: 279

(2017-18 Academic year onwards)

2017

2. COURSE CONTENT

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2. COURSE CONTENT

2.1 Title of course

These regulations shall be called as "Master of Pharmacy (M.Pharm. – Pharmaceutical Analysis) Degree Program - Credit Based Semester System (CBSS) of the Kerala University of Health sciences. They shall come into effect from the Academic Year 2017-18 onwards. The regulations framed are subject to modifications from time to time by the authorities of the University.

2.2 Objectives of course

To generate Pharmacy Post Graduates with profound knowledge in various branches of Pharmaceutical Sciences to meet with the rapidly increasing demands put forward by-

- Pharmaceutical Manufacturing
- Pharmaceutical Research & Development
- Pharmacological research including preclinical & clinical studies.
- Herbal Drug Research
- Pharmaceutical & Herbal Drug Analysis
- Clinical Toxicology & Toxicological Analysis

To discover the potential to become faculty in Pharmaceutical Sciences with unmatched quality and excellence, so as to educate the future pharmacy generation (Undergraduate, Post graduate, and Doctoral).

2.3 Medium of Instruction

Medium of instruction and examination shall be in English.

2.4 Course Outline

The specialization in M.Pharm. Program is given in Table 1.

Table – 1: M.Pharm. Specialization and its code

S.No	Specialization	Code
1.	Pharmaceutical Analysis	MPA

The course of study for M.Pharm Pharmaceutical Analysis shall include Semester wise Theory & Practical as given in Table – 2 & 3. The number of hours to be devoted to each theory and practical course in any semester shall not be less than that shown in Table – 2 & 3.

Table – 2: Course of study for M.Pharm. I & II Semester

Course Code	Course	Credit Hours	Credit Points	Hrs./wk	Marks
Semester I					
MPA 101T	Modern Pharmaceutical Analysis	4	4	4	100
MPA 102T	Advanced Pharmaceutical Analysis	4	4	4	100
MPA 103T	Pharmaceutical Validation	4	4	4	100
MPA 104T	Food Analysis	4	4	4	100
MPA 105P	Pharmaceutical Analysis- I	12	6	12	150
-	Seminar /Assignment	7	4	7	100
Total		35	26	35	650
Semester II					
MPA 201T	Advanced Instrumental Analysis	4	4	4	100
MPA 202T	Modern Bio-Analytical Techniques	4	4	4	100
MPA 203T	Quality Control and Quality Assurance	4	4	4	100
MPA 204T	Herbal and Cosmetic Analysis	4	4	4	100
MPA 205P	Pharmaceutical Analysis – II	12	6	12	150
-	Seminar /Assignment	7	4	7	100
Total		35	26	35	650

Table – 3: Course of study for M. Pharm. III & IV Semester

Course Code	Course	Credit Hours	Credit Points
Semester III			
MRM 301T	Research Methodology and Biostatistics*	4	4
-	Journal Club	1	1
-	Discussion / Presentation (proposal presentation)	2	2
-	Research Work*	28	14
Total		35	21
Semester IV			
-	Journal Club	1	1
-	Research Work	31	16
-	Discussion / Final Presentation	3	3
Total		35	20

*Non University Exam

Program/Course credit structure

As per the philosophy of Credit Based Semester System, certain quantum of academic work viz. theory classes, practical classes, seminars, assignments, etc. are measured in terms of credits. On satisfactory completion of the courses, a candidate earns credits. The amount of credit associated with a course is dependent upon the number of hours of instruction per week in that course. Similarly the credit associated with any of the other academic, co/extracurricular activities is dependent upon the quantum of work expected to be put in for each of these activities per week/per activity.

Credit assignment

a) Theory and Laboratory courses

Courses are broadly classified as Theory and Practical. Theory courses consist of lecture (L) and Practical (P) courses consist of hours spent in the laboratory. Credits (C) for a course is dependent on the number of hours of instruction per week in that course, and is obtained by using a multiplier of one (1) for lecture and a multiplier of half (1/2) for practical (laboratory) hours. Thus, for example, a theory course having four lectures per week throughout the semester carries a credit of 4. Similarly, a practical having four laboratory hours per week throughout semester carries a credit of 2. The contact hours of seminars, assignments and research work shall be treated as that of practical courses for the purpose of calculating credits. i.e., the contact hours shall be multiplied by 1/2. Similarly, the contact hours of journal club, research work presentations and discussions with the supervisor shall be considered as theory course and multiplied by 1.

b) Minimum credit requirements

The minimum credit points required for the award of M. Pharm. degree is 95. However based on the credit points earned by the students under the head of co-curricular activities, a student shall earn a maximum of 100 credit points. These credits are divided into Theory courses, Practical, Seminars, Assignments, Research work, Discussions with the supervisor, Journal club and Co-Curricular activities over the duration of four semesters. The credits are distributed semester-wise as shown in Table 4. Courses generally progress in sequence, building competencies and their positioning indicates certain academic maturity on the part of the learners. Learners are expected to follow the semester-wise schedule of courses given in the syllabus.

Table – 4: Semester wise credits distribution

Semester	Credit Points
I	26
II	26
III	21
IV	20
Co-curricular Activities (attending Conference, Scientific Presentations and other scholarly Activities)	Minimum = 02 Maximum = 07*
Total Credit Points	Minimum = 95 Maximum = 100

*Credit points for Co-curricular Activities

Table – 5: Guidelines for Awarding Credit Points for Co-curricular Activities

Name of the Activity	MaximumCredit Points Eligible / Activity
Participation in National Level Seminar/ Conference/ Workshop / Symposium / Training Programs (related to the specialization of the student)	01
Participation in international Level Seminar/ Conference/ Workshop/ Symposium/ Training Programs (related to the specialization of the student)	02
Academic Award/Research Award from State Level/ National Agencies	01
Academic Award/Research Award from International Agencies	02
Research / Review Publication in National Journals (Indexed in Scopus / Web of Science)	01
Research / Review Publication in International Journals (Indexed in Scopus / Web of Science)	02

Note: International Conference: Held outside India

International Journal: The Editorial Board outside India

*The credit points assigned for extracurricular and or co-curricular activities shall be given by the Principals of the colleges and the same shall be submitted to the University. The criteria to acquire this credit point shall be defined by the colleges from time to time.

Program Committee

1. The M. Pharm. programme shall have a Programme Committee constituted by the Head of the institution in consultation with all the Heads of the departments.
2. The composition of the Programme Committee shall be as follows:
   A teacher at the cadre of Professor shall be the Chairperson; One Teacher from each M.Pharm specialization and four student representatives (two from each academic year), nominated by the Head of the institution.
3. Duties of the Programme Committee:
   i. Periodically reviewing the progress of the classes.
   ii. Discussing the problems concerning curriculum, syllabus and the conduct of classes.
   iii. Discussing with the course teachers on the nature and scope of assessment for the course and the same shall be announced to the students at the beginning of respective semesters.
   iv. Communicating its recommendation to the Head of the institution on academic matters.
   v. The Programme Committee shall meet at least twice in a semester preferably at the end of each sessional exam and before the end semester exam.

2.5 Duration

The program of study for M.Pharm. shall extend over a period of four semesters (two academic years). The curricula and syllabi for the program shall be prescribed from time to time by the Kerala University of Health sciences.

The duration for the completion of the program shall be fixed as double the actual duration of the program and the students have to pass within the said period, otherwise they have to get fresh Registration.

2.6 Syllabus

PHARMACEUTICAL ANALYSIS (MPA)

MODERN PHARMACEUTICAL ANALYTICAL TECHNIQUES

(MPA 101T)

Scope

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

Objectives

After completion of course student is able to know about chemicals and excipients

- The analysis of various drugs in single and combination dosage forms
- Theoretical and practical skills of the instruments

THEORY **60 Hrs**

1. a. UV-Visible spectroscopy: Introduction, Theory, Laws, Instrumentation associated with UV-Visible spectroscopy, Choice of solvents and solvent effect and Applications of UV-Visible spectroscopy, Difference/ Derivative spectroscopy. — 10 Hrs

   b. IR spectroscopy: Theory, Modes of Molecular vibrations, Sample handling, Instrumentation of Dispersive and Fourier - Transform IR Spectrometer, Factors affecting vibrational frequencies and Applications of IR spectroscopy, Data Interpretation.

   c. Spectroflourimetry: Theory of Fluorescence, Factors affecting fluorescence (Characterestics of drugs that can be analysed by flourimetry), Quenchers, Instrumentation and Applications of fluorescence spectrophotometer.

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

2. NMR spectroscopy: Quantum numbers and their role in NMR, Principle, Instrumentation, Solvent requirement in NMR, Relaxation process, NMR signals in various compounds, Chemical shift, Factors influencing chemical shift, Spin-Spin coupling, Coupling constant, Nuclear magnetic double resonance, Brief — 10 Hrs

outline of principles of FT-NMR and 13C NMR. Applications of NMR spectroscopy.

3.	Mass Spectroscopy: Principle, Theory, Instrumentation of Mass Spectroscopy, Different types of ionization like electron impact, chemical, field, FAB and MALDI, APCI, ESI, APPI Analyzers of Quadrupole and Time of Flight, Mass fragmentation and its rules, Meta stable ions, Isotopic peaks and Applications of Mass spectroscopy.	10 Hrs
4.	Chromatography: Principle, apparatus, instrumentation, chromatographic parameters, factors affecting resolution, isolation of drug from excipients, data interpretation and applications of the following: a) Thin Layer chromatography b) High Performance Thin Layer Chromatography c) Ion exchange chromatography d) Column chromatography e) Gas chromatography f) High Performance Liquid chromatography g) Ultra High Performance Liquid chromatography h) Affinity chromatography i) Gel Chromatography	10 Hrs
5.	a. Electrophoresis: Principle, Instrumentation, Working conditions, factors affecting separation and applications of the following: a) Paper electrophoresis b) Gel electrophoresis c) Capillary electrophoresis d) Zone electrophoresis e) Moving boundary electrophoresis f) Iso electric focusing b. X ray Crystallography: Production of X rays, Different X ray methods, Bragg's law, Rotating crystal technique, X ray powder technique, Types of crystals and applications of X-ray diffraction	10 Hrs
6.	Potentiometry: Principle, working, Ion selective Electrodes and Application of potentiometry. Thermal Techniques: Principle, thermal transitions and Instrumentation (Heat flux and power-compensation and designs), Modulated DSC, Hyper DSC, experimental parameters (sample preparation, experimental conditions,	10 Hrs

calibration, heating and cooling rates, resolution, source of errors) and their influence, advantage and disadvantages, pharmaceutical applications.

Differential Thermal Analysis (DTA): Principle, instrumentation and advantage and disadvantages, pharmaceutical applications, derivative differential thermal analysis (DDTA). TGA: Principle, instrumentation, factors affecting results, advantage and disadvantages, pharmaceutical applications.

REFERENCES

1. Spectrometric Identification of Organic compounds - Robert M Silverstein, Sixth edition, John Wiley & Sons, 2004.
2. Principles of Instrumental Analysis - Doglas A Skoog, F. James Holler, Timothy A. Nieman, 5th edition, Eastern press, Bangalore, 1998.
3. Instrumental methods of analysis – Willards, 7th edition, CBS publishers.
4. Practical Pharmaceutical Chemistry – Beckett and Stenlake, Vol II, 4th edition, CBS Publishers, New Delhi, 1997.
5. Organic Spectroscopy - William Kemp, 3rd edition, ELBS, 1991.
6. Quantitative Analysis of Drugs in Pharmaceutical formulation - P D Sethi, 3rd Edition, CBS Publishers, New Delhi, 1997.
7. Pharmaceutical Analysis - Modern Methods – Part B - J W Munson, Vol 11, Marcel. Dekker Series
8. Spectroscopy of Organic Compounds, 2nd edn., P.S/Kalsi, Wiley estern Ltd ., Delhi .
9. Textbook of Pharmaceutical Analysis, KA.Connors, 3rd Edition, John Wiley & Sons, 1982.

ADVANCED PHARMACEUTICAL ANALYSIS

(MPA 102T)

Scope

This subject deals with the various aspects of Impurity, Impurities in new drug products, in residual solvents, Elemental impurities, Impurity profiling and characterization of degradents, Stability testing of phytopharmaceuticals and their protocol preparation. It also covers the biological testing of various vaccines and their principle and procedure.

Objective

After completion of the course students shall able to know,

- Appropriate analytical skills required for the analytical method development.
- Principles of various reagents used in functional group analysis that renders necessary support in research methodology and demonstrates its application in the practical related problems.
- Analysis of impurities in drugs, residual solvents and stability studies of drugs and biological products

THEORY **60 Hrs**

1. Impurity and stability studies: 10 Hrs

   Definition, classification of impurities in drug Substance or Active Pharmaceutical Ingredients and quantification of impurities as per

   ICH guidelines

   Impurities in new drug products:

   Rationale for the reporting and control of degradation products, reporting degradation products content of batches, listing of degradation products in specifications, qualification of degradation products

   Impurities in residual solvents:

   General principles, classification of residual solvents, Analytical procedures, limits of residual solvents, reporting levels of residual solvents

2. Elemental impurities: 10 Hrs

Element classification, control of elemental impurities, Potential Sources of elemental Impurities, Identification of Potential Elemental Impurities, analytical procedures, instrumentation & C, H, N and S analysis

Stability testing protocols:

Selection of batches, container orientation, test parameters, sampling frequency, specification, storage conditions, recording of results, concept of stability, commitment etc. Important mechanistic and stability related information provided by results of study of factors like temperature, pH, buffering species ionic strength and dielectric constant etc. on the reaction rates. With practical considerations.

3. Impurity profiling and degradent characterization: Method 10 Hrs

development, Stability studies and concepts of validation accelerated stability testing & shelf life calculation, WHO and ICH stability testing guidelines, Stability zones, steps in development, practical considerations. Basics of impurity profiling and degradent characterization with special emphasis. Photostability testing guidelines, ICH stability guidelines for biological products

4. Stability testing of phytopharmaceuticals: 10 Hrs

Regulatory requirements, protocols, HPTLC/HPLC finger printing, interactions and complexity.

5. Biological tests and assays of the following: 10 Hrs

a. Adsorbed Tetanus vaccine b. Adsorbed Diphtheria vaccine

c. Human anti haemophilic vaccine d. Rabies vaccine e. Tetanus Anti toxin f. Tetanus Anti serum g. Oxytocin h. Heparin sodium IP i. Antivenom. PCR, PCR studies for gene regulation, instrumentation (Principle and Procedures)

6. Immunoassays (IA) 10 Hrs

Basic principles, Production of antibodies, Separation of bound and unbound drug, Radioimmunoassay, Optical IA, Enzyme IA, Fluoro IA, Luminiscence IA, Quantification and applications of IA.

REFERENCES

1. Vogel's textbook of quantitative chemical analysis - Jeffery J Bassett, J. Mendham, R. C. Denney, 5th edition, ELBS, 1991.
2. Practical Pharmaceutical Chemistry - Beckett and Stenlake, Vol II, 4th Edition, CBS publishers, New Delhi, 1997.
3. Textbook of Pharmaceutical Analysis - K A Connors, 3rd Edition, John Wiley & Sons, 1982.
4. Pharmaceutical Analysis - Higuchi, Brochmman and Hassen, 2nd Edition, Wiley – Inter science Publication, 1961.
5. Quantitative Analysis of Drugs in Pharmaceutical formulation – P D Sethi, 3rd Edition, CBS Publishers New Delhi, 1997.
6. Pharmaceutical Analysis- Modern methods - J W Munson – Part B, Volume 11, Marcel Dekker Series.
7. The Quantitative analysis of Drugs - D C Carratt, 3rd edition, CBS Publishers, NewDelhi, 1964.
8. Indian Pharmacopoeia Vol I , II & III 2007, 2010, 2014.
9. Methods of sampling and microbiological examination of water, first revision, BIS
10. Practical HPLC method development – Snyder, Kirkland, Glajch, 2nd edition, John Wiley & Sons.
11. Analytical Profiles of drug substances – Klaus Florey, Volume 1 – 20, Elsevier, 2005
12. Analytical Profiles of drug substances and Excipients – Harry G Brittan, Volume 21 – 30, Elsevier, 2005.
13. The analysis of drugs in biological fluids - Joseph Chamberlain, 2nd edition, CRC press, London.
14. ICH Guidelines for impurity profiles and stability studies.

PHARMACEUTICAL VALIDATION

(MPA 103T)

Scope

The main purpose of the subject is to understand about validation and how it can be applied to industry and thus to improve the quality of the products. The subject covers the complete information about validation, types, methodology and application.

Objectives

Upon completion of the subject student shall be able to

- Explain the aspect of validation
- Carryout validation of manufacturing processes
- Apply the knowledge of validation to instruments and equipments
- Validate the manufacturing facilities

THEORY **60 Hrs**

1. Introduction: Definition of Qualification and Validation, Advantage of Validation, Streamlining of Qualification & Validation process and Validation Master Plan. — 12 Hrs

   Qualification: User Requirement Specification, Design Qualification, Factory Acceptance Test (FAT)/ Site Acceptance Test (SAT), Installation Qualification, Operational Qualification, Performance Qualification, Re-Qualification (Maintaining status- Calibration Preventive Maintenance, Change management), Qualification of Manufacturing Equipments, Qualification of Analytical Instruments and Laboratory equipments.

2. Qualification of analytical instruments: Electronic balance, pH meter, UV-Visible spectrophotometer, FTIR, GC, HPLC, HPTLC — 12 Hrs

   Qualification of Glassware: Volumetric flask, pipette, Measuring cylinder, beakers and burette.

3. Validation of Utility systems: Pharmaceutical Water System & pure steam, HVAC system, Compressed air and nitrogen. — 12 Hrs

   Cleaning Validation: Cleaning Validation - Cleaning Method development, Validation and validation of analytical method used in cleaning. Cleaning of Equipment, Cleaning of Facilities. Cleaning in place

4. Analytical method validation: General principles, Validation of analytical method as per ICH guidelines and USP. 12 Hrs

   Computerized system validation: Electronic records and digital significance-21 CFR part 11 and GAMP 5.

5. General Principles of Intellectual Property: Concepts of Intellectual Property (IP), Intellectual Property Protection (IPP), Intellectual Property Rights (IPR); Economic importance, mechanism for protection of Intellectual Property – patents, Copyright, Trademark; Factors affecting choice of IP protection;Penalties for violation; Role of IP in pharmaceutical industry;Global ramification and financial implications. Filing a patent applications; patent application forms and guidelines. Types patent applications-provisional and non-provisional, PCT and convention patent applications; International patenting requirement procedures and costs; Rights and responsibilities of a patentee;Practical aspects regarding maintaining of a Patent file; Patent infringement meaning and scope. Significance of transfer technology (TOT), IP and ethics-positive and negative aspects of IPP; Societal responsibility, avoiding unethical practices. 12 Hrs

REFERENCES

1. B. T. Loftus & R. A. Nash, "Pharmaceutical Process Validation", Drugs and Pharm Sci. Series, Vol. 129, 3rd Ed., Marcel Dekker Inc., N.Y.
2. The Theory & Practice of Industrial Pharmacy, 3rd edition, Leon Lachman, Herbert A. Lieberman, Joseph. L. Karig, Varghese Publishing House, Bombay.
3. Validation Master plan by Terveeks or Deeks, Davis Harwood International publishing.
4. Validation of Aseptic Pharmaceutical Processes, 2nd Edition, by Carleton & Agalloco, (Marcel Dekker).
5. Michael Levin, Pharmaceutical Process Scale-Up‖, Drugs and Pharm. Sci. Series, Vol. 157,2nd Ed., Marcel Dekker Inc., N.Y.
6. Validation Standard Operating Procedures: A Step by Step Guide for Achieving Compliance in the Pharmaceutical, Medical Device, and Biotech Industries, Syed Imtiaz Haider
7. Pharmaceutical Equipment Validation: The Ultimate Qualification Handbook, Phillip A. Cloud, Interpharm Press
8. Validation of Pharmaceutical Processes: Sterile Products, Frederick J. Carlton (Ed.) and James Agalloco (Ed.), Marcel Dekker, 2nd Ed.
9. Analytical Method validation and Instrument Performance Verification by Churg Chan, Heiman Lam, Y.C. Lee, Yue. Zhang, Wiley Inter Science.

FOOD ANALYSIS

(MPA 104T)

Scope

This course is designed to impart knowledge on analysis of food constituents and finished food products. The course includes application of instrumental analysis in the determination of pesticides in variety of food products.

Objectives

At completion of this course student shall be able to understand various analytical techniques in the determination of

- Food constituents
- Food additives
- Finished food products
- Pesticides in food
- And also student shall have the knowledge on food regulations and legislations

THEORY **60 Hrs**

1. Carbohydrates: classification and properties of food carbohydrates, General methods of analysis of food carbohydrates, Changes in food carbohydrates during processing, Digestion, absorption and metabolism of carbohydrates, Dietary fibre, Crude fibre and application of food carbohydrates — 12 Hrs

   Proteins: Chemistry and classification of amino acids and proteins, Physico-Chemical properties of protein and their structure, general methods of analysis of proteins and amino acids, Digestion, absorption and metabolism of proteins.

2. Lipids: Classification, general methods of analysis, refining of fats and oils; hydrogenation of vegetable oils, Determination of adulteration in fats and oils, Various methods used for measurement of spoilage of fats and fatty foods. — 12 Hrs

   Vitamins: classification of vitamins, methods of analysis of vitamins, Principles of microbial assay of vitamins of B-series.

3. Food additives: Introduction, analysis of Preservatives, antioxidants, artificial sweeteners, flavors, flavor enhancers, stabilizers, thickening and jelling agents. — 12 Hrs

   Pigments and synthetic dyes: Natural pigments, their occurrence and characteristic properties, permitted synthetic dyes, Non-permitted synthetic

dyes used by industries, Method of detection of natural, permitted and non-permitted dyes.

4. General Analytical methods for milk, milk constituents and milk products like ice cream, milk powder, butter, margarine, cheese including adulterants and contaminants of milk. 12 Hrs

   Analysis of fermentation products like wine, spirits, beer and vinegar.

5. Pesticide analysis: Effects of pest and insects on various food, use of pesticides in agriculture, pesticide cycle, organophosphorus and organochlorine pesticides analysis, determination of pesticide residues in grain, fruits, vegetables, milk and milk products. 12 Hrs

   Legislation regulations of food products with special emphasis on BIS, Agmark, FDA and US-FDA.

REFERENCES

1. The chemical analysis of foods – David Pearson, Seventh edition, Churchill Livingstone, Edinburgh London, 1976
2. Introduction to the Chemical analysis of foods – S. Nielsen, Jones & Bartlett publishers, Boston London, 1994.
3. Official methods of analysis of AOAC International, sixth edition, Volume I & II, 1997.
4. Analysis of Food constituents – Multon, Wiley VCH.
5. Dr. William Horwitz, Official methods of analysis of AOAC International, 18th edition, 2005.

PHARMACEUTICAL ANALYSIS PRACTICALS - II

(MPA 105P)

1. Analysis of Pharmacopoeial compounds and their formulations by UV Vis spectrophotometer
2. Simultaneous estimation of multi component containing formulations by UV spectrophotometry
3. Experiments based on HPLC
4. Experiments based on Gas Chromatography
5. Estimation of riboflavin/quinine sulphate by fluorimetry
6. Estimation of sodium/potassium by flame photometry
7. Assay of official compounds by different titrations
8. Assay of official compounds by instrumental techniques.
9. Quantitative determination of hydroxyl group.
10. Quantitative determination of amino group
11. Colorimetric determination of drugs by using different reagents
12. Impurity profiling of drugs
13. Calibration of glasswares
14. Calibration of pH meter
15. Calibration of UV-Visible spectrophotometer
16. Calibration of FTIR spectrophotometer
17. Calibration of GC instrument
18. Calibration of HPLC instrument
19. Cleaning validation of any one equipment
20. Determination of total reducing sugar
21. Determination of proteins
22. Determination of saponification value, Iodine value, Peroxide value, Acid value in food products
23. Determination of fat content and rancidity in food products
24. Analysis of natural and synthetic colors in food
25. Determination of preservatives in food
26. Determination of pesticide residue in food products
27. Analysis of vitamin content in food products
28. Determination of density and specific gravity of foods
29. Determination of food additives

ADVANCED INSTRUMENTAL ANALYSIS

(MPA 201T)

Scope

This subject deals with various hyphenated analytical instrumental techniques for identification, characterization and quantification of drugs. Instruments dealt are LC-MS, GC-MS, and hyphenated techniques.

Objectives

After completion of course student is able to know,

- interpretation of the NMR, Mass and IR spectra of various organic compounds
- theoretical and practical skills of the hyphenated instruments
- identification of organic compounds

THEORY **60 Hrs**

1. HPLC: Principle, instrumentation, pharmaceutical applications, peak shapes, capacity factor, selectivity, plate number, plate height, resolution, band broadening, pumps, injector, detectors, columns, column problems, gradient HPLC, HPLC solvents, trouble shooting, sample preparation, method development, New developments in HPLC-role and principles of ultra, nano liquid chromatography in pharmaceutical analysis. Immobilized polysaccharide CSP's: Advancement in enantiomeric separations, revised phase Chiral method development and HILIC approaches. HPLC in Chiral analysis of pharmaceuticals. Preparative HPLC, practical aspects of preparative HPLC. — 12 Hrs

2. Biochromatography: Size exclusion chromatography, ion exchange chromatography, ion pair chromatography, affinity chromatography general principles, stationary phases and mobile phases. — 12 Hrs

   Gas chromatography: Principles, instrumentation, derivatization, head space sampling, columns for GC, detectors, quantification.

   High performance Thin Layer chromatography: Principles, instrumentation, pharmaceutical applications.

3. Super critical fluid chromatography: Principles, instrumentation, pharmaceutical applications. — 12 Hrs

   Capillary electrophoresis: Overview of CE in pharmaceutical analysis, basic

configuration, CE characteristics, principles of CE, methods and modes of CE. General considerations and method development in CE, Crown ethers as buffer additives in capillary electrophoresis. CE-MS hyphenation.

4. Mass spectrometry: Principle, theory, instrumentation of mass spectrometry, different types of ionization like electron impact, chemical, field, FAB and MALD, APCI, ESI, APPI mass fragmentation and its rules, meta stable ions, isotopic peaks and applications of mass spectrometry. LC-MS hyphenation and DART MS analysis. Mass analysers (Quadrpole, Time of flight, FT-ICR, ion trap and Orbitrap) instruments. MS/MS systems (Tandem: QqQ, TOF-TOF;Q-IT, Q-TOF, LTQ-FT, LTQ-Orbitrap. 12 Hrs

5. NMR spectroscopy: Quantum numbers and their role in NMR, Principle, Instrumentation, Solvent requirement in NMR, Relaxation process, NMR signals in various compounds, Chemical shift, Factors influencing chemical shift, Spin-Spin coupling, Coupling constant, Nuclear magnetic double resonance, Brief outline of principles of FT-NMR with reference to 13CNMR:Spin spin and spin lattice relaxation phenomenon. 13C NMR, 1-D and 2-D NMR, NOESY and COSY techniques, Interpretation and Applications of NMR spectroscopy. LC-NMR hyphenations. 12 Hrs

REFERENCES

1. Spectrometric Identification of Organic compounds - Robert M Silverstein, Sixth edition, John Wiley & Sons, 2004.
2. Principles of Instrumental Analysis - Doglas A Skoog, F. James Holler, Timothy A. Nieman, 5th edition, Eastern press, Bangalore, 1998.
3. Instrumental methods of analysis – Willards, 7th edition, CBS publishers.
4. Organic Spectroscopy - William Kemp, 3rd edition, ELBS, 1991.
5. Quantitative analysis of Pharmaceutical formulations by HPTLC - P D Sethi, CBS Publishers, New Delhi.
6. Quantitative Analysis of Drugs in Pharmaceutical formulation - P D Sethi, 3rd Edition, CBS Publishers, New Delhi, 1997.
7. Pharmaceutical Analysis- Modern methods – Part B - J W Munson, Volume 11 Marcel Dekker Series, .
8. Organic Spectroscopy by Donald L. Paviya, 5th Edition.

MODERN BIO-ANALYTICAL TECHNIQUES

(MPA 202T)

Scope

This subject is designed to provide detailed knowledge about the importance of analysis of drugs in biological matrices.

Objectives

Upon completion of the course, the student shall be able to understand

- Extraction of drugs from biological samples
- Separation of drugs from biological samples using different techniques
- Guidelines for BA/BE studies.

THEORY **60 Hrs**

1. Extraction of drugs and metabolites from biological matrices: General need, principle and procedure involved in the Bioanalytical methods such as Protein precipitation, Liquid - Liquid extraction and Solid phase extraction and other novel sample preparation approach. — 12 Hrs

   Bioanalytical method validation: USFDA and EMEA guidelines.

2. Biopharmaceutical Consideration: — 12 Hrs

   Introduction, Biopharmaceutical Factors Affecting Drug Bioavailability, In Vitro: Dissolution and Drug Release Testing, Alternative Methods of Dissolution Testing Transport models, Biopharmaceutics Classification System. Solubility: Experimental methods. Permeability: In-vitro, in-situ and In-vivo methods.

3. Pharmacokinetics and Toxicokinetics: — 12 Hrs

   Basic consideration, Drug interaction (PK-PD interactions), The effect of protein-binding interactions, The effect of tissue-binding interactions, Cytochrome P450-based drug interactions, Drug interactions linked to transporters. Microsomal assays Toxicokinetics-Toxicokinetic evaluation in preclinical studies, Importance and applications of toxicokinetic studies. LC-MS in bioactivity screening and proteomics.

4. Cell culture techniques — 12 Hrs

   Basic equipments used in cell culture lab. Cell culture media, various types of cell

culture, general procedure for cell cultures; isolation of cells, subculture, cryopreservation, characterization of cells and their applications. Principles and applications of cell viability assays (MTT assays), Principles and applications of flow cytometry.

5. Metabolite identification: 12 Hrs

In-vitro / in-vivo approaches, protocols and sample preparation. Microsomal approaches (Rat liver microsomes (RLM) and Human liver microsomes (HLM) in Met –ID. Regulatory perspectives.

In-vitro assay of drug metabolites & drug metabolizing enzymes.

Drug Product Performance, In Vivo: Bioavailability and Bioequivalence:

Drug Product Performance, Purpose of Bioavailability Studies, Relative and Absolute Availability. Methods for Assessing Bioavailability, Bioequivalence Studies, Design and Evaluation of Bioequivalence Studies, Study Designs, Crossover Study Designs, Generic Biologics (Biosimilar Drug Products), Clinical Significance of Bioequivalence Studies.

REFERENCES

1. Analysis of drugs in Biological fluids - Joseph Chamberlain, 2nd Edition. CRC Press, Newyork. 1995.
2. Principles of Instrumental Analysis - Doglas A Skoog, F. James Holler, Timothy A. Nieman, 5th edition, Eastern press, Bangalore, 1998.
3. Pharmaceutical Analysis - Higuchi, Brochmman and Hassen, 2nd Edition, Wiley – Interscience Publications, 1961.
4. Pharmaceutical Analysis- Modern methods – Part B - J W Munson, Volume 11 Marcel Dekker Series,
5. Practical HPLC method Development – Snyder, Kirkland, Glaich, 2nd Edition, John Wiley & Sons, New Jercy. USA.
6. Chromatographic Analysis of Pharmaceuticals – John A Adamovics, 2nd Edition, Marcel Dekker, Newyork, USA. 1997.
7. Chromatographic methods in clinical chemistry & Toxicology – Roger L Bertholf, Ruth E Winecker, John Wiley & Sons, New Jercy, USA. 2007.
8. Good Laboratory Practice Regulations, 2nd Edition, Sandy Weinberg Vol. 69, Marcel Dekker Series, 1995.
9. Good laboratory Practice Regulations – Allen F. Hirsch, Volume 38, Marcel Dekker Series, 1989.
10. ICH, USFDA & CDSCO Guidelines.
11. Palmer

QUALITY CONTROL AND QUALITY ASSURANCE

(MPA 203T)

Scope

This course deals with the various aspects of quality control and quality assurance aspects of pharmaceutical industries. It covers the important aspects like cGMP, QC tests, documentation, quality certifications, GLP and regulatory affairs.

Objectives

At the completion of this subject it is expected that the student shall be able to know

- the cGMP aspects in a pharmaceutical industry
- to appreciate the importance of documentation
- to understand the scope of quality certifications applicable to Pharmaceutical industries
- to understand the responsibilities of QA & QC departments

THEORY **60 Hrs**

1. Concept and Evolution of Quality Control and Quality Assurance Good Laboratory Practice, GMP, Overview of ICH Guidelines - QSEM, with special emphasis on Q-series guidelines. — 12 Hrs

   Good Laboratory Practices: Scope of GLP, Definitions, Quality assurance unit, protocol for conduct of nonclinical testing, control on animal house, report preparation and documentation

2. cGMP guidelines according to schedule M, USFDA (inclusive of CDER and CBER) Pharmaceutical Inspection Convention (PIC), WHO and EMEA covering: Organization and personnel responsibilities, training, hygiene and personal records, drug industry location, design, construction and plant lay out, maintenance, sanitation, environmental control, utilities and maintenance of sterile areas, control of contamination and Good Warehousing Practice. CPCSEA guidelines. — 12 Hrs

3. Analysis of raw materials, finished products, packaging materials, in process quality control (IPQC), Developing specification (ICH Q6 and Q3) — 12 Hrs

   Purchase specifications and maintenance of stores for raw materials. In process quality control and finished products quality control for following formulation in Pharma industry according to Indian, US and British pharmacopoeias: tablets,

capsules, ointments, suppositories, creams, parenterals, ophthalmic and surgical products (How to refer pharmacopoeias), Quality control test for containers, closures and secondary packing materials.

4. Documentation in pharmaceutical industry: Three tier documentation, Policy, Procedures and Work instructions, and records (Formats), Basic principles- How to maintain, retention and retrieval etc. Standard operating procedures (How to write), Master Formula Record, Batch Formula Record, Quality audit plan and reports. Specification and test procedures, Protocols and reports. Distribution records. Electronic data. 12 Hrs

5. Manufacturing operations and controls: Sanitation of manufacturing premises, mix-ups and cross contamination, processing of intermediates and bulk products, packaging operations, IPQC, release of finished product, process deviations, charge-in of components, time limitations on production, drug product inspection, expiry date calculation, calculation of yields, production record review, change control, sterile products, aseptic process control, packaging. 12 Hrs

REFERENCES

1. Quality Assurance Guide by organization of Pharmaceutical Procedures of India, 3rd revised edition, Volume I & II, Mumbai, 1996.
2. Good Laboratory Practice Regulations, 2nd Edition, Sandy Weinberg Vol.69, Marcel Dekker Series, 1995.
3. Quality Assurance of Pharmaceuticals- A compedium of Guide lines and Related materials Vol I & II, 2nd edition, WHO Publications, 1999.
4. How to Practice GMP's – P P Sharma, Vandana Publications, Agra, 1991.
5. The International Pharmacopoeia – vol I, II, III, IV & V - General Methods of Analysis and Quality specification for Pharmaceutical Substances, Excepients and Dosage forms, 3rd edition, WHO, Geneva, 2005.
6. Good laboratory Practice Regulations – Allen F. Hirsch, Volume 38, Marcel Dekker Series, 1989.
7. ICH guidelines
8. ISO 9000 and total quality management
9. The drugs and cosmetics act 1940 – Deshpande, Nilesh Gandhi, 4th edition, Susmit Publishers, 2006.
10. QA Manual – D.H. Shah, 1st edition, Business Horizons, 2000.

11. Good Manufacturing Practices for Pharmaceuticals a plan for total quality control – Sidney H. Willig, Vol. 52, 3rd edition, Marcel Dekker Series.
12. Steinborn L. GMP/ISO Quality Audit Manual for Healthcare Manufacturers and Their Suppliers, Sixth Edition, (Volume 1 - With Checklists and Software Package). Taylor & Francis; 2003.
13. Sarker DK. Quality Systems and Controls for Pharmaceuticals. John Wiley & Sons; 2008.

HERBAL AND COSMETIC ANALYSIS

(MPA 204T)

Scope

This course is designed to impart knowledge on analysis of herbal products. Regulatory requirements, herbal drug interaction with monographs. Performance evaluation of cosmetic products is included for the better understanding of the equipments used in cosmetic industries for the purpose.

Objectives

At completion of this course student shall be able to understand

- Determination of herbal remedies and regulations
- Analysis of natural products and monographs
- Determination of Herbal drug-drug interaction
- Principles of performance evaluation of cosmetic products.

THEORY **60 Hrs**

1. Herbal remedies- Toxicity and Regulations: Herbals vs Conventional drugs, Efficacy of herbal medicine products, Validation of Herbal Therapies, Pharmacodynamic and Pharmacokinetic issues. Herbal drug standardization: WHO and AYUSH guidelines. — 12 Hrs

2. Adulteration and Deterioration: Introduction, types of adulteration/substitution of herbal drugs, Causes and Measure of adulteration, Sampling Procedures, Determination of Foreign Matter, DNA Finger printing techniques in identification of drugs of natural origin, heavy metals, pesticide residues, phototoxin and microbial contamination in herbal formulations. — 12 Hrs

   Regulatory requirements for setting herbal drug industry:

   Global marketing management, Indian and international patent law as applicable herbal drugs and natural products and its protocol.

3. Testing of natural products and drugs: Effect of herbal medicine on clinical laboratory testing, Adulterant Screening using modern analytical instruments, Regulation and dispensing of herbal drugs, Stability testing of natural products, protocol. — 12 Hrs

   Monographs of Herbal drugs: Study of monographs of herbal drugs and

comparative study in IP, USP, Ayurvedic Pharmacopoeia, American herbal Pharmacopoeia, British herbal Pharmacopoeia, Siddha and Unani Pharmacopoeia, WHO guidelines in quality assessment of herbal drugs.

4. Herbal drug-drug interaction: WHO and AYUSH guidelines for safety monitoring of natural medicine, Spontaneous reporting schemes for bio drug adverse reactions, bio drug-drug and bio drug-food interactions with suitable examples. Challenges in monitoring the safety of herbal medicines. 12 Hrs

5. Evaluation of cosmetic products: Determination of acid value, ester value, saponification value, iodine value, peroxide value, rancidity, moisture, ash, volatile matter, heavy metals, fineness of powder, density, viscosity of cosmetic raw materials and finished products. Study of quality of raw materials and general methods of analysis of raw material used in cosmetic manufacture as per BIS. 12 Hrs

   Indian Standard specification laid down for sampling and testing of various cosmetics in finished forms such as baby care products, skin care products, dental products, personal hygiene preparations, lips sticks. Hair products and skin creams by the Bureau Indian Standards.

REFERENCES

1. Pharmacognosy by Trease and Evans
2. Pharmacognosy by Kokate, Purohit and Gokhale
3. Quality Control Methods for Medicinal Plant, WHO, Geneva
4. Pharmacognosy & Pharmacobiotechnology by Ashutosh Kar
5. Essential of Pharmacognosy by Dr.S.H.Ansari
6. Cosmetics – Formulation, Manufacturing and Quality Control, P.P. Sharma, 4th edition, Vandana Publications Pvt. Ltd., Delhi
7. Indian Standard specification, for raw materials, BIS, New Delhi.
8. Indian Standard specification for 28 finished cosmetics BIS, New Delhi
9. Harry's Cosmeticology 8th edition
10. Suppliers catalogue on specialized cosmetic excipients
11. Wilkinson, Moore, seventh edition, George Godwin. Poucher's Perfumes, Cosmetics and Soaps
12. Hilda Butler, 10th Edition, Kluwer Academic Publishers. Handbook of Cosmetic Science and Technology, 3rd Edition,

PHARMACEUTICAL ANALYSIS PRACTICALS - I

(MPA 205P)

1. Comparison of absorption spectra by UV and Wood ward – Fiesure rule
2. Interpretation of organic compounds by FT-IR
3. Interpretation of organic compounds by NMR
4. Interpretation of organic compounds by MS
5. Determination of purity by DSC in pharmaceuticals
6. Identification of organic compounds using FT-IR, NMR, CNMR and Mass spectra
7. Bio molecules separation utilizing various sample preparation techniques and Quantitative analysis of components by gel electrophoresis.
8. Bio molecules separation utilizing various sample preparation techniques and Quantitative analysis of components by HPLC techniques.
9. Isolation of analgesics from biological fluids (Blood serum and urine).
10. Protocol preparation and performance of analytical/Bioanalytical method validation.
11. Protocol preparation for the conduct of BA/BE studies according to guidelines.
12. In process and finished product quality control tests for tablets, capsules, parenterals and creams
13. Quality control tests for Primary and secondary packing materials
14. Assay of raw materials as per official monographs
15. Testing of related and foreign substances in drugs and raw materials
16. Preparation of Master Formula Record.
17. Preparation of Batch Manufacturing Record.
18. Quantitative analysis of rancidity in lipsticks and hair oil
19. Determination of aryl amine content and Developer in hair dye
20. Determination of foam height and SLS content of Shampoo.
21. Determination of total fatty matter in creams (Soap, skin and hair creams).
22. Determination of acid value and saponification value.
23. Determination of calcium thioglycolate in depilatories

Semester III

MRM 301T - Research Methodology & Biostatistics

UNIT – I

General Research Methodology: Research, objective, requirements, practical difficulties, review of literature, study design, types of studies, strategies to eliminate errors/bias, controls, randomization, crossover design, placebo, blinding techniques.

UNIT – II

Biostatistics: Definition, application, sample size, importance of sample size, factors influencing sample size, dropouts, statistical tests of significance, type of significance tests, parametric tests(students "t" test, ANOVA, Correlation coefficient, regression), non-parametric tests (wilcoxan rank tests, analysis of variance, correlation, chi square test), null hypothesis, P values, degree of freedom, interpretation of P values.

UNIT – III

Medical Research: History, values in medical ethics, autonomy, beneficence, non-maleficence, double effect, conflicts between autonomy and beneficence/non-maleficence, euthanasia, informed consent, confidentiality, criticisms of orthodox medical ethics, importance of communication, control resolution, guidelines, ethics committees, cultural concerns, truth telling, online business practices, conflicts of interest, referral, vendor relationships, treatment of family members, sexual relationships, fatality.

UNIT – IV

CPCSEA guidelines for laboratory animal facility: Goals, veterinary care, quarantine, surveillance, diagnosis, treatment and control of disease, personal hygiene, location of animal facilities to laboratories, anesthesia, euthanasia, physical facilities, environment, animal husbandry, record keeping, SOPs, personnel and training, transport of lab animals.

UNIT – V

Declaration of Helsinki: History, introduction, basic principles for all medical research, and additional principles for medical research combined with medical care.

2.7 Total number of hour

As mentioned in Course outline (clause 2.4)

2.8 Branches if any, with definition

As mentioned in Syllabus (clause 2.6)

2.9 Teaching Learning methods

A regular record of attendance both in Theory, Practical, Seminar, Assignment, Journal club, Discussion with the supervisor, Research work presentation and Dissertation shall be maintained by the department / teaching staff of respective courses.

2.10 Content of each subject in each year

As mentioned in Syllabus (clause 2.6)

2.11 No: of hours per subject

As mentioned in Syllabus (clause 2.6)

2.12 Practical Training

As mentioned in Course outline (clause 2.4)

2.13 Records

To be maintained for all Practical Work

2.14 Dissertation

As mentioned in Project work to be done (clause 2.16)

2.15 Speciality Training if ANY

As mentioned in Syllabus (clause 2.6)

2.16 Project work to be done if any

All the students shall undertake a project under the supervision of a teacher in Semester III to IV and submit a report. 4 copies of the project report shall be submitted (typed & bound copy not less than 75 pages).

The internal and external examiner appointed by the University shall evaluate the project at the time of the Practical examinations of other semester(s). The projects shall be evaluated as per the criteria given below.

Evaluation of Dissertation Book:

Objective(s) of the work done	50 Marks
Methodology adopted	150 Marks
Results and Discussions	250 Marks
Conclusions and Outcomes	50 Marks
Total	500 Marks

Evaluation of Presentation:

Presentation of work	100 Marks
Communication skills	50 Marks
Question and answer skills	100 Marks
Total	250 Marks

2.17 Any other Requirements [CME, Paper Publishing, etc,.]

As mentioned in Course outline (clause 2.4)

2.18 Prescribed/Recommended textbooks for each subject

As mentioned in Syllabus (clause 2.6)

2.19 Reference books

As mentioned in Syllabus (clause 2.6)

2.20 Journals

All Pharmacy and related Medical Journals

2.21 Logbook

Registers to be maintained

3. EXAMINATION

3.1 Eligibility to appear for exams

A candidate is required to put in at least 80% attendance in individual courses considering theory and practical separately. The candidate shall complete the prescribed course satisfactorily to be eligible to appear for the respective examinations.

3.2 Schedule of Regular / Supplementary exams

Semester examinations will be conducted once in every six months after fulfilling 100 working days.

Table: 6 - Question paper pattern for end semester theory & practical examinations

Question paper pattern for end semester theory examinations			
I.	Long Answers	3 X 10	30 Marks
II.	Short Answers	9 X 5	45 Marks
		Total	**75 Marks**
Question paper pattern for end semester practical examinations			
I.	Synopsis		15 Marks
II.	Experiment - I		40 Marks
III.	Experiment – II		30 Marks
IV.	Viva voce		15 Marks
	Total		**100 Marks**

3.3 Scheme of examination showing maximum marks and minimum marks

The End Semester Examinations for each theory and practical Course through semesters I to IV shall be conducted by the respective university except for the subject with asterisk symbol (*) in table – 8 for which examinations shall be conducted by the subject experts at college level and the marks/grades shall be submitted to the university.

Schemes for internal assessments and end semester examinations are given in table below

Table – 7: Schemes for internal assessments and end semester examinations

Course code	Course	Internal Assessment				End Semester Exams		Total Marks
		Continuous Mode	Sessional Exams		Total	Marks	Duration	
			Marks	Duration				
SEMESTER I								
MPA 101T	Modern Pharmaceutical Analysis	10	15	1 Hr	25	75	3 Hrs	100
MPA 102T	Advanced Pharmaceutical Analysis	10	15	1 Hr	25	75	3 Hrs	100
MPA 103T	Pharmaceutical Validation	10	15	1 Hr	25	75	3 Hrs	100
MPA 104T	Food Analysis	10	15	1 Hr	25	75	3 Hrs	100
MPA 105P	Pharmaceutical Analysis- I	20	30	6 Hrs	50	100	6 Hrs	150
-	Seminar /Assignment	-	-	-	-	-	-	100
Total								650
SEMESTER II								
MPA 201T	Advanced Instrumental Analysis	10	15	1 Hr	25	75	3 Hrs	100
MPA 202T	Modern Bio-Analytical Techniques	10	15	1 Hr	25	75	3 Hrs	100
MPA 203T	Quality Control and Quality Assurance	10	15	1 Hr	25	75	3 Hrs	100
MPA 204T	Herbal and Cosmetic Analysis	10	15	1 Hr	25	75	3 Hrs	100
MPA 205P	Pharmaceutical Analysis – II	20	30	6 Hrs	50	100	6 Hrs	150
-	Seminar /Assignment	-	-	-	-	-	-	100
Total								650

Table – 8: Schemes for internal assessments and end semester examinations

(Semester III& IV)

Course code	Course	Internal Assessment				End Semester Exams		Total Marks
		Continuous Mode	Sessional Exams		Total	Marks	Duration	
			Marks	Duration				
SEMESTER III								
MRM 301T	Research Methodology and Biostatistics*	10	15	1 Hr	25	75	3 Hrs	100
-	Journal Club	-	-	-	25	-	-	25
-	Discussion / Presentation (proposal presentation)	-	-	-	50	-	-	50
-	Research Work*	-	-	-	-	350	1 Hr	350
Total								525
SEMESTER IV								
-	Journal club	-	-	-	25	-	-	25
-	Discussion / Presentation (proposal presentation)	-	-	-	75	-	-	75
-	Research Work and Colloquium	-	-	-	-	400	1 Hr	400
Total								500

*Non University Examination

Table – 9: Scheme for awarding internal assessment

Theory	
Criteria	**Maximum Marks**
Attendance (Refer Table – 10)	8
Student – Teacher interaction	2
Total	10
Practical	
Attendance (Refer Table – 10)	10
Based on Practical Records, Regular viva voce, etc.	10
Total	20

Table – 10: Guidelines for the allotment of marks for attendance

Percentage of Attendance	Theory	Practical
95 – 100	8	10
90 – 94	6	7.5
85 – 89	4	5
80 – 84	2	2.5
Less than 80	0	0

Allowed to keep terms (ATKT):

No student shall be admitted to any examination unless he/she fulfills the norms given in clause 3.1. ATKT rules are applicable as follows:

A student shall be eligible to carry forward all the courses of I and II semesters till the III semester examinations. However, he/she shall not be eligible to attend the courses of IV semester until all the courses of I, II and III semesters are successfully completed.

A student shall be eligible to get his/her CGPA upon successful completion of the courses of I to IV semesters within the stipulated time period as per the norms.

Note: Grade AB should be considered as failed and treated as one head for deciding ATKT. Such rules are also applicable for those students who fail to register for examination(s) of any course in any semester.

Grading of performances

a) Letter grades and grade points allocations:

Based on the performances, each student shall be awarded a final letter grade at the end of the semester for each course. The letter grades and their corresponding grade points are given in Table – 11.

Table – 11: Letter grades and grade points equivalent to Percentage of marks and performances

Percentage of Marks obtained	Letter Grade	Grade point	Performance
90.00 – 100	O	10	Outstanding
80.00 – 89.99	A	9	Excellent
70.00 – 79.99	B	8	Good
60.00 – 69.99	C	7	Fair
50.00 – 59.99	D	6	Average
Less than 50	F	0	Fail
Absent	AB	0	Fail

A learner who remains absent for any end semester examination shall be assigned a letter grade of AB and a corresponding grade point of zero. He/she should reappear for the said evaluation/examination in due course.

b) The Semester grade point average (SGPA)

The performance of a student in a semester is indicated by a number called 'Semester Grade Point Average' (SGPA). The SGPA is the weighted average of the grade points obtained in all the courses by the student during the semester. For example, if a student takes five courses (Theory/Practical) in a semester with credits C1, C2, C3 and C4 and the student's grade points in these courses are G1, G2, G3 and G4, respectively, and then students' SGPA is equal to:

$$SGPA = \frac{C_1G_1 + C_2G_2 + C_3G_3 + C_4G_4}{C_1 + C_2 + C_3 + C_4}$$

The SGPA is calculated to two decimal points. It should be noted that, the SGPA for any semester shall take into consideration the F and ABS grade awarded in that semester. For example if a learner has a F or ABS grade in course 4, the SGPA shall then be computed as:

$$SGPA = \frac{C_1G_1 + C_2G_2 + C_3G_3 + C_4*ZER0}{C_1 + C_2 + C_3 + C_4}$$

c) Cumulative Grade Point Average (CGPA)

The CGPA is calculated with the SGPA of all the IV semesters to two decimal points and is indicated in final grade report card/final transcript showing the grades of all IV semesters and their courses. The CGPA shall reflect the failed status in case of F grade(s), till the course(s) is/are passed. When the course(s) is/are passed by obtaining a pass grade on subsequent examination(s) the CGPA shall only reflect the new grade and not the fail grades earned earlier.The CGPA is calculated as:

$$CGPA = \frac{C_1S_1 + C_2S_2 + C_3S_3 + C_4S_4}{C_1 + C_2 + C_3 + C_4}$$

where C_1, C_2, C_3,…. is the total number of credits for semester I,II,III,…. And S_1, S_2, S_3… is the SGPA of semester I, II, III…. .

3.4 Papers in each year

As mentioned in Course outline (clause 2.4)

3.5 Details of theory exams

As mentioned in Schedule of regular / Supplementary Exams (clause 3.2)

3.6 Model question paper for each subject with question paper pattern

As mentioned in Schedule of regular / Supplementary Exams (clause 3.2)See Annexure

3.7 Internal assessment component

As mentioned in Scheme of examination. (Clause 3.3)

- Two sessional exams shall be conducted for each theory / practical course as per the schedule fixed by the college(s). The average marks of two sessional exams shall be computed for internal assessment as per the requirements
- A student shall have the opportunity to improve his/her performance only once in the sessional exam component of the internal assessment. The re-conduct of the sessional exam shall be completed before the commencement of next end semester theory examinations.

3.8 Details of practical / clinical practicum exams.

As mentioned in Schedule of regular / Supplementary Exams (clause 3.2) Scheme of examination. (Clause 3.3)

3.9 Number of examiners (Internal & External) and their qualifications

- A post graduate (PG) degree in M. Pharm shall be eligible as teacher.
- A post graduate degree in M. Pharm with 5 years Post PG experience is eligible as internal examiner.
- A post graduate degree in M. Pharm with 10 years Post PG is eligible as external examiner.
- A post graduate degree in M. Pharm with 5 years Post PG is eligible to guide maximum of 5 candidates for M. Pharm dissertation.

For the evaluation of Practical Examination of I & II semesters one internal and one external examiner shall be appointed by the University. Details of project evaluation are given under clause 2.16

3.10 Details of viva:

As mentioned in Schedule of regular / Supplementary Exams (clause 3.2) Scheme of examination. (Clause 3.3)

4. INTERNSHIP

Not applicable

5. ANNEXURES

5.1 Check Lists for Monitoring:

Log Book, Seminar Assessment etc. to be formulated by the curriculum committee of the concerned Institution.

Q P CODE REG NO

MODEL QUESTION PAPER
M.PHARM PHARMACEUTICAL ANALYSIS

FIRST SEMESTER M'PHARM DEGREE EXAMINATIONS

PAPER – I – MODERN PHARMACEUTICAL ANALYTICAL TECHNIQUES (MPA 101T)

- answer all questions

Time: 3 hours Maximum: Marks: 75

Essay s (3x10=30)

1. Explain the theory of fluorescence. What are the factors affecting fluorescence ?
2. Classify chromatographic methods based on mechanism of separation and add a note on column chromatography
3. What is the principle of NMR spectroscopy? What are its applications.

Short notes (9X5=45)

4. Compare flame emission and atomic absorption spectroscopy
5. Discuss about gel electrophoresis
6. What is Bragg's law? Describe rotating crystal technique in x-ray crystallography.
7. Write a note on ion selective electrodes
8. Discuss about the principle and instrumentation of differential thermal analysis
9. Briefly explain the principle and working of potentiometer
10. Write about MALDI. Explain principle and applications of MALDI
11. Sample handing techniques in IR spectroscopy
12. Write briefly on derivative UV spectroscopy

Q P CODE REG NO

MODEL QUESTION PAPER
M.PHARM PHARMACEUTICAL ANALYSIS

FIRST SEMESTER M'PHARM DEGREE EXAMINATIONS

PAPER – II – ADVANCED PHARMACEUTICAL ANALYSIS(MPA102T)

- answer all questions

Time: 3 hours Maximum: Marks: 75

Essay s (3x10=30)

1. What are the methods of quantification of impurities as per ICH guidelines?
2. What are the protocols for selection of batches and sampling frequency for stability testing?
3. What are the biological tests for assay of adsorbed tetanus vaccine?

Short notes (9x5=45)

4. Methods of production of antibodies in immunoassays
5. What are the photo stability guidelines?
6. Give the importance of HPTLC finger printing in stability testing of phyto pharmaceuticals
7. Classify residual solvents and what are their limits?
8. Discuss about analysis of nitrogen and sulphur as impurities
9. What are the ICH stability guide lines for biological products?
10. Discuss on the stability related information provided by results of temperature on the reaction rates
11. Write a note on accelerated stability testing
12. Assay of oxytocin

Q P CODE REG NO

MODEL QUESTION PAPER
M.PHARM PHARMACEUTICAL ANALYSIS

FIRST SEMESTER M'PHARM DEGREE EXAMINATIONS

PAPER – III –PHARMACEUTICAL VALIDATION (MPA103T)

- answer all questions

Time: 3 hours Maximum: Marks: 75

Essays (3x10=30)

1. Describe FTIR and PH meter
2. How the analytical method used in cleaning of equipments validation ?
3. Describe the procedure and guidelines for applying for an Indian patent

Short notes (9x5=45)

4. Short note on qualification of manufacturing equipments ?
5. How can glass wares like volumetric flask and pipette be validated ?
6. Discuss on HVAC system?
7. Note on installation qualification?
8. Computerizes system validation in pharmaceutical industry?
9. Significance of transfer technology?
10. Discuss factory acceptance test?
11. Cleaning facility in pharmaceutical manufacturing firm. Give a brief account
12. HPLC finger printing ?

Q P CODE REG NO

MODEL QUESTION PAPER
M.PHARM PHARMACEUTICAL ANALYSIS

FIRST SEMESTER M'PHARM DEGREE EXAMIN
PAPER – IV – FOOD ANALYSIS (MPA 104 T)

Time: 3 hours Maximum: Marks: 75

- answer all questions

Essays (10x3=30)

1. What are the general methods of analysis of food carbohydrates?
2. Write about natural pigments and their characteristic properties
3. Write about the analysis of wine and beer

Short notes (9x5=45)

4. Classify proteins. How are proteins digested and absorbed?
5. Write a note on microbial assay of B complex vitamins
6. What are the methods for measurement of spoilage of fats?
7. Write about thickening agents as food additives
8. What are the permitted synthetic drugs used by food industries? What are their methods of detection?
9. What are the general analytical methods for milk powder?
10. How is the analysis of organo phosphorous pesticides done?
11. What are the effects of pests on various food items?
12. What are the changes occurring in food carbohydrates during processing?

REGULATIONS2017

Syllabus

Kerala University of Health Sciences

Thrissur - 680596

POST GRADUATE COURSE IN PHARMACY

Master of Pharmacy

(M.Pharm. Pharmacology)

Course code: 280

(2017-18 Academic year onwards)

2017

2. COURSE CONTENT

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2.9	**Teaching learning methods**	
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2.11	**No: of hours per subject**	
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3. EXAMINATIONS

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4. INTERNSHIP

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2. COURSE CONTENT

2.1 Title of course

These regulations shall be called as "Master of Pharmacy (M.Pharm. – Pharmacology) Degree Program - Credit Based Semester System (CBSS) of the Kerala University of Health sciences. They shall come into effect from the Academic Year 2017-18 onwards. The regulations framed are subject to modifications from time to time by the authorities of the University.

2.2 Objectives of course

To generate Pharmacy Post Graduates with profound knowledge in various branches of Pharmaceutical Sciences to meet with the rapidly increasing demands put forward by-

- Pharmaceutical Manufacturing
- Pharmaceutical Research & Development
- Pharmacological research including preclinical & clinical studies.
- Herbal Drug Research
- Pharmaceutical & Herbal Drug Analysis
- Clinical Toxicology & Toxicological Analysis

To discover the potential to become faculty in Pharmaceutical Sciences with unmatched quality and excellence, so as to educate the future pharmacy generation (Undergraduate, Post graduate, and Doctoral).

2.3 Medium of Instruction

Medium of instruction and examination shall be in English.

2.4 Course Outline

The specialization in M.Pharm. Program is given in Table 1.

Table – 1: M.Pharm. Specialization and its code

S.No	Specialization	Code
1.	Pharmacology	MPL

The course of study for M.Pharm Pharmacology shall include Semester wise Theory & Practical as given in Table – 2 & 3. The number of hours to be devoted to each theory and practical course in any semester shall not be less than that shown in Table – 2 & 3.

Table – 2: Course of study for M.Pharm. I & II Semester

Course Code	Course	Credit Hours	Credit Points	Hrs./wk	Marks
Semester I					
MPL 101T	Modern Pharmaceutical Analytical Techniques	4	4	4	100
MPL 102T	Advanced Pharmacology-I	4	4	4	100
MPL 103T	Pharmacological and Toxicological Screening Methods-I	4	4	4	100
MPL 104T	Cellular and Molecular Pharmacology	4	4	4	100
MPL 105P	Experimental Pharmacology –I	12	6	12	150
-	Seminar /Assignment	7	4	7	100
Total		35	26	35	650
Semester II					
MPL 201T	Advanced Pharmacology II	4	4	4	100
MPL 202T	Pharmacological and Toxicological Screening Methods –II	4	4	4	100
MPL 203T	Principles of Drug Discovery	4	4	4	100
MPL 204T	Clinical research and Pharmacovigilance	4	4	4	100
MPL 205P	Experimental Pharmacology -II	12	6	12	150
-	Seminar /Assignment	7	4	7	100
Total		35	26	35	650

Table – 3: Course of study for M. Pharm. III & IV Semester

Course Code	Course	Credit Hours	Credit Points
Semester III			
MRM 301T	Research Methodology and Biostatistics*	4	4
-	Journal Club	1	1
-	Discussion / Presentation (proposal presentation)	2	2
-	Research Work*	28	14
Total		35	21
Semester IV			
-	Journal Club	1	1
-	Research Work	31	16
-	Discussion / Final Presentation	3	3
Total		35	20

*Non University Exam

Program/Course credit structure

As per the philosophy of Credit Based Semester System, certain quantum of academic work viz. theory classes, practical classes, seminars, assignments, etc. are measured in terms of credits. On satisfactory completion of the courses, a candidate earns credits. The amount of credit associated with a course is dependent upon the number of hours of instruction per week in that course. Similarly the credit associated with any of the other academic, co/extracurricular activities is dependent upon the quantum of work expected to be put in for each of these activities per week/per activity.

Credit assignment

a) Theory and Laboratory courses

Courses are broadly classified as Theory and Practical. Theory courses consist of lecture (L) and Practical (P) courses consist of hours spent in the laboratory. Credits (C) for a course is dependent on the number of hours of instruction per week in that course, and is obtained by using a multiplier of one (1) for lecture and a multiplier of half (1/2) for practical (laboratory) hours. Thus, for example, a theory course having four lectures per week throughout the semester carries a credit of 4. Similarly, a practical having four laboratory hours per week throughout semester carries a credit of 2. The contact hours of seminars, assignments and research work shall be treated as that of practical courses for the purpose of calculating credits. i.e., the contact hours shall be multiplied by 1/2. Similarly, the contact hours of journal club, research work presentations and discussions with the supervisor shall be considered as theory course and multiplied by 1.

b) Minimum credit requirements

The minimum credit points required for the award of M. Pharm. degree is 95. However based on the credit points earned by the students under the head of co-curricular activities, a student shall earn a maximum of 100 credit points. These credits are divided into Theory courses, Practical, Seminars, Assignments, Research work, Discussions with the supervisor, Journal club and Co-Curricular activities over the duration of four semesters. The credits are distributed semester-wise as shown in Table 4. Courses generally progress in sequence, building competencies and their positioning indicates certain academic maturity on the part of the learners. Learners are expected to follow the semester-wise schedule of courses given in the syllabus.

Table – 4: Semester wise credits distribution

Semester	Credit Points
I	26
II	26
III	21
IV	20
Co-curricular Activities (attending Conference, Scientific Presentations and other scholarly Activities)	Minimum = 02 Maximum = 07*
Total Credit Points	Minimum = 95 Maximum = 100

*Credit points for Co-curricular Activities

Table – 5: Guidelines for Awarding Credit Points for Co-curricular Activities

Name of the Activity	MaximumCredit Points Eligible / Activity
Participation in National Level Seminar/ Conference/ Workshop / Symposium / Training Programs (related to the specialization of the student)	01
Participation in international Level Seminar/ Conference/ Workshop/ Symposium/ Training Programs (related to the specialization of the student)	02
Academic Award/Research Award from State Level/ National Agencies	01
Academic Award/Research Award from International Agencies	02
Research / Review Publication in National Journals (Indexed in Scopus / Web of Science)	01
Research / Review Publication in International Journals (Indexed in Scopus / Web of Science)	02

Note: International Conference: Held outside India

International Journal: The Editorial Board outside India

*The credit points assigned for extracurricular and or co-curricular activities shall be given by the Principals of the colleges and the same shall be submitted to the University. The criteria to acquire this credit point shall be defined by the colleges from time to time.

Program Committee

1. The M. Pharm. programme shall have a Programme Committee constituted by the Head of the institution in consultation with all the Heads of the departments.
2. The composition of the Programme Committee shall be as follows:
   A teacher at the cadre of Professor shall be the Chairperson; One Teacher from each M.Pharm specialization and four student representatives (two from each academic year), nominated by the Head of the institution.
3. Duties of the Programme Committee:
   i. Periodically reviewing the progress of the classes.
   ii. Discussing the problems concerning curriculum, syllabus and the conduct of classes.
   iii. Discussing with the course teachers on the nature and scope of assessment for the course and the same shall be announced to the students at the beginning of respective semesters.
   iv. Communicating its recommendation to the Head of the institution on academic matters.
   v. The Programme Committee shall meet at least twice in a semester preferably at the end of each sessional exam and before the end semester exam.

2.5 Duration

The program of study for M.Pharm. shall extend over a period of four semesters (two academic years). The curricula and syllabi for the program shall be prescribed from time to time by the Kerala University of Health sciences.

The duration for the completion of the program shall be fixed as double the actual duration of the program and the students have to pass within the said period, otherwise they have to get fresh Registration.

2.6 Syllabus

PHARMACOLOGY (MPL)

MODERN PHARMACEUTICAL ANALYTICAL TECHNIQUES

(MPL 101T)

Scope

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

Objectives

After completion of course student is able to know about,

- Chemicals and Excipients
- The analysis of various drugs in single and combination dosage forms
- Theoretical and practical skills of the instruments

THEORY **60 Hrs**

1. UV-Visible spectroscopy: Introduction, Theory, Laws, Instrumentation associated with UV-Visible spectroscopy, Choiceof solvents and solvent effect and Applications of UV-Visible spectroscopy, Difference/ Derivative spectroscopy. 10 Hrs

   IR spectroscopy: Theory, Modes of Molecular vibrations, Sample handling, Instrumentation of Dispersive and Fourier - TransformIR Spectrometer, Factors affecting vibrational frequencies and Applications of IR spectroscopy, Data Interpretation.

   Spectroflourimetry: Theory of Fluorescence, Factors affecting fluorescence (Characterestics of drugs that can be analysed by flourimetry), Quenchers, Instrumentation and Applications of fluorescence spectrophotometer.

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

2. NMR spectroscopy: Quantum numbers and their role in NMR, Principle, Instrumentation, Solvent requirement in NMR, Relaxation process, NMR signals in various compounds, Chemical shift, Factors influencing chemical shift, Spin-Spin coupling, Coupling constant, Nuclear magnetic double resonance, Brief 10 Hrs

outline of principles of FT-NMR and 13C NMR. Applications of NMR spectroscopy.

3. Mass Spectroscopy: Principle, Theory, Instrumentation of Mass Spectroscopy, Different types of ionization like electron impact, chemical, field, FAB and MALDI, APCI, ESI, APPI Analyzers of Quadrupole and Time of Flight, Mass fragmentation and its rules, Meta stable ions, Isotopic peaks and Applications of Mass spectroscopy. 10 Hrs

4. Chromatography: Principle, apparatus, instrumentation, chromatographic parameters, factors affecting resolution, isolation of drug from excipients, data interpretation and applications of the following: 10 Hrs

   a) Thin Layer chromatography
   b) High Performance Thin Layer Chromatography
   c) Ion exchange chromatography
   d) Column chromatography
   e) Gas chromatography
   f) High Performance Liquid chromatography
   g) Ultra High Performance Liquid chromatography
   h) Affinity chromatography
   i) Gel Chromatography

5. Electrophoresis: Principle, Instrumentation, Working conditions, factors affecting separation and applications of the following: 10 Hrs

   a) Paper electrophoresis b) Gel electrophoresis c) Capillary electrophoresis d) Zone electrophoresis e) Moving boundary electrophoresis f) Iso electric focusing

   X ray Crystallography: Production of X rays, Different X ray methods, Bragg's law, Rotating crystal technique, X ray powder technique, Types of crystals and applications of X-ray diffraction.

6. Potentiometry: Principle, working, Ion selective Electrodes and Application of potentiometry. 10 Hrs

   Thermal Techniques: Principle, thermal transitions and Instrumentation (Heat

flux and power-compensation and designs), Modulated DSC, Hyper DSC, experimental parameters (sample preparation, experimental conditions, calibration, heating and cooling rates, resolution, source of errors) and their influence, advantage and disadvantages, pharmaceutical applications. Differential Thermal Analysis (DTA): Principle, instrumentation and advantage and disadvantages, pharmaceutical applications, derivative differential thermal analysis (DDTA). TGA: Principle, instrumentation, factors affecting results, advantage and disadvantages, pharmaceutical applications.

REFERENCES

1. Spectrometric Identification of Organic compounds - Robert M Silverstein, Sixth edition, John Wiley & Sons, 2004.
2. Principles of Instrumental Analysis - Doglas A Skoog, F. James Holler, Timothy A. Nieman, 5th edition, Eastern press, Bangalore, 1998.
3. Instrumental methods of analysis – Willards, 7th edition, CBS publishers.
4. Practical Pharmaceutical Chemistry – Beckett and Stenlake, Vol II, 4th edition, CBS Publishers, New Delhi, 1997.
5. Organic Spectroscopy - William Kemp, 3rd edition, ELBS, 1991.
6. Quantitative Analysis of Drugs in Pharmaceutical formulation - P D Sethi, 3rd Edition, CBS Publishers, New Delhi, 1997.
7. Pharmaceutical Analysis - Modern Methods – Part B - J W Munson, Vol 11, Marcel. Dekker Series
8. Spectroscopy of Organic Compounds, 2nd edn., P.S/Kalsi, Wiley estern Ltd Delhi, .
9. Textbook of Pharmaceutical Analysis, KA.Connors, 3rd Edition, John Wiley & Sons, 1982.

ADVANCED PHARMACOLOGY - I

(MPL 102T)

Scope

The subject is designed to strengthen the basic knowledge in the field of pharmacology and to impart recent advances in the drugs used for the treatment of various diseases. In addition, this subject helps the students to understand the concepts of drug action and mechanisms involved

Objectives

Upon completion of the course the student shall be able to :

- Discuss the pathophysiology and pharmacotherapy of certain diseases
- Explain the mechanism of drug actions at cellular and molecular level
- Understand the adverse effects, contraindications and clinical uses of drugs used in treatment of diseases

THEORY **60 Hrs**

1. General Pharmacology — 12 Hrs

   a. Pharmacokinetics: The dynamics of drug absorption, distribution, biotransformation and elimination. Concepts of linear and non-linear compartment models. Significance of Protein binding.

   b. Pharmacodynamics: Mechanism of drug action and the relationship between drug concentration and effect. Receptors, structural and functional families of receptors, quantitation of drug receptors interaction and elicited effects.

2. Neurotransmission — 12 Hrs

   a. General aspects and steps involved in neurotransmission.

   b. Neurohumoral transmission in autonomic nervous system (Detailed study about neurotransmitters- Adrenaline and Acetyl choline).

   c. Neurohumoral transmission in central nervous system (Detailed study about neurotransmitters- histamine, serotonin, dopamine, GABA, glutamate and glycine].

   d. Non adrenergic non cholinergic transmission (NANC). Co- transmission

   Systemic Pharmacology

A detailed study on pathophysiology of diseases, mechanism of action, pharmacology and toxicology of existing as well as novel

drugs used in the following systems

Autonomic Pharmacology

Parasympathomimetics and lytics, sympathomimetics and lytics, agents affecting

neuromuscular junction

3. Central nervous system Pharmacology — 12 Hrs

General and local anesthetics

Sedatives and hypnotics, drugs used to treat anxiety.

Depression, psychosis, mania, epilepsy, neurodegenerative diseases.

Narcotic and non-narcotic analgesics.

4. Cardiovascular Pharmacology — 12 Hrs

Diuretics, antihypertensives, antiischemics, anti- arrhythmics, drugs for heart failure and hyperlipidemia.

Hematinics, coagulants , anticoagulants, fibrinolytics and anti- platelet drugs

5. Autocoid Pharmacology — 12 Hrs

The physiological and pathological role of Histamine, Serotonin, Kinins Prostaglandins Opioid autocoids.Pharmacology of antihistamines, 5HT antagonists.

REFEERENCES

1. The Pharmacological Basis of Therapeutics, Goodman and Gillman‘s
2. Principles of Pharmacology. The Pathophysiologic basis of drug Therapy by David E Golan, Armen H, Tashjian Jr, Ehrin J,Armstrong, April W, Armstrong, Wolters, Kluwer-Lippincott Williams & Wilkins Publishers.
3. Basic and Clinical Pharmacology by B.G Katzung
4. Hand book of Clinical Pharmacokinetics by Gibaldi and Prescott.
5. Applied biopharmaceutics and Pharmacokinetics by Leon Shargel and Andrew B.C Yu..
6. Graham Smith. Oxford textbook of Clinical Pharmacology.
7. Avery Drug Treatment
8. Dipiro Pharmacology, Pathophysiological approach.

9. Green Pathophysiology for Pharmacists.
10. Robbins & Cortan Pathologic Basis of Disease, 9th Ed. (Robbins Pathology)
11. A Complete Textbook of Medical Pharmacology by Dr. S.K Srivastava published by APC Avichal Publishing Company
12. KD.Tripathi. Essentials of Medical Pharmacology.
13. Modern Pharmacology with Clinical Applications, Craig Charles R. & Stitzel Robert E., Lippincott Publishers.
14. Clinical Pharmacokinetics & Pharmacodynamics : Concepts and Applications – Malcolm Rowland and Thomas N.Tozer, Wolters Kluwer, Lippincott Williams & Wilkins Publishers.
15. Applied biopharmaceutics and Pharmacokinetics, Pharmacodynamics and Drug metabolism for industrial scientists.
16. Modern Pharmacology, Craig CR. & Stitzel RE, Little Brown & Company.

PHARMACOLOGICAL AND TOXICOLOGICAL SCREENING METHODS - I

(MPL 103T)

Scope

This subject is designed to impart the knowledge on preclinical evaluation of drugs and recent experimental techniques in the drug discovery and development. The subject content helps the student to understand the maintenance of laboratory animals as per the guidelines, basic knowledge of various in-vitro and in-vivo preclinical evaluation processes

Objectives

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

- Appraise the regulations and ethical requirement for the usage of experimental animals.
- Describe the various animals used in the drug discovery process and good laboratory practices in maintenance and handling of experimental animals
- Describe the various newer screening methods involved in the drug discovery process
- Appreciate and correlate the preclinical data to humans

THEORY **60 Hrs**

1. Laboratory Animals — 12 Hrs

   Common laboratory animals: Description, handling and applications of different species and strains of animals.

   Transgenic animals: Production, maintenance and applications Anaesthesia and euthanasia of experimental animals.Maintenance and breeding of laboratory animals.CPCSEA guidelines to conduct experiments on animals.

   Good laboratory practice.

   Bioassay-Principle, scope and limitations and methods

2. Preclinical screening of new substances for the pharmacological activity using in vivo, in vitro, and other possible animal alternative models. — 12 Hrs

   General principles of preclinical screening. CNS Pharmacology: behavioral and muscle co ordination, CNS stimulants and depressants, anxiolytics, anti-psychotics, anti epileptics and nootropics. Drugs for neurodegenerative diseases

like Parkinsonism, Alzheimers and multiple sclerosis. Drugs acting on Autonomic Nervous System.

3. Preclinical screening of new substances for the pharmacological activity using in vivo, in vitro, and other possible animal alternative models. 12 Hrs

   Respiratory Pharmacology: anti-asthmatics, drugs for COPD and anti allergics. Reproductive Pharmacology: Aphrodisiacs and antifertility agents Analgesics, antiinflammatory and antipyretic agents. Gastrointestinal drugs: anti ulcer, anti - emetic, anti- diarrheal and laxatives.

4. Preclinical screening of new substances for the pharmacological activity using in vivo, in vitro, and other possible animal alternative models. 12 Hrs

   Cardiovascular Pharmacology: antihypertensives, antiarrythmics, antianginal, antiatherosclerotic agents and diuretics. Drugs for metabolic disorders like anti-diabetic, antidyslipidemic agents. Anti cancer agents. Hepatoprotective screening methods.

5. Preclinical screening of new substances for the pharmacological activity using in vivo, in vitro, and other possible animal alternative models. 12 Hrs

   Iimmunomodulators, Immunosuppressants and immunostimulants

   General principles of immunoassay: theoretical basis and optimization of immunoassay, heterogeneous and homogenous immunoassay systems. Immunoassay methods evaluation;protocol outline, objectives and preparation. Immunoassay for digoxin and insulin

   Limitations of animal experimentation and alternate animal experiments.

   Extrapolation of in vitro data to preclinical and preclinical to humans

REFERENCES

1. Biological standardization by J.H. Burn D.J. Finney and I.G. Goodwin
2. Screening methods in Pharmacology by Robert Turner. A
3. Evaluation of drugs activities by Laurence and Bachrach
4. Methods in Pharmacology by Arnold Schwartz.
5. Fundamentals of experimental Pharmacology by M.N.Ghosh
6. Pharmacological experiment on intact preparations by Churchill Livingstone
7. Drug discovery and Evaluation by Vogel H.G.
8. Experimental Pharmacology by R.K.Goyal.

9. Preclinical evaluation of new drugs by S.K. Guta
10. Handbook of Experimental Pharmacology, SK.Kulkarni
11. Practical Pharmacology and Clinical Pharmacy, SK.Kulkarni, 3rd Edition.
12. David R.Gross. Animal Models in Cardiovascular Research, 2nd Edition, Kluwer Academic Publishers, London, UK.
13. Screening Methods in Pharmacology, Robert A.Turner.
14. Rodents for Pharmacological Experiments, Dr.Tapan Kumar chatterjee.
15. Practical Manual of Experimental and Clinical Pharmacology by Bikash Medhi (Author), Ajay Prakash (Author)

CELLULAR AND MOLECULAR PHARMACOLOGY

(MPL 104T)

Scope:

The subject imparts a fundamental knowledge on the structure and functions of cellular components and help to understand the interaction of these components with drugs. This information will further help the student to apply the knowledge in drug discovery process.

Objectives:

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

- Explain the receptor signal transduction processes.
- Explain the molecular pathways affected by drugs.
- Appreciate the applicability of molecular pharmacology and biomarkers in drug discovery process.
- Demonstrate molecular biology techniques as applicable for pharmacology

THEORY **60 Hrs**

1. Cell biology 12 Hrs

   Structure and functions of cell and its organellesGenome organization. Gene expression and its regulation, importance of siRNA and micro RNA, gene mapping and gene sequencing

   Cell cycles and its regulation.

   Cell death– events, regulators, intrinsic and extrinsic pathways of apoptosis.

   Necrosis and autophagy.

2. Cell signaling 12 Hrs

   Intercellular and intracellular signaling pathways.

   Classification of receptor family and molecular structure ligand gated ion channels; G-protein coupled receptors, tyrosine kinase receptors and nuclear receptors.

   Secondary messengers: cyclic AMP, cyclic GMP, calcium ion, inositol 1,4,5-trisphosphate, (IP3), NO, and diacylglycerol.Detailed study of following intracellular signaling pathways: cyclic AMP signaling pathway, mitogen-

activated protein kinase (MAPK)signaling, Janus kinase (JAK)/signal transducer and activator of transcription (STAT) signaling pathway.

3.	Principles and applications of genomic and proteomic tools DNA electrophoresis, PCR (reverse transcription and real time), Gene sequencing, micro array technique, SDS page, ELISA and western blotting, Recombinant DNA technology and gene therapy Basic principles of recombinant DNA technology-Restriction enzymes, various types of vectors. Applications of recombinant DNA technology. Gene therapy- Various types of gene transfer techniques, clinical applications and recent advances in gene therapy.	12 Hrs
4.	Pharmacogenomics Gene mapping and cloning of disease gene. Genetic variation and its role in health/ pharmacology Polymorphisms affecting drug metabolism Genetic variation in drug transporters Genetic variation in G protein coupled receptors Applications of proteomics science: Genomics, proteomics, metabolomics, functionomics, nutrigenomics Immunotherapeutics Types of immunotherapeutics, humanisation antibody therapy, Immunotherapeutics in clinical practice	12 Hrs
5.	a. Cell culture techniques Basic equipments used in cell culture lab. Cell culture media, various types of cell culture, general procedure for cell cultures;isolation of cells, subculture, cryopreservation, characterization of cells and their application. Principles and applications of cell viability assays, glucose uptake assay, Calcium influx assays Principles and applications of flow cytometry b. Biosimilars	12 Hrs

REFERENCES:

1. The Cell, A Molecular Approach. Geoffrey M Cooper.
2. Pharmacogenomics: The Search for Individualized Therapies. Edited by J. Licinio and M -L. Wong
3. Handbook of Cell Signaling (Second Edition) Edited by Ralph A. et.al
4. Molecular Pharmacology: From DNA to Drug Discovery. John Dickenson et.al
5. Basic Cell Culture protocols by Cheril D.Helgason and Cindy L.Miller
6. Basic Cell Culture (Practical Approach) by J. M. Davis (Editor)
7. Animal Cell Culture: A Practical Approach by John R. Masters (Editor)
8. Current porotocols in molecular biology vol I to VI edited by Frederick M.Ausuvel et la.

PHARMACOLOGICAL PRACTICAL - I

(MPL 105P)

1. Analysis of pharmacopoeial compounds and their formulations by UV Vis spectrophotometer
2. Simultaneous estimation of multi component containing formulations by UV spectrophotometry
3. Experiments based on HPLC
4. Experiments based on Gas Chromatography
5. Estimation of riboflavin/quinine sulphate by fluorimetry
6. Estimation of sodium/potassium by flame photometry

Handling of laboratory animals.

1. Various routes of drug administration.
2. Techniques of blood sampling, anesthesia and euthanasia of experimental animals.
3. Functional observation battery tests (modified Irwin test)
4. Evaluation of CNS stimulant, depressant, anxiogenics and anxiolytic, anticonvulsant activity.
5. Evaluation of analgesic, anti-inflammatory, local anesthetic, mydriatic and miotic activity.
6. Evaluation of diuretic activity.
7. Evaluation of antiulcer activity by pylorus ligation method.
8. Oral glucose tolerance test.
9. Isolation and identification of DNA from various sources (Bacteria, Cauliflower, onion, Goat liver).
10. Isolation of RNA from yeast
11. Estimation of proteins by Braford/Lowry's in biological samples.
12. Estimation of RNA/DNA by UV Spectroscopy
13. Gene amplification by PCR.
14. Protein quantification Western Blotting.
15. Enzyme based in-vitro assays (MPO, AChEs, α amylase, α glucosidase). 16. Cell viability assays (MTT/Trypan blue/SRB).
16. DNA fragmentation assay by agarose gel electrophoresis.
17. DNA damage study by Comet assay.
18. Apoptosis determination by fluorescent imaging studies.
19. Pharmacokinetic studies and data analysis of drugs given by different routes of administration using softwares

20. Enzyme inhibition and induction activity
21. Extraction of drug from various biological samples and estimation of drugs in biological fluids using different analytical techniques (UV)
22. Extraction of drug from various biological samples and estimation of drugs in biological fluids using different analytical techniques (HPLC)

REFERENCES

1. CPCSEA, OECD, ICH, USFDA, Schedule Y, EPA guidelines,
2. Fundamentals of experimental Pharmacology by M.N.Ghosh
3. Handbook of Experimental Pharmacology by S.K. Kulkarni.
4. Drug discovery and Evaluation by Vogel H.G.
5. Spectrometric Identification of Organic compounds - Robert M Silverstein,
6. Principles of Instrumental Analysis - Doglas A Skoog, F. James Holler, Timothy A. Nieman,
7. Vogel‘s Text book of quantitative chemical analysis - Jeffery, Basset, Mendham, Denney,
8. Basic Cell Culture protocols by Cheril D. Helgason and Cindy L.Mille
9. Basic Cell Culture (Practical Approach) by J. M. Davis (Editor)
10. Animal Cell Culture: A Practical Approach by John R. Masters (Editor)
11. Practical Manual of Experimental and Clinical Pharmacology by Bikash Medhi(Author), Ajay Prakash (Author) Jaypee brothers’ medical publishers Pvt. Ltd

ADVANCED PHARMACOLOGY - II

(MPL 201T)

Scope

The subject is designed to strengthen the basic knowledge in the field of pharmacology and to impart recent advances in the drugs used for the treatment of various diseases. In addition, the subject helps the student to understand the concepts of drug action and mechanism involved

Objectives

Upon completion of the course the student shall be able to:

- Explain the mechanism of drug actions at cellular and molecular level
- Discuss the Pathophysiology and pharmacotherapy of certain diseases
- Understand the adverse effects, contraindications and clinical uses of drugs used in treatment of diseases

THEORY **60 Hrs**

1.	Endocrine Pharmacology Molecular and cellular mechanism of action of hormones such as growth hormone, prolactin, thyroid, insulin and sex hormones Anti-thyroid drugs, Oral hypoglycemic agents, Oral contraceptives, Corticosteroids. Drugs affecting calcium regulation	12 Hrs
2.	Chemotherapy Cellular and molecular mechanism of actions and resistance of antimicrobial agents such as ß-lactams, aminoglycosides, quinolones, Macrolide antibiotics. Antifungal, antiviral, and anti-TB drugs.	12 Hrs
3.	Chemotherapy Drugs used in Protozoal Infections Drugs used in the treatment of Helminthiasis Chemotherapy of cancer Immunopharmacology Cellular and biochemical mediators of inflammation and immune response. Allergic or hypersensitivity reactions. Pharmacotherapy of asthma and COPD. Immunosuppressants and Immunostimulants	12 Hrs

4. GIT Pharmacology — 12 Hrs

Antiulcer drugs, Prokinetics, antiemetics, anti-diarrheals and drugs for constipation and irritable bowel syndrome.

Chronopharmacology

Biological and circadian rhythms, applications of chronotherapy in various diseases like cardiovascular disease, diabetes, asthma and peptic ulcer

5. Free radicals Pharmacology — 12 Hrs

Generation of free radicals, role of free radicals in etiopathology of various diseases such as diabetes, neurodegenerative diseases and cancer.

Protective activity of certain important antioxidant

Recent Advances in Treatment:

Alzheimer's disease, Parkinson's disease, Cancer, Diabetes mellitus

REFERENCES

1. The Pharmacological basis of therapeutics- Goodman and Gill man's
2. Principles of Pharmacology. The Pathophysiologic basis of drug therapy by David E Golan et al.
3. Basic and Clinical Pharmacology by B.G -Katzung
4. Pharmacology by H.P. Rang and M.M. Dale.
5. Hand book of Clinical Pharmacokinetics by Gibaldi and Prescott.
6. Text book of Therapeutics, drug and disease management by E T. Herfindal and Gourley.
7. Applied biopharmaceutics and Pharmacokinetics by Leon Shargel and Andrew B.C Yu.
8. Handbook of Essential Pharmacokinetics, Pharmacodynamics and Drug Metabolism for Industrial Scientists
9. Robbins & Cortan Pathologic Basis of Disease, 9th Ed. (Robbins Pathology)
10. A Complete Textbook of Medical Pharmacology by Dr. S.K Srivastava published by APC Avichal Publishing Company.
11. KD.Tripathi. Essentials of Medical Pharmacology
12. Principles of Pharmacology. The Pathophysiologic basis of drug Therapy by David E Golan, Armen H, Tashjian Jr, Ehrin J,Armstrong, April W, Armstrong, Wolters, Kluwer-Lippincott Williams & Wilkins Publishers

1)

PHARMACOLOGICAL AND TOXICOLOGICAL SCREENING METHODS-II

(MPL 202T)

Scope:

This subject imparts knowledge on the preclinical safety and toxicological evaluation of drug & new chemical entity. This knowledge will make the student competent in regulatory toxicological evaluation.

Objectives:

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

- Explain the various types of toxicity studies.
- Appreciate the importance of ethical and regulatory requirements for toxicity studies.
- Demonstrate the practical skills required to conduct the preclinical toxicity studies.

THEORY **60 Hrs**

1.	Basic definition and types of toxicology (general, mechanistic, regulatory and descriptive) Regulatory guidelines for conducting toxicity studies OECD, ICH, EPA and Schedule Y OECD principles of Good laboratory practice (GLP) History, concept and its importance in drug development	12 Hrs
2.	Acute, sub-acute and chronic- oral, dermal and inhalational studies as per OECD guidelines. Acute eye irritation, skin sensitization, dermal irritation & dermal toxicity studies. Test item characterization- importance and methods in regulatory toxicology studies	12 Hrs
3.	Reproductive toxicology studies, Male reproductive toxicity studies, female reproductive studies (segment I and segment III), teratogenecity studies (segment II) Genotoxicity studies (Ames Test, in vitro and in vivo Micronucleus and Chromosomal aberrations studies) In vivo carcinogenicity studies	12 Hrs

4.	IND enabling studies (IND studies)- Definition of IND, importance of IND, industry perspective, list of studies needed for IND submission. Safety pharmacology studies- origin, concepts and importance of safety pharmacology. Tier1- CVS, CNS and respiratory safety pharmacology, HERG assay. Tier2- GI, renal and other studies	12 Hrs
5.	Toxicokinetics- Toxicokinetic evaluation in preclinical studies, saturation kinetics Importance and applications of toxicokinetic studies. Alternative methods to animal toxicity testing.	12 Hrs

REFERENCES

1. Hand book on GLP, Quality practices for regulated non-clinical research and development (http://www.who.int/tdr/publications/documents/glp- handbook.pdf).
2. Schedule Y Guideline: drugs and cosmetics (second amendment) rules, 2005, ministry of health and family welfare (department of health) New Delhi
3. Drugs from discovery to approval by Rick NG.
4. Animal Models in Toxicology, 3rd Edition, Lower and Bryan
5. OECD test guidelines.
6. Principles of toxicology by Karen E. Stine, Thomas M. Brown.
7. Guidance for Industry M3(R2) Nonclinical Safety Studies for the Conduct of Human Clinical Trials and Marketing Authorization for Pharmaceuticals (http://www.fda.gov/downloads/drugs/guidancecomplianceregulatoryinformation/guidances/ucm073246.pdf)

PRINCIPLES OF DRUG DISCOVERY

(MPL 203T)

Scope:

The subject imparts basic knowledge of drug discovery process. This information will make the student competent in drug discovery process

Objectives:

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

- Explain the various stages of drug discovery.
- Appreciate the importance of the role of genomics, proteomics and bioinformatics in drug discovery
- Explain various targets for drug discovery.
- Explain various lead seeking method and lead optimization
- Appreciate the importance of the role of computer aided drug design in drug discovery

THEORY **60 Hrs**

1. An overview of modern drug discovery process: Target identification, target validation, lead identification and lead Optimization. Economics of drug discovery. — 12 Hrs

   Target Discovery and validation-Role of Genomics, Proteomics and Bioinformatics. Role of Nucleic acid microarrays, Protein microarrays, Antisense technologies, siRNAs, antisense oligonucleotides, Zinc finger proteins. Role of transgenic animals in target validation.

2. Lead Identification- combinatorial chemistry & high throughput screening, in silico lead discovery techniques, Assay development for hit identification. — 12 Hrs

   Protein structure

   Levels of protein structure, Domains, motifs, and folds in protein structure. Computational prediction of protein structure: Threading and homology modeling methods. Application of NMR and X-ray crystallography in protein structure prediction

3. Rational Drug Design — 12 Hrs

   Traditional vs rational drug design, Methods followed in traditional drug design, High throughput screening, Concepts of Rational Drug Design, Rational Drug

	Design Methods: Structure and Pharmacophore based approaches Virtual Screening techniques: Drug likeness screening, Concept of pharmacophore mapping and pharmacophore based Screening,	
4.	Molecular docking: Rigid docking, flexible docking, manual docking; Docking based screening. De novo drug design. Quantitative analysis of Structure Activity Relationship History and development of QSAR, SAR versus QSAR, Physicochemical parameters, Hansch analysis, Fee Wilson analysis and relationship between them.	12 Hrs
5.	QSAR Statistical methods – regression analysis, partial least square analysis (PLS) and other multivariate statistical methods. 3D-QSAR approaches like COMFA and COMSIA Prodrug design-Basic concept, Prodrugs to improve patient acceptability, Drug solubility, Drug absorption and distribution, site specific drug delivery and sustained drug action. Rationale of prodrug design and practical consideration of prodrug design	12 Hrs

REFERENCES

1. MouldySioud. Target Discovery and Validation Reviews and Protocols: Volume 2 Emerging Molecular Targetsand Treatment Options. 2007 Humana Press Inc.
2. Darryl León. Scott MarkelIn. Silico Technologies in Drug Target Identification and Validation. 2006 by Taylor and Francis Group, LLC.
3. Johanna K. DiStefano. Disease Gene Identification. Methods and Protocols. Springer New York Dordrecht Heidelberg London.
4. Hugo Kubiny. QSAR: Hansch Analysis and Related Approaches. Methods and Principles in Medicinal Chemistry. Publisher Wiley-VCH
5. Klaus Gubernator, Hans-Joachim Böhm. Structure-Based Ligand Design. Methods and Principles in Medicinal Chemistry. Publisher Wiley-VCH
6. Abby L . Parrill. M . Rami Reddy. Rational Drug Design. Novel Methodology and Practical Applications. ACS Symposium Series;American Chemical Society: Washington, DC, 1999.
7. J. Rick Turner. New drug development design, methodology and, analysis. John Wiley & Sons, Inc., New Jersey.

8. CLINICAL RESEARCH AND PHARMACOVIGILANCE

(MPL 204T)

Scope:

This subject will provide a value addition and current requirement for the students in clinical research and pharmacovigilance. It will teach the students on conceptualizing, designing, conducting, managing and reporting of clinical trials. This subject also focuses on global scenario of Pharmacovigilance in different methods that can be used to generate safety data. It will teach the students in developing drug safety data in Pre-clinical, Clinical phases of Drug development and post market surveillance.

Objectives:

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

- Explain the regulatory requirements for conducting clinical trial
- Demonstrate the types of clinical trial designs
- Explain the responsibilities of key players involved in clinical trials
- Execute safety monitoring, reporting and close-out activities
- Explain the principles of Pharmacovigilance
- Detect new adverse drug reactions and their assessment
- Perform the adverse drug reaction reporting systems and communication in Pharmacovigilance

THEORY **60 Hrs**

1. Regulatory Perspectives of Clinical Trials: 12 Hrs
   Origin and Principles of International Conference on Harmonization - Good Clinical Practice (ICH-GCP) guidelines
   Ethical Committee: Institutional Review Board, Ethical Guidelines for Biomedical Research and Human Participant- Schedule Y, ICMR
   Informed Consent Process: Structure and content of an Informed Consent Process Ethical principles governing informed consent process

2. Clinical Trials: Types and Design 12 Hrs
   Experimental Study- RCT and Non RCT,
   Observation Study: Cohort, Case Control, Cross sectional
   Clinical Trial Study Team
   Roles and responsibilities of Clinical Trial Personnel: Investigator, Study Coordinator, Sponsor, Contract Research Organization and its management

3.	Clinical Trial Documentation- Guidelines to the preparation of documents, Preparation of protocol, Investigator Brochure, Case Report Forms, Clinical Study Report Clinical Trial Monitoring- Safety Monitoring in CT Adverse Drug Reactions: Definition and types. Detection and reporting methods. Severity and seriousness assessment.Predictability and preventability assessment, Management of adverse drug reactions; Terminologies of ADR.	12 Hrs
4.	Basic aspects, terminologies and establishment of pharmacovigilance History and progress of pharmacovigilance, Significance of safety monitoring, Pharmacovigilance in India and international aspects, WHO international drug monitoring programme, WHO and Regulatory terminologies of ADR, evaluation of medication safety, Establishing pharmacovigilance centres in Hospitals, Industry and National programmes related to pharmacovigilance. Roles and responsibilities in Pharmacovigilance	12 Hrs
5.	Methods, ADR reporting and tools used in Pharmacovigilance International classification of diseases, International Non- proprietary names for drugs, Passive and Active surveillance, Comparative observational studies, Targeted clinical investigations and Vaccine safety surveillance. Spontaneous reporting system and Reporting to regulatory authorities, Guidelines for ADRs reporting. Argus, Aris G Pharmacovigilance, VigiFlow, Statistical methods for evaluating medication safety data.	12 Hrs
6.	Pharmacoepidemiology, pharmacoeconomics, safety pharmacology	12 Hrs

REFERENCES

1. Central Drugs Standard Control Organization- Good Clinical Practices, Guidelines for Clinical Trials on Pharmaceutical Products in India. New Delhi: Ministry of Health; 2001.
2. International Conference on Harmonization of Technical requirements for registration of Pharmaceuticals for human use. ICH Harmonized Tripartite Guideline. Guideline for Good Clinical Practice.E6; May 1996.
3. Ethical Guidelines for Biomedical Research on Human Subjects 2000. Indian Council of Medical Research, New Delhi.
4. Textbook of Clinical Trials edited by David Machin, Simon Day and Sylvan Green, March 2005, John Wiley and Sons.
5. Clinical Data Management edited by R K Rondels, S A Varley, C F Webbs. Second Edition, Jan 2000, Wiley Publications.
6. Handbook of clinical Research. Julia Lloyd and Ann Raven Ed. Churchill Livingstone.
7. Principles of Clinical Research edited by Giovanna di Ignazio, Di Giovanna and Haynes.

PHARMACOLOGICAL PRACTICAL - II

(MPL 205P)

1. To record the DRC of agonist using suitable isolated tissues preparation.
2. To study the effects of antagonist/potentiating agents on DRC of agonist using suitable isolated tissue preparation.
3. To determine to the strength of unknown sample by matching bioassay by using suitable tissue preparation.
4. To determine to the strength of unknown sample by interpolation bioassay by using suitable tissue preparation
5. To determine to the strength of unknown sample by bracketing bioassay by using suitable tissue preparation
6. To determine to the strength of unknown sample by multiple point bioassay by using suitable tissue preparation.
7. Estimation of PA2 values of various antagonists using suitable isolated tissue preparations.
8. To study the effects of various drugs on isolated heart preparations
9. Recording of rat BP, heart rate and ECG.
10. Recording of rat ECG
11. Drug absorption studies by averted rat ileum preparation.
12. Acute oral toxicity studies as per OECD guidelines.
13. Acute dermal toxicity studies as per OECD guidelines.
14. Repeated dose toxicity studies- Serum biochemical, haematological, urine analysis, functional observation tests and histological studies.
15. Drug mutagenicity study using mice bone-marrow chromosomal aberration test.
16. Protocol design for clinical trial.(3 Nos.)
17. Design of ADR monitoring protocol.
18. In-silico docking studies. (2 Nos.)
19. In-silico pharmacophore based screening.
20. In-silico QSAR studies.
21. ADR reporting

REFERENCES

1. Fundamentals of experimental Pharmacology-by M.N.Ghosh
2. Hand book of Experimental Pharmacology-S.K.Kulakarni
3. Text book of in-vitro practical Pharmacology by Ian Kitchen
4. Bioassay Techniques for Drug Development by Atta-ur-Rahman, Iqbal choudhary and William Thomsen

5. Applied biopharmaceutics and Pharmacokinetics by Leon Shargel and Andrew B.C.Yu.
6. Handbook of Essential Pharmacokinetics, Pharmacodynamics and Drug Metabolism for Industrial Scientists.

Semester III

MRM 301T - Research Methodology & Biostatistics

UNIT – I

General Research Methodology: Research, objective, requirements, practical difficulties, review of literature, study design, types of studies, strategies to eliminate errors/bias, controls, randomization, crossover design, placebo, blinding techniques.

UNIT – II

Biostatistics: Definition, application, sample size, importance of sample size, factors influencing sample size, dropouts, statistical tests of significance, type of significance tests, parametric tests(students "t" test, ANOVA, Correlation coefficient, regression), non-parametric tests (wilcoxan rank tests, analysis of variance, correlation, chi square test), null hypothesis, P values, degree of freedom, interpretation of P values.

UNIT – III

Medical Research: History, values in medical ethics, autonomy, beneficence, non-maleficence, double effect, conflicts between autonomy and beneficence/non-maleficence, euthanasia, informed consent, confidentiality, criticisms of orthodox medical ethics, importance of communication, control resolution, guidelines, ethics committees, cultural concerns, truth telling, online business practices, conflicts of interest, referral, vendor relationships, treatment of family members, sexual relationships, fatality.

UNIT – IV

CPCSEA guidelines for laboratory animal facility: Goals, veterinary care, quarantine, surveillance, diagnosis, treatment and control of disease, personal hygiene, location of animal facilities to laboratories, anesthesia, euthanasia, physical facilities, environment, animal husbandry, record keeping, SOPs, personnel and training, transport of lab animals.

UNIT – V

Declaration of Helsinki: History, introduction, basic principles for all medical research, and additional principles for medical research combined with medical care.

2.7 Total number of hour

As mentioned in Course outline (clause 2.4)

2.8 Branches if any, with definition

As mentioned in Syllabus (clause 2.6)

2.9 Teaching Learning methods

A regular record of attendance both in Theory, Practical, Seminar, Assignment, Journal club, Discussion with the supervisor, Research work presentation and Dissertation shall be maintained by the department / teaching staff of respective courses.

2.10 Content of each subject in each year

As mentioned in Syllabus (clause 2.6)

2.11 No: of hours per subject

As mentioned in Syllabus (clause 2.6)

2.12 Practical Training

As mentioned in Course outline (clause 2.4)

2.13 Records

To be maintained for all Practical Work

2.14 Dissertation

As mentioned in Project work to be done (clause 2.16)

2.15 Speciality Training if ANY

As mentioned in Syllabus (clause 2.6)

2.16 Project work to be done if any

All the students shall undertake a project under the supervision of a teacher in Semester III to IV and submit a report. 4 copies of the project report shall be submitted (typed & bound copy not less than 75 pages).

The internal and external examiner appointed by the University shall evaluate the project at the time of the Practical examinations of other semester(s). The projects shall be evaluated as per the criteria given below.

Evaluation of Dissertation Book:

Objective(s) of the work done	50 Marks
Methodology adopted	150 Marks
Results and Discussions	250 Marks
Conclusions and Outcomes	50 Marks
Total	500 Marks

Evaluation of Presentation:

Presentation of work	100 Marks
Communication skills	50 Marks
Question and answer skills	100 Marks
Total	250 Marks

2.17 Any other Requirements [CME, Paper Publishing, etc,.]

As mentioned in Course outline (clause 2.4)

2.18 Prescribed/Recommended textbooks for each subject

As mentioned in Syllabus (clause 2.6)

2.19 Reference books

As mentioned in Syllabus (clause 2.6)

2.20 Journals

All Pharmacy and related Medical Journals

2.21 Logbook

Registers to be maintained

3. EXAMINATION

3.1 Eligibility to appear for examinations

A candidate is required to put in at least 80% attendance in individual courses considering theory and practical separately. The candidate shall complete the prescribed course satisfactorily to be eligible to appear for the respective examinations.

3.2 Schedule of Regular / Supplementary exams

Semester examinations will be conducted once in every six months after fulfilling 100 working days.

Table: 6 - Question paper pattern for end semester theory & practical examinations

Question paper pattern for end semester theory examinations			
I.	Long Answers	3 X 10	30 Marks
II.	Short Answers	9 X 5	45 Marks
		Total	**75 Marks**
Question paper pattern for end semester practical examinations			
I.	Synopsis		15 Marks
II.	Experiment - I		40 Marks
III.	Experiment – II		30 Marks
IV.	Viva voce		15 Marks
	Total		**100 Marks**

3.3 Scheme of examination showing maximum marks and minimum marks

The End Semester Examinations for each theory and practical Course through semesters I to IV shall be conducted by the respective university except for the subject with asterisk symbol (*) in table – 8 for which examinations shall be conducted by the subject experts at college level and the marks/grades shall be submitted to the university.

Schemes for internal assessments and end semester examinations are given in table below

Table – 7: Schemes for internal assessments and end semester examinations

Course code	Course	Internal Assessment				End Semester Exams		Total Marks
		Continuous Mode	Sessional Exams		Total	Marks	Duration	
			Marks	Duration				
SEMESTER I								
MPL 101T	Modern Pharmaceutical Analytical Techniques	10	15	1 Hr	25	75	3 Hrs	100
MPL 102T	Advanced Pharmacology-I	10	15	1 Hr	25	75	3 Hrs	100
MPL 103T	Pharmacological and Toxicological Screening Methods-I	10	15	1 Hr	25	75	3 Hrs	100
MPL 104T	Cellular and Molecular Pharmacology	10	15	1 Hr	25	75	3 Hrs	100
MPL 105P	Experimental Pharmacology –I	20	30	6 Hrs	50	100	6 Hrs	150
-	Seminar /Assignment	-	-	-	-	-	-	100
Total								
SEMESTER II								
MPL 201T	Advanced Pharmacology II	10	15	1 Hr	25	75	3 Hrs	100
MPL 202T	Pharmacological and Toxicological Screening Methods –II	10	15	1 Hr	25	75	3 Hrs	100
MPL 203T	Principles of Drug Discovery	10	15	1 Hr	25	75	3 Hrs	100
MPL 204T	Clinical research and Pharmacovigilance	10	15	1 Hr	25	75	3 Hrs	100
MPL 205P	Experimental Pharmacology –II	20	30	6 Hrs	50	100	6 Hrs	150
-	Seminar /Assignment	-	-	-	-	-	-	100
Total								650

Table – 8: Schemes for internal assessments and end semester examinations

(Semester III& IV)

Course code	Course	Internal Assessment				End Semester Exams		Total Marks
		Continuous Mode	Sessional Exams		Total	Marks	Duration	
			Marks	Duration				
SEMESTER III								
MRM 301T	Research Methodology and Biostatistics*	10	15	1 Hr	25	75	3 Hrs	100
-	Journal Club	-	-	-	25	-	-	25
-	Discussion / Presentation (proposal presentation)	-	-	-	50	-	-	50
-	Research Work*	-	-	-	-	350	1 Hr	350
Total								525
SEMESTER IV								
-	Journal club	-	-	-	25	-	-	25
-	Discussion / Presentation (proposal presentation)	-	-	-	75	-	-	75
-	Research Work and Colloquium	-	-	-	-	400	1 Hr	400
Total								500

*Non University Examination

Table – 9: Scheme for awarding internal assessment

Theory	
Criteria	**Maximum Marks**
Attendance (Refer Table – 10)	8
Student – Teacher interaction	2
Total	10
Practical	
Attendance (Refer Table – 10)	10
Based on Practical Records, Regular viva voce, etc.	10
Total	20

Table – 10: Guidelines for the allotment of marks for attendance

Percentage of Attendance	Theory	Practical
95 – 100	8	10
90 – 94	6	7.5
85 – 89	4	5
80 – 84	2	2.5
Less than 80	0	0

Allowed to keep terms (ATKT):

No student shall be admitted to any examination unless he/she fulfills the norms given in clause 3.1. ATKT rules are applicable as follows:

A student shall be eligible to carry forward all the courses of I and II semesters till the III semester examinations. However, he/she shall not be eligible to attend the courses of IV semester until all the courses of I, II and III semesters are successfully completed.

A student shall be eligible to get his/her CGPA upon successful completion of the courses of I to IV semesters within the stipulated time period as per the norms.

Note: Grade AB should be considered as failed and treated as one head for deciding ATKT. Such rules are also applicable for those students who fail to register for examination(s) of any course in any semester.

Grading of performances

a) Letter grades and grade points allocations:

Based on the performances, each student shall be awarded a final letter grade at the end of the semester for each course. The letter grades and their corresponding grade points are given in Table – 11.

Table – 11: Letter grades and grade points equivalent to Percentage of marks and performances

Percentage of Marks obtained	Letter Grade	Grade point	Performance
90.00 – 100	O	10	Outstanding
80.00 – 89.99	A	9	Excellent
70.00 – 79.99	B	8	Good
60.00 – 69.99	C	7	Fair
50.00 – 59.99	D	6	Average
Less than 50	F	0	Fail
Absent	AB	0	Fail

A learner who remains absent for any end semester examination shall be assigned a letter grade of AB and a corresponding grade point of zero. He/she should reappear for the said evaluation/examination in due course.

b) The Semester grade point average (SGPA)

The performance of a student in a semester is indicated by a number called 'Semester Grade Point Average' (SGPA). The SGPA is the weighted average of the grade points obtained in all the courses by the student during the semester. For example, if a student takes five courses (Theory/Practical) in a semester with credits C1, C2, C3 and C4 and the student's grade points in these courses are G1, G2, G3 and G4, respectively, and then students' SGPA is equal to:

$$SGPA = \frac{C_1G_1 + C_2G_2 + C_3G_3 + C_4G_4}{C_1 + C_2 + C_3 + C_4}$$

The SGPA is calculated to two decimal points. It should be noted that, the SGPA for any semester shall take into consideration the F and ABS grade awarded in that semester. For example if a learner has a F or ABS grade in course 4, the SGPA shall then be computed as:

$$SGPA = \frac{C_1G_1 + C_2G_2 + C_3G_3 + C_4*ZER0}{C_1 + C_2 + C_3 + C_4}$$

c) Cumulative Grade Point Average (CGPA)

The CGPA is calculated with the SGPA of all the IV semesters to two decimal points and is indicated in final grade report card/final transcript showing the grades of all IV semesters and their courses. The CGPA shall reflect the failed status in case of F grade(s), till the course(s) is/are passed. When the course(s) is/are passed by obtaining a pass grade on subsequent examination(s) the CGPA shall only reflect the new grade and not the fail grades earned earlier.The CGPA is calculated as:

$$CGPA = \frac{C_1S_1 + C_2S_2 + C_3S_3 + C_4S_4}{C_1 + C_2 + C_3 + C_4}$$

where C_1, C_2, C_3,…. is the total number of credits for semester I,II,III,…. And S_1, S_2, S_3… is the SGPA of semester I, II, III…. .

3.4 Papers in each year

As mentioned in Course outline (clause 2.4)

3.5 Details of theory exams

As mentioned in Schedule of regular / Supplementary Exams (clause 3.2)

3.6 Model question paper for each subject with question paper pattern

As mentioned in Schedule of regular / Supplementary Exams (clause 3.2)See Annexure

3.7 Internal assessment component

As mentioned in Scheme of examination. (Clause 3.3)

- Two sessional exams shall be conducted for each theory / practical course as per the schedule fixed by the college(s). The average marks of two sessional exams shall be computed for internal assessment as per the requirements
- A student shall have the opportunity to improve his/her performance only once in the sessional exam component of the internal assessment. The re-conduct of the sessional exam shall be completed before the commencement of next end semester theory examinations.

3.8 Details of practical / clinical practicum exams.

As mentioned in Schedule of regular / Supplementary Exams (clause 3.2) Scheme of examination. (Clause 3.3)

3.9 Number of examiners (Internal & External) and their qualifications

- A post graduate (PG) degree in M. Pharm shall be eligible as teacher.
- A post graduate degree in M. Pharm with 5 years Post PG experience is eligible as internal examiner.
- A post graduate degree in M. Pharm with 10 years Post PG is eligible as external examiner.
- A post graduate degree in M. Pharm with 5 years Post PG is eligible to guide maximum of 5 candidates for M. Pharm dissertation.

For the conduct of practical examination of I semester one external examiner and 2 internal examiners (one faculty dealing with the respective speciality and one faculty dealing Modern Analytical and Research methods) shall be appointed by the University. For the evaluation of Practical Examination of II semester one internal and one external examiner shall be appointed by the university.

3.10 Details of viva:

As mentioned in Schedule of regular / Supplementary Exams (clause 3.2) Scheme of examination. (Clause 3.3)

4. INTERNSHIP

Not applicable

5. ANNEXURES

5.1 Check Lists for Monitoring:

Log Book, Seminar Assessment etc. to be formulated by the curriculum committee of the concerned Institution.

REGULATIONS2017

Syllabus

Kerala University of Health Sciences

Thrissur - 680596

POST GRADUATE COURSE IN PHARMACY

Master of Pharmacy

(M.Pharm. – Pharmacy Practice)

Course code: 281

(2017-18 Academic year onwards)

2017

2. COURSE CONTENT

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2.2	**Objectives of course**	
2.3	**Medium of instruction:**	
2.4	**Course outline**	
2.5	**Duration**	**7**
2.6	**Syllabus**	**8**
2.7	**Total number of hour**	30
2.8	**Branches if any with definition**	
2.9	**Teaching learning methods**	
2.10	**Content of each subject in each year**	
2.11	**No: of hours per subject**	
2.12	**Practical training**	
2.13	**Records**	
2.14	**Dissertation: As per Dissertation Regulations of KUHS**	
2.15	**Speciality training if any**	
2.16	**Project work to be done if any**	
2.17	**Any other requirements [CME, Paper Publishing etc.]**	**31**
2.18	**Prescribed/recommended textbooks for each subject**	
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3. EXAMINATIONS

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4. INTERNSHIP

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5. ANNEXURES

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2. COURSE CONTENT

2.1 Title of course

These regulations shall be called as "Master of Pharmacy (M.Pharm. – Pharmacy Practice) Degree Program - Credit Based Semester System (CBSS) of the Kerala University of Health sciences. They shall come into effect from the Academic Year 2017-18 onwards. The regulations framed are subject to modifications from time to time by the authorities of the University.

2.2 Objectives of course

To generate Pharmacy Post Graduates with profound knowledge in various branches of Pharmaceutical Sciences to meet with the rapidly increasing demands put forward by-

- Pharmaceutical Manufacturing
- Pharmaceutical Research & Development
- Pharmacological research including preclinical & clinical studies.
- Herbal Drug Research
- Pharmaceutical & Herbal Drug Analysis
- Clinical Toxicology & Toxicological Analysis

To discover the potential to become faculty in Pharmaceutical Sciences with unmatched quality and excellence, so as to educate the future pharmacy generation (Undergraduate, Post graduate, and Doctoral).

2.3 Medium of Instruction

Medium of instruction and examination shall be in English.

2.4 Course Outline

The specialization in M.Pharm. Program is given in Table 1.

Table – 1: M.Pharm. Specialization and its code

S.No	Specialization	Code
1.	Pharmacy Practice	MPP

The course of study for M.Pharm Pharmacy Practice shall include Semester wise Theory & Practical as given in Table – 2 & 3. The number of hours to be devoted to each theory and practical course in any semester shall not be less than that shown in Table – 2 & 3.

Table – 2: Course of study for M.Pharm. I & II Semester

Course Code	Course	Credit Hours	Credit Points	Hrs./wk	Marks
Semester I					
MPP 101T	Clinical Pharmacy Practice	4	4	4	100
MPP 102T	Pharmacotherapeutics-1	4	4	4	100
MPP 103T	Hospital & Community Pharmacy	4	4	4	100
MPP 104T	Clinical Research	4	4	4	100
MPP 105P	Pharmacy Practice Practical I	12	6	12	150
-	Seminar /Assignment	7	4	7	100
Total		35	26	35	650
Semester II					
MPP 201T	Principles of Quality use of Medicines	4	4	4	100
MPP 202T	Pharmacotherapeutics II	4	4	4	100
MPP 203T	Clinical Pharmacokinetics and therapeutic Drug Monitoring	4	4	4	100
MPP 204T	Pharmacoepidemiology & Pharmacoeconomics	4	4	4	100
MPP 205P	Pharmacy Practice Practical II	12	6	12	150
-	Seminar /Assignment	7	4	7	100
Total		35	26	35	650

Table – 3: Course of study for M. Pharm. III & IV Semester

Course Code	Course	Credit Hours	Credit Points
Semester III			
MRM 301T	Research Methodology and Biostatistics*	4	4
-	Journal Club	1	1
-	Discussion / Presentation (proposal presentation)	2	2
-	Research Work*	28	14
Total		35	21
Semester IV			
-	Journal Club	1	1
-	Research Work	31	16
-	Discussion / Final Presentation	3	3
Total		35	20

*Non University Exam

Program/Course credit structure

As per the philosophy of Credit Based Semester System, certain quantum of academic work viz. theory classes, practical classes, seminars, assignments, etc. are measured in terms of credits. On satisfactory completion of the courses, a candidate earns credits. The amount of credit associated with a course is dependent upon the number of hours of instruction per week in that course. Similarly the credit associated with any of the other academic, co/extracurricular activities is dependent upon the quantum of work expected to be put in for each of these activities per week/per activity.

Credit assignment

a) Theory and Laboratory courses

Courses are broadly classified as Theory and Practical. Theory courses consist of lecture (L) and Practical (P) courses consist of hours spent in the laboratory. Credits (C) for a course is dependent on the number of hours of instruction per week in that course, and is obtained by using a multiplier of one (1) for lecture and a multiplier of half (1/2) for practical (laboratory) hours. Thus, for example, a theory course having four lectures per week throughout the semester carries a credit of 4. Similarly, a practical having four laboratory hours per week throughout semester carries a credit of 2. The contact hours of seminars, assignments and research work shall be treated as that of practical courses for the purpose of calculating credits. i.e., the contact hours shall be multiplied by 1/2. Similarly, the contact hours of journal club, research work presentations and discussions with the supervisor shall be considered as theory course and multiplied by 1.

b) Minimum credit requirements

The minimum credit points required for the award of M. Pharm. degree is 95. However based on the credit points earned by the students under the head of co-curricular activities, a student shall earn a maximum of 100 credit points. These credits are divided into Theory courses, Practical, Seminars, Assignments, Research work, Discussions with the supervisor, Journal club and Co-Curricular activities over the duration of four semesters. The credits are distributed semester-wise as shown in Table 4. Courses generally progress in sequence, building competencies and their positioning indicates certain academic maturity on the part of the learners. Learners are expected to follow the semester-wise schedule of courses given in the syllabus.

Table – 4: Semester wise credits distribution

Semester	Credit Points
I	26
II	26
III	21
IV	20
Co-curricular Activities (attending Conference, Scientific Presentations and other scholarly Activities)	Minimum = 02 Maximum = 07*
Total Credit Points	Minimum = 95 Maximum = 100

*Credit points for Co-curricular Activities

Table – 5: Guidelines for Awarding Credit Points for Co-curricular Activities

Name of the Activity	MaximumCredit Points Eligible / Activity
Participation in National Level Seminar/ Conference/ Workshop / Symposium / Training Programs (related to the specialization of the student)	01
Participation in international Level Seminar/ Conference/ Workshop/ Symposium/ Training Programs (related to the specialization of the student)	02
Academic Award/Research Award from State Level/ National Agencies	01
Academic Award/Research Award from International Agencies	02
Research / Review Publication in National Journals (Indexed in Scopus / Web of Science)	01
Research / Review Publication in International Journals (Indexed in Scopus / Web of Science)	02

Note: International Conference: Held outside India

International Journal: The Editorial Board outside India

*The credit points assigned for extracurricular and or co-curricular activities shall be given by the Principals of the colleges and the same shall be submitted to the University. The criteria to acquire this credit point shall be defined by the colleges from time to time.

Program Committee

1. The M. Pharm. programme shall have a Programme Committee constituted by the Head of the institution in consultation with all the Heads of the departments.
2. The composition of the Programme Committee shall be as follows:
   A teacher at the cadre of Professor shall be the Chairperson; One Teacher from each M.Pharm specialization and four student representatives (two from each academic year), nominated by the Head of the institution.
3. Duties of the Programme Committee:
   i. Periodically reviewing the progress of the classes.
   ii. Discussing the problems concerning curriculum, syllabus and the conduct of classes.
   iii. Discussing with the course teachers on the nature and scope of assessment for the course and the same shall be announced to the students at the beginning of respective semesters.
   iv. Communicating its recommendation to the Head of the institution on academic matters.
   v. The Programme Committee shall meet at least twice in a semester preferably at the end of each sessional exam and before the end semester exam.

2.5 Duration

The program of study for M.Pharm. shall extend over a period of four semesters (two academic years). The curricula and syllabi for the program shall be prescribed from time to time by the Kerala University of Health sciences.

The duration for the completion of the program shall be fixed as double the actual duration of the program and the students have to pass within the said period, otherwise they have to get fresh Registration.

2.6 Syllabus

PHARMACY PRACTICE (MPP)

CLINICAL PHARMACY PRACTICE

(MPP 101T)

Scope

This course is designed to impart the basic knowledge and skills that are required to practice pharmacy including the provision of pharmaceutical care services to both healthcare professionals and patients in clinical settings.

Objectives

Upon completion of this course it is expected that students shall be able to:

- Understand the elements of pharmaceutical care and provide comprehensive patient care services
- Interpret the laboratory results to aid the clinical diagnosis of various disorders
- Provide integrated, critically analyzed medicine and poison information to enable healthcare professionals in the efficient patient management

THEORY **60 Hrs**

1. Introduction to Clinical Pharmacy: Definition, evolution and scope of clinical pharmacy, International and national scenario of clinical pharmacy practice, Pharmaceutical care
   Clinical Pharmacy Services: Ward round participation, Drug therapy review (Drug therapy monitoring including medication order review, chart endorsement, clinical review and pharmacist interventions) — 12 Hrs

2. Clinical Pharmacy Services: Patient medication history interview, Basic concept of medicine and poison information services, Basic concept of pharmacovigilance, Hemovigilance, Materiovigilance and AEFI, Patient medication counselling, Drug utilisation evaluation, Documentation of clinical pharmacy services, Quality assurance of clinical pharmacy services. — 12 Hrs

3. Patient Data Analysis:
   Patient Data & Practice Skills: Patient's case history - its structure and significances in drug therapy management, Common medical abbreviations and terminologies used in clinical practice, Communication skills: verbal and non- — 12 Hrs

	verbal communications, its applications in patient care services. Lab Data Interpretation: Hematological tests, Renal function tests Liver function tests	
4.	Lab Data Interpretation: Tests associated with cardiac disorders, Pulmonary function tests, Thyroid function tests, Fluid and electrolyte balance, Microbiological culture sensitivity tests	12 Hrs
5.	Medicines & Poison Information ServicesMedicine Information Service: Definition and need for medicine information service, Medicine information resources, Systematic approach in answering medicine information queries, Preparation of verbal and written response, Establishing a drug information centre. Poison Information Service: Definition, need, organization and functions of poison information centre.	12 Hrs

REFERENCES

1. A Textbook of Clinical Pharmacy Practice – Essential concepts and skills – Parthasarathi G, Karin Nyfort-Hansen and Milap Nahata
2. Practice Standards and Definitions - The Society of Hospital Pharmacists of Australia
3. Basic skills in interpreting laboratory data - Scott LT, American Society of Health System Pharmacists Inc
4. Relevant review articles from recent medical and pharmaceutical literature.

PHARMACOTHERAPEUTICS-I

(MPP 102T)

Scope

This course aims to enable the students to understand the different treatment approaches in managing various disease conditions. Also, it imparts knowledge and skills in optimizing drug therapy of a patient by individualizing the treatment plan through evidence-based medicines.

Objectives

Upon completion of this course it is expected that students shall be able to:

- Describe and explain the rationale for drug therapy
- Summarize the therapeutic approach for management of various disease conditions including reference to the latest available evidence
- Discuss the clinical controversies in drug therapy and evidence based medicine
- Prepare individualized therapeutic plans based on diagnosis
- Identify the patient specific parameters relevant in initiating drug therapy, and monitoring therapy (including alternatives, time- course of clinical and laboratory indices of therapeutic response and adverse effect/s)

THEORY **60 Hrs**

Etiopathogenesis and pharmacotherapy of diseases associated with following systems

1.	Cardiovascular system: Hypertension, Congestive cardiac failure, Acute coronary syndrome, Arrhythmias, Hyperlipidemias.	12 Hrs
2.	Respiratory system: Asthma, Chronic obstructive airways disease, Drug induced pulmonary diseases Endocrine system: Diabetes, Thyroid diseases	12 Hrs
3.	Gastrointestinal system: Peptic ulcer diseases, Reflux esophagitis, Inflammatory bowel diseases, Jaundice & hepatitis	12 Hrs
4.	Gastrointestinal system: Cirrhosis, Diarrhea and Constipation, Drug-induced liver disease Hematological diseases: Anemia, Deep vein thrombosis, Drug induced hematological disorders	12 Hrs

5.	Bone and joint disorders: Rheumatoid arthritis, Osteoarthritis, Gout, Osteoporosis Dermatological Diseases: Psoriasis, Eczema and scabies, impetigo, drug induced skin disorders Ophthalmology: Conjunctivitis, Glaucoma	12 Hrs

REFERENCES

1. Roger and Walker. Clinical Pharmacy and Therapeutics – Churchill Livingstone publication
2. Joseph T. Dipiro et al. Pharmacotherapy: A Pathophysiologic Approach- Appleton & Lange
3. Robins SL. Pathologic basis of disease -W.B. Saunders publication
4. Eric T. Herfindal. Clinical Pharmacy and Therapeutics- Williams and Wilkins Publication
5. Lloyd Young and Koda-Kimble MA Applied Therapeutics: The clinical Use of Drugs- Lippincott Williams and Wilkins
6. Chisholm- Burns Wells Schwinghammer Malone and Joseph P Dipiro. Pharmacotherapy Principles and practice-– McGraw Hill Publication
7. Carol Mattson Porth. Principles of Pathophysiology- Lippincott Williams and Wilkins
8. Harrison's. Principles of Internal Medicine - McGraw Hill
9. Relevant review articles from recent medical and pharmaceutical literature

HOSPITAL & COMMUNITY PHARMACY

(MPP 103T)

Scope

This course is designed to impart basic knowledge and skills that are required to practice pharmacy in both hospital and community settings.

Objectives

Upon completion of this course it is expected that students shall be able to:

- Understand the organizational structure of hospital pharmacy
- Understand drug policy and drug committees
- Know about procurement & drug distribution practices
- Know the admixtures of radiopharmaceuticals
- Understand the community pharmacy management
- Know about value added services in community pharmacies

THEORY **60 Hrs**

1.	Introduction to Hospitals – Definition, classification, organizational structure Hospital Pharmacy: Definition, Relationship of hospital pharmacy department with other departments, Organizational structure, legal requirements, work load statistics, Infrastructural requirements, Hospital Pharmacy Budget and Hospital Pharmacy management Hospital Drug Policy: Pharmacy & Therapeutics Committee, Infection Control committee, Research & Ethics Committee, Management of Medicines as per NABH	12 Hrs
2.	Hospital Formulary Guidelines and its development, Developing Therapeutic guidelines, Drug procurement process, and methods of Inventory control, Methods of Drug distribution, Intravenous admixtures, Hospital Waste Management	12 Hrs
3.	Education and training: Training of technical staff, training and continuing education for pharmacists, Pharmacy students, Medical staff and students, Nursing staff and students, Formal and informal meetings and lectures, Drug and therapeutics newsletter. Community Pharmacy Practice: Definition, roles & responsibilities of community	12 Hrs

pharmacists, and their relationship with other health care providers.

Community Pharmacy management: Legal requirements to start community pharmacy, site selection, lay out & design, drug display, super drug store model, accounts and audits, Good dispensing practices, Different softwares & databases used in community pharmacies. Entrepreneurship in community pharmacy.

4. Prescription – Legal requirements & interpretation, prescription related problems — 12 Hrs

Responding to symptoms of minor ailments: Head ache, pyrexia, menstrual pains, food and drug allergy,

OTC medication: Rational use of over the counter medications Medication counseling and use of patient information leaflets Medication adherence – Definition, factors influencing adherence behavior, strategies to improve medication adherencePatient referrals to the doctors

ADR monitoring in community pharmacies

5. Health Promotion – Definition and health promotion activities, family planning, Health screening services, first aid, prevention of communicable and non-communicable diseases, smoking cessation, Child & mother care — 12 Hrs

National Health Programs- Role of Community Pharmacist in Malaria and TB control programs

Home Medicines review program – Definition, objectives, Guidelines, method and outcomes

Research in community pharmacy Practice

REFERENCES

1. Hospital Pharmacy - Hassan WE. Lea and Febiger publication.
2. Textbook of hospital pharmacy - Allwood MC and Blackwell.
3. Avery's Drug Treatment, Adis International Limited.
4. Community Pharmacy Practice – Ramesh Adepu, BSP Publishers, Hyderabad
5. Remington Pharmaceutical Sciences.
6. Relevant review articles from recent medical and pharmaceutical literature

CLINICAL RESEARCH

(MPP 104T)

Scope

This course aims to provide the students an opportunity to learn drug development process especially the phases of clinical trials and also the ethical issues involved in the conduct of clinical research. Also, it aims to imparts knowledge and develop skills on conceptualizing, designing, conducting and managing clinical trials.

Objectives

Upon completion of this course it is expected that students shall be able to:

- Know the new drug development process.
- Understand the regulatory and ethical requirements.
- Appreciate and conduct the clinical trials activities
- Know safety monitoring and reporting in clinical trials
- Manage the trial coordination process

THEORY **60 Hrs**

1.	Drug development process: Introduction, various approaches to drug discovery, Investigational new drug application submission Ethics in Biomedical Research: Ethical Issues in Biomedical Research – Principles of ethics in biomedical research, Ethical committee [institutional review board] - its constitution and functions, Challenges in implementation of ethical guidelines, ICH GCP guidelines and ICMR guidelines in conduct of Clinical trials, Drug Safety Reporting.	12 Hrs
2.	Types and Designs used in Clinical Research: Planning and execution of clinical trials, Various Phases of clinical trials, Bioavailability and Bioequivalence studies, Randomization techniques (Simple randomization, restricted randomization, blocking method and stratification), Types of research designs based on Controlling Method (Experimental, Quasi experimental, and Observational methods) Time Sequences (Prospective and Retrospective), Sampling methods (Cohort study, case Control study and cross sectional study), Health outcome measures (Clinical & Physiological, Humanistic and economic)	12 Hrs

Clinical Trial Study team: Roles and responsibilities of:Investigator, Study Coordinator, Sponsor, Monitor, Contract Research Organization.

3. Clinical trial Documents: Guidelines to the preparation of following documents: Protocols, Investigator's Brochure, Informed Consent Form, Case report forms, Contracts and agreements, Dairy Cards — 12 Hrs

Clinical Trial Start up activities: Site Feasibility Studies, Site/Investigator selection, Pre-study visit, Investigator meeting, Clinical trial agreement execution, Ethics committee document preparation and submission

4. Investigational Product: Procurement and Storage of investigation product — 12 Hrs

Filing procedures: Essential documents for clinical trial, Trial Master File preparation and maintenance, Investigator Site File, Pharmacy File, Site initiation visit, Conduct, Report and Follow up Clinical Trial Monitoring and Close out:

Preparation and conduct of monitoring visit: Review of source documents, CRF, ICF, IP storage, accountability and reconciliation, Study Procedure, EC communications, Safety reporting, Monitoring visit reporting and follow-up

Close-Out visit: Study related documents collection, Archival requirement, Investigational Product reconciliation and destruction, Close-Out visit report.

5. Quality Assurance and Quality Control in Clinical Trials: Types of audits, Audit criteria, Audit process, Responsibilities of stakeholders in audit process, Audit follow-up and documentation, Audit resolution and Preparing for FDA inspections, Fraud and misconduct management — 12 Hrs

Data Management

Infrastructure and System Requirement for Data Management: Electronic data capture systems, Selection and implementation of new systems, System validation and test procedures, Coding dictionaries, Data migration and archival

Clinical Trial Data Management: Standard Operating Procedures, Data management plan, CRF & Data base design considerations, Study set-up, Data entry, CRF tracking and corrections, Data cleaning, Managing laboratory and ADR data, Data transfer and database lock, Quality Control and Quality Assurance in CDM, Data mining and warehousing.

REFERENCES

1. Principles and practice of pharmaceutical medicine, Second edition. Authors:Lionel. D. Edward, Aadrew.J.Flether Anthony W Fos , Peter D Sloaier Publisher:Wiley;
2. Handbook of clinical research. Julia Lloyd and Ann Raven Ed. Churchill Livingstone
3. Principles of Clinical Research edited by Giovanna di Ignazio, Di Giovanna and Haynes.
4. Central Drugs Standard Control Organization. Good Clinical Practices- Guidelines for Clinical Trials on Pharmaceutical Products in India. New Delhi: Ministry of Health.
5. International Conference on Harmonisation of Technical requirements for registration of Pharmaceuticals for human use. ICH Harmonised Tripartite Guideline. Guideline for Good Clinical Practice.E6; May 1996.
6. Ethical Guidelines for Biomedical Research on Human Subjects. Indian Council of Medical Research, New Delhi.
7. Textbook of Clinical Trials edited by David Machin, Simon Day and Sylvan Green, John Wiley and Sons.
8. Clinical Data Management edited by R K Rondels, S A Varley, C F Webbs. Second Edition, Jan 2000, Wiley Publications.
9. Goodman & Gilman: JG Hardman, LE Limbard, McGraw Hill Publications. 10. Relevant review articles from recent medical and pharmaceutical literature.

PHARMACY PRACTICE PRACTICAL – I

(MPP 105P)

Pharmacy Practice practical component includes experiments covering important topics of the courses Clinical Pharmacy Practice, Pharmacotherapeutics-I, Hospital & Community Pharmacy and Clinical Research.

List of Experiments (24)

1. Treatment Chart Review (one)
2. Medication History Interview (one)
3. Patient Medication Counseling (two)
4. Drug Information Query (two)
5. Poison Information Query (one)
6. Lab Data Interpretation (two)
7. Presentation of clinical cases of various disease conditions adopting Pharmaceutical Care Plan Model (eight)
8. ABC Analysis of a given list of medications (one)
9. Preparation of content of a medicine, with proper justification, for the inclusion in the hospital formulary (one)
10. Formulation and dispensing of a given IV admixtures (one)
11. Preparation of a patient information leaflet (two)
12. Preparation of Study Protocol (one)
13. Preparation of Informed Consent Form (one)

PRINCIPLES OF QUALITY USE OF MEDICINES

(MPP 201T)

Scope:

This course is designed to impart basic knowledge and skills that are required to practice quality use of medicines (QUM) in different healthcare settings and also to promote quality use of medicines, in clinical practice, through evidence-based medicine approach.

Objectives:

Upon completion of this course it is expected that students shall be able to:

- Understand the principles of quality use of medicines
- Know the benefits and risks associated with use of medicines
- Understand regulatory aspects of quality use of medicines
- Identify and resolve medication related problems
- Promote quality use of medicines
- Practice evidence-based medicines

THEORY **60 Hrs**

1.	Introduction to Quality use of medicines (QUM): Definition and Principles of QUM, Key partners and responsibilities of the partners, Building blocks in QMC, Evaluation process in QMC, Communication in QUM, Cost effective prescribing.	12 Hrs
2.	Concepts in QUM Evidence based medicine: Definition, concept of evidence based medicine, Approach and practice of evidence based medicine in clinical settings Essential drugs: Definition, need, concept of essential drug, National essential drug policy and list Rational drug use: Definition, concept and need for rational drug use, Rational drug prescribing, Role of pharmacist in rational drug use.	12 Hrs
3.	QUM in various settings: Hospital settings, Ambulatory care/Residential care, Role of health care professionals in promoting the QUM, Strategies to promote the QUM, Impact of QUM on E-health, integrative medicine and multidisciplinary care. QUM in special population: Pediatric prescribing, Geriatric prescribing,	12 Hrs

Prescribing in pregnancy and lactation, Prescribing in immune compromised and organ failure patients.

4. Regulatory aspects of QUM in India: Regulation including scheduling, Regulation of complementary medicines, Regulation of OTC medicines, Professional responsibility of pharmacist, Role of industry in QUM in medicine development. 12 Hrs

5. Medication errors: Definition, categorization and causes of medication errors, Detection and prevention of medication errors, Role of pharmacist in monitoring and management of medication errors 12 Hrs

   Pharmacovigilance: Definition, aims and need for pharmacovigilance, Types, predisposing factors and mechanism of adverse drug reactions (ADRs), Detection, reporting and monitoring of ADRs, Causality assessment of ADRs, Management of ADRs, Role of pharmacist in pharmacovigilance.

REFERENCES:

1. A Textbook of Clinical Pharmacy Practice – Essential concepts and skills – Parthasarathi G, Karin Nyfort-Hansen and Milap Nahata
2. Andrews EB, Moore N. Mann's Pharmacovigilance
3. Dipiro JT, Talbert RL, Yee GC. Pharmacotherapy: A Pathophysiologic Approach
4. Straus SE, Richardson WS, Glasziou P, Haynes RB. Evidence-Based Medicine: How to practice and teach it
5. Cohen MR. Medication Errors
6. Online:
   - http://medicinesaustralia.com.au/files/2012/05/MA_QUM_External_Reduced.pdf
   - http://curriculum.racgp.org.au/statements/quality-use-of-medicines/
   - http://www.rug.nl/research/portal/files/14051541/Chapter_2.pdf
7. Relevant review articles from recent medical and pharmaceutical literature.

PHARMACOTHERAPEUTICS II

(MPP 202T)

Scope

This course aims to enable the students to understand the different treatment approaches in managing various disease conditions. Also, it imparts knowledge and skills in optimizing drug therapy of a patient by individualizing the treatment plan through evidence-based medicines.

Objectives

Upon completion of this course it is expected that students shall be able to:

- Describe and explain the rationale for drug therapy
- Summarize the therapeutic approach for management of various disease conditions including reference to the latest available evidence
- Discuss the clinical controversies in drug therapy and evidence based medicine
- Prepare individualized therapeutic plans based on diagnosis
- Identify the patient specific parameters relevant in initiating drug therapy, and monitoring therapy (including alternatives, time- course of clinical and laboratory indices of therapeutic response and adverse effect/s)

THEORY		**60 Hrs**
1.	Nervous system: Epilepsy, Parkinson's disease, Stroke, Headache, Alzheimer's disease, Neuralgias and Pain pathways and Pain management.	12 Hrs
2.	Psychiatric disorders: Schizophrenia, Depression, Anxiety disorders, Sleep disorders, Drug induced psychiatric disorders Renal system: Acute renal failure, Chronic renal failure, Renal dialysis, Drug induced renal disease	12 Hrs
3.	Infectious diseases: General guidelines for the rational use of antibiotics and surgical prophylaxis, Urinary tract infections, Respiratory tract infections, Gastroenteritis, Tuberculosis, Malaria, Bacterial endocarditis, Septicemia.	12 Hrs
4.	Infectious diseases: Meningitis, HIV and opportunistic infections, Rheumatic fever, Dengue fever, H1N1, Helmenthiasis, Fungal infections Gynecological disorders: Dysmenorrhea, Hormone replacement therapy.	12 Hrs
5.	Oncology: General principles of cancer chemotherapy, pharmacotherapy of breast cancer, lung cancer, head & neck cancer, hematological malignancies,	12 Hrs

Management of nausea and vomiting, Palliative care

REFERENCES

1. Roger and Walker. Clinical Pharmacy and Therapeutics – Churchill Livingstone publication.
2. Joseph T. Dipiro et al. Pharmacotherapy: A Pathophysiologic Approach- Appleton & Lange
3. Robins SL. Pathologic basis of disease -W.B. Saunders publication
4. Eric T. Herfindal. Clinical Pharmacy and Therapeutics- Williams and Wilkins Publication
5. Lloyd Young and Koda-Kimble MA Applied Therapeutics: The clinical Use of Drugs- Lippincott Williams and Wilkins
6. Chisholm- Burns Wells Schwinghammer Malone and Joseph P Dipiro. Pharmacotherapy Principles and practice-– McGraw Hill Publication
7. Carol Mattson Porth. Principles of Pathophysiology- Lippincott Williams and Wilkins
8. Harrison's. Principles of Internal Medicine - McGraw Hill
9. Relevant review articles from recent medical and pharmaceutical literature

CLINICAL PHARMACOKINETICS AND THERAPEUTIC DRUG MONITORING

(MPP 203T)

Scope

This course is designed to enable students to understand the basics principles and applications of pharmacokinetics in designing the individualized dosage regimen, to interpret the plasma drug concentration profile in altered pharmacokinetics, drug interactions and in therapeutic drug monitoring processes to optimize the drug dosage regimen. Also, it enables students to understand the basic concepts of pharmacogenetics, pharmacometrics for modeling and simulation of pharmacokinetic data.

Objectives

Upon completion of this course it is expected that students shall be able to:

- Design the drug dosage regimen for individual patients
- Interpret and correlate the plasma drug concentrations with patients' therapeutic outcomes
- Recommend dosage adjustment for patients with renal/ hepatic impairment
- Recommend dosage adjustment for paediatrics and geriatrics
- Manage pharmacokinetic drug interactions
- Apply pharmacokinetic parameters in clinical settings
- Interpret the impact of genetic polymorphisms of individuals on pharmacokinetics and or pharmacodynamics of drugs
- Do pharmacokinetic modeling for the given data using the principles of pharmacometrics

THEORY **60 Hrs**

1.	Introduction to Clinical pharmacokinetics: Compartmental and Non compartmental models, Renal and non-renal clearance, Organ extraction and models of hepatic clearance, Estimation and determinants of bioavailability, Multiple dosing, Calculation of loading and maintenance doses Designing of dosage regimens: Determination of dose and dosing intervals, Conversion from intravenous to oral dosing, Nomograms and Tabulations in designing dosage regimen.	12 Hrs
2.	Pharmacokinetics of Drug Interaction: Pharmacokinetic drug interactions,	12

	Inhibition and Induction of Drug metabolism, Inhibition of Biliary Excretion Pharmacogenetics: Genetic polymorphism in Drug metabolism:Cytochrome P-450 Isoenzymes, Genetic Polymorphism in Drug Transport and Drug Targets, Pharmacogenetics and Pharmacokinetic / Pharmacodynamic considerations Introduction to Pharmacometrics: Introduction to Bayesian Theory, Adaptive method or Dosing with feedback, Analysis of Population pharmacokinetic Data.	Hrs
3.	Non Linier Mixed Effects Modelling: The Structural or Base Model, Modeling Random Effects, Modeling Covariate Relationships, Mixture Model, Estimation Methods, Model Building Techniques, Covariate Screening Methods, Testing the model assumptions, Precision of the parameter estimates and confidence intervals, Model misspecification and violation of the model assumptions, Model Validation, Simulation of dosing regimens and dosing recommendations, Pharmacometrics software.	12 Hrs
4.	Altered Pharmacokinetics: Drug dosing in the elderly, Drug dosing in the paediatrics, Drug dosing in the obese patients, Drug dosing in the pregnancy and lactation, Drug dosing in the renal failure and extracorporeal removal of drugs, Drug dosing in the in hepatic failure.	12 Hrs
5.	Therapeutic Drug monitoring: Introduction, Individualization of drug dosage regimen (Variability – Genetic, age, weight, disease and Interacting drugs), Indications for TDM, Protocol for TDM, Pharmacokinetic/Pharmacodynamic Correlation in drug therapy, TDM of drugs used in the following conditions: Cardiovascular disease: Digoxin, Lidocaine, Amiodarone; Seizure disorders:Phenytoin, Carbamazepine, Sodium Valproate; Psychiatric conditions: Lithium, Fluoxetine, Amitriptyline; Organ transplantations: Cyclosporine; Cytotoxic Agents: Methotrexate, 5-FU, Cisplatin; Antibiotics: Vancomycin, Gentamicin, Meropenem.	12 Hrs

REFERENCES

1. Leon Shargel, Susanna Wu-Pong, Andrew Yu. Applied Biopharmaceutics & Pharmacokinetics. New York: Mc Graw Hill.
2. Peter L. Bonate. Pharmacokinetic - Pharmacodynamic Modeling and Simulation. Springer Publications.

3. Michael E. Burton, Leslie M. Shaw, Jerome J. Schentag, William E.Evans. Applied Pharmacokinetics & Pharmacodynamics: Principles of Therapeutic Drug Monitoring. Iippincott Williams & Wilkins.
4. Steven How-Yan Wong, Irving Sunshine. Handbook of Analytical Therapeutic Drug Monitoring and Toxicology. CRC Press, USA.
5. Soraya Dhillon, Andrzej Kostrzewski. Clinical pharmacokinetics. 1st edition. London: Pharmaceutical Press.
6. Joseph T.Dipiro, William J.Spruill, William E.Wade, Robert A.Blouin and Jane M.Pruemer .Concepts in Clinical Pharmacokinetics. American Society of Health-System Pharmacists, USA.
7. Malcolm Rowland, Thomas N. Tozer .Clinical Pharmacokinetics and pharmacodynamics: concepts and applications. Iippincott Williams & Wilkins, USA.
8. Evans, Schentag, Jusko. Applied pharmacokinetics. American Society of Health system Pharmacists, USA.
9. Michael E. Winter. Basic Clinical Pharmacokinetics. Iippincott Williams & Wilkins, USA.
10. Milo Gibaldi. Biopharmaceutics and Clinical Pharmacokinetics. Pharma Book Syndicate, USA.
11. Dhillon and Kostrzewski. Clinical pharmacokinetics. Pharmaceutical Press, London.
12. John E .Murphy. Clinical Pharmacokinetics. 5th edition. US: American Society of Health-System Pharmacist, USA.
13. Relevant review articles from recent medical and pharmaceutical literature

2)

PHARMACOEPIDEMIOLOGY & PHARMACOECONOMICS

(MPP 204T)

Scope

This course enables students to understand various pharmacoepidemiological methods and their clinical applications. Also, it aims to impart knowledge on basic concepts, assumptions, terminology, and methods associated with Pharmacoeconomics and health related outcomes, and when should be appropriate Pharmacoeconomic model should be applied for a health care regimen.

Objectives

Upon completion of this course it is expected that students shall be able to:

- Understand the various epidemiological methods and their applications
- Understand the fundamental principles of Pharmacoeconomics.
- Identify and determine relevant cost and consequences associated with pharmacy products and services.
- Perform the key Pharmacoeconomics analysis methods
- Understand the Pharmacoeconomic decision analysis methods and its applications.
- Describe current Pharmacoeconomic methods and issues.
- Understand the applications of Pharmacoeconomics to various pharmacy settings.

THEORY **60 Hrs**

1.	Introduction to Pharmacoepidemiology: Definition, Scope, Need, Aims & Applications; Outcome measurement: Outcome measures, Drug use measures: Monetary units, Number of prescriptions, units of drug dispensed, defined daily doses, prescribed daily doses, Diagnosis and Therapy surveys, Prevalence, Incidence rate, Monetary units, number of prescriptions, unit of drugs dispensed, defined daily doses and prescribed daily doses, medications adherence measurements. Concept of risk: Measurement of risk, Attributable risk and relative risk, Time-risk relationship and odds ratio	12 Hrs
2.	Pharmacoepidemiological Methods: Qualitative models: Drug Utilization Review; Quantitative models: case reports, case series, Cross sectional studies, Cohort and case control studies, Calculation of Odds' ratio, Meta analysis models, Drug effects study in populations: Spontaneous reporting, Prescription event	12 Hrs

monitoring, Post marketing surveillance, Record linkage systems, Applications of Pharmacoepidemiology

3. Introduction to Pharmacoeconomics: Definition, history of Pharmacoeconomics, Need of Pharmacoeconomic studies in Indian healthcare system. 12 Hrs

   Cost categorization and resources for cost estimation: Direct costs. Indirect costs. Intangible costs.

   Outcomes and Measurements of Pharmacoeconomics: Types of outcomes: Clinical outcome, Economic outcomes, Humanistic outcomes; Quality Adjusted Life Years, Disability Adjusted Life Years Incremental Cost Effective Ratio, Average Cost Effective Ratio. Person Time, Willingness To Pay, Time Trade Off and Discounting.

4. Pharmacoeconomic evaluations: Definition, Steps involved, Applications, Advantages and disadvantages of the following Pharmacoeconomic models: Cost Minimization Analysis (CMA), Cost Benefit Analysis (CBA), Cost Effective Analysis (CEA), Cost Utility Analysis (CUA), Cost of Illness (COI), Cost Consequences Analysis (COA). 12 Hrs

5. Definition, Steps involved, Applications, Advantages and disadvantages of the following: 12 Hrs

   Health related quality of life (HRQOL): Definition, Need for measurement of HRQOL, Common HRQOL measures.

   Definition, Steps involved, Applications of the following:

   Decision Analysis and Decision tree, Sensitivity analysis, Markov Modeling, Software used in pharmacoeconomic analysis, Applications of Pharmacoeconomics.

REFERENCES

1. Rascati K L. Essentials of Pharmacoeconomics, Woulters Kluwer Lippincott Williams & Wilkins, Philadelphia.
2. Thomas E Getzen. Health economics. Fundamentals and Flow of Funds. John Wiley & Sons, USA.
3. Andrew Briggs, Karl Claxton, Mark Sculpher. Decision Modelling for Health Economic Evaluation, Oxford University Press, London.

4. Michael Drummond, Mark Sculpher, George Torrence, Bernie O'Brien and Greg Stoddart. Methods for the Economic Evaluation of Health Care Programmes Oxford University Press, London.
5. George E Mackinnon III. Understanding health outcomes and pharmacoeconomics.
6. Graker, Dennis. Pharmacoeconomics and outcomes.
7. Walley, Pharmacoeconomics.
8. Pharmacoeconomic – ed. by Nowakowska – University of Medical Sciences, Poznan.
9. Relevant review articles from recent medical and pharmaceutical literature

PHARMACY PRACTICE PRACTICAL - II

(MPP 205P)

Pharmacy Practice practical component includes experiments covering important topics of the courses Principles of Quality Use of Medicines, Pharmacotherapeutics-II, Clinical Pharmacokinetics & Therapeutic Drug Monitoring and Pharmacoepidemiology and Pharmacoeconomics.

List of Experiments (24)

1. Causality assessment of adverse drug reactions (three)
2. Detection and management of medication errors (three)
3. Rational use of medicines in special population (three)
4. Presentation of clinical cases of various disease conditions adopting Pharmaceutical Care Plan Model (eight)
5. Calculation of Bioavailability and Bioequivalence from the given data (two)
6. Interpretation of Therapeutic Drug Monitoring reports of a given patient (three)
7. Calculation of various Pharmacoeconomic outcome analysis for the given data (two)

Semester III

MRM 301T - Research Methodology & Biostatistics

UNIT – I

General Research Methodology: Research, objective, requirements, practical difficulties, review of literature, study design, types of studies, strategies to eliminate errors/bias, controls, randomization, crossover design, placebo, blinding techniques.

UNIT – II

Biostatistics: Definition, application, sample size, importance of sample size, factors influencing sample size, dropouts, statistical tests of significance, type of significance tests, parametric tests(students "t" test, ANOVA, Correlation coefficient, regression), non-parametric tests (wilcoxan rank tests, analysis of variance, correlation, chi square test), null hypothesis, P values, degree of freedom, interpretation of P values.

UNIT – III

Medical Research: History, values in medical ethics, autonomy, beneficence, non-maleficence, double effect, conflicts between autonomy and beneficence/non-maleficence, euthanasia, informed consent, confidentiality, criticisms of orthodox medical ethics, importance of communication, control resolution, guidelines, ethics committees, cultural concerns, truth telling, online business practices, conflicts of interest, referral, vendor relationships, treatment of family members, sexual relationships, fatality.

UNIT – IV

CPCSEA guidelines for laboratory animal facility: Goals, veterinary care, quarantine, surveillance, diagnosis, treatment and control of disease, personal hygiene, location of animal facilities to laboratories, anesthesia, euthanasia, physical facilities, environment, animal husbandry, record keeping, SOPs, personnel and training, transport of lab animals.

UNIT – V

Declaration of Helsinki: History, introduction, basic principles for all medical research, and additional principles for medical research combined with medical care.

2.7 Total number of hour

As mentioned in Course outline (clause 2.4)

2.8 Branches if any, with definition

As mentioned in Syllabus (clause 2.6)

2.9 Teaching Learning methods

A regular record of attendance both in Theory, Practical, Seminar, Assignment, Journal club, Discussion with the supervisor, Research work presentation and Dissertation shall be maintained by the department / teaching staff of respective courses.

2.10 Content of each subject in each year

As mentioned in Syllabus (clause 2.6)

2.11 No: of hours per subject

As mentioned in Syllabus (clause 2.6)

2.12 Practical Training

As mentioned in Course outline (clause 2.4)

2.13 Records

To be maintained for all Practical Work

2.14 Dissertation

As mentioned in Project work to be done (clause 2.16)

2.15 Speciality Training if ANY

As mentioned in Syllabus (clause 2.6)

2.16 Project work to be done if any

All the students shall undertake a project under the supervision of a teacher in Semester III to IV and submit a report. 4 copies of the project report shall be submitted (typed & bound copy not less than 75 pages).

The internal and external examiner appointed by the University shall evaluate the project at the time of the Practical examinations of other semester(s). The projects shall be evaluated as per the criteria given below.

Evaluation of Dissertation Book:

Objective(s) of the work done	50 Marks
Methodology adopted	150 Marks
Results and Discussions	250 Marks
Conclusions and Outcomes	50 Marks
Total	500 Marks

Evaluation of Presentation:

Presentation of work	100 Marks
Communication skills	50 Marks
Question and answer skills	100 Marks
Total	250 Marks

2.17 Any other Requirements [CME, Paper Publishing, etc,.]

As mentioned in Course outline (clause 2.4)

2.18 Prescribed/Recommended textbooks for each subject

As mentioned in Syllabus (clause 2.6)

2.19 Reference books

As mentioned in Syllabus (clause 2.6)

2.20 Journals

All Pharmacy and related Medical Journals

2.21 Logbook

Registers to be maintained

3. EXAMINATION

3.1 Eligibility to appear for examinations

A candidate is required to put in at least 80% attendance in individual courses considering theory and practical separately. The candidate shall complete the prescribed course satisfactorily to be eligible to appear for the respective examinations.

3.2 Schedule of Regular / Supplementary exams

Semester examinations will be conducted once in every six months after fulfilling 100 working days.

Table: 6 - Question paper pattern for end semester theory & practical examinations

Question paper pattern for end semester theory examinations			
I.	Long Answers	3 X 10	30 Marks
II.	Short Answers	9 X 5	45 Marks
		Total	**75 Marks**
Question paper pattern for end semester practical examinations			
I.	Synopsis		15 Marks
II.	Experiment - I		40 Marks
III.	Experiment – II		30 Marks
IV.	Viva voce		15 Marks
	Total		**100 Marks**

3.3 Scheme of examination showing maximum marks and minimum marks

The End Semester Examinations for each theory and practical Course through semesters I to IV shall be conducted by the respective university except for the subject with asterisk symbol (*) in table – 8 for which examinations shall be conducted by the subject experts at college level and the marks/grades shall be submitted to the university.

Schemes for internal assessments and end semester examinations are given in table below

Table – 7: Schemes for internal assessments and end semester examinations

Course code	Course	Internal Assessment				End Semester Exams		Total Marks
		Continuous Mode	Sessional Exams		Total	Marks	Duration	
			Marks	Duration				
SEMESTER I								
MPP 101T	Clinical Pharmacy Practice	10	15	1 Hr	25	75	3 Hrs	100
MPP 102T	Pharmacotherapeutics-1	10	15	1 Hr	25	75	3 Hrs	100
MPP 103T	Hospital & Community Pharmacy	10	15	1 Hr	25	75	3 Hrs	100
MPP 104T	Clinical Research	10	15	1 Hr	25	75	3 Hrs	100
MPP 105P	Pharmacy Practice Practical I	20	30	6 Hrs	50	100	6 Hrs	150
-	Seminar /Assignment	-	-	-	-	-	-	100
Total								
SEMESTER II								
MPP 201T	Principles of Quality use of Medicines	10	15	1 Hr	25	75	3 Hrs	100
MPP 202T	Pharmacotherapeutics II	10	15	1 Hr	25	75	3 Hrs	100
MPP 203T	Clinical Pharmacokinetics and therapeutic Drug Monitoring	10	15	1 Hr	25	75	3 Hrs	100
MPP 204T	Pharmacoepidemiology & Pharmacoeconomics	10	15	1 Hr	25	75	3 Hrs	100
MPP 205P	Pharmacy Practice Practical II	20	30	6 Hrs	50	100	6 Hrs	150
-	Seminar /Assignment	-	-	-	-	-	-	100
Total								650

Table – 8: Schemes for internal assessments and end semester examinations

(Semester III& IV)

Course code	Course	Internal Assessment				End Semester Exams		Total Marks
		Continuous Mode	Sessional Exams		Total	Marks	Duration	
			Marks	Duration				
SEMESTER III								
MRM 301T	Research Methodology and Biostatistics*	10	15	1 Hr	25	75	3 Hrs	100
-	Journal Club	-	-	-	25	-	-	25
-	Discussion / Presentation (proposal presentation)	-	-	-	50	-	-	50
-	Research Work*	-	-	-	-	350	1 Hr	350
Total								525
SEMESTER IV								
-	Journal club	-	-	-	25	-	-	25
-	Discussion / Presentation (proposal presentation)	-	-	-	75	-	-	75
-	Research Work and Colloquium	-	-	-	-	400	1 Hr	400
Total								500

*Non University Examination

Table – 9: Scheme for awarding internal assessment

Theory	
Criteria	**Maximum Marks**
Attendance (Refer Table – 10)	8
Student – Teacher interaction	2
Total	10
Practical	
Attendance (Refer Table – 10)	10
Based on Practical Records, Regular viva voce, etc.	10
Total	20

Table – 10: Guidelines for the allotment of marks for attendance

Percentage of Attendance	Theory	Practical
95 – 100	8	10
90 – 94	6	7.5
85 – 89	4	5
80 – 84	2	2.5
Less than 80	0	0

Allowed to keep terms (ATKT):

No student shall be admitted to any examination unless he/she fulfills the norms given in clause 3.1. ATKT rules are applicable as follows:

A student shall be eligible to carry forward all the courses of I and II semesters till the III semester examinations. However, he/she shall not be eligible to attend the courses of IV semester until all the courses of I, II and III semesters are successfully completed.

A student shall be eligible to get his/her CGPA upon successful completion of the courses of I to IV semesters within the stipulated time period as per the norms.

Note: Grade AB should be considered as failed and treated as one head for deciding ATKT. Such rules are also applicable for those students who fail to register for examination(s) of any course in any semester.

Grading of performances

a) Letter grades and grade points allocations:

Based on the performances, each student shall be awarded a final letter grade at the end of the semester for each course. The letter grades and their corresponding grade points are given in Table – 11.

Table – 11: Letter grades and grade points equivalent to Percentage of marks and performances

Percentage of Marks obtained	Letter Grade	Grade point	Performance
90.00 – 100	O	10	Outstanding
80.00 – 89.99	A	9	Excellent
70.00 – 79.99	B	8	Good
60.00 – 69.99	C	7	Fair
50.00 – 59.99	D	6	Average
Less than 50	F	0	Fail
Absent	AB	0	Fail

A learner who remains absent for any end semester examination shall be assigned a letter grade of AB and a corresponding grade point of zero. He/she should reappear for the said evaluation/examination in due course.

b) The Semester grade point average (SGPA)

The performance of a student in a semester is indicated by a number called 'Semester Grade Point Average' (SGPA). The SGPA is the weighted average of the grade points obtained in all the courses by the student during the semester. For example, if a student takes five courses (Theory/Practical) in a semester with credits C1, C2, C3 and C4 and the student's grade points in these courses are G1, G2, G3 and G4, respectively, and then students' SGPA is equal to:

$$SGPA = \frac{C_1G_1 + C_2G_2 + C_3G_3 + C_4G_4}{C_1 + C_2 + C_3 + C_4}$$

The SGPA is calculated to two decimal points. It should be noted that, the SGPA for any semester shall take into consideration the F and ABS grade awarded in that semester. For example if a learner has a F or ABS grade in course 4, the SGPA shall then be computed as:

$$SGPA = \frac{C_1G_1 + C_2G_2 + C_3G_3 + C_4*ZER0}{C_1 + C_2 + C_3 + C_4}$$

c) Cumulative Grade Point Average (CGPA)

The CGPA is calculated with the SGPA of all the IV semesters to two decimal points and is indicated in final grade report card/final transcript showing the grades of all IV semesters and their courses. The CGPA shall reflect the failed status in case of F grade(s), till the course(s) is/are passed. When the course(s) is/are passed by obtaining a pass grade on subsequent examination(s) the CGPA shall only reflect the new grade and not the fail grades earned earlier.The CGPA is calculated as:

$$CGPA = \frac{C_1S_1 + C_2S_2 + C_3S_3 + C_4S_4}{C_1 + C_2 + C_3 + C_4}$$

where C_1, C_2, C_3,…. is the total number of credits for semester I,II,III,…. And S_1, S_2, S_3… is the SGPA of semester I, II, III…. .

3.4 Papers in each year

As mentioned in Course outline (clause 2.4)

3.5 Details of theory exams

As mentioned in Schedule of regular / Supplementary Exams (clause 3.2)

3.6 Model question paper for each subject with question paper pattern

As mentioned in Schedule of regular / Supplementary Exams (clause 3.2).see Annexure

3.7 Internal assessment component

As mentioned in Scheme of examination. (Clause 3.3)

- Two sessional exams shall be conducted for each theory / practical course as per the schedule fixed by the college(s). The average marks of two sessional exams shall be computed for internal assessment as per the requirements
- A student shall have the opportunity to improve his/her performance only once in the sessional exam component of the internal assessment. The re-conduct of the sessional exam shall be completed before the commencement of next end semester theory examinations.

3.8 Details of practical / clinical practicum exams.

As mentioned in Schedule of regular / Supplementary Exams (clause 3.2) Scheme of examination. (Clause 3.3)

3.9 Number of examiners (Internal & External) and their qualifications

- A post graduate (PG) degree in M. Pharm shall be eligible as teacher.
- A post graduate degree in M. Pharm with 5 years Post PG experience is eligible as internal examiner.
- A post graduate degree in M. Pharm with 10 years Post PG is eligible as external examiner.
- A post graduate degree in M. Pharm with 5 years Post PG is eligible to guide maximum of 5 candidates for M. Pharm dissertation.

For the evaluation of Practical Examination of I & II semesters one internal and one external examiner shall be appointed by the University. Details of project evaluation are given under clause 2.16

3.10 Details of viva:

As mentioned in Schedule of regular / Supplementary Exams (clause 3.2) Scheme of examination. (Clause 3.3)

4. INTERNSHIP

Not applicable

5. ANNEXURES

5.1 Check Lists for Monitoring:

Log Book, Seminar Assessment etc. to be formulated by the curriculum committee of the concerned Institution.

MODEL QUESTION PAPER

Q P CODE REG NO

MODEL QUESTION PAPER M.PHARM PHARMACOLOGY

FIRST SEMESTER M.PHARM DEGREE EXAMINATIONS

PAPER 1 MODERN PHARMACEUTICAL ANALYTICAL TECHNIQUES (MPA101T)

Time 3Hrs Max marks75

Answer all questions

Essays (3x10=30)

1 Discuss in detail NMR Spectroscopy

2 Explain instrumentation application and working of Flourescene spectroscopy

3 Give a detailed explanation of HPTLCand HPLC

Short Notes

4 Gel Electro phoresis

5 Instrumentatio in IR spectrometer

6 Braggs Law

7 Choice of solvents and solvent effect in UV spectral study

8 Fragmentation pattern in MASS spectrometry

9 XRAY Diffraction Study

10 Meta stable ion and isotropic peaks

11 Ion selective electrodes

12 Principle of MASS spectrometer

M.PHARM PHARMACOLOGY MODEL QUESTION PAPER

Q.P .CODE REG No

FIRST SEMESTER M.PHARM DEGREE EXAMINATIONS

PAPER 11 ADVANCED PHARMACOLOGY 1

Tlme 3Hrs Max marks 75

ANSWER ALL QUESTIONS

Essays (3X10=30)

1 Describe dynamics of drug absorption and distribution

2 Discuss in detail histamines and antihistamines

3 Explain mechanism of drug action,relationship between drug concentration and drug effect

Short notes *9x5=4*

4 compartment model

5 Adrenalin

6 Parasympathomimetics

7 Sedatives and hypnotics

8 Prostaglandins

9 Narcotic and non narcotic analgesics

10 Drugs to treat anxiety

11 Antiplatelet drugs

12 Significance of protein binding

Q P CODE NO REG NO

FIRST SEMESTER M.PHARM DEGREE EXAMINATIONS

PAPER – I11 PHARMACOLOGICAL AND TOXICOLOGICAL SCREENING METHODS 1(MPL102T)

Time: 3 hours Answer all questions Max marks 75

Essays (3x10=30)

1. Discuss in detail various methods employed in the screening of analgesics
2. Describe the guidelines of CPCSEA to maintain animal house
3. Explain the protocol outline and preparationof immunoassay

Short notes on (9x5=45)

4. Limitation of Bioassay
5. Write the steps of giving anaesthesia of experimental animals
6. Explain invitroassay of antidiabetic drugs
7. Discuss briefly about hepatoprotective screening methods
8. Write a note on in vivo method of assay of anti diarrheal drugs
9. Biochemical methods alternative to animal experiments
10. Write briefly on screening methods of drugs for Alzheimers disease
11. What are the possible animal alternative model forscreening of Anticancer agents

12 in vivo method for screening immunostimulant activity

Q P CODE NO REG NO

FIRST SEMESTER M.PHARM DEGREE EXAMINATIONS

PAPER – IV – CELLULAR AND MOLECULAR PHARMACOLOGY

Time: 3 hours Answer all questions Max marks 75

Essays (3x10=30)

1 Discuss about molecular structure of ligand gated ion channels
2 Describe cell cycle. What are the factors regulating cell cycle.
3 What are the general procedure for cell cultures

Short Notes

(9x5=45

4 Applications of recombinant DNA technology
5 Write about genetic variation in G protein coupled receptors
6 Explain the recent advances in gene therapy
7 Discuss briefly about metabolomics
8 Write a note on calcium inflexed assay
9 What are the various types of gene transfer techniques
10 What is the principle of ELISA assays?
11 Write briefly on Janus Kinase signal transducer
12 What is the significance of RNA and its types