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

2. COURSE CONTENT

3. EXAMINATIONS

4. INTERNSHIP

5. ANNEXURES

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

3. EXAMINATIONS

4. INTERNSHIP

5. ANNEXURES

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.
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

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.
4. "Organic Chemistry" Vol I and II. I.L. Finar. ELBS, Sixth ed., 1995.
5. Carey, Organic chemistry, 5th edition (Viva Books Pvt. Ltd.)
6. Organic synthesis-the disconnection approach, S. Warren, Wily India
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

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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)
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13. S.D. Shukla & G.N. Pandey: A text book of Chemical Technology Vol. II, Vikas Publishing House
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15. Shreve: Chemical Process Mc Grawhill, .
16. B.K.Sharma: Industrial Chemistry, Goel Publishing House
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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

3. EXAMINATIONS

4. INTERNSHIP

5. ANNEXURES

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

3. EXAMINATIONS

4. INTERNSHIP

5. ANNEXURES

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.

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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

3. EXAMINATIONS

4. INTERNSHIP

5. ANNEXURES

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

3. EXAMINATIONS

4. INTERNSHIP

5. ANNEXURES

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

KERALA UNIVERSITY OF HEALTH SCIENCES

Thrissur - 680596

SYLLABUS

POST GRADUATE COURSE IN PHARMACY

Master of Pharmacy (M. Pharm.)

INDUSTRIAL PHARMACY	MIP
KUHS Course Code	533

(2022-23 Academic year onwards)

2022

Course of study for M.Pharm. I & II Semester

MIP	Industrial Pharmacy				
Course Code	**Course**	**Credit Hours**	**Credit Points**	**Hrs./wk**	**Marks**
Semester I					
MIP 101T	Modern Pharmaceutical Analytical Techniques	4	4	4	100
MIP 102T	Pharmaceutical Formulation Development	4	4	4	100
MIP 103T	Novel Drug delivery systems	4	4	4	100
MIP 104T	Intellectual Property Rights & Regulatory Affairs	4	4	4	100
MIP 105P	Industrial Pharmacy Practical - I	12	6	12	150
-	Seminar/Assignment	7	4	7	100
Total		**35**	**26**	**35**	**650**
Semester II					
MIP 201T	Advanced Biopharmaceutics and Pharmacokinetics	4	4	4	100
MIP 202T	Scale up and Technology Transfer	4	4	4	100
MIP 203T	Pharmaceutical Production Technology	4	4	4	100
MIP 204T	Entrepreneurship Management	4	4	4	100
MIP 205P	Industrial Pharmacy Practical – II	12	6	12	150
-	Seminar /Assignment	7	4	7	100
Total		**35**	**26**	**35**	**650**

Course of study for M. Pharm. III & IV Semester

Course Code	**Course**	**Credit Hours**	**Credit Points**	**Marks**
Semester III				
MRM 301T	Research Methodology and Biostatistics	4	4	100
-	Journal Club	1	1	25
-	Discussion / Presentation (proposal presentation)	2	2	25
-	Research Work	28	14	350
Total		**35**	**21**	**500**
Semester IV				
-	Journal Club	1	1	25
-	Pre submission Discussion / Presentation	3	3	75
-	Research Work	31	16	400
Total		**35**	**20**	**500**

INDUSTRIAL PHARMACY (MIP)

SEMESTER - I

MODERN PHARMACEUTICAL ANALYTICAL TECHNIQUES (MPT 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

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

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

THEORY **60 Hrs**

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

   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 (Characteristics 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:** Principle, Instrumentation, 10 Hrs 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.

3. **Mass Spectroscopy:** Principle, Theory, Instrumentation of Mass Spectroscopy, 9 Hrs 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.

4. **Chromatography:** Principle, apparatus, instrumentation, chromatographic 9 Hrs 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

5. a.Electrophoresis: Principle, Instrumentation, Working conditions, factors affecting separation and applications of the following: 9 Hrs

i) Paper electrophoresis ii) Gel electrophoresis iii) Capillary electrophoresis iv) Zone electrophoresis v) Moving boundary electrophoresis vi) 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. 9 Hrs

b. Thermal Techniques: i) Differential scanning calorimetry (DSC): 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.

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

7. Immunological assays: RIA (Radio immuno assay), ELISA, Bioluminescence assays. 4 Hrs

REFERENCES

1. Spectrometric Identification of Organic compounds - Robert M Silverstein, 6th Edition, John Wiley & Sons, 2004.
2. Principles of Instrumental Analysis - Douglas 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, CBSPublishers, 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 Edition, P.S. Kalsi, Wiley Eastern Ltd, Delhi.
9. Textbook of Pharmaceutical Analysis, K.A. Connors, 3rd Edition, John Wiley & Sons, 1982.

PHARMACEUTICAL FORMULATION DEVELOPMENT (MIP 102T)

Scope:

This course is designed to impart knowledge and skills necessary to train the students on par with the routine of Industrial activities in R&D and F&D.

Objectives:

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

- The scheduled activities in a Pharmaceutical firm.
- The pre formulation studies of pilot batches of pharmaceutical industry.
- The significance of dissolution and product stability

THEORY **60 Hrs**

1. Preformulation Studies: 12 Hrs

Molecular optimization of APIs (drug substances), crystal morphology and variations, powder flow, structure modification, drug-excipient compatibility studies, methods of determination.

2 a) Formulation Additives: Study of different formulation additives, factors influencing their incorporation, role of formulation development and processing, new developments in excipient science.

b) Design of experiments: Optimization techniques in Pharmaceutical Formulation: Concept and parameters of optimization, Optimization techniques in pharmaceutical formulation and processing. Quality by design- concept and applications. Statistical design, Response surface method, Contour designs, Factorial designs and application in product and process development.

3. Solubility: 12 Hrs

Importance, experimental determination, phase- solubility analysis, pH-solubility profile, solubility techniques to improve solubility and utilization of analytical methods – cosolvency, salt formation, complexation, solid dispersion, micellar solubilization and hydrotropy.

4. Dissolution: 12 Hrs

Theories, mechanisms of dissolution, in-vitro dissolution testing models – sink and non-sink. Factors influencing dissolution and intrinsic dissolution studies. Dissolution test apparatus – designs, dissolution testing for conventional and controlled release products. Data handling and correction factor. Biorelevent media, in-vitro and in-vivo correlations, levels of correlations.

5. Product Stability: 12 Hrs

Degradation kinetics, mechanisms, stability testing of drugs and pharmaceuticals, factors influencing-media effects and pH effects, accelerated stability studies, interpretation of kinetic data (API & tablets). Solid state stability and shelf life assignment. Stability protocols, reports and ICH guidelines.

REFERENCES

1. Lachman L, Lieberman HA, Kanig JL. The Theory and Practice of Industrial Pharmacy, 3 ed., Varghese Publishers, Mumbai 1991.

2. S inko PJ. Martin's physical pharmacy and pharmaceutical sciences, 5 ed., B.I. Publications Pvt. Ltd, Noida, 2006.

3. Lieberman HA, Landchman L, Schwartz JB. Pharmaceutical dosage forms: Tablets Vol. I-III, 2 ed., CBS Publishers & distributors, New Delhi, 2005.

4. Conners KA. A Text book of pharmaceutical analysis Wells JI. Pharmaceutical preformulation: The physicochemical properties of drug substances. Ellis Horwood Ltd., England, 1998.

5. Yalkowsky SH. Techniques of solubilization of drugs. Vol-12. Marcel Dekker Inc., New York, 1981

6. Dressman J, Kramer J. Pharmaceutical dissolution testing. Saurah printer pvt. Ltd., New Delhi,2005.

7. Sethi PD. Quantitative analysis of drugs in pharmaceutical formulations, 3 ed., CBS publications, New Delhi, 2008.
8. Carstensen JT, Rhodes CT. Drug stability principles and practices, 3rd Edition CBS Publishers & distributors, New Delhi, 2005.
9. Yoshioka S, Stella VJ. Stability of drugs and dosage forms, Springer (India) Pvt. Ltd., New Delhi, 2006.
10. Banker GS, Rhodes CT. Modern Pharmaceutics, 4th Edition, Marcel Dekker Inc, New York, 2005.
11. W. Grimm - Stability testing of drug products.
12. Mazzo DJ. International stability testing. Eastern Press Pvt. Ltd., Bangalore, 1999.
13. Beckett AH, Stenlake JB, Practical Pharmaceutical Chemistry, Part-I & II, 4th Edition, CBS Publishers & Distributors, New Delhi.
14. Indian Pharmacopoeia. Controller of Publication. Delhi, 1996.
15. British Pharmacopoeia. British Pharmacopoeia Commission Office, London, 2008.
16. United States Pharmacopoeia. United States Pharmacopeial Convention, Inc, USA, 2003.
17. Encyclopaedia of Pharm. Technology, Vol I – III.
18. Wells J. I. Pharmaceutical Preformulation: The physicochemical properties of drug substances, Ellis Horwood Ltd. England, 1988

NOVEL DRUG DELIVERY SYSTEMS (MIP 103T)

Scope:

This course is designed to impart knowledge and skills necessary to train the students in the area of novel drug delivery systems.

Objective:

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

- The need, concept, design and evaluation of various customized, sustained and controlled release dosage forms.
- To formulate and evaluate various novel drug delivery systems

THEORY **60 Hrs**

1. Concept & Models for NDDS: 10 Hrs

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

Carriers for Drug Delivery: Polymers/co-polymers-Introduction, classification, characterization, polymerization techniques, application in CDDS/NDDS, biodegradable & natural polymers.

2. Study of Various DDS: 10 Hrs

Concepts, design, formulation & evaluation of controlled release oral DDS, Mucoadhesive DDS (buccal, nasal, pulmonary) Pulsatile, colon specific, liquid sustained release systems, Ocular delivery systems

3. Transdermal Drug Delivery Systems: 8 Hrs

Theory, design, formulation & evaluation including iontophoresis and other latest developments in skin delivery systems.

4. Sub-Micron Cosmeceuticals: 4 Hrs

Biology, formulation science and evaluation of various cosmetics for skin, hair, nail, eye etc and it's regulatory aspects.

5. Targeted Drug Delivery Systems: 10 Hrs

Importance, concept, biological process and events involved in drug targeting, design, formulation & evaluation, methods in drug targeting – nanoparticles, liposomes, niosomes, pharmacosomes, resealed erythrocytes, microspheres, magnetic microspheres. Specialized pharmaceutical emulsions – multiple emulsions, micro-emulsions.

6. Protein / Peptide Drug Delivery Systems: 6 Hrs

Concepts, delivery techniques, formulation, stability testing, causes of protein destabilization, stabilization methods.

7. Biotechnology in Drug Delivery Systems: 6 Hrs

Brief review of major areas-recombinant DNA technology, monoclonal antibodies, gene therapy.

8. New trends for Personalized Medicine: 6 Hrs

Introduction, Definition, Pharmacogenetics, Categories of Patients for Personalized Medicines: Customized drug delivery systems, Bioelectronic Medicines, 3D printing of pharmaceuticals, Telepharmacy.

REFERENCES

1. Novel Drug Delivery System, Y.W. Chein, Vol 50, Marcel Dekker, NY.
2. Controlled Drug Delivery Systems, Robinson, Vol 29, Marcel Dekker, NY.
3. Transdermal Controlled Systemic Medications, YW Chein, Vol 31, Marcel Dekker, NY.
4. Bioadhesive DDS, E. Mathiowitz, Vol 98, Marcel Dekker, NY.
5. Nasal System Drug Delivery, K.S.E. Su, Vol 39, Marcel Dekker, NY.
6. Drug Delivery Devices, Vol 32, P Tyle Marcel Dekker, NY.
7. Polymers for Controlled Drug Delivery, P.J. Tarcha, CRC Press.
8. Pharmaceutical Biotechnology, Vyas, CBS, Delhi.
9. Biotechnology of Industrial Antibiotics, E.J. Vandamme, Marcel Dekker, NY.
10. Protein Formulation & Delivery, E.J. McNally, Vol 99, Marcel Dekker, NY.
11. Drug Targeting, M.H. Rubinstein, John Wiley, NY.

INTELLECTUAL PROPERTY RIGHTS & REGULATORY AFFAIRS (MIP 104T)

Scope

This course is designed to impart knowledge and skills necessary to train the students to be on par with the routine of Industrial activities in drug regulatory affairs

Objectives

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

- Assist in Regulatory Audit process.
- Establish regulatory guidelines for drug and drug products
- The Regulatory requirements for contract research organizations

THEORY **60 Hrs**

1. Definition, Need for patenting, Types of Patents, Conditions to be satisfied by an invention to be patentable, Introduction to patent search. Parts of patents. Filling of patents. The essential elements of patent; Guidelines for preparation of laboratory note book, Non-obviousness in Patent. 10 Hrs

2. Documentation in pharmaceutical industry: 10 Hrs
Site Master File (SMF), Drug Master File (DMF). Master Formula Record, Batch Manufacturing Record and its calculations, Batch Reconciliation, Batch Packaging Records, Print pack specifications, Distribution records, Certificate of Analysis (CoA)

3. Regulatory requirements for product approval. 10 Hrs
NDA & ANDA, CTD & eCTD, ICH – Q, S, E, M Guidelines. Differences between generic drug products and brand name products.
Clinical Trials: Schedule Y, Clinical trial documentation, preparation of protocols, Different types of studies.

4. Role of GATT, TRIPS, and WIPO. 10 Hrs
Brief introduction to Trademark protection and WHO Patents. IPR's and its types,

5. Brief introduction to CDSCO. WHO, USFDA, EMEA, TGA, MHRA, MCC, ANVISA. 10 Hrs
Organisation, Responsibilities and Functioning of Drug regulatory authorities in India. Central and State Drug Licensing authorities

6. Regulatory requirements for contract research organization. 10 Hrs
Regulations for Biosimilars.

REFERENCES:

1. Pharmaceutical Process Validation: By Fra R. Berry and Robert A. Nash, Vol 57, 2nd Edition
2. Applied Production and Operation Management By Evans, Anderson and Williams
3. GMP for pharmaceuticals Material Management by K.K. Ahuja Published by CBS publishers
4. ISO 9000-Norms and explanations
5. GMP for pharmaceuticals- Willing S.H. Marcel and Dekker

INDUSTRIAL PHARMACY PRACTICAL - I (MIP 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 / GC
4. Estimation of riboflavin/quinine sulphate by fluorimetry
5. Estimation of sodium/potassium by flame photometry
6. Effect of surfactants on the solubility of drugs.
7. Effect of pH on the solubility of drugs.
8. Stability studies of drugs in dosage forms at 25^{o}C, 60% RH and 40^{o}C, 75% RH
9. Compatibility evaluation of drugs and excipients (DSC & FTIR).
10. Preparation and evaluation of different polymeric membranes.
11. Formulation and evaluation of sustained release oral matrix tablet/ oral reservoir system.
12. Formulation and evaluation of microspheres / microcapsules.
13. Formulation and evaluation of transdermal drug delivery systems.
14. Design and evaluation of face wash, body- wash, creams, lotions, shampoo, toothpaste, lipstick.
15. Electrophoresis of protein solution.
16. Preparation and evaluation of Liposome delivery system.

SEMESTER – II

ADVANCED BIOPHARMACEUTICS & PHARMACOKINETICS (MIP 201T)

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.

Objectives

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

- The basic concepts in Biopharmaceutics and pharmacokinetics.
- The use of raw data and derive the pharmacokinetic models and parameters to best describe the process of drug absorption, distribution, metabolism and elimination.
- To critically evaluate Biopharmaceutics studies involving drug product equivalency.
- To design and evaluate dosage regimens of the drugs using pharmacokinetic and biopharmaceutical parameters.

THEORY **60 Hrs**

1. Absorption of Drugs: 10 Hrs

The Gastrointestinal Tract, Mechanism & Factors affecting drug absorption, Formulation and physicochemical factors. Rate-Limiting Steps in Drug 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. Physicochemical Nature of the Drug Formulation.

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. Permeability: In-vitro, in-situ and In-vivo methods.

2. Biopharmaceutical Considerations in Drug Product Design and In Vitro Drug Product Performance: 10 Hrs

Biopharmaceutical Factors Affecting Drug Bioavailability, The Biopharmaceutics Classification System, Factors Affecting Drug Product Performance.

3. In Vitro Dissolution and Drug Release Testing, Dissolution rate, Dissolution process, 10 Hrs

Noyes–Whitney equation and drug dissolution, Factors affecting the dissolution rate. Solubility: Experimental methods. Compendial Methods of Dissolution, Alternative Methods of Dissolution Testing, Meeting Dissolution Requirements, Problems of Variable Control in Dissolution Testing Performance of Drug Products; In Vitro–In Vivo Correlation, Dissolution Profile Comparisons, Drug Product Stability Considerations in the Design of a Drug Product.

4. Drug Product Performance, In Vivo Bioavailability and Bioequivalence: 10 Hrs

Drug Product Performance, Purpose of Bioavailability Studies, Relative and Absolute Availability, Methods for Assessing Bioavailability, Design and Evaluation of Bioequivalence Studies, Study Designs, Crossover Study Designs, Evaluation of the Data, Bioequivalence Example, Study Submission and Drug Review Process, , Generic Biologics (Biosimilar Drug Products), Clinical Significance of Bioequivalence Studies, Special Concerns in Bioavailability and Bioequivalence Studies, Generic Substitution.

5. Pharmacokinetics: 10 Hrs

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 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.

6. Application of Pharmacokinetics: 10 Hrs

Modified-Release Drug Products, Targeted Drug Delivery Systems and Biotechnological Products. Relationship between Pharmacokinetics including Pharmacodynamics: Generation of a pharmacokinetic–pharmacodynamic (PKPD) equation, Pharmacokinetic and pharmacodynamic, interactions. Pharmacokinetics and pharmacodynamics of biotechnology drugs: Introduction, Proteins and peptides, Monoclonal antibodies, Oligonucleotides, Vaccines (immunotherapy), Gene therapies.

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.J aiswal., Vallab Prakashan, 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, Lea and Febiger, Philadelphia, 1970
7. Clinical Pharmacokinetics, Concepts and Applications 3rd edition by Malcolm Rowland and Thom~ N. Tozer, Lea and Febiger, Philadelphia, 1995
8. Dissolution, Bioavailability and Bioequivalence, Abdou. H.M, Mack Publishing Company, Pennsylvania 1989
9. Biopharmaceutics and Clinical Pharmacokinetics, An Introduction, 4th edition, revised and expanded 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,1st edition, Sunil S Jambhekar and Philip J Breen, pharmaceutical press, RPS Publishing,2009.
13. Absorption and Drug Development- Solubility, Permeability, and Charge State, Alex Avdeef, John Wiley & Sons, Inc,2003.

SCALE UP AND TECHNOLOGY TRANSFER (MIP 202T)

Scope

This course is designed to impart knowledge and skills necessary to train the students to be on scale up, technology transfer process and industrial safety issues.

Objectives:

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

- Manage the scale up process in pharmaceutical industry.
- Assist in technology transfer.
- Establish safety guidelines, which prevent industrial hazards.

THEORY **60 Hrs**

1. Pilot plant design: 12 Hrs

Basic requirements for design, lay out, facility, equipment selection, for tablets, capsules, liquid orals, parenteral and semisolid preparations.

Scale up: Importance, Technology transfer from R & D to pilot plant to plant scale, process scale up for tablets, capsules, liquid orals, semisolids, parenteral, NDDS products – stress on formula, equipments, product uniformity, stability, raw materials, physical layout, input, in-process and finished product specifications, Steps in Technology transfer process, problems encountered during transfer of technology.

2. Validation: 12 Hrs

General concepts, types, procedures & protocols, documentation, Validation Master Plan. Analytical method validation, cleaning validation. Vendor qualification.

3. Equipment Qualification: 12 Hrs

Importance, DQ, IQ, OQ, PQ for equipments – autoclave, DHS, membrane filter, rapid mixer granulator, cone blender, FBD, tablet compression machine, liquid filling and sealing machine. Aseptic room validation.

4. Process validation: 12 Hrs

Importance, validation of mixing, granulation, drying, compression, tablet coating, liquid filling and sealing, sterilization, water process systems, environmental control.

5. Industrial safety: 12 Hrs

Hazards – fire, mechanical, electrical, chemical and pharmaceutical, Monitoring & prevention systems, safety management. industrial effluent testing & treatment. Control of environmental pollution. Solid waste management.

REFERENCES

1. Pharmaceutical process validation, JR Berry, Nash, Vol 57, Marcel Dekker, NY.
2. Pharmaceutical Production facilities, design and applications, by GC Cole, Taylor and Francis.
3. Pharmaceutical project management, T. Kennedy, Vol 86, Marcel Dekker, NY.
Varghese Publ. Bombay.
4. Tablet machine instruments in pharmaceuticals, PR Watt, John Wiley.
5. Pharmaceutical dosage forms, Tablets, Vol 1, 2, 3 by Lachman, Lieberman, Marcel Dekker, NY.

6. Pharmaceutical dosage forms, Parenteral medications, Vol 1, 2 by K.E. Avis, Marcel Dekker, NY.
7. Dispersed system Vol 1, 2, 3 by Lachman, Lieberman, Marcel Dekker, NY.
8. Subrahmanyam, CVS, Pharmaceutical production and Management, 2007, Vallabh Prakashan, Dehli.

PHARMACEUTICAL PRODUCTION TECHNOLOGY (MIP 203T)

Scope

This course is designed to impart knowledge and skills necessary to train the students to be on par with the routine of Industrial activities in Production

Objectives:

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

- Handle the scheduled activities in a Pharmaceutical firm.
- Manage the production of large batches of pharmaceutical formulations.

THEORY **60 Hrs**

1. Production Area design: 6 Hrs

selection of plant location, Design & layout of plant for bulk drugs & formulations. Process flow & Work Study. Concept of TQM, GLP, GMP, Orange book/guide.

2. Improved Tablet Production: 10 Hrs

Tablet production process, unit operation improvements, granulation and pelletization equipments, continuous and batch mixing, rapid mixing granulators, rota granulators, spheronizers and marumerisers, and other specialized granulation and drying equipments. Problems encountered.

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

3. Parenteral Production: 10 Hrs

Area planning & environmental control, wall and floor treatment, fixtures and machineries, change rooms, personnel flow, utilities & equipment location, engineering and maintenance.

4. Lyophilization & Spray drying Technology: 10 Hrs

Principles, process, freeze-drying and spray drying equipments

5. Capsule Production: 10 Hrs

Production process, improved capsule manufacturing and filling machines for hard and soft gelatin capsules. Layout and problems encountered.

Disperse Systems Production: Production processes, applications of mixers, mills, disperse equipments including fine solids dispersion, problems encountered.

Packaging Technology: Types of packaging materials, machinery, labeling, package printing for different dosage forms.

6. Air Handling Systems: 8 Hrs

Study of AHUs, humidity & temperature control, air filtration systems, dust collectors. Validation of HVAC systems. Water Treatment Process: Techniques and maintenance – RO, DM, ultra – filtration, WFI.

7. Material handling of Raw materials, Packaging materials and Finished Goods. 6 Hrs

Pharmaceutical production planning & Control.

Applications of Computers in pharmaceutical production and packaging. Process automation technology (PAT) in Pharmaceutical manufacturing.

REFERENCES

1. The Theory & Practice of Industrial Pharmacy, L. Lachman. Varghese Publ. Bombay.
2. Modern Pharmaceutics by Banker, Vol 72, Marcel Dekker, NY.
3. Pharmaceutical Dosage Forms, Vol 1, 2, 3 by Lachman, Lieberman, Marcel Dekker, NY.
4. Pharmaceutical Dosage Forms, Parentral medications, Vol 1, 2 by K.E. Avis, Marcel Dekker, NY.
5. Pharmaceutical Production Facilities, design and applications, by G.C. Cole, Taylor and Francis.
6. Dispersed System Vol 1, 2, 3 by Lachman, Lieberman, Marcel Dekker, NY.
7. Product design and testing of polymeric materials by N.P. Chezerisionoff.
8. Pharmaceutical Project Management, T.Kennedy, Vol 86, Marcel Dekker, NY.
9. Packaging Pharmaceutical and Health Care, H.Lockhard.
10. Quality Control of Packaging Materials in Pharmaceutical Industy, Kharburn, Marcel Dekker, NY.
11. Freeze drying / Lyophilization of Pharmaceuticals & Biological Products, L. Ray, Vol 96, Marcel Dekker, NY.
12. Tablet Machine Instrumentation in Pharmaceuticals, PR Watt, Ellis Horwoods, UK.

ENTREPRENEURSHIP MANAGEMENT (MIP 204T)

Scope

This course is designed to impart knowledge and skills necessary to train the students on entrepreneurship management.

Objectives:

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

- The Role of enterprise in national and global economy
- Dynamics of motivation and concepts of entrepreneurship
- Demands and challenges of Growth Strategies and Networking

THEORY **60 Hrs**

1. Conceptual Frame Work: 12 Hrs

Concept need and process in entrepreneurship development. Role of enterprise in national and global economy. Types of enterprise – Merits and Demerits. Government policies and schemes for enterprise development. Institutional support in enterprise development and management

2. General principles of Business organization & administration, 12 Hrs

Styles of management, Decision making.

Entrepreneur: Entrepreneurial motivation & morale – dynamics of motivation. Entrepreneurial competency–Concepts. Developing Entrepreneurial competencies - requirements and understanding the process of entrepreneurship development, self-awareness, interpersonal skills, creativity, assertiveness, achievement, factors affecting entrepreneur role. Time management

3. Launching and Organising An Enterprise: 12 Hrs

Environment scanning – Information, sources, schemes of assistance, problems. Enterprise selection, market assessment, enterprise feasibility study, SWOT Analysis. Resource mobilisation - finance, technology, raw material, site and manpower. Costing and marketing management and quality control. Feedback, monitoring and evaluation.

General principles of HR & Financial management. Auditing and Budgetary control.

4. Growth Strategies and Networking: 12 Hrs

Performance appraisal and assessment. Profitability and control measures, demands and challenges. Need for diversification. Future Growth – Techniques of expansion and diversification, vision strategies. Concept and dynamics. Methods, Joint venture, co-ordination and feasibility study.

5. Preparing project proposal to start on new enterprise project work: 12 Hrs

Feasibility Report, Planning, Resource mobilization and implementation

Business Ethics

REFERENCES

1. Akhauri, M.M.P. (1990): Entrepreneurship for Women in India, NIESBUD, New Delhi.
2. Hisrich, R.D & Brush, C.G. (1996) The Women Entrepreneurs, D.C. Health& Co., Toranto.
3. Hisrich, R.D. and Peters, M.P. (1995): Entrepreneurship – Starting, Developing and Managing a New Enterprise, Richard D., Inwin, INC, USA.
4. Meredith, G.G. et al (1982): Practice of Entrepreneurship, ILO, Geneva.
5. Patel, V.C. (1987): Women Entrepreneurship – Developing NewEntrepreneurs, Ahmedabad EDII.

INDUSTRIAL PHARMACY PRACTICAL - II (MIP 205P)

1. Improvement of dissolution characteristics of slightly soluble drug by Solid dispersion technique.
3. Protein binding studies of a highly protein bound drug & poorly protein bound drug
4. Bioavailability studies of Paracetamol (Animal).
5. Pharmacokinetic and IVIVC data analysis by standard Pharmacokinetic software
6. In vitro cell studies for permeability and metabolism
7. Formulation and evaluation of tablets
8. Formulation and evaluation of capsules
9. Formulation and evaluation of injections
10. Formulation and evaluation of emulsion
11. Formulation and evaluation of suspension.
12. Formulation and evaluation of enteric coating tablets.
13. Preparation and evaluation of a freeze dried formulation.
14. Preparation and evaluation of a spray dried formulation.

SEMESTER – III

RESEARCH METHODOLOGY & BIOSTATISTICS (MRM 301T)

UNIT – I

General Research Methodology: Research, objective, requirements, practical difficulties, types of research, scientific methods of research, types of studies, study design.

Review of literature - Sources of information. Searching of library documents and databases online and offline (Pubmed, Biological abstracts, other databases in pharmaceutical sciences). Introduction to internet searching using advanced search tools.

UNIT – II

Collection and analysis of data: Types of data and data collection techniques, processing of data, coding, tabulation and analysis of data.

Biostatistics: Definition, application, sample size, importance of sample size, factors influencing sample size, dropouts, statistical tests of significance, type of significance tests, parametric tests (Student's 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, different software for statistical analysis.

UNIT – III

Medical Research: History, values in medical ethics, strategies to eliminate errors/bias, controls, randomisation, cross over design, placebo, blinding techniques 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, vendor relationships, treatment of family members.

UNIT – IV

CPCSEA guidelines for laboratory animal facility: Goals, location of animal facilities to laboratories, anaesthesia, euthanasia, physical facilities, environment, animal husbandry, record keeping, SOPs, personnel and training, transport of lab animals.

UNIT – V

Technical writing, thesis/research report writing, structure of thesis, editing and formatting, reference citations, abstracting, plagiarism and paraphrasing, tools for writing good research report.

UNIT – VI

Research reporting - poster presentation, seminar and conference presentation, publishing in journals, copyright.

REFERENCE BOOKS

1. Atiya Khanum Irfan Ali Khan, Biostatistics for Pharmacy, 2nd Edition, 2007, Ukaaz Publications, Hyderabad.
2. C. George Thomas. Research Methodology and Scientific Writing First edition, 2016, Ane Books Pvt. Ltd.; New Delhi.
3. C. R Kothari. Research Methodology: Methods and Techniques. New Age International (P)Ltd, Publishers. New Delhi.
4. Mahajan, B.K. Methods in Biostatistics for Medical Students and Research workers, 7th

Edition 2008 Jaypee Brothers.
5. Putul Mahanta , Medical Writing: A Guide for Medicos, Educators and Researchers Jaypee Brothers Medical Publishers; First edition (2018).
6. Ranjan Das, Biomedical Research Methodology: Including Biostatistical Applications. 1st Edn. Jaypee Brothers.
7. Ranjit Kumar, Research Methodology: A Step-by-Step Guide for Beginners, 3rd Edition 2011, Sage Publications India Pvt. Ltd., New Delhi.
8. Sharma Suresh. Research Methodology and Biostatistics- A Comprehensive Guide for Health Care Professionals. 1st Edn. Elsevier India.
9. Sunder Rao. P.S.S and Richard. J. An introduction to Biostatistics: A manual for students in health sciences. Prentice-Hall of India Pvt. Ltd Publishers.

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MODEL QUESTION PAPER

QP CODE:…… **Reg No…….**

First Semester M. Pharm. Degree Examinations 2022

M. Pharm. (Industrial Pharmacy)

PAPER - I – MODERN PHARMACEUTICAL ANALYTICAL TECHNIQUES (MIP 101T)

- Answer all questions

Time: 3 hours Maximum: Marks: 75

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.

MODEL QUESTION PAPER

QP CODE:…… **Reg No…….**

First Semester M. Pharm. Degree Examinations 2022

M. Pharm. (Industrial Pharmacy)

Paper II – Pharmaceutical Formulation Development (MIP 102T)

Time: 3 Hours **Total Marks: 75**

Answer all questions.
Draw diagrams wherever necessary.

Essays **(3x10=30)**

1. What do you mean by Drug Excipient compatibility? Discuss in detail the methods employed for its determination.

2. Discuss the various techniques employed in optimisation of Pharmaceutical formulations.

3. What is drug stability? Explain the stability testing protocols of drugs and pharmaceuticals.

Short Notes **(9x5=45)**

4. Sink and Non sink models.

5. Shelf life assignment.

6. Response surface method.

7. Cosolvency.

8. IVIVC.

9. Hydrotropy.

10. Powder flow.

11. Dissolution test apparatus.

12. Crystal morphology.

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MODEL QUESTION PAPER

QP CODE:…… **Reg No…….**

First Semester M. Pharm. Degree Examinations 2022

M. Pharm. (Industrial Pharmacy)

Paper III – Novel Drug Delivery Systems (MIP 103T)

Time: 3 Hours **Total Marks: 75**

Answer all questions.
Draw diagrams wherever necessary.

Essays **(3x10=30)**

1. Explain the various carriers for Drug delivery.
2. Explain the Pharmacokinetic design for Drug Delivery Systems.
3. Explain the formulation and evaluation of Targeted Drug delivery systems.

Short Notes **(9x5=45)**

4. Activation modulated DDS.
5. Mucoadhesive DDS.
6. Ocular Delivery systems.
7. Colon specific drug delivery.
8. Evaluation of Skin delivery systems.
9. Formulation and evaluation of shampoos.
10. Peptide drug delivery techniques.
11. rDNA technology.
12. Bioelectronic medicines.

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MODEL QUESTION PAPER

QP CODE:…… **Reg No…….**

First Semester M. Pharm. Degree Examinations 2022

M. Pharm. (Industrial Pharmacy)

Paper IV – Intellectual Property Rights & Regulatory Affairs (MIP 104T)

Time: 3 Hours **Total Marks: 75**

Answer all questions.
Draw diagrams wherever necessary.

Essays **(3x10=30)**

1. Explain Site Master File and Drug Master File.

2. Explain the functioning of Drug Regulatory Authorities in India.

3. Explain the protocols for Clinical trial documentation.

Short Notes **(9x5=45)**

4. Role of GATT

5. Batch Manufacturing Record.

6. Types of Patents.

7. NDA & ANDA.

8. Trademark protection.

9. Regulatory requirements for contract research organisations.

10. Regulations for biosimilars.

11. ICH guidelines.

12. Generic drug products.

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MODEL QUESTION PAPER

QP CODE:…… **Reg No…….**

Second Semester M. Pharm. Degree Examinations 2022

M. Pharm. (Industrial Pharmacy)

Paper I – Advanced Biopharmaceutics & Pharmacokinetics (MIP 201T)

Time: 3 Hours **Total Marks: 75**

Answer all questions.
Draw diagrams wherever necessary.

Essays **(3x10=30)**

1. Explain the mechanisms and factors affecting Drug absorption.

2. Explain one compartment model for extra vascular administration with various pharmacokinetic parameters.

3. Explain Bioequivalence and various bioequivalence study designs.

Short Notes **(9x5=45)**

4. BCS.

5. Biopharmaceutical considerations of tablets as a dosage form.

6. Drug Product Performance.

7. Drug product stability considerations.

8. Bio similar drug products.

9. Pharmacokinetics of Proteins & peptides.

10. pH partition theory in absorption.

11. IV infusion and loading dose.

12. Different theories of dissolution process.

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MODEL QUESTION PAPER

QP CODE:…… **Reg No…….**

Second Semester M. Pharm. Degree Examinations 2022

M. Pharm. (Industrial Pharmacy)

Paper II – Scale Up and Technology Transfer (MIP 202T)

Time: 3 Hours **Total Marks: 75**

Answer all questions.
Draw diagrams wherever necessary.

Essays **(3x10=30)**

1. Explain the basic requirements of Scale up of tablet manufacture.

2. Explain the general concepts and protocols for equipment validation.

3. What is process validation. Explain the process validation protocols for tablet compression and coating.

Short Notes **(9x5=45)**

4. Scale up of semisolid dosage forms.

5. Problems encountered during Transfer of Technology.

6. Industrial effluent testing.

7. Mechanical hazards and its prevention.

8. Validation of Water process systems.

9. Vendor qualification.

10. Cleaning validation.

11. Concept of safety management

12. Solid waste management.

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MODEL QUESTION PAPER

QP CODE:…… **Reg No…….**

Second Semester M. Pharm. Degree Examinations 2022

M. Pharm. (Industrial Pharmacy)

Paper III – Pharmaceutical Production Technology (MIP 203T)

Time: 3 Hours **Total Marks: 75**

Answer all questions.
Draw diagrams wherever necessary.

Essays **(3x10=30)**

1. Explain the design and layout for the production of tablets.

2. Explain the salient features in the production of parenteral preparations.

3. Explain the application and validation of HVAC systems in a manufacturing unit.

Short Notes **(9x5=45)**

4. Spheronisers and marumerisers.

5. Fluidised bed coating technology.

6. Production planning and control

7. Concept of TQM.

8. Orange Book

9. Freeze drying

10. Packaging of parenterals.

11. Production and storage of water for injection.

12. Hard gelatin capsule filling.

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MODEL QUESTION PAPER

QP CODE:…… **Reg No…….**

Second Semester M. Pharm. Degree Examinations 2022

M. Pharm. (Industrial Pharmacy)

Paper IV – Entrepreneurship Management (MIP 204T)

Time: 3 Hours **Total Marks: 75**

Answer all questions.
Draw diagrams wherever necessary.

Essays **(3x10=30)**

1. Explain the important steps in launching a pharmaceutical enterprise.

2. Explain the general principles of Financial management.

3. Explain the competencies required for an entrepreneur.

Short Notes **(9x5=45)**

4. Government policies for enterprise development.

5. Styles of management.

6. Motivation & Morale.

7. Time management.

8. SWOT analysis.

9. Resource mobilisation of raw materials.

10. Expansion and diversification.

11. Business ethics.

12. Marketing management.

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KERALA UNIVERSITY OF HEALTH SCIENCES

Thrissur - 680596

SYLLABUS

POST GRADUATE COURSE IN PHARMACY

Master of Pharmacy (M. Pharm.)

PHARMACEUTICAL QUALITY ASSURANCE	**MQA**
KUHS Course Code	**530**

(2022-23 Academic year onwards)

2022

Course of study for M.Pharm. I & II Semester

MQA	Pharmaceutical Quality Assurance				
Course Code	**Course**	**Credit Hours**	**Credit Points**	**Hrs./wk**	**Marks**
Semester I					
MQA 101T	Modern Pharmaceutical Analytical Techniques	4	4	4	100
MQA 102T	Quality Management Systems	4	4	4	100
MQA 103T	Quality Control and Quality Assurance	4	4	4	100
MQA 104T	Product Development and Technology Transfer	4	4	4	100
MQA 105P	Quality Assurance Practical - I	12	6	12	150
-	Seminar/Assignment	7	4	7	100
Total		**35**	**26**	**35**	**650**
Semester II					
MQA 201T	Hazards and Safety Management	4	4	4	100
MQA 202T	Pharmaceutical Validation	4	4	4	100
MQA 203T	Audits and Regulatory Compliance	4	4	4	100
MQA 204T	Pharmaceutical Manufacturing Technology	4	4	4	100
MQA 205P	Quality Assurance Practical – II	12	6	12	150
-	Seminar /Assignment	7	4	7	100
Total		**35**	**26**	**35**	**650**

Course of study for M. Pharm. III & IV Semester

Course Code	**Course**	**Credit Hours**	**Credit Points**	**Marks**
Semester III				
MRM 301T	Research Methodology and Biostatistics	4	4	100
-	Journal Club	1	1	25
-	Discussion / Presentation (proposal presentation)	2	2	25
-	Research Work	28	14	350
Total		**35**	**21**	**500**
Semester IV				
-	Journal Club	1	1	25
-	Pre submission Discussion / Presentation	3	3	75
-	Research Work	31	16	400
Total		**35**	**20**	**500**

PHARMACEUTICAL QUALITY ASSURANCE (MQA)

SEMESTER – I

MODERN PHARMACEUTICAL ANALYTICAL TECHNIQUES (MPT 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:

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

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

THEORY **60 Hrs**

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

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 (Characteristics 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.

9. NMR spectroscopy: Principle, Instrumentation, 10 Hrs 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.

10. Mass Spectroscopy: Principle, Theory, Instrumentation of Mass Spectroscopy, 9 Hrs 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. Chromatography: Principle, apparatus, instrumentation, chromatographic 9 Hrs 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

12. a.Electrophoresis: Principle, Instrumentation, Workingconditions, factors affecting separation and applications of the following: 9 Hrs

1) Paper electrophoresis 2) Gel electrophoresis 3) Capillary electrophoresis 4) Zone electrophoresis 5) Moving boundary electrophoresis 6) 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.

13. a. Potentiometry: Principle, working, Ion selective Electrodes and Application of potentiometry. 9 Hrs

b. Thermal Techniques: i) Differential scanning calorimetry (DSC): 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.

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

13. Immunological assays: RIA (Radio immuno assay), ELISA, Bioluminescence assays. 4 Hrs

REFERENCES

10. Spectrometric Identification of Organic compounds - Robert M Silverstein, 6th Edition, JohnWiley & Sons, 2004.
11. Principles of Instrumental Analysis - Douglas A Skoog, F. James Holler, Timothy A. Nieman,5th Edition, Eastern Press, Bangalore, 1998.
12. Instrumental Methods of Analysis - Willards, 7th Edition, CBS publishers.
13. Practical Pharmaceutical Chemistry - Beckett and Stenlake, Vol II, 4th Edition, CBS Publishers, New Delhi, 1997.
14. Organic Spectroscopy - William Kemp, 3rd Edition, ELBS, 1991.
15. Quantitative Analysis of Drugs in Pharmaceutical formulation - P.D. Sethi, 3rd Edition, CBSPublishers, New Delhi, 1997.
16. Pharmaceutical Analysis-Modern Methods-Part B-J.W. Munson, Vol 11, Marcel Dekker Series.
17. Spectroscopy of Organic Compounds, 2nd Edition, P.S. Kalsi, Wiley Eastern Ltd, Delhi.
18. Textbook of Pharmaceutical Analysis, K.A. Connors, 3rd Edition, John Wiley & Sons, 1982.

QUALITY MANAGEMENT SYSTEMS
(MQA 102T)

Scope:

This course is designed to impart fundamental knowledge and concepts about various quality management principles and systems utilized in the manufacturing industry. It also aids in understanding the quality evaluation in the pharmaceutical industries.

Objectives:

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

- · The importance of quality
- · ISO management systems
- · Tools for quality improvement
- · Analysis of issues in quality
- · Quality evaluation of pharmaceuticals
- · Stability testing of drug and drug substances
- · Statistical approaches for quality

THEORY **60 Hrs**

1. Introduction to Quality: 12 Hrs

Evolution of Quality, Definition of Quality, Dimensions of Quality.
Quality as a Strategic Decision: Meaning of strategy and strategic quality management, mission and vision statements, quality policy, Quality objectives, strategic planning and implementation, McKinsey 7s model, Competitive analysis, Management commitment to quality.
Customer Focus: Meaning of customer and customer focus, Classification of customers, Customer perception of quality, Factors affecting customer perception, Customer requirements, Meeting customer needs and expectations, Customer satisfaction and Customer delight, Handling customer complaints, Cost of Quality: Cost of quality, Categories of cost of Quality, Models of cost of quality, Optimising costs, Preventing cost of quality.

2. Pharmaceutical quality Management: 12 Hrs

Basics of Quality Management, Total Quality Management (TQM), Principles of Six sigma, ISO 9001:2008, 9001:2015, ISO 14001:2004, Pharmaceutical Quality Management – ICH Q10, Knowledge management, Quality Metrics, Operational Excellence and Quality Management Review. OSHAS guidelines, WHO Certification Scheme, NABL certification and accreditation.

3. Six System Inspection model: 12 Hrs

Quality Management system, Production system, Facility and Equipment system, Laboratory control system, Materials system, Packaging and labeling system.
Quality systems: Change Management/ Change control. Deviations, Out of Specifications (OOS), Out of Trend (OOT), Complaints - evaluation and handling, Investigation and determination of root cause, Corrective & Preventive Actions (CAPA), Returns and Recalls, Vendor Qualification, Annual Product Reviews, Batch Review and Batch Release.

4. Drug Stability: 12 Hrs

ICH guidelines for stability testing of drug substances and drug products.
Study of ICH Q8, Quality by Design and Process development report, Accelerated Stability Study,
Quality risk management: Introduction, risk assessment, risk control, risk review, risk management tools, HACCP, risk ranking and filtering according to ICH Q9 guidelines

5. Statistical Process control (SPC): 8 Hrs

Definition and Importance of SPC, Quality measurement in manufacturing, Statistical control charts - concepts and general aspects, Advantages of statistical control, Process capability, Estimating Inherent or potential capability from a control chart analysis, Measuring process control and quality improvement, Pursuit of decreased process variability.

6. Regulatory Compliance through Quality Management and development of Quality Culture. 4 Hrs

Benchmarking: Definition of benchmarking, Reasons for benchmarking, Types of Benchmarking, Benchmarking process, Advantages of benchmarking, Limitations of benchmarking.

REFERENCES

1. Al Endres. Implementing Juran's Road Map for Quality Leadership: Benchmarks and Results, Wiley, 2000.
2. Jiju Antony, David Preece. Understanding, Managing and Implementing Quality: Frameworks, Techniques and Cases, Routledge, 2002.
3. Edward E. Lawler; Susan Albers Mohrman; George Benson, Jossey-Bass. Organizing for High Performance: Employee Involvement, TQM, Reengineering and Knowledge Management in the Fortune 1000: The CEO Report 2001.
4. James W. Fairfield Sonn. Corporate Culture and the Quality Organization Quorum Books, 2001.
5. Christine Avery; Diane Zabel. The Quality Management Sourcebook: An International Guide to Materials and Resources, Routledge, 1997.
6. Nancy R. Tague. The Quality Toolbox, Second Edition, ASQ Publications.
7. Joseph M. Juran and Joseph A. De Feo. Juran's Quality Handbook, Sixth Edition, ASQ Publications.
8. Duke Okes. Root Cause Analysis, The Core of Problem Solving and Corrective Action, 2009, ASQ Publications.

QUALITY CONTROL AND QUALITY ASSURANCE
(MQA 103T)

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 completion of this course 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. Introduction: **12 Hrs**

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.

Good Laboratory Practices: Scope of GLP, Definitions, Quality assurance unit, protocol for conduct of non-clinical 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: **12 Hrs**

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.

3. Analysis of raw materials, finished products, packaging materials, **12 Hrs**

in process quality control (IPQC), Developing specification (ICH Q6 and Q3). Purchase specifications and maintenance of stores for raw materials. In process quality control and finished products quality control for following dosage forms 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: **12 Hrs**

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 Batch Record, Batch Manufacturing Record, Quality audit plan and reports. Specification and test procedures, Protocols and reports. Distribution records. Electronic data handling. Submission documents for regulators DMFs, as Common Technical Document and Electronic Common Technical Documentation (CTD, eCTD).

5. Manufacturing operations and controls: 12 Hrs

Sanitation of manufacturing premises, mix-ups and cross contamination, processing of intermediates and bulk products, packaging operations, 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,

Introduction, scope and importance of intellectual property rights. Concept of trade mark, copyright and patents.

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 compendium of Guide lines and Related materials Vol I & II, 2nd edition, WHO Publications, 1999.
4. How to Practice GMP's – PP 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.
14. Dean DA, Evans ER and Hall IH. Pharmaceutical Packaging Technology. London, Taylor & Francis, UK, 2005.
15. Quality control of packaging materials in the pharmaceutical industry by Kenneth Harburn Vol 4, Taylor and Francis, 2019.
16. Schedule M and Schedule N.

PRODUCT DEVELOPMENT AND TECHNOLOGY TRANSFER
(MQA 104T)

Scope

This deal with technology transfer covers the activities associated with Drug Substance, Drug Product and analytical tests and methods, required following candidate drug selection to completion of technology transfer from R&D to the first receiving site and technology transfer related to post-marketing changes in manufacturing places.

Objectives

Upon completion of this course the student should be able to

· To understand the new product development process

· To understand the necessary information to transfer technology from R&D to actual manufacturing by sorting out various information obtained during R&D

· To elucidate necessary information to transfer technology of existing products between various manufacturing places

THEORY **60 Hrs**

1. **Principles of Drug discovery and development:** **12 Hrs**

Introduction, Stages of clinical research process. Development and informational content for Investigational New Drugs Application (IND), New Drug Application (NDA), Abbreviated New Drug Application (ANDA), Supplemental New Drug Application (SNDA), Scale Up Post Approval Changes (SUPAC) and Bulk active chemical Post approval changes (BACPAC), Post marketing surveillance, Product registration guidelines – CDSCO, USFDA.

2. Pre-formulation studies: **12 Hrs**

Introduction/concept, organoleptic properties, purity, impurity profiles, particle size, shape and surface area. Solubility, Methods to improve solubility of Drugs: Surfactants & its importance, co-solvency. Techniques for the study of Crystal properties and polymorphism. Pre-formulation protocol, Stability testing during product development.

3. **Pilot plant scale up:** 12 Hrs

Concept, Significance, design, layout of pilot plant scale up study, operations, large scale manufacturing techniques (formula, equipment, process, stability and quality control) of solids, liquids, semisolid and parenteral dosage forms. New era of drug products: opportunities and challenges.

4. **Pharmaceutical packaging:** 12 hrs

Pharmaceutical dosage form and their packaging requirements, Pharmaceutical packaging materials, Medical device packaging, Enteral Packaging, Aseptic packaging systems, Container closure systems, Issues facing modern drug packaging, Selection and evaluation of Pharmaceutical packaging materials.
Quality control test: Containers, closures and secondary packing materials.

5. **Technology transfer:** 12 hrs

Development of technology by R & D, Technology transfer from R & D to production, Optimization and Production, Qualitative and quantitative technology models.
Documentation in technology transfer: Development report, technology transfer plan and Exhibit.

REFERENCES

1. Charles G. Smith, James T and O. Donnell. The process of new drug discovery and development. I and IIEdition (2006) CRC Press, Group of Taylor and Francis.

2. Leon Lac Lachman, Herbert A. Liberman, Theory and Practice of Industrial Pharmacy. Marcel Dekker Inc. New York.
3. Sidney H Willing, Murray M, Tuckerman. Williams Hitchings IV, Good manufacturing of pharmaceuticals (A Plan for total quality control) 3rd Edition. Bhalani publishing house Mumbai.
4. Leon Lachman, Herbert A. Liberman, Joseph B. Schwartz. Tablets Vol. I, II, III 2nd Edn. (1989) Marcel Dekker Inc. New York.
5. Milo Gibaldi, Text book of Bio- Pharmaceutics and clinical Pharmacokinetics.3rd Edn, Lea & Febriger, Philadelphia.
6. Vandana V. Patrevale. John I. Disouza. Maharukh T. Rustomji. Pharmaceutical product development. CRC Press, Group of Taylor and Francis.
7. Abdou H.M, Dissolution, Bioavailability and Bio-Equivalence. Mack Publishing Company, Eastern Pennsylvania.
8. Alfonso & Gennaro, Remingtons Pharmaceutical Sciences, 19th Edn.(1995)OO2C Lippincott; Williams and Wilkins A Wolters Kluwer Company, Philadelphia.
9. D.A. Sawant, The Pharmaceutical Sciences; the Pharma Path way 'Pure and applied Pharmacy' Pragathi Books Pvt. Ltd.
10. D.A. Dean. E.R. Evans, I.H. Hall. Pharmaceutical Packaging technology 1st Edition (Reprint 2006). Taylor and Francis. London and New York.

QUALITY ASSURANCE PRACTICAL - I
(MQA 105P)

PRACTICALS

1. Analysis of Pharmacopoeial compounds in bulk and in their formulations (tablet/ capsules/ semisolids) by UV Vis spectrophotometer
2. Simultaneous estimation of multi-drug 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 or AAS
7. Case studies on
   - · Total Quality Management
   - · Six Sigma
   - · Change Management/ Change control. Deviations,
   - · Out of Specifications (OOS)
   - · Out of Trend (OOT)
   - · Corrective & Preventive Actions (CAPA)
   - · Deviations
8. Development of Stability study protocol
9. Estimation of process capability
10. In process and finished product quality control tests for tablets, capsules, parenterals and semisolid dosage forms.
11. Assay of raw materials as per official monographs
12. Testing of related and foreign substances in drugs and raw materials
13. To carry out pre formulation study for tablets, parenterals (2 experiments).
14. To study the effect of pH on the solubility of drugs, (1 experiment)
15. Quality control tests for Primary and secondary packaging materials
16. Accelerated stability studies (1 experiment)
17. Improved solubility of drugs using surfactant systems (1 experiment)
18. Improved solubility of drugs using co-solvency method (1 experiment)
19. Determination of pKa and Log p of drugs.

SEMESTER – II
HAZARDS AND SAFETY MANAGEMENT
(MQA 201T)

Scope:

This course is designed to convey the knowledge necessary to understand issues related to different kinds of hazard and their management. Basic theoretical and practical discussions integrate the proficiency to handle the emergency situation in the pharmaceutical product development process and provides the principle based approach to solve the complex tribulations.

Objectives:

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

· Understand about environmental problems among learners.

· Impart basic knowledge about the environment and its allied problems.

· Develop an attitude of concern for the industry environment.

· Ensure safety standards in pharmaceutical industry

· Provide comprehensive knowledge on the safety management

· Empower any ideas to clear mechanism and management in different kinds of hazard management system

· Teach the method of Hazard assessment, procedure, methodology for provide safe industrial atmosphere.

THEORY **60 Hrs**

1. Multidisciplinary nature of environmental studies: **12 Hrs**

Natural Resources, Renewable and non-renewable resources and associated problems,

a) Forest resources; b) Water resources; c) Mineral resources; d) Energy resources; e) Land resources

Ecosystems: Concept of an ecosystem and Structure and function of an ecosystem. Environmental hazards: Hazards based on Air, Water, Soil and Radioisotopes.

2. Air based hazards: 12 Hrs

Sources, Types of Hazards, Air circulation maintenance industry for sterile area and non-sterile area, Preliminary Hazard Analysis (PHA) Fire protection system: Fire prevention, types of fire extinguishers and critical Hazard management system.

3. Chemical based hazards: 12 Hrs

Sources of chemical hazards, Hazards of Organic synthesis, sulphonating hazard, Organic solvent hazard, Control measures for chemical hazards, Management of combustible gases, Toxic gases and Oxygen displacing gases management, Regulations for chemical hazard, Management of over-Exposure to chemicals and TLV concept.

4. Fire and Explosion: 12 hrs

Introduction, Industrial processes and Safety and hazards regulations, Fire protection system: Fire prevention, types of fire extinguishers and critical Hazard management system mechanical and chemical explosion, multiphase reactions, transport effects and global rates. Preventive and protective management from fires and explosion electricity passivation, ventilation, and sprinkling, proofing, relief systems -relief valves, flares, scrubbers.

5. Hazard and risk management: 12 Hrs

Self-protective measures against workplace hazards. Critical training for risk management, Process of hazard management, ICH guidelines on risk assessment and Risk management methods and Tools.

Factory act and rules, fundamentals of accident prevention, elements of safety programme and safety management, Physicochemical measurements of effluents, BOD, COD, Determination of some contaminants, Effluent treatment procedure.

REFERENCES

1. Y.K. Sing, Environmental Science, New Age International Pvt.. Publishers, Bangalore.
2. "Quantitative Risk Assessment in Chemical Process Industries" American Institute ofChemical Industries, Centre for Chemical Process safety.
3. Bharucha Erach, The Biodiversity of India, Mapin Publishing Pvt. Ltd., Ahmedabad – 380 013, India.
4. Hazardous Chemicals: Safety Management and Global Regulations, T.S.S. Dikshith, CRC press.

PHARMACEUTICAL VALIDATION
(MQA 202T)

Scope:

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

Objectives:

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

- · The concepts of calibration, qualification and validation
- · The qualification of various equipments and instruments
- · Process validation of different dosage forms
- · Validation of analytical method for estimation of drugs
- · Cleaning validation of equipments employed in the manufacture of pharmaceuticals

THEORY **60 Hrs**

1. Introduction to validation: 10 Hrs

Definition of Calibration, Qualification and Validation, Scope, frequency and importance. Difference between calibration and validation. Calibration of weights and measures. Advantages of Validation, scope of Validation, Organization for Validation, Validation Master plan, Types of Validation, Streamlining of qualification & Validation process.

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).

2.Qualification of manufacturing equipment: 10 Hrs

Dry Powder Mixers, Fluid Bed and Tray dryers, Tablet Compression (Machine), Dry heat sterilization/Tunnels, Autoclaves, Membrane filtration, Capsule filling machine.

Qualification of analytical instruments: UV-Visible spectrophotometer, FTIR, DSC, GC, HPLC, HPTLC, LC-MS.

3.Qualification of laboratory equipments: 10 Hrs

Hardness tester, Friability test apparatus, tap density tester, Disintegration tester, Dissolution test apparatus

Validation of Utility systems: Pharmaceutical water system & pure steam, HVAC system, Compressed air and nitrogen.

4.Process Validation: **10 Hrs**

Concept, Process and documentation of Process Validation. Prospective, Concurrent & Retrospective Validation, Re-validation criteria, Process Validation of various formulations (Coated tablets, Capsules, Ointment/Creams, Liquid Orals and aerosols.), Aseptic filling: Media fill validation, USFDA guidelines on Process Validation- A life cycle approach.

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

5. Cleaning Validation: 10 Hrs

Cleaning Method development, Validation of analytical method used in cleaning, Cleaning of Equipment, Cleaning of Facilities. Cleaning in place (CIP). Validation of facilities in sterile and non-sterile plant.

Computerized system validation: Electronic records and digital signature-21 CFR Part 11 and GAMP

6. General Principles of Intellectual Property: 10 Hrs

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 application; 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.

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).
6. Michael Levin, Pharmaceutical Process Scale-Up", Drugs and Pharm. Sci. Series, Vol. 157,2nd Ed., Marcel Dekker Inc., N.Y.
7. Validation Standard Operating Procedures: A Step by Step Guide for Achieving Compliance in the Pharmaceutical, Medical Device, and Biotech Industries, Syed Imtiaz Haider
8. Pharmaceutical Equipment Validation: The Ultimate Qualification Handbook, Phillip A. Cloud, Interpharm Press.
9. Validation of Pharmaceutical Processes: Sterile Products, Frederick J. Carlton (Ed.) and James Agalloco (Ed.), Marcel Dekker.
10. Analytical Method validation and Instrument Performance Verification by Churg Chan, Heiman Lam, Y.C. Lee, Yue. Zhang, Wiley Interscience.
11. Huber L. Validation and Qualification in Analytical Laboratories. Informa Healthcare
12. Wingate G. Validating Corporate Computer Systems: Good IT Practice for Pharmaceutical Manufacturers. Interpharm Press.
13. LeBlanc DA. Validated Cleaning Technologies for Pharmaceutical Manufacturing. Interpharm Press.

AUDITS AND REGULATORY COMPLIANCE
(MPA 203T)

Scope:

This course deals with the understanding and process for auditing in pharmaceutical industries. This subject covers the methodology involved in the auditing process of different in pharmaceutical industries.

Objectives:

Upon completion of this course the student should be able to:

- To understand the importance of auditing
- To understand the methodology of auditing
- To carry out the audit process
- To prepare the auditing report
- To prepare the check list for auditing

THEORY **60 Hrs**

1. Introduction: 12 Hrs

Objectives, Management of audit, types of audit, responsibilities, Planning process, information gathering, administration, Classifications of deficiencies.

2. Role of quality systems and audits in pharmaceutical manufacturing environment: 12 Hrs

cGMP Regulations, Quality assurance functions, Quality systems approach, Management responsibilities, Resource, Manufacturing operations, Evaluation activities, Transitioning to quality system approach, Audit checklist for drug industries.

3. Auditing of vendors and production department: 12 Hrs

Bulk Pharmaceutical Chemicals and packaging material Vendor audit, Warehouse and weighing, Dry Production: Granulation, tableting, coating, capsules, sterile production and packaging.

4. Auditing of Microbiological laboratory: 12 Hrs

Auditing the manufacturing process, Product and process information, General areas of interest in the building raw materials, Water, Packaging materials.

5. Auditing of Quality Assurance and engineering department: 12 Hrs

Quality Assurance Maintenance, Critical systems: HVAC, Water, Water for Injection systems.

REFERENCES

1. Karen Ginsbury and Gil Bismuth, Compliance auditing for Pharmaceutical Manufacturers. Interpharm/CRC, Boca Raton, London New York, Washington D.C.
2. Shayne Cox Gad. Pharmaceutical Manufacturing Handbook, Regulations and Quality Wiley-Interscience, A John Wiley and sons, Inc., Publications.
3. Rosamund M. Baird, Norman A. Hodges, Stephen P. Denyar. Handbook of microbiological Quality control. CRC Press. 2000.
4. Donald C. Singer, Raluca-loana Stefan, Jacobus F. Van Staden. Laboratory auditing for quality and regulatory compliance. Taylor and Francis (2005).

PHARMACEUTICAL MANUFACTURING TECHNOLOGY
(MQA 204T)

Scope:

This course is designed to impart knowledge and skills necessary to train the students with the industrial activities during Pharmaceutical Manufacturing.

Objectives:

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

· The common practice in the pharmaceutical industry developments, plant layout and production planning.
· Will be familiar with the principles and practices of aseptic process technology, non-sterile manufacturing technology and packaging technology.
· Have a better understanding of principles and implementation of Quality by design (QbD) and process analytical technology (PAT) in pharmaceutical manufacturing.

THEORY **60 Hrs**

1. Pharmaceutical industry developments: 12 Hrs

Legal requirements and Licenses for API and formulation industry, Plant location Factors influencing.
Plant layout: Factors influencing, Special provisions, Storage space requirements, sterile and aseptic area layout.
Production planning: General principles, production systems, calculation of standard cost, process planning, routing, loading, scheduling, dispatching of records, production control.

2. Aseptic process technology: 12 Hrs

Manufacturing, manufacturing flowcharts, in process-quality control tests for following sterile dosage forms: Ointment, Suspension and Emulsion, Dry powder, Solution (Small Volume & large Volume).
Advanced sterile product manufacturing technology: Area planning & environmental control, wall and floor treatment, fixtures and machineries, change rooms, personnel flow, utilities & utilities equipment location, engineering and maintenance.
Process Automation in Pharmaceutical Industry: With specific reference to manufacturing of sterile semisolids, Small Volume Parenterals & Large Volume Parenterals (SVP & LVP), Monitoring of Parenteral manufacturing facility, Cleaning in Place (CIP), Sterilization in Place (SIP), Prefilled Syringe, Powdered Jet, Needle Free Injections, and Form Fill Seal Technology (FFS). Lyophilization technology: Principles, process, equipment.

3. Non sterile manufacturing process technology: 12 Hrs

Manufacturing, manufacturing flowcharts, in process-quality control tests for following Non-Sterile solid dosage forms: Tablets (compressed & coated), Capsules (Hard & Soft).

Advance non-sterile solid product manufacturing technology: Process Automation in Pharmaceutical Industry with specific reference to manufacturing of tablets and coated products, Improved Tablet Production: Tablet production process, granulation and pelletization equipments, continuous and batch mixing, rapid mixing granulators, rota granulators, spheronizers and marumerisers, and other specialized granulation and drying equipments. Problems encountered.

Coating technology: Process, equipments, particle coating, fluidized bed coating, application techniques. Problems encountered.

4. Containers and closures for pharmaceuticals: 12 Hrs

Types, performance, assuring quality of glass; types of plastics used, Drug plastic interactions, biological tests,

modification of plastics by drugs; different types of closures and closure liners; film wrapper; blister packs; bubble packs; shrink packaging; foil / plastic pouches, bottle seals, tape seals, breakable seals and sealed tubes; quality control of packaging material and filling equipment, flexible packaging, product package compatibility, transit worthiness of package, Stability aspects of packaging. Evaluation of stability of packaging material.

5. Quality by design (QbD) and process analytical technology(PAT): 12 Hrs

Current approach and its limitations. Why QbD is required, Advantages, Elements of QbD, Terminology: QTPP. CMA, CQA, CPP, RLD, Design space, Design of Experiments, Risk Assessment and mitigation/minimization. Quality by Design, Formulations by Design, QbD for drug products, QbD for Drug Substances, QbD for Excipients, Analytical QbD. FDA initiative on process analytical technology. PAT as a driver for improving quality and reducing costs: quality by design (QbD), QA, QC and GAMP. PAT guidance, standards and regulatory requirements.

REFERENCES

1. Lachman L, Lieberman HA, Kanig JL. The theory and practice of industrial pharmacy, 3rd ed., Varghese Publishers, Mumbai 1991.
2. Sinko PJ. Martin's physical pharmacy and pharmaceutical sciences, 5 ed., B.I. Publications Pvt. Ltd, Noida, 2006.
3. Lieberman HA, Lachman L, Schwartz JB. Pharmaceutical dosage forms: tablets Vol. I-III, 2nd ed., CBS Publishers & distributors, New Delhi, 2005.
4. Banker GS, Rhodes CT. Modern Pharmaceutics, 4th ed., Marcel Dekker Inc, New York, 2005.
5. Sidney H Willing, Murray M, Tuckerman. Williams Hitchings IV, Good manufacturing of pharmaceuticals (A Plan for total quality control) 3rd Edition. Bhalani Publishing House, Mumbai.
6. Indian Pharmacopoeia, Controller of Publication, Delhi, 1996.
7. British Pharmacopoeia. British Pharmacopoeia Commission Office, London, 2008.
8. United States Pharmacopoeia. United States Pharmacopeial Convention, Inc, USA, 2003.
9. Dean DA, Evans ER and Hall IH. Pharmaceutical Packaging Technology. London, Taylor & Francis, 1st Edition. UK.
10. Edward J Bauer. Pharmaceutical Packaging Handbook. 2009. Informa Health care USA Inc. New york.
11. Shaybe Cox Gad. Pharmaceutical Manufacturing Handbook. John Willey and Sons, New Jersey, 2008.

QUALITY ASSURANCE PRACTICAL – II PRACTICALS
(MQA 205P)

1. Organic contaminants residue analysis by HPLC.
2. Estimation of Metallic contaminants by Flame photometer
3. Identification of antibiotic residue by TLC
4. Estimation of Hydrogen Sulphide in Air.
5. Estimation of Chlorine in Work Environment.
6. Sampling and analysis of SO_2 using Colorimetric method
7. Qualification of following Pharma equipment
   a. Autoclave
   b. Hot air oven
   c. Powder Mixer (Dry)
   d. Tablet Compression Machine
8. Validation of an analytical method for a drug
9. Validation of a processing area
10. Qualification of at least two analytical instruments
11. Cleaning validation of one equipment
12. Qualification of Pharmaceutical Testing Equipment (Dissolution testing apparatus, Friability Apparatus, Disintegration Tester)
13. Check list for Bulk Pharmaceutical Chemicals vendors
14. Check list for tableting production.
15. Check list for sterile production area
16. Check list for Water for injection.
17. Design of plant layout: Sterile and non-sterile
18. Case study on application of QbD
19. Case study on application of PAT

SEMESTER – III

RESEARCH METHODOLOGY & BIOSTATISTICS (MRM 301T)

UNIT – I

General Research Methodology: Research, objective, requirements, practical difficulties, types of research, scientific methods of research, types of studies, study design.

Review of literature - Sources of information. Searching of library documents and databases online and offline (Pubmed, Biological abstracts, other databases in pharmaceutical sciences). Introduction to internet searching using advanced search tools.

UNIT – II

Collection and analysis of data: Types of data and data collection techniques, processing of data, coding, tabulation and analysis of data.

Biostatistics: Definition, application, sample size, importance of sample size, factors influencing sample size, dropouts, statistical tests of significance, type of significance tests, parametric tests (Student's 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, different software for statistical analysis.

UNIT – III

Medical Research: History, values in medical ethics, strategies to eliminate errors/bias, controls, randomisation, cross over design, placebo, blinding techniques 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, vendor relationships, treatment of family members.

UNIT – IV

CPCSEA guidelines for laboratory animal facility: Goals, location of animal facilities to laboratories, anaesthesia, euthanasia, physical facilities, environment, animal husbandry, record keeping, SOPs, personnel and training, transport of lab animals.

UNIT – V

Technical writing, thesis/research report writing, structure of thesis, editing and formatting, reference citations, abstracting, plagiarism and paraphrasing, tools for writing good research report.

UNIT – VI

Research reporting - poster presentation, seminar and conference presentation, publishing in journals, copyright.

REFERENCE BOOKS

10. Atiya Khanum Irfan Ali Khan, Biostatistics for Pharmacy, 2nd Edition, 2007, UkaazPublications, Hyderabad.
11. C. George Thomas. Research Methodology and Scientific Writing First edition, 2016, AneBooks Pvt. Ltd.; New Delhi.
12. C. R Kothari. Research Methodology: Methods and Techniques. New Age International (P)Ltd, Publishers. New Delhi.

13. Mahajan, B.K. Methods in Biostatistics for Medical Students and Research workers, 7thEdition 2008 Jaypee Brothers.
14. Putul Mahanta , Medical Writing: A Guide for Medicos, Educators and Researchers JaypeeBrothers Medical Publishers; First edition (2018).
15. Ranjan Das, Biomedical Research Methodology: Including Biostatistical Applications. 1stEdn. Jaypee Brothers.
16. Ranjit Kumar, Research Methodology: A Step-by-Step Guide for Beginners, 3rd Edition 2011,Sage Publications India Pvt. Ltd., New Delhi.
17. Sharma Suresh. Research Methodology and Biostatistics- A Comprehensive Guide for HealthCare Professionals. 1st Edn. Elsevier India.
18. Sunder Rao. P.S.S and Richard. J. An introduction to Biostatistics: A manual for students inhealth sciences. Prentice-Hall of India Pvt. Ltd Publishers.

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Q P CODE REG NO

MODEL QUESTION PAPER
M.PHARM PHARMACEUTICAL QUALITY ASSURANCE
FIRST SEMESTER M. PHARM DEGREE EXAMINATIONS

PAPER - I – MODERN PHARMACEUTICAL ANALYTICAL TECHNIQUES (MQA 101T)

- Answer all questions

Time: 3 hours Maximum Marks: 75

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.

Q P CODE REG NO

MODEL QUESTION PAPER
M.PHARM PHARMACEUTICAL QUALITY ASSURANCE
FIRST SEMESTER M. PHARM DEGREE EXAMINATIONS

PAPER - II – QUALITY MANAGEMENT SYSTEM (MQA 102T)

- Answer all questions

Time: 3 hours Maximum Marks: 75

Essays (3x10=30)

1. Discuss stability testing of drug substances according to ICH guideline.

2. Explain quality policy and objectives, strategic planning and implementation

3. Briefly explain risk assessment, risk management tools, risk ranking and filtering according to ICH Q9 guidelines.

Short notes (9X5=45)

4. Write a note on Classification of customers and factors affecting customer perception.

5. Write a note on Total Quality Management.

6. Write notes on

    a) Hazard Analysis and Critical Control Point (HACCP).

    b) McKinsey 7s model.

7. Write a note on Quality by Design according to ICH.

8. Discuss about Out of Specifications (OOS) and Out of Trend (OOT).

9. Write a note on procedure of NABL accreditation.

10. Write a note on Vendor Qualification.

11. Explain the advantages of statistical control and Process capability.

12. Briefly explain reasons, types, advantages and limitations of benchmarking.

Q P CODE REG NO

MODEL QUESTION PAPER
M.PHARM PHARMACEUTICAL QUALITY ASSURANCE
FIRST SEMESTER M. PHARM DEGREE EXAMINATIONS

PAPER - III – QUALITY CONTROL & QUALITY ASSURANCE (MQA 103T)

- Answer all questions

Time: 3 hours Maximum Marks: 75

Essays (3x10=30)

1. Write an informative note on purchase specifications and maintenance of stores for raw materials.

2. Write in detail protocol for conducting non-clinical testing and control on animal house.

3. What are the basic principles of documentation in Pharma industry? Discuss in detail about Master batch record and electronic data handling.

Short notes (9x5=45)

4. Write a short note on positive and negative aspects of IPR.

5. Discuss In-process quality control and finished process quality control for parenteral dosage form.

6. Write an informative note on three tier documentation.

7. Write a note on Good Warehousing practice.

8. What are the scopes of GLP in quality assurance unit?

9. Write a short note on handling of waste and scrap disposal.

10. Write an informative note on CTD.

11. Write a brief note on mix-ups and cross contamination.

12. Write a note on cGMP guidelines according to schedule M.

Q P CODE REG NO

MODEL QUESTION PAPER
M.PHARM PHARMACEUTICAL QUALITY ASSURANCE
FIRST SEMESTER M. PHARM DEGREE EXAMINATIONS

PAPER - IV – PRODUCT DEVELOPMENT & TECHNOLOGY TRANSFER (MQA 104T)

- Answer all questions

Time: 3 hours Maximum Marks: 75

Essays (3x10=30)

1. Enlist various ANDA certification clauses. Discuss in detail about para IV.

2. Discuss in detail the development of technology by R&D. Add a note on optimisation and quantitative technology models.

3. Write an informative note on solubility parameters that influence the pre-formulation study.

Short notes (9x5=45)

4. Discuss Hatch-Waxman amendment. What are its benefits?

5. Enumerate various centres run by FDA. Write an informative note on CFSAN.

6. Discuss different methods of post marketing surveillance.

7. Discus enteric and aseptic packaging systems.

8. Discuss quality control tests for glass and plastic containers.

9. What does SUPAC guidelines define? Discuss about SUPAC-IR.

10. Discuss the scale up study and manufacturing techniques of parenteral dosage forms.

11. Write a note on different techniques for the study of crystal properties and polymorphism.

12. Discuss the different techniques for the study of crystal properties and polymorphism.

Q P CODE REG NO

MODEL QUESTION PAPER
M.PHARM PHARMACEUTICAL QUALITY ASSURANCE
SECOND SEMESTER M. PHARM DEGREE EXAMINATIONS

PAPER - I – HAZARDS & SAFETY MANAGEMENT (MQA 201T)

- Answer all questions

Time: 3 hours Maximum Marks: 75

Essays (3x10=30)

1. Write in detail about ICH guidelines for risk assessment and risk management.

2. Explain the sources of chemical hazards. Discuss different control measures for its management.

3. Explain the preventive and protective management from fires and explosion. Add a note on its safety and hazards regulation.

Short notes (9x5=45)

4. Differentiate renewable and non-renewable resources.

5. Write a note on hazards based on radio isotopes.

6. Write in detail about accident prevention according to factory Act and rules.

7. How do you manage the combustible gases, toxic gases and Oxygen displacing gases?

8. Discuss in detail about types of toxins.

9. Explain how air circulation is maintained for sterile and non-sterile area in an industry.

10. Write a note on self-protective measures against workplace hazards.

11. Write a note on biological oxygen demand (BOD) and chemical oxygen demand (COD).

12. Write a note on preliminary hazard analysis (PHA).

Q P CODE REG NO

MODEL QUESTION PAPER
M.PHARM PHARMACEUTICAL QUALITY ASSURANCE
SECOND SEMESTER M. PHARM DEGREE EXAMINATIONS

PAPER - II – PHARMACEUTICAL VALIDATION (MQA 202T)

- Answer all questions

Time: 3 hours Maximum Marks: 75

Essays (3x10=30)

1. What is qualification of analytical instruments? Write short note on calibration of HPLC, HPTLC and UV-Vis spectrophotometer.

2. What is process validation: Briefly discuss the USFDA guideline for process validation. Write short note on Process Validation of tablet coating.

3. Write a brief note on validation of analytical method as per ICH guidelines.

Short notes (9x5=45)

4. Briefly explain the Technology transfer. Draw the blank format for the TOT.

5. Draw the blank format for the Qualification of Disintegration tester and Dissolution test apparatus.

6. Explain cleaning method development and validation.

7. What is the difference between the calibration and validation? Explain the advantages of validation.

8. Enumerate the different step for patent filing. Explain the provisional and non-provisional patent.

9. Discuss the role of intellectual property in pharmaceutical industry.

10. Write note on qualification of Fluid Bed and Tray dryers.

11. What is the importance of Re-qualification?

12. Explain the factors affecting choice of IP protection.

Q P CODE REG NO

MODEL QUESTION PAPER
M.PHARM PHARMACEUTICAL QUALITY ASSURANCE
SECOND SEMESTER M. PHARM DEGREE EXAMINATIONS

PAPER - III – AUDITS & REGULATORY COMPLIANCE (MQA 203T)

- Answer all questions

Time: 3 hours Maximum Marks: 75

Essays (3x10=30)

1. Explain the auditing in granulation and tablet manufacturing process.

2. Discuss in detail about responsibilities, management and planning process of an audit.

3. Explain the cGMP regulations and quality system operations for audits in pharmaceutical manufacturing.

Short notes (9x5=45)

4. Explain Auditing of packaging.

5. Discuss in detail about audit checklist for capsules.

6. What is a compliance audit? What are the activities of compliance department?

7. How do internal auditors gather and analyse information.

8. Classify the deficiencies during audit.

9. Discuss in detail about audit checklist for drug industries.

10. Discuss auditing of microbiological laboratory.

11. Write a note on auditing of sterile production.

12. Explain in detail about auditing of HVAC system.

Q P CODE REG NO

MODEL QUESTION PAPER
M.PHARM PHARMACEUTICAL QUALITY ASSURANCE
SECOND SEMESTER M. PHARM DEGREE EXAMINATIONS

PAPER – IV – **PHARMACEUTICAL MANUFACTURING TECHNOLOGY (MQA 204T)**

- Answer all questions

Time: 3 hours Maximum Marks: 75

Essays (3x10=30)

1. What is QbD? Why is it required? Discuss different elements of QbD.
2. Explain the area planning, environment control and utilities of sterile product manufacturing.
3. Discuss how stability of packaging material is evaluated.

Short notes (9x5=45)

4. Discuss legal requirements for API and formulation in industry.
5. Discuss process automation with specific reference to sterile semisolid dosage form.
6. Write principle and equipment for lyophilisation.
7. Discuss the in-process quality control tests for compressed and coated tablets.
8. Write in detail about the stability aspects of packaging.
9. Write about different types of closures and closure liner.
10. Write a note on process analytical technology (PAT) guidance and its regulatory requirements.
11. Explain scheduling and dispatching of records in production plan.
12. Write a note on application techniques and problems encountered in coating technology.

KERALA UNIVERSITY OF HEALTH SCIENCES

Thrissur - 680596

SYLLABUS

POST GRADUATE COURSE IN PHARMACY

Master of Pharmacy (M. Pharm.)

PHARMACEUTICAL REGULATORY AFFAIRS	MRA
KUHS Course Code	529

(2022-23 Academic year onwards)

2022

Course of study for M.Pharm. I & II Semester

MRA	Pharmaceutical Regulatory Affairs				
Course Code	**Course**	**Credit Hours**	**Credit Points**	**Hrs./wk**	**Marks**
Semester I					
MRA 101T	Good Regulatory Practices	4	4	4	100
MRA 102T	Documentation and Regulatory Writing	4	4	4	100
MRA 103T	Clinical Research Regulations	4	4	4	100
MRA 104T	Drug Regulations & Intellectual Property Rights	4	4	4	100
MRA 105P	Regulatory Affairs Practical - I	12	6	12	150
-	Seminar/Assignment	7	4	7	100
Total		**35**	**26**	**35**	**650**
Semester II					
MRA 201T	Regulatory Aspects of Drugs & Cosmetics	4	4	4	100
MRA 202T	Regulatory Aspects of Herbals & Biologicals	4	4	4	100
MRA 203T	Regulatory Aspects of Medical Devices	4	4	4	100
MRA 204T	Regulatory Aspects of Food & Nutraceuticals	4	4	4	100
MRA 205P	Regulatory Affairs Practical – II	12	6	12	150
-	Seminar /Assignment	7	4	7	100
Total		**35**	**26**	**35**	**650**

Course of study for M. Pharm. III & IV Semester

Course Code	**Course**	**Credit Hours**	**Credit Points**	**Marks**
Semester III				
MRM 301T	Research Methodology and Biostatistics	4	4	100
-	Journal Club	1	1	25
-	Discussion / Presentation (proposal presentation)	2	2	25
-	Research Work	28	14	350
Total		**35**	**21**	**500**
Semester IV				
-	Journal Club	1	1	25
-	Pre submission Discussion / Presentation	3	3	75
-	Research Work	31	16	400
Total		**35**	**20**	**500**

PHARMACEUTICAL REGULATORY AFFAIRS (MRA)

SEMESTER I
GOOD REGULATORY PRACTICES (MRA 101T)

Scope:

This course is designed to impart fundamental knowledge on various Good Regulatory Practices viz., cGMP, GLP, GALP and GDP for Pharmaceuticals, Cosmetics, Food & Nutraceuticals, Medical devices, In-vitro Diagnostic Medical Devices (IVDs) and biological products and understand the rationale behind these requirements and will propose ways and means of complying with them.

Objectives:

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

- The key regulatory and compliance elements with respect to Good Manufacturing Practices, Good Laboratory Practices, Good Automated Laboratory Practices and Good Documentation Practices.
- Prepare and implement the check lists and SOPs for various Good Regulatory Practices
- Implement Good Regulatory Practices in the Healthcare and related Industries
- Prepare for the readiness and conduct of audits and inspections.

THEORY **60 Hrs**

1. **Current Good Manufacturing Practices:** 12 Hrs

Introduction:, US cGMP Part 210 and Part 211.EC Principles of GMP (Directive 91/356/EEC) Article 6 to Article 14 and WHO cGMP guidelines GAMP-5; Medical device and IVDs Global Harmonization Task Force(GHTF) Guidance docs.

2. **Good Laboratory Practices:** 1 2 H rs

Introduction, USFDA GLP Regulations (Subpart A to Subpart K), Controlling the GLP inspection process, Documentation, Audit, goals of Laboratory Quality Audit, Audit tools, Future of GLP regulations, relevant ISO and Quality Council of India(QCI) Standards

3. **Good Automated Laboratory Practices:** 12 Hrs

Introduction to GALP,Principles of GALP, GALP Requirements, SOPs of GALP,Training Documentation, 21 CFR Part 11, General check list of21CFR Part 11, Software Evaluation checklist, relevant ISO and QCI Standards.

4. **Good Distribution Practices:** 12 Hrs

Introduction to GDP, Legal GDP requirements put worldwide, Principles, Personnel, Documentation, Premises and Equipment, Deliveries to Customers, Returns, Self-Inspection, Provision of information, Stability testing principles, WHO GDP, USP GDP (Supply chain integrity), relevant CDSCO guidance and ISO standards

5. **Quality management systems:** 12 Hrs

Concept of Quality, Total Quality Management, Quality by design, Six Sigma concept, Out of Specifications (OOS), Change control. Validation: Types of Validation, Types of Qualification, Validation master plan (VMP), Analytical Method Validation. Validation of utilities, [Compressed air, steam, water systems, Heat Ventilation and Air conditioning (HVAC)]and Cleaning Validation. The International Conference on Harmonization (ICH) process, ICH guidelines to establish quality, safety and efficacy of drug substances and products, ISO 13485, Sch MIII and other relevant CDSCO regulatory guidance documents.

REFERENCES

1. Good Laboratory Practice Regulations, by Sandy Weinberg, Fourth EditionDrugs and the Pharmaceutical Sciences, Vol.168
2. Good Pharmaceutical Manufacturing practice, Rational and compliance byJohn Sharp, CRC Press

3. Establishing a cGMP Laboratory Audit System, A practical Guide by David M. Bleisner, Wiley Publication.
4. How to practice GLP by PP Sharma, Vandana Publications.
5. Laboratory Auditing for Quality and Regulatory compliance by DonaldC. Singer, Drugs and the Pharmaceutical Sciences, Vol.150
6. Drugs & Cosmetics Act, Rules & Amendments

DOCUMENTATION AND REGULATORY WRITING (MRA 102T)

Scope:

This course is designed to impart fundamental knowledge on documentationand general principles involved in regulatory writing and submission to agencies.

Objectives:

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

- _ Know the various documents pertaining to drugs in pharmaceuticalindustry
- _ Understand the basics of regulatory compilation
- _ Create and assemble the regulation submission as per therequirements of agencies
- _ Follow up the submissions and post approval document requirements

THEORY **60 Hrs**

1. **Documentation in pharmaceutical industry:** 12 Hrs

Exploratory Product Development Brief (EPDB) for Drug substance and Drug product, Product Development Plan (PDP), Product Development Report (PDR), Master Formula Record, Batch Manufacturing Record and its calculations, Batch Reconciliation, Batch Packaging Records, Print pack specifications, Distribution records, Certificate of Analysis (CoA), Site Master File and Drug Master Files (DMF).

2. **Dossier preparation and submission:** 12 hrs

Introduction and overview of dossiers, contents and organization of dossier, binders and sections, compilation and review of dossier. Paper submissions, overview and modules of CTD, electronic CTD submissions; Electronic submission: Planning electronic submission, requirements for submission, regulatory bindings and requirements, Tool and Technologies, electronic dossier submission process and validating the submission, Electronic Submission Gateway (ESG). Non eCTD electronic submissions (NeeS), Asian CTD formats (ACTD) submission. Organizing, process and validation of submission. Submission in Sugam system of CDSCO.

3. **Audits:** 12 Hrs

Introduction, Definition, Summary, Types of audits, GMPcompliance audit, Audit policy, Internal and External Audits, Second Party Audits, External third party audits, Auditing strategies, Preparation and conducting audit, Auditing strategies, audit analysis, audit report, audit follow up. Auditing/inspection of manufacturing facilities by regulatory agencies. Timelines for audits/inspection. GHTF study group 4 guidance document. ISO 13485.

4.**Inspections:** 12Hrs

Pre-approval inspections, Inspection of pharmaceutical manufacturers, Inspection of drug distribution channels, Quality systems requirements for national good manufacturing practice inspectorates, inspection report, model certificate of good manufacturing practices, Root cause analysis, Corrective and Preventive action (CAPA).

5. **Product life cycle management:** 12 Hrs

Prior Approval Supplement (PAS), Post Approval Changes [SUPAC], Changes Being Effected in 30 Days (CBE-30), Annual Report, Post marketing Reporting Requirements, Post approval Labeling Changes, Lifecycle Management, FDA Inspection and Enforcement, Establishment Inspection Report (EIR), Warning Letters, Recalls, Seizure and Injunctions. ISO Risk Management Standard

REFERENCES:

1. Compliance auditing for Pharmaceutical Manufacturers. Karen Ginsbury and Gil Bismuth, Interpharm/CRC, Boca Raton, London New York, Washington D.C.
2. Pharmaceutical Manufacturing Handbook, Regulations and Quality by Shayne Cox Gad. Wiley-Interscience, A John Wiley and sons, Inc., Publications.
3. Handbook of microbiological Quality control. Rosamund M. Baird, Norman A. Hodges, Stephen P. Denyar. CRC Press. 2000.
4. Laboratory auditing for quality and regulatory compliance. Donald C. Singer, Raluca-loana Stefan, Jacobus F. Van Staden. Taylor and Francis (2005).
5. Implementing Juran's Road Map for Quality Leadership: Benchmarks and Results, By Al Endres, Wiley, 2000
6. Understanding, Managing and Implementing Quality: Frameworks, Techniques and Cases, By Jiju Antony; David

Preece, Routledge, 2002

7. Organizing for High Performance: Employee Involvement, TQM, Reengineering, and Knowledge Management in the Fortune 1000: The CEO Report By Edward E. Lawler; Susan Albers Mohrman; George Benson, Jossey-Bass, 2001
8. Corporate Culture and the Quality Organization By James W. Fairfield- Sonn, Quorum Books, 2001
9. The Quality Management Sourcebook: An International Guide to Materials and Resources By Christine Avery; Diane Zabel, Routledge, 1997
10. The Quality Toolbox, Second Edition, Nancy R. Tague, ASQ Publications
11. Juran's Quality Handbook, Sixth Edition, Joseph M. Juran and Joseph A. De Feo, ASQ Publications
12. Root Cause Analysis, The Core of Problem Solving and Corrective Action, Duke Okes, 2009, ASQ Publications
13. International Medical Device Regulators Forum (IMDRF) Medical Device Single Audit Program (MDSAP)

CLINICAL RESEARCH REGULATIONS (MRA 103T)

Scope:

This course is designed to impart the fundamental knowledge on the clinical development process of drugs, pharmaceuticals and Medical Devices, phases and conduct of clinical trials and research, regulations and guidance governing the conduct of clinical research in India, USA and EU. It prepares the students to learn in detail on various laws, legislations and guidance related to safety, efficacy, ethical conduct and regulatory approval of clinical research.

Objectives:

Upon completion of the course, the student shall be able to (know, do andappreciate)

- History, origin and ethics of clinical and biomedical research andevaluation
- Clinical drug, medical device development process and different typesand phases of clinical trials
- Regulatory requirements and guidance for conduct of clinical trials andresearch

THEORY **60 Hrs**

1. **Clinical Drug Development Process:** 12 Hrs
   - Different types of Clinical Studies
   - Phases of clinical trials, Clinical Trial protocol
   - Phase 0studies
   - Phase I and subtype studies (single ascending, multiple ascending, dose escalation, methods, food effect studies, drug – drug interaction, PK endpoints
   - Phase IIstudies (proof of concept or principle studies to establish efficacy)
   - Phase IIIstudies (Multi ethnicity, global clinical trial, registration studies)
   - Phase IV studies (Post Marketing Studies; PSUR)

   Clinical Investigation and Evaluation of Medical Devices & IVDs

2 **Ethics in Clinical Research:** 12 Hrs

   - Historical Perspectives: Nuremberg Code, Thalidomide study, Nazis Trials, Tuskegee Syphilis Study, The Belmont Report,The declaration of Helsinki
   - Origin of International Conference on Harmonization - GoodClinical Practice (ICH-GCP) guidelines.
   - The ethics of randomized clinical trials
   - The role of placebo in clinical trials
   - Ethics of clinical research in special population
   - Institutional Review Board/Independent Ethics Committee/Ethics Committee – composition, roles, responsibilities, review and approval process and ongoing monitoring of safety data
   - Data safety monitoring boards.
   - Responsibilities of sponsor, CRO, and investigator in ethical conduct of clinical research
   - Ethical principles governing informed consent process
   - Patient Information Sheet and Informed Consent Form
   - The informed consent process and documentation

3 **Regulations g o v e r n i n g Clinical Trials** 12 Hrs

   India: Clinical Research regulations in India – Schedule Y & Medical Device Guidance

   USA: Regulations to conduct drug studies in USA (FDA)

   - NDA 505(b)(1) of the FD&C Act (Application for approval of a new drug)
   - NDA 505(b)(2) of the FD&C Act (Application for approval of a new drug that relies, at least in part, on data not developed by the applicant)
   - ANDA 505(j) of the FD&C Act (Application for approval of a generic drug product)
   - FDA Guidance for Industry - Acceptance of Foreign Clinical Studies
   - FDA Clinical Trials Guidance Document: Good ClinicalPractice

   EU: Clinical Research regulations in European Union (EMA)

4 **Clinical Research R e l a t e d Guidelines** 12 Hrs

   - Good Clinical Practice Guidelines (ICH GCP E6)

_ Indian GCP Guidelines
_ ICMR Ethical Guidelines for Biomedical Research
_ CDSCO guidelines
GHTF study group 5 guidance documents
Regulatory Guidance on Efficacy and Safety ICH Guidance's
_ E4 – Dose Response Information to support DrugRegistration
_ E7 – Studies in support of General Population: Geriatrics
_ E8 – General Considerations of Clinical Trials
_ E10 – Choice of Control Groups and Related Issues inClinical Trials,
_ E 11 – Clinical Investigation of Medicinal Products in thePediatric Population
_ General biostatics principle applied in clinical research

5 USA & EU GuidanceUSA: FDA Guidance 12 Hrs

_ CFR 21Part 50: Protection of Human Subjects
_ CFR 21Part 54: Financial Disclosure by Clinical Investigators
_ CFR 21Part 312: IND Application
_ CFR 21Part 314: Application for FDA Approval to Market aNew Drug
_ CFR 21Part 320: Bioavailability and bioequivalencerequirements
_ CFR 21Part 812: Investigational Device Exemptions
_ CFR 21Part 822: Post-market surveillance
_ FDA Safety Reporting Requirements for INDs and BA/BE Studies
_ FDA Med Watch
_ Guidance for Industry: Good Pharmacovigilance Practicesand Pharmacoepidemiologic Assessment
European Union: EMA Guidance
_ EU Directives 2001
_ EudraLex (EMEA) Volume 3 – Scientific guidelines formedicinal products for human use
_ EU Annual Safety Report (ASR)
_ Volume 9A – Pharmacovigilance for Medicinal Products forHuman Use
_ EU MDD with respect to clinical research
_ ISO 14155

REFERENCES

1. Clinical Trials and Human Research: A Practical Guide to Regulatory Compliance By Fay A. Rozovsky and Rodney K. Adams
2. HIPAA and Human Subjects Research: A Question and Answer Reference Guide By Mark Barnes, JD, LLM and Jennifer Kulynych, JD, PhD
3. Principles and Practices of Clinical Research, Second Edition Edited by John I. Gallin and Frederick P. Ognibene
4. Reviewing Clinical Trials: A Guide for the Ethics Committee; Johan PE Karlberg and Marjorie A Speers; Karlberg, Johan Petter Einar, Hong Kong.
5. International Pharmaceutical Product Registration: Aspects of Quality, Safety and Efficacy; Anthony C. Cartwright; Taylor & Francis Inc., USA.
6. New Drug Approval Process: The Global Challenge; Guarino, Richard A; Marcel Dekker Inc., NY.
7. FDA regulatory affairs: a guide for prescription drugs, medical devices, and biologics; Douglas J. Pisano, David Mantus; CRC Press, USA
8. Country Specific Guidelines from official websites.
9. Drugs & Cosmetics Act & Rules and Amendments

RECOMMENDED WEBSITES:

1. EU Clinical Research Directive 2001: http://www.eortc.be/services/doc/clinical-eudirective-04-april-01.pdf
2. Code of Federal Regulations, FDA: http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/cfrsearch.cfm
3. Guidelines of International Conference on Harmonization: http://www. ich.org/products/guidelines.html
4. Eudralex Guidelines: http://www.gmpcompliance.info/euguide.htm
5. FDA New Drug Application: http://www.fda.gov/regulatoryinformation/legislation/FederalFoodDrugandCosmetic ActFDCAct/FDCActChapterVDrugsandDevices/ucm108125.htm
6. Medicines and Healthcare products Regulatory Agency: http://www.mhra.gov.uk
7. Central Drugs Standard Control Organization Guidance for Industry:http://cdsco.nic.in/CDSCO-GuidanceForIndustry.pdf
8. ICMR Ethical Guidelines for Biomedical Research: http://icmr.nic.in/ethical_guidelines.pdf

DRUG REGULATIONS AND INTELLECTUAL PROPERTY RIGHTS (MRA 104T)

Scope:

This course is designed to impart fundamental knowledge on regulations and legislation in India w.r.t. Drugs & Cosmetics, Medical Devices, Biologicals & Herbals, and Food & Nutraceuticals. It prepares the students for basic regulatory requirements in India of Drugs & Cosmetics, Medical Devices, Biologicals & Herbals, and Food & Nutraceuticals. for manufacture, import & registration, export, sale, marketing authorization, clinical trials and intellectual property rights.

Objectives:

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

- Know different Acts and guidelines that regulate Drugs & Cosmetics, Medical Devices, Biologicals & Herbals, and Food & Nutraceuticals industry in India.
- Understand the approval process and regulatory requirements for Drugs & Cosmetics, Medical Devices, Biologicals & Herbals, and Food & Nutraceuticals

THEORY **60 Hrs**

1. **Biologicals & Herbals, and Food & NutraceuticalsActs and Rules (with latest amendments):** 12 Hrs

(1) Drugs and Cosmetics Act 1940 and Rules 1945: DPCO and NPPA

(2) Other relevant provisions (rules schedules and guidelines for approval of Drugs & Cosmetics, Medical Devices, Biologicals & Herbals, and Food & Nutraceuticals in India

Other relevant Acts: Narcotics Drugs and Psychotropic Substances Act; Medicinal and Toilet Preparations (Excise Duties) Act, 1955; Pharmacy Act, 1948; Drugs and Magic Remedies (Objectionable Advertisements) Act, 1955; Prevention of Cruelty to Animals Act.

2. **Regulatory requirements and approval procedures for Drugs & Cosmetics Medical Devices, Biologicals & Herbals, and Food & Nutraceuticals:** 12 Hrs

CDSCO (Central Drug Standard Control Organization) and State Licensing Authority: Organization, Responsibilities

- Rules, regulations, guidelines and standards for regulatory filing of Drugs & Cosmetics, Medical Devices, Biologicals & Herbals, and Food & Nutraceuticals
- Format and contents of Regulatory dossier filing Clinical trial/ investigations

3. **Indian Pharmacopoeial Standards, BIS standards and ISO and other relevant standards** 12 Hrs

4. Bioavailability and Bioequivalence data (BA &BE), BCS Classification of Drugs, Regulatory Requirements for Bioequivalence study 12 Hrs
Stability requirements: ICH and WHO

Guidelines for Drug testing in animals/Preclinical Studies

Animal testing: Rationale for conducting studies, CPCSEAGuidelines
Ethical guidelines for human participants ICMR-DBT Guidelines for Stem Cell Research

5. **Intellectual Property Rights:** 12 Hrs
Patent, Trademark, Copyright, Industrial Designs and Geographical Indications, Indian Patent Scenario. IPR vs Regulatory Affairs

REFERENCES

1. Manual of Patent Practice & Procedure, 3rd Edition, by The Patent Officeof India.
2. Patent Failure How Judges, Bureaucrats, and Lawyers put innovators atrisk by James Bessen and Michael J. Meurer.
3. Principles and Practice of Clinical Trial Medicine by Richard Chin andBruce Y. Lee.
4. Ethical Guidelines for Biomedical Research on Human Participants byIndian Council of Medical Research New Delhi 2006.
5. CPCSEA Guidelines for Laboratory Animal Facility by Committee for thepurpose of control and supervision on experiments on animals (CPCSEA).

6. ICH E6 Guideline — Good Clinical Practice| by ICH Harmonised Tripartite
7. Guidance for Industry on Submission of Clinical Trial Application for Evaluating Safety and Efficacy by CDSCO (Central Drug Standard Control Organisation)
8. Guidance for Industry on Requirement of Chemical & Pharmaceutical Information including Stability Study Data before approval of clinical trials / BE studies by CDSCO
9. Guidelines for Import and Manufacture of Medical Devices by CDSCO
10. Guidelines from official website of CDSCO

REGULATORY AFFAIRS PRACTICAL – I (MRA 105P)

1. Case studies (4 Nos.) of each of Good Pharmaceutical Practices.
2. Documentation for in process and finished products Quality control tests for Solid, liquid, Semisolid and Sterile preparations.
3. Preparation of SOPs, Analytical reports (Stability and validation)
4. Protocol preparation for documentation of various types of records (BMR,MFR, DR)
5. Labeling comparison between brand & generics.
6. Preparation of clinical trial protocol for registering trial in India
7. Registration for conducting BA/ BE studies in India
8. Import of drugs for research and developmental activities
9. Preparation of regulatory dossier as per Indian CTD format and submissionin SUGAM
10. Registering for different Intellectual Property Rights in India
11. GMP Audit Requirements as per CDSCO
12. Preparation and documentation for Indian Patent application.
13. Preparation of checklist for registration of IND as per ICH CTD format.
14. Preparation of checklist for registration of NDA as per ICH CTD format.
15. Preparation of checklist for registration of ANDA as per ICH CTD format.
16. Case studies on response with scientific rationale to USFDA Warning Letter
17. Preparation of submission checklist of IMPD for EU submission.
18. Comparison study of marketing authorization procedures in EU.
19. Comparative study of DMF system in US, EU and Japan
20. Preparation of regulatory submission using eCTD software
21. Preparation of Clinical Trial Application (CTA) for US submission
22. Preparation of Clinical Trial Application (CTA) for EU submission
23. Comparison of Clinical Trial Application requirements of US, EU and Japanof a dosage form.
24. Regulatory requirements checklist for conducting clinical trials in India.
25. Regulatory requirements checklist for conducting clinical trials in Europe.
26. Regulatory requirements checklist for conducting clinical trials in USA

SEMESTER II

REGULATORY ASPECTS OF DRUGS & COSMETICS (MRA 201T)

Scope

This course is designed to impart the fundamental knowledge on the drug development process, regulatory requirements for approval of new drugs, drug products and cosmetics in regulated and semi-regulated countries. It prepares the students to learn in detail on the regulatory requirements, documentation requirements, and registration procedures for marketing the drug products and cosmetics in regulated and semi-regulated countries.

Objectives:

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

- Process of drug discovery and development and generic productdevelopment
- Regulatory approval process and registration procedures for API anddrug products in US, EU
- Cosmetics regulations in regulated and semi-regulated countries
- A comparative study of India with other global regulated markets

THEORY **60 Hrs**

1. **USA & CANADA:** 12 Hrs

Organization structure and functions of FDA. Federal register and Code of Federal Regulations (CFR), History and evolution of United States Federal, Food, Drug and Cosmetic Act (FFDCA), Hatch Waxman act and Orange book, Purple book, Drug Master Files (DMF) system in US, Regulatory Approval

Process for Investigational New Drug (IND), New Drug Application (NDA), Abbreviated New Drug Application (ANDA), Supplemental New Drug Application (SNDA); Regulatory requirements for Orphan drugs and Combination Products, Changes to an approved NDA / ANDA. Regulatory considerations for manufacturing, packaging and labeling of pharmaceuticals in USA. Legislation and regulations for import, manufacture, distribution and sale of cosmetics in USA and Canada.

2. **European Union & Australia:** 1 2 H r s

Organization and structure of EMA & EDQM, General guidelines, Active Substance Master Files (ASMF) system in EU, Content and approval process of IMPD, Marketing Authorization procedures in EU (Centralized procedure, Decentralized procedure, Mutual recognition procedure and National Procedure). Regulatory considerations for manufacturing, packaging and labeling of pharmaceuticals in EU, Eudralex directives for human medicines, Variations & extensions, Compliance of European Pharmacopoeia (CEP)/ Certificate of Suitability (CoS), Marketing Authorization (MA) transfers, Qualified Person (QP) in EU. Legislation and regulations for import, manufacture, distribution and sale of cosmetics in European Union & Australia.

3. **Japan:** 12 Hrs

Organization of the PMDA, Pharmaceutical Laws and regulations, types of registration applications, DMF system in Japan, drug regulatory approval process, Regulatory considerations for manufacturing, packaging and labeling of pharmaceuticals in Japan, Post marketing surveillance in Japan. Legislation and regulations for import, manufacture, distribution and sale of cosmetics in Japan

4. **Emerging Market:** 12 Hrs

Introduction, Countries covered, Study of the world map, study of various committees across the globe (ASEAN, APEC, EAC, GCC, PANDRH, SADC)

WHO: WHO, GMP, Regulatory Requirements for registration of drugs and post approval requirements in WHO through prequalification programme, Certificate of Pharmaceutical Product (CoPP) - General and Country Specific (South Africa, Egypt, Algeria and Morocco, Nigeria, Kenya and Botswana)

5. **Brazil, ASEAN, CIS and GCC Countries:** 12 Hrs

ASIAN Countries: Introduction to ACTD, R e g u l a t o r y Requirements for registration of drugs and post approval requirements in China and South Korea & Association of Southeast Asian Nations (ASEAN) Region i.e. Vietnam, Malaysia, Philippines, Singapore and Thailand.

CIS (Commonwealth Independent States): Regulatory pre- requisites related to Marketing authorization requirements for drugs and post approval requirements in CIS countries i.e. Russia, Kazakhstan and Ukraine GCC (Gulf Cooperation Council) for Arab states: Regulatory pre-requisites related to Marketing authorization requirements for drugs and post approval requirements in Saudi Arabia and UAE

Legislation and regulations for import, manufacture, distribution and sale of cosmetics in Brazil, ASEAN, CIS and GCC Countries.

REFERENCES:

1. Generic Drug Product Development, Solid Oral Dosage forms, Leon Shargel and Isader Kaufer, Marcel Dekker series, Vol.143
2. The Pharmaceutical Regulatory Process, Edited by Ira R. Berry Marcel Dekker Series, Vol.144
3. 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.
4. New Drugs Approval Process: Accelerating Global Restrictions By Richard A. Guarino MD, 5th Edn, Drugs and Pharmaceuticals, Vol. 190.
5. Guidebook for drug regulatory submissions / Sandy Weinberg. By JohnWiley & Sons. Inc.
6. Drugs: From Discovery to Approval, Second Edition By Rick Ng
7. New Drug Development: A Regulatory Overview, Eighth Edition By MarkMathieu
8. Pharmaceutical Risk Management By Jeffrey E. Fetterman, Wayne L. Pines and Gary H. Slatko
9. Preparation and Maintenance of the IND Application in eCTD Format ByWilliam K. Sietsema
10. Country Specific Guidelines from official websites.
11. http://www.who.int/medicines/areas/quality_safety/regulation_legislation/ ListMRAWebsites.pdf
12. Roadmap to an ASEAN economic community Edited by Denis Hew. ISEAS Publications, Singapore 2005, ISBN981-230-347-2
13. ASEAN, Rodolfo C. Severino, ISEAS Publications, Singapore 2005, ISBN 978-981-230-750-7
14. Building a Future with Brics: The Next Decade for Offshoring, Mark Kobayashi-Hillary, Springer
15. Outsourcing to India: The Offshore Advantage, Mark Kobayashi-Hillary, Springer Trade performance and Regional Integration of the CIS Countries, Lev Freinkman,
16. The world Bank, Washington, DC, ISBN: 0-8212-5896-0
17. Global Pharmaceutical Policy: Ensuring Medicines for Tomorrow's World ByFrederick M. Abbott, Graham Dukes, Maurice Nelson Graham Dukes 139
18. The Gulf Cooperation Council: A Rising Power and Lessons for ASEAN by Linda Low and Lorraine Carlos Salazar (Nov 22, 2010)
19. Doing Business in the Asean Countries, Balbir Bhasin, Business Expert Press ISBN:13:978-1-60649-108-9
20. Realizing the ASEAN Economic Community: A Comprehensive Assessment, Michael G Plummer (Editor), Chia Siow Yue (Editor), Instute of South East Asian studies, Singapore.

REGULATORY ASPECTS OF HERBAL AND BIOLOGICALS (MRA 202T)

Scope

This course is designed to impart fundamental knowledge on Regulatory Requirements, Licensing and Registration, Regulation on Labelling of Biologics in India, USA and Europe
It prepares the students to learn in detail on Regulatory Requirements for
biologics, Vaccines and Blood Products

Objectives

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

- Know the regulatory Requirements for Biologics and Vaccines
- Understand the regulation for newly developed biologics and biosimilars
- Know the pre-clinical and clinical development considerations of biologics
- Understand the Regulatory Requirements of Blood and/or Its Components Including Blood Products and label requirements

THEORY **60 Hrs**

1. India: 12 Hrs

Introduction, Applicable Regulations and Guidelines, Principles for Development of Similar Biologics, Data Requirements for Preclinical Studies, Data Requirements for Clinical Trial Application, Data Requirements for Market Authorization Application, Post-Market Data for Similar Biologics, Pharmacovigilance. GMP and GDP.

2. USA: 12 Hrs

Introduction to Biologics; biologics, biological and biosimilars, different biological products, difference between generic drug and biosimilars, laws, regulations and guidance on biologics/ biosimilars, development and approval of biologics and biosimilars (IND, PMA, BLA, NDA, 510(k), pre-clinical and clinical development considerations, advertising, labelling and packing of biologics

3. European Union: 12 Hrs

Introduction to Biologics; directives, scientific guidelines and guidance related to biologics in EU, comparability/ biosimilarity assessment, Plasma master file, TSE/ BSE evaluation, development and regulatory approval of biologics (Investigational medicinal products and biosimilars), pre-clinical and clinical development considerations; stability, safety,advertising, labelling and packing of biologics in EU.

4. Vaccine regulations in India, US and European Union: 12 Hrs

Clinicalevaluation, Marketing authorisation, Registration or licensing, Quality assessment, Pharmacovigilance, Additional requirements Blood and Blood Products Regulations in India, US and EuropeanUnion: Regulatory Requirements of Blood and/or Its Components Including Blood Products, Label Requirements, ISBT(International Society of Blood Transfusion) and IHN (International Haemovigilence Network)

5. Herbal Products: 12 Hrs

Quality, safety and legislation for herbalproducts in India, USA and European Union.

REFERENCES

1. FDA Regulatory Affairs: A Guide for Prescription Drugs, Medical Devices,and Biologics, Douglas J. Pisano, David S. Mantus; Informa ,2008
2. Biological Drug Products: Development and Strategies; WeiWang, Manmohan Singh; Wiley ,2013
3. Development of Vaccines: From Discovery to Clinical Testing; ManmohanSingh, Indresh K. Srivastava; Wiley, 2011
4. www.who.int/biologicals/en
5. www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/
6. www.ihn-org.com
7. www.isbtweb.org
8. Guidelines on Similar Biologics: Regulatory Requirements for MarketingAuthorization in India
9. www.cdsco.nic.in
10. www.ema.europa.eu › scientific guidelines › Biologicals
11. www.fda.gov/biologicsbloodVaccines/GuidanceCompliance Regulatory Information (Biologics)

REGULATORY ASPECTS OF MEDICAL DEVICES (MRA 203T)

Scope:

This course is designed to impart the fundamental knowledge on the medical devices and in vitro diagnostics, basis of classification and product life cycle of medical devices, regulatory requirements for approval of medical devices in regulated countries like US, EU and Asian countries along with WHO regulations. It prepares the students to learn in detail on the harmonization initiatives, quality and ethical considerations, regulatory and documentation requirements for marketing medical devices and IVDs in regulated countries.

Objectives:

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

- basics of medical devices and IVDs, process of development, ethicaland quality considerations
- harmonization initiatives for approval and marketing of medical devicesand IVDs
- regulatory approval process for medical devices and IVDs in India, US,Canada, EU, Japan and ASEAN
- clinical evaluation and investigation of medical devices and IVDs

THEORY **60 Hrs**

1. **Medical Devices:** 12 Hrs

Introduction, Definition, Risk based classification and Essential Principles of Medical Devices and IVDs. Differentiating medical devices IVDs and Combination Products from that of pharmaceuticals, History of Medical Device Regulation, Product Lifecycle of Medical Devices andClassification of Medical Devices.
IMDRF/GHTF: Introduction, Organizational Structure, Purpose and Functions, Regulatory Guidelines, Working Groups, Summary Technical Document (STED), Global Medical Device Nomenclature (GMDN).

2. **Ethics:** 1 2 H rs

Clinical Investigation of Medical Devices, ClinicalInvestigation Plan for Medical Devices, Good Clinical Practice for Clinical Investigation of medical devices (ISO 14155:2011) Quality: Quality System Regulations of Medical Devices: ISO13485, Quality Risk Management of Medical Devices: ISO14971, Validation and Verification of Medical device, AdverseEvent Reporting of Medical device

3. **USA:** 12 Hrs

Introduction, Classification, Regulatory approval process for Medical Devices (510k) Premarket Notification, Pre-Market Approval (PMA), Investigational Device Exemption (IDE) and In vitro Diagnostics, Quality System Requirements 21 CFR Part 820,Labeling requirements 21 CFR Part 801, Post marketing surveillance of MD and Unique Device Identification (UDI). Basics of In vitro diagnostics, classification and approval process.

4. **European Union:** 12 Hrs

Introduction, Classification, Regulatory approval process for Medical Devices
(Medical Device Directive, Active Implantable Medical Device Directive) and In vitro Diagnostics (In Vitro Diagnostics Directive),CE certification process.
Basics of In vitro diagnostics, classification and approval process.

5. **ASEAN, China & Japan:** 12 Hrs

Medical Devices and IVDs, Regulatory registration procedures, Quality System requirements and clinical evaluation and investigation.
IMDRF study groups and guidance documents.

REFERENCES

1. FDA regulatory affairs: a guide for prescription drugs, medical devices, andbiologics by Douglas J. Pisano, David Mantus.
2. Medical Device Development: A Regulatory Overview by Jonathan S. Kahan
3. Medical Product Regulatory Affairs: Pharmaceuticals, Diagnostics, Medical Devices by John J. Tobin and Gary Walsh
4. Compliance Handbook for Pharmaceuticals, Medical Devices andBiologics by Carmen Medina
5. Country Specific Guidelines from official websites.

REGULATORY ASPECTS OF FOOD & NUTRACEUTICALS (MRA 204T)

Scope:

This course is designed to impart the fundamental knowledge on Regulatory Requirements, Registration and Labeling Regulations of Nutraceuticals in India, USA and Europe.
It prepares the students to learn in detail on Regulatory Aspects for nutraceuticals and food supplements.

Objectives:

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

- Know the regulatory Requirements for nutraceuticals
- Understand the regulation for registration and labeling of nutraceuticalsand food supplements in India, USA and Europe.

THEORY **60 Hrs**

1. **Nutraceuticals:** 12 Hrs

Introduction, History of Food and Nutraceutical Regulations, Meaning of Nutraceuticals, Dietary Supplements, Functional Foods, Medical Foods, Scope and Opportunities in Nutraceutical Market.

2. **Global Aspects**: 12 Hrs

WHO guidelines on nutrition. NSF International: Its Role in the Dietary Supplements and Nutraceuticals Industries, NSF Certification, NSF Standards for Food and Dietary Supplements. Good Manufacturing Practices for Nutraceuticals.

3. **India:** 12 Hrs

Food Safety and Standards Act, Food Safety and Standards Authority of India: Organization and Functions, Regulations for import, manufacture and sale of nutraceutical products in India, Recommended Dietary Allowances (RDA) in India.

4. **USA:** 12 Hrs

US FDA Food Safety Modernization Act, Dietary Supplement Health and Education Act. U.S. regulations for manufacture and sale of nutraceuticals and dietary supplements, Labelling Requirements and Label Claims for Dietary Supplements, Recommended Dietary Allowances (RDA) in the U.S

5. **European Union:** 12 Hrs

European Food Safety Authority (EFSA): Organization and Functions. EU Directives and regulations for manufacture and sale of nutraceuticals and dietary supplements. Nutrition labelling. European Regulation on Novel Foods and Novel Food Ingredients. Recommended Dietary Allowances (RDA) in Europe.

REFERENCES

1. Regulation of Functional Foods and Nutraceuticals: A Global Perspectiveby Clare M. Hasler (Wiley Online Library)
2. Nutraceutical and Functional Food Regulations in the United States andAround the World by Debasis Bagchi (Academic Press, Elsevier)
3. http://www.who.int/publications/guidelines/nutrition/en/
4. http://www.europarl.europa.eu/RegData/etudes/STUD/2015/536324/IPOL_ STU(2015)536324_EN.pdf
5. Handbook of Nutraceuticals by Yashwant Pathak (CRC Press)
6. Food Regulation: Law, Science, Policy and Practice by Neal D. Fortin(Wiley)
7. Country Specific Guidelines from official websites.

REGULATORY AFFAIRS PRACTICAL - II(MRA 205P)

1. Case studies on
2. Change Management/ Change control. Deviations
3. Corrective & Preventive Actions (CAPA)
4. Documentation of raw materials analysis as per official monographs
5. Preparation of audit checklist for various agencies
6. Preparation of submission to FDA using eCTD software
7. Preparation of submission to EMA using eCTD software
8. Preparation of submission to MHRA using eCTD software
9. Preparation of Biologics License Applications (BLA)
10. Preparation of documents required for Vaccine Product Approval
11. Comparison of clinical trial application requirements of US, EU andIndia of Biologics
12. Preparation of Checklist for Registration of Blood and Blood Products
13. Registration requirement comparison study in 5 emerging markets (WHO) and preparing check list for market authorization
14. Registration requirement comparison study in emerging markets (BRICS) and preparing check list for market authorization
15. Registration requirement comparison study in emerging markets (China and South Korea) and preparing check list for market authorization
16. Registration requirement comparison study in emerging markets (ASEAN) and preparing check list for market authorization
17. Registration requirement comparison study in emerging markets (GCC) and preparing check list for market authorization
18. Checklists for 510k and PMA for US market
19. Checklist for CE marking for various classes of devices for EU
20. STED Application for Class III Devices
21. Audit Checklist for Medical Device Facility
22. Clinical Investigation Plan for Medical Devices

SEMESTER-III

RESEARCH METHODOLOGY & BIOSTATISTICS (MRM 301T)

UNIT –I

General Research Methodology: Research, objective, requirements, practical difficulties, types of research, scientific methods of research, types of studies, study design.

Review of literature - Sources of information. Searching of library documents and databases online and offline (Pubmed, Biological abstracts, other databases in pharmaceutical sciences). Introduction to internet searching using advanced search tools.

UNIT – II

Collection and analysis of data: Types of data and data collection techniques, processing of data, coding, tabulation and analysis of data.

Biostatistics: Definition, application, sample size, importance of sample size, factors influencing sample size, dropouts, statistical tests of significance, type of significance tests, parametric tests (Student's 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, different software for statistical analysis.

UNIT – III

Medical Research: History, values in medical ethics, strategies to eliminate errors/bias, controls, randomisation, cross over design, placebo, blinding techniques 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, vendor relationships, treatment of family members.

UNIT – IV

CPCSEA guidelines for laboratory animal facility: Goals, location of animal facilities to laboratories, anaesthesia, euthanasia, physical facilities, environment, animal husbandry, record keeping, SOPs, personnel and training, transport of lab animals.

UNIT – V

Technical writing, thesis/research report writing, structure of thesis, editing and formatting, reference citations, abstracting, plagiarism and paraphrasing, tools for writing good research report.

UNIT – VI

Research reporting - poster presentation, seminar and conference presentation, publishing in journals, copyright.

REFERENCE BOOKS

19. Atiya Khanum Irfan Ali Khan, Biostatistics for Pharmacy, 2nd Edition, 2007, UkaazPublications, Hyderabad.
20. C. George Thomas. Research Methodology and Scientific Writing First edition, 2016, AneBooks Pvt. Ltd.; New Delhi.
21. C. R Kothari. Research Methodology: Methods and Techniques. New Age International

(P)Ltd, Publishers. New Delhi.
22. Mahajan, B.K. Methods in Biostatistics for Medical Students and Research workers, 7thEdition 2008 Jaypee Brothers.
23. Putul Mahanta , Medical Writing: A Guide for Medicos, Educators and Researchers JaypeeBrothers Medical Publishers; First edition (2018).
24. Ranjan Das, Biomedical Research Methodology: Including Biostatistical Applications. 1stEdn. Jaypee Brothers.
25. Ranjit Kumar, Research Methodology: A Step-by-Step Guide for Beginners, 3rd Edition 2011,Sage Publications India Pvt. Ltd., New Delhi.
26. Sharma Suresh. Research Methodology and Biostatistics- A Comprehensive Guide for HealthCare Professionals. 1st Edn. Elsevier India.
27. Sunder Rao. P.S.S and Richard. J. An introduction to Biostatistics: A manual for students inhealth sciences. Prentice-Hall of India Pvt. Ltd Publishers.

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Q P CODE REG NO

MODEL QUESTION PAPER
M.PHARM PHARMACEUTICAL REGULATORY AFFAIRS
FIRST SEMESTER M. PHARM DEGREE EXAMINATIONS

PAPER - I – GOOD REGULATORY PRACTICES (MRA 101T)

Answer all questions

Time: 3 hours Maximum Marks: 75

Essays (3x10=30)

1. Write in detail about USGMP with reference to part210 and part 211.
2. Write in detail about USFDA GLP regulations
3. Write in detail about the principles and requirements of GALP

SHORT NOTES (9X5=45)

4. Write briefly about WHO cGMP guidelines
5. Write briefly about concept of ISO
6. Write a note on software evaluation checklist
7. Write a note on stability testing principles
8. Describe the goals of laboratory quality audit
9. Write briefly about cleaning validation
10. Write a note on validation master plan
11. Write briefly about training documentation of GALP
12. Write a note on total quality management

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MODEL QUESTION PAPER
M.PHARM PHARMACEUTICAL REGULATORY AFFAIRS
FIRST SEMESTER M. PHARM DEGREE EXAMINATIONS

PAPER - II – DOCUMENTATION AND REGULATORY WRITING (MRA 102T)

Answer all questions

Time: 3 hours Maximum Marks: 75

Essays (3x10=30)

1. What is product development report (PDR) Discuss the significance of PDR
2. Define CTD and eCTD. Describe the modules of ICH -CTD format with granularity
3. Discuss the Root cause analysis of deviation. Describe the corrective and preventive action.

SHORT NOTES **(9×5=45)**

4. Describe about Batch Manufacturing record and its calculations
5. What is Drug Master file (DMF) Discuss the types of DMFs
6. Outline the contents and organization of dossiers
7. Differentiate Internal, External, second party and external third-party audits.
8. Describe the quality systems requirements of national good distribution practices
9. Discuss the post approval changes (SUPAC) process for an approved drug product
10. Describe the process of post approval labelling changes
11. Discuss the electronic submission process and validating the submission
12. Discuss the Non eCTD electronic submission (NeeS) format and its difference with CTD.

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MODEL QUESTION PAPER
M.PHARM PHARMACEUTICAL REGULATORY AFFAIRS
FIRST SEMESTER M. PHARM DEGREE EXAMINATIONS

PAPER – III CLINICAL RESEARCH REGULATIONS (MRA 103T)

Answer all questions

Time: 3 hours Maximum Marks: 75

Essays (3x10=30)

1. Explain the responsibilities of sponsors, CRO and investigator in ethical conduct of clinical research
2. Enumerate the application procedure for approval of NDA 505 (b) (1).
3. Explain the principles of ICMR Ethical Guidelines for biomedical research

SHORT NOTES (9×5=45)

4. Write a note on Phase 0 studies
5. Define and explain ethical principles of informed consent process
6. Write a note on role of placebo in clinical trials
7. Explain the clinical trial protocol
8. Write a note on ANDA and its approval procedure
9. Explain regulatory requirements of BA/BE studies
10. Discuss on EU directives 2001
11. Enumerate the Indian GCP guidelines
12. Write a note on 21 CFR part 312 (IND application)

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MODEL QUESTION PAPER

M.PHARM PHARMACEUTICAL REGULATORY AFFAIRS

FIRST SEMESTER M. PHARM DEGREE EXAMINATIONS

PAPER – IV - REGULATIONS AND LEGISLATIONS FOR DRUGS &COSMETICS, MEDICAL DEVICES, BIOLOGICALS &HERBALS, AND FOOD &NUTRACEUTICALS IN INDIA AND INTELLECTUAL PROPERTY RIGHTS (MRA 104T)

Answer all questions

Time: 3 hours Maximum Marks: 75

Essays (3x10=30)

1. Describe in detail about WHO patent IPR and its types
2. Discuss Indian pharmacopoeial standards BIS and ISO in detail
3. Ethical guidelines for human participants ICMR -DBT

SHORT NOTES (9×5=45)

4. Guidelines for stem cell research
5. Write about the parts of patent
6. DPCO and NPPA
7. CDSCO responsibilities
8. Guidelines for preclinical studies
9. Regulatory requirements for bioequivalence study
10. Guidelines for stem cell research
11. ICH stability requirements
12. BCS classification of drugs

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MODEL QUESTION PAPER
M.PHARM REGULATORY AFFAIRS
SECOND SEMESTER M. PHARM DEGREE EXAMINATIONS

PAPER - I – REGULATORY ASPECTS OF DRUGS & COSMETICS (MRA 201T)

Answer all questions

Time: 3 hours Maximum Marks: 75

Essays (3x10=30)

1. Discuss in detail the organization and structure of EMA. Also discuss one marketing authorization procedure in EU.
2. Give regulatory requirements for Investigational New Drug (IND) submission, Format & content of IND,content of Investigation Brochure.
3. What are the Legislation and Regulations for manufacture and sale of cosmetics in ASEAN and CIS?

Short notes (9x5=45)

4. What are the regulatory considerations for manufacturing in Japan?
5. Write the full form of the following: a. CFR b. FFDCA DMF c. CIS d. ANDA e. ASEAN
6. What is Drug Master Files (DMF)? Discuss different types of DMFs.
7. Explain the regulatory consideration for packaging and labelling of pharmaceutical in EU.
8. Explain the Pharmaceuticals and Medical Devices Agency (PMDA) and discuss its functions.
9. Write a note on WHO in relation to registration.
10. Explain the relation of Hatch Waxman act with respect to 30 month stay.
11. Discuss the regulation approval process for NDA.
12. Write a role of FDA in various countries in the new drug development.

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MODEL QUESTION PAPER
M.PHARM REGULATORY AFFAIRS
SECOND SEMESTER M. PHARM DEGREE EXAMINATIONS

PAPER – II – REGULATORY ASPECTS OF HERBALS AND BIOLOGICALS (MRA 202T)

Answer all questions

Time: 3 hours Maximum Marks: 75

Essays (3x10=30)

1. What are the various requirements and procedures for registering and marketing vaccines in India?
2. Compare the pre-clinical and clinical development considerations for biologicals in USA and European Union.
3. Write in the detail about various data requirements for Pre-clinical and clinical studies in India.

Short notes (9x5=45)

4. Write not on Pharmacovigilance.
5. Labelling and packaging requirements for Blood products for European market
6. Process and requirements for BLA
7. Discuss about format and contents of an IND application.
8. Describe about regulations for quality and safety of herbal products in India.
9. Discuss about laws and regulations on biologics and biosimilars.
10. Write not on Plasma master file.
11. Discuss about stability, safety guidelines in European Union.
12. Describe about GMP requirements for equipment, container and closures.

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MODEL QUESTION PAPER
M.PHARM REGULATORY AFFAIRS
SECOND SEMESTER M. PHARM DEGREE EXAMINATIONS

PAPER – III – REGULATORY ASPECTS OF MEDICAL DEVICES (MRA 203T)

Answer all questions

Time: 3 hours Maximum Marks: 75

Essays (3x10=30)

1. Explain in detail the validation and verification of Medical devices.
2. Explain the Quality system requirements (21 CFR Part 820) and labeling requirements (21 CFR Part 801) ofmedical devices in US.
3. Discuss the major highlights for the devices and *in vitro* diagnostics as per European Union?

Short notes (9X5=45)

4. Discuss IVD's.
5. Write note on Summary Technical Documents.
6. What is the clinical evaluation and investigation procedure of medical devices in China?
7. What are post marketing surveillance of medical devices?
8. What are the necessary requirements for Premarket Notification 510K Submission for Medical Device?
9. Pre-marketed approval as per US FDA.
10. Give risk-based classification and essential principles of medical devices with examples.
11. Explain the regulatory registration procedure of IVDs in Japan.
12. Explain the adverse event reporting of medical devices.

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MODEL QUESTION PAPER
M.PHARM REGULATORY AFFAIRS
SECOND SEMESTER M. PHARM DEGREE EXAMINATIONS

PAPER – IV – REGULATORY ASPECTS OF FOOD & NEUTRACEUTICALS (MRA 204T)

Answer all questions

Time: 3 hours Maximum Marks: 75

Essays (3x10=30)

1. Discuss the regulations for import of nutraceuticals according to FSSAI.
2. Explain regulatory requirements and its approval procedure for Nutraceuticals, Cosmetics and Biologics in India.
3. What are dietary supplements and medical foods? Giving examples critically explain their role in human body.

Short notes (9X5=45)

4. Mention the critical considerations about good manufacturing practices for nutraceuticals
5. Write the functions of Food Safety and Standards Authority of India (FSSAI).
6. Comment on the chemicals other than vitamins and minerals whose addition to food is prohibited according toEFSA.
7. Discuss the US FDA dietary supplement health and education act.
8. What are dietary fibres? Explain their importance as functional foods.
9. What are medical foods, functional foods and nutraceuticals? Giving examples explain their role in healthcare.
10. Summarize the prohibition orders served under FSSAI Act.
11. Labelling requirements for dietary supplements in USA.
12. Write a note on the RDA for calcium and iron in US.