DEPARTMENT OF PHARMACEUTICAL SCIENCES
GURUGRAM UNIVERSITY, GURUGRAM
(A State Govt. University Established Under Haryana Act 17 Of 2017)

Date: 25-10-2023

POST GRADUATE BOARD OF STUDIES Meeting Agenda

Date: 26th October 2023

Time: 11:00 AM

Location: Office of Chairperson, Department of Pharmaceutical Sciences

Meeting Attendees:

Prof. Abhay Singh Yadav | Prof. Dhirender Kaushik | Prof. Karan Vashisth (Attended Virtually)

Dr. Harlokesh Yadav | Dr. Parijat Pandey

Agenda:

1. Syllabus Approval: M. Pharmacy Pharmaceutics Program (Annexure A)
2. Syllabus Approval: Ph.D. Program (Annexure B)
3. Examiner Panel Appointment for M. Pharmacy (Pharmacology, Pharmaceutical Chemistry and Pharmaceutics) 1st and 2nd Semester (Sent to examination branch)
4. Starting of Pharm. D. Course
5. Constitution of Complaint Committee regarding Examination (Sent to examination branch)
6. Tentative schedule of next PGBOS Meeting

26/10/2023 | 26/10/2023 | Parijat 26/10/23

26.10.2023

Gurugram University, Gurugram

(Established by the State Legislature Act 17/2017)

Sector 51, Gurugram -122003 (HARYANA)

Minutes of the Meeting of the PG Board of Studies in the Department of Pharmaceutical Sciences of Gurugram University, Gurugram held on 26th October 2023 at 11:00 AM in the office of Chairperson, Department of Pharmaceutical Sciences of the University.

Minutes of the meeting of PG Board of Studies held on 26th October 2023 at 11:00 AM in the office of Chairperson, Department of Pharmaceutical Sciences of the University

Members Present:

1.	Prof. Abhay Singh Yadav	Convener
2.	Prof. Karan Vashisht	Outside Expert
3.	Prof. Harlokesh Narayan Yadav	Outside Expert
4.	Prof. Dhirender Kaushik	Member
5.	Dr. Parijat Pandey	Member

At the outset the Convener of PG BOS extended a hearty welcome to all the members for attending the meeting of the Board of Studies. Thereafter, the agenda items were taken up and after detailed deliberations, the following decisions were taken:

Item No. PG BOS/01*/01:**

Agenda: 1. Syllabus Approval: M. Pharmacy Pharmaceutics Program

Resolution/Decision: The syllabus of M. Pharmacy Pharmaceutics Program as per PCI has been approved (Annexure A)

Item No. PG BOS/01/02:

Agenda: 2. Syllabus Approval: Ph.D. Program

Resolution/Decision: The syllabus approval of Ph.D. Program has been approved (Annexure B)

Item No. PG BOS/01/03:

Agenda: 3. Examiner Panel Appointment for M. Pharmacy (Pharmacology, Pharmaceutical Chemistry) 1st to 4th Semester and M. Pharmacy (Pharmaceutics) 1st and 2nd Semester

Resolution/Decision: The Examiner Panel Appointment for M. Pharmacy (Pharmacology, Pharmaceutical Chemistry) 1st to 4th Semester and M. Pharmacy (Pharmaceutics) 1st and 2nd Semester has been finalized (Annexure C)

Item No. PG BOS/01/04:

Agenda: 4. Starting of Pharm. D. Course

Resolution/Decision: As recommended by the Committee, the starting of Pharm. D. Course has been postponed till next session

Item No. PG BOS/01/05:

Agenda: 5. Constitution of Complaint Committee regarding Examination

Resolution/Decision: Constitution of Complaint Committee regarding Examination has been finalized (Annexure D)

Item No. Table Agenda:

Table Agenda: Regarding recruitment of regular faculty

Resolution/Decision: The committee recommended that 17 regular faculties (Assistant professor) should be appointed to carry out the work more effectively in the department.

Item No. PG BOS/01/06:

Agenda: 6. Tentative schedule of next PGBOS Meeting

Resolution/Decision: The next PGBOS meeting has been schedule on 1st week of March 2024.

Meeting ended with the vote of thanks to the Chair.

26.10.2023	26/X/2023	Attended Virtually
Prof. Abhay Singh Yadav	**Prof. Dhirender Kaushik**	**Prof. Karan Vashisth**
26/10/23	Parijat 26/X/23	
Dr. Harlokesh Yadav	**Dr. Parijat Pandey**	

Table - 2: Course of study for M. Pharm. (Pharmaceutics)

Course Code	Course	Credit Hours	Credit Points	Hrs./wk	Marks
Semester I					
MPH101T	Modern Pharmaceutical Analytical Techniques	4	4	4	100
MPH102T	Drug Delivery System	4	4	4	100
MPH103T	Modern Pharmaceutics	4	4	4	100
MPH104T	Regulatory Affair	4	4	4	100
MPH105P	Pharmaceutics Practical I	12	6	12	150
-	Seminar/Assignment	7	4	7	100
Total		35	26	35	650
Semester II					
MPH201T	Molecular Pharmaceutics (Nano Tech and Targeted DDS)	4	4	4	100
MPH202T	Advanced Biopharmaceutics & Pharmacokinetics	4	4	4	100
MPH203T	Computer Aided Drug Delivery System	4	4	4	100
MPH204T	Cosmetic and Cosmeceuticals	4	4	4	100
MPH205P	Pharmaceutics Practical II	12	6	12	150
-	Seminar/Assignment	7	4	7	100
	Total	35	26	35	650

Table - 12: Course of study for M. Pharm. III Semester
(Common for All Specializations)

Course Code	Course	Credit Hours	Credit Points
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

* Non University Exam

Table - 13: Course of study for M. Pharm. IV Semester
(Common for All Specializations)

Course Code	Course	Credit Hours	Credit Points
-	Journal Club	1	1
-	Research Work	31	16
-	Discussion/Final Presentation	3	3
Total		35	20

Table - 14: 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

Tables - 1616 : Schemes for internal assessments and end semester (Pharmaceutics- MPH)

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 Pharmaceutics	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								650
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	Cosmetic	10	15	1 Hr	25	75	3 Hrs	100

204T	and Cosmeceuticals							
MPH 205P	Pharmaceutics Practical I	20	30	6 Hrs	50	100	6 Hrs	150
-	Seminar /Assignment	-	-	-	-	-	-	100
Total								650

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: 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	11 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 diffraction methods, Bragg's law, Rotating crystal technique, X ray powder technique, Types of crystals and applications of X-ray diffraction.	11 Hrs
6	Immunological assays : RIA (Radio immuno assay), ELISA, Bioluminescence assays.	5 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. 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 enhancers, Transdermal Drug Delivery Systems, Formulation and evaluation.	10 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, production and planning control, Sales forecasting, budget and cost control, industrial and personal relationship. Concept of Total Quality Management. — 10 Hrs

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

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: 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. — 12 Hrs

2	Biopharmaceutic considerations in drug product design and In Vitro Drug Product Performance: Introduction, biopharmaceutic factors affecting drug 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.	12 Hrs
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 k_{max} and v_{max}. 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
   b. Quality-by-Design In Pharmaceutical Development: Introduction, ICH Q8 guideline, Regulatory and industry views on QbD, Scientifically based QbD - examples of application. — 12 Hrs
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, ASBT, OCT, OATP, BBB-Choline Transporter. — 12 Hrs

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 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	12 Hrs
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.
Perfumes; Classification of perfumes. Perfume ingredients listed as allergens in EU regulation. — 12 Hrs

	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.

Department of Pharmaceutical Sciences

Scheme of Examination

For

Ph.D. Course Work

From The Academic Session 2023-24

Scheme of Examination

Ph.D. Course work (Pharmaceutical Sciences)

Course Code	Title of the course	Theory marks	Internal marks	Practical marks	External marks	Total marks	Credits L+T+P	Time
Ph.D. Pharm. 101	Research Methodology	70	30			100	3+0+1	3 hrs theory +2 hrs Lab
Ph.D. Pharm. 102	Review of Literature		50		50	100	3+1+0	4 hrs
Ph.D. Pharm. 103	Advances in Pharmaceutical Sciences	70	30			100	3+1+0	4 hrs
Ph.D. Pharm. 104	Research and Publication	35	15			50	2+0+0	2 hrs
							14	

Research Methodology
Ph.D. Pharm. 101

Maximum marks: 100
Internal marks: 30
External marks: 70
Time: 3 Hrs (Theory)

Course Objective:

1. To acquaint the knowledge of research or step by step process of research: identification of research problem, understanding research designs. data collection, data analysis and interpretation. preparation and presentation of report.
2. To equip the students with a basic understanding of research methodology and to provide an insight into the application of analytical tools and techniques with the help of SPSS and other analytical software.

Course Outcome: The scholar will have a better understanding of research that will guide the researcher at every step of his/her research journey.

Unit I

Nature of and scope Research Methodology: Detining Research, Scientific Research, Types of Research, Theory Generation; Research Process, Problem Formulation and Statement of Research Objectives.

Unit II

Research Design: Meaning, Types of Research Design; Methods of Data Collection: Observation and Survey Methods, Primary Data, Secondary Data; Attitude Measurement Techniques: Measurement and Scaling; Questionnaire Design: Validity and Reliability; Sample Design: Sampling Methods.

Unit III

Statistical Analysis: Basic Concepts of Statistical Analysis; Introduction to Probability and Probability Distributions; Sampling Distribution. Statistical Tests: Hypothesis Formulation and Testing; Parametric and Non-parametric tests; Model Building: Simple and Multiple Regression; Introduction to Multivariate Data Analysis Techniques.

Unit IV

Data Analysis in SPSS: Reliability test, One Sample t-test, t-test with more than one sample repeated measures t-test and independent sample t-test; One-way and Two-way between groups ANOVA with post-hoc comparisons; One-way analysis of Covariance (ANCOVA); Chi-square tests. Correlation, Regression-linear, Polynomial, Binary regression, Regression with Dummy Variables, Logistic
Regression; OLS regression and its assumption, Factor analysis- Exploratory Factor analysis and Confirmatory Factor Analysis, SEM Measurement model.

Lab work (2 hours a week):

Introduction to SPSS; SPSS Environment - Data Editor, Viewer and Draft Viewer, Chart Editor, Text Output Editor, Toolbar, Menus, Dialogue Boxes, Opening and Saving Files. Preparation of Data Files: Defining Variables — Variables Labels, Value Labels, Missing Values, Variable Types, Column Format, Measurement Level; Data Entry. Inserting and Deleting Cases and Variables, Moving Variables.

Data Screening and Transformation: Errors in data entry; Accessing Normality — Histograms. stem and leaf plots and box plots, Kolmogorov — Smirnov and Shapiro Wilk Statistics, Skewness and Kurtosis: Assessing normality by group. Variable Transformation; Data Transformation — Recode, Compute, Data Selection. Descriptive Statistics

Suggested Readings:

1. Aczel & Sounderpandian. Complete Business Statistics, McGraw-Hill.
2. Anderson, sweeney & Williams, Statistics for Business and Economics. Cengage Learning.
3. Bajpai naval, Business Research Methods, Pearson.
4. Beri, G.C., Marketing Research, Tata McGraw Hill Education, NewDelhi.
5. Carver & Nash. Doing Data Analysis with SPSS, Cengage Learning.
6. Chauhan Ajay,Researeli Analytics: A Practical Approach to Data Analysis
7. Chawla. D., Sondhi, N Research Methodology: Concept and cases. Vikas Publishing House. New Delhi
8. Cooper Donald R. & Schindler Pamela S., Business Research Methods. McGraw-I lilt.
9. Dooley. D., Social Research Methods. Prentice Hall, NewJerscy.
10. field, Andy. Discovering Statistics Using IBM SPSS Statistics, SAGE Publications, New Dellii.1
11. Julie Pallant. SPSS survival manual, tata McGraw Hill
12. KiranPandya, SmrutiBulsari, Sanjay Sinha. SPSS in Simple Steps. Wiley India.
13. Krishnaswamy, K. N.. Sivakumar, A. I. and Kathirajan, M., Management Research Methodology: Integration of Principles. Mcthods and Techniques Pearson, NewDelhi.
14. Kumar. R. Research Methodology: A step-by step guide for beginners. SAGE, NewDelhi.
15. Levin. R.. Rubin, D.S., Rastogi, S., Siddiqui, M.H.. Statistics for Management. Pearson Education NewDelhi.
16. Malhotra, N. Dash, S. Marketing Research: An Applied Orientation. Pearson, NewDelhi.
17. Nargundkar, R., Marketing Research: Text and Cases. rata McGraw Hill Education, New Delhi.
18. Sheridan .1 Coakes. l.yndall Steed and PetaDzidie. SPSS for Windows Analysis without Anguish. Wiles India.
19. Zikmund William G., Business Research Methods. ('engage Learning.
20. Kothari, C.R. Research Methodology: Methods and 'techniques. New Age International Publishers, New Delhi.

Instructions for External Examiner: The question paper shall be divided in two sections. Section 'A' shall comprise of Seven short answer type questions from whole of the syllabus carrying two marks each, which shall be compulsory. Answer to each question should not exceed 100 words normally. Section

'B' shall comprise S questions (2 questions from each unit). The Scholars will be required to attempt four questions selecting one question of 14 marks from each unit All questions will carry equal marks.

Instructions for internal examiner: The internal assessment should be spread evenly throughout the course work. Below are the suggestive components for 30 marks. A teacher has a choice to change these components as per the need.

S.No	Course Assessment Components	Marks\ weightage (%)
1.	Assessment 1: Assignment 1\quiz\ Case analysis (A)	10
2.	Assessment 2: Assignment 1\quiz\ Case analysis (A)	10
3.	Assessment 3: presentations (P)	10
	Internal assessment (IA) (1+2+3)	30 (30 %)
	End Term examination (EE)	70 (70%)
	Total Marks (IA+EE)	**100**

Review of Literature
Ph.D. Pharm. 102

Maximum Marks: 100
Internal Marks: 50
External Marks: 50
Time: 4 Hrs.

Course Objective:

1. To acquaint the knowledge of Review of Literature and different types of review
2. To equip the students with a basic understanding of research proposal and report writing.

Course Outcome: After completion of the session, you will be able to understand the basics of literature review, differentiate between Traditional vs. systematic review, how to search and select literature, and the use of digital methods for exploring and mapping the literature, Different reading strategies. The scholar will have a better understanding of starting of research that will guide the researcher at every step of report writing.

Unit I

Review of Literature; Meaning. Purpose of the review, Identification of the literature, organizing the literature. Different reading strategies. Monitoring your progress through the literature matrix

Unit II

Literature Review; Types of Literature Reviews; Narrative or Traditional Literature Reviews, Critically Appraised Topic (CAT), Scoping reviews, Systematic Literature Reviews. Annotated Bibliographies, Sources of Literature- Web of science, Scopus. MDPI, Wiley, Sage Journals, Taylor and Francis.

Unit III

Identification of Research Gaps, Research Questions Framing, Objective Framing through Reviews, Identification of Scale and Extraction of Variable of research from Review of Literature. Methodological Decision. Future Research and Scope. Research Proposal and Contents of Research Proposal.). Model & Concept Development **through** Review of Literature.

Unit IV

Report Writing; Structure and Components (Format) of Research Report, Types of Report, Principles of report writing & Characteristics of Good Research Report. Bibliography and Reference Writing; Harvard and MLA, APA Style of Reference Writing and Other Reference Styles. Annexurc used in Reports. Software used in Review of Literature (WOS. Mcndcicy).

Suggested Readings:

1. Adler. Stier and Clark. How it's done: An Invitation to Social Research
2. Becker, Writing for Social Sciences: How to start and finish your thesis, book, or article
3. Cooper, Schindler, Social Sciences Research Methods: Salkind, Exploring research.
4. Booth, A., Papaioannou, D., & Sutton, A. (2012). Systematic approaches to a successful literature review
5. Fink, A. (2010). Conducting research literature reviews: from the Internet to paper
6. Galvin, J. (2006). Writing literature reviews: A guide for students of the social and behavioral sciences
7. Machi, L. A., & McEvoy, B. T. (2012). The literature review: Six steps to NUCCOS

S.No	Course Assessment components	Marks
1.	Concept paper\working paper\review paper submissioin	50 (50%)
2.	Presentation and viva voce (End term)	50 (50%)
	Total marks	**100**

Instruction for viva voce-

Viva voice of 50 marks must be conducted by inviting an external examiner.

Advances in Pharmaceutical Sciences
Ph.D. Pharm. 103

Theory : (4 hrs/wk)
Internal marks = 30
External marks = 70
Duration of examination = 03 hours

1. **Central Drug Standard Control Organisation (CDSCO)**: Functions and responsibilities Investigational New Drug: Need of an IND, Content and Format of an IND application, Submission of an IND, FDA review of IND. **The New Drug Application:** Overview, Law regulations and Guidance, new drug development and approval, NDA development preclinical investigation, new drug application (phase I, phase II, phase IV and post marketing surveillance),contents of the NDA (chemistry, manufacturing, testing, packaging, labelling, controls, preclinical, clinical data), Human Pharmaco-kinetic and bioavailability testing requirements, Common technical document (CTD) for NDA, Submission, review and maintenance of NDA.
2. **Drug Design:** Approaches to drug design, method of variation, biochemical and physiological approaches. Lead compound - Search & Optimization: Search of lead compound from natural products and other sources, selection of test compounds. Methods of lead optimization – synthesis of analogs, variation of substituents, extension of structure, ring versus chain structures, bioisosterism, ring contraction and expansion. Hansch analysis, Free-Wilson analysis, Craig plot, Topliss scheme, CoMFA analysis.
3. **Extraction:** Different techniques adopted for the extraction of phytoconstituents like Maceration, percolation, sonication, soxhlet assisted extraction, ultrasound assisted extraction, super critical carbon dioxide extraction and Microwave assisted extraction. In-vivo and in-vitro in-situ studies.
4. **Common animal models for selected categories of drugs**: anti-hypertensive, anti- inflammatory, anti-diabetic, anti-ulcer, anti-oxidants, anti-depressant, anti-convulsant, analgesics, local anaesthetics, anti-malarial, anti-microbial, antibacterial antifungal and anti-cancer.

Instructions For External Examiner: The question paper shall be divided in 2 sections. Section A shall comprise of seven short type questions from whole of the syllabus carrying two marks each, which shall be compulsory. Answer to each question should not exceed 100 words normally. Section B shall comprise 8 questions(2 questions from each unit) The scholars will be required

to attempt four questions selecting one question of 14 marks from each unit. A ll questions will carry equal marks.

Instructions For Internal Examiner: The internal assessment should be spread evenly throughout the course work. Below are the suggestive components for 30 marks. A teacher has a choice to change these components as per the need.

S.No	Course Assessment Components	Marks\weightage(%)
1.	Assessment 1: Assignment 1\quiz\ Case analysis (A)	10
2.	Assessment 2: Assignment 1\quiz\ Case analysis (A)	10
3.	Assessment 3: presentations (P)	10
	Internal assessment (IA) (1+2+3)	30 (30 %)
	End Term examination (EE)	70 (70%)
	Total Marks (IA+EE)	**100**

Suggested Readings:

1. Drug discovery and evaluation by Vogel H.G.
2. Methods in Pharmacology by Arnold Schwartz.
3. Screening Methods In Pharmacology, Robert A. Turner.
4. Fundamentals of Experimental Pharmacology by M.N. Ghosh.
5. Innovative Approaches In Drug Discovery Book 2017
6. Drug Absorption Studies: In Situ, In Vitro, and In Silico Models : VII (Biotechnology: Pharmaceutical Aspects)
7. Clinical Trials and Human Research: A Practical Guide to Regulatory Compliance By Fay A.Rozovsky and Rodney K. Adams.
8. Handbook of Experimental Pharmacology, SK. Kulkarni.
9. Biopharmaceutics and Clinical Pharmacokinetics, An Introduction, 4th edition,revised and expanded by Robert. E. Notari, Marcel Dekker Inc, New York and Basel,1987.

Research and Publication Ethics

Ph.D. Pharm 104

Maximum Marks: 50
External Marks: 35
Internal Marks: 15
Time: 2 Hrs.

Course Objectives:

- To compare the Scholars about basics of philosophy of science and ethics
- To educate the Scholars about research integrity and publication ethics.
- To vigilant the Scholars about research misconduct and predatory publications.
- To inform the Scholars about indexing and citation databases, open-access publications
- To inform the Scholars about research metrics (citations, h-index, Impact Factor. etc.) and plagiarism tools.

Course Outcomes: Scholars should be able to -

- Understand about the publication ethics and publication misconduct
- Aware about falsification, fabrication, and plagiarism
- Use Citation databases and understand about impact factor of journal
- Use plagiarism software like Turnitin, URKUND
- Identify Predatory publishers and journals

Unit - I

Introduction to philosophy: definition, nature and scope, concept, Branches; Ethics: definition, moral philosoplids. nature of moral judgments and reactions; Ethics with respect to science and research.

Unit-II

Intellectual honesty and research integrity: Scientific misconducts: Falsification. Fabrication, and Plagiarism (FFP): Redundant publications: duplicate and overlapping publications, Salami Slicing: Selective reporting and misrepresentation of data.

Unit - III

Citation databases: Web of Science, Scopus; Open access publications and initiatives; Publication ethics: definition, introduction and importance; Best practices / standards setting initiatives and guidelines: COPE, WAME, etc.

Unit - IV

Conflicts of interest; Publication misconduct: definition, concept, problems that lead to unethical behavior and vice versa; Violation of publication ethics, authorship and contributor ship; Identification of publication misconduct, complaints and appeals: Predatory publishers and journals.

References:

1) Bird, A. (2006). Philosophy of Science, Routledge
2) Mac 1ntyre & Alasdair (1967). A Short History of Rthics. London.
3) Chaddah, P. (2108). Ethics in Competitive Research: Do not Get Scoped; Do not get Plagiarized.
4) National Academy of Sciences, National Academy of Engineering and Institute of Medicine. (2009). On Being a Scientist: A Guide to Responsible Conduct in Research: Third Edition. National Academies Press.
5) Resnik, D. B. (2011). What is Ethics in Research & Why is it Important. National Institute of Environmental Health Sciences, 1-10, Retrieved from https://www.nichsmagov/researchiresourcesibioethics/whatisiindex.cfin
6) Beall, J. (2012), Predatory Publishers are Corrupting Open Access. Nature, 489(7415). 179 Imps://doi.org/10.1038/489179a
7) Indian National Science Academy ([NSA), Ethics in Science Education, Research and Governance (2019). http://www. Insaindia.res.in/pdf/Ethics_Book.pdf

Instructions for External Examiner: The question paper shall be divided in two sections. **Section 'A'** shall comprise of short answer type questions from whole of the syllabus carrying one/two marks each for a total of 7 marks, which shall be compulsory. Answer to each question should not exceed 50 words normally. **Section `B'** shall comprise 8 questions (2 questions from each unit). The Scholars will be required to attempt four questions selecting one question from each unit. All questions will carry 7 marks. All questions will carry equal marks.

Instructions for internal Examiner: The internal assessment will be based on the discussion presentation class participation! quizzes/assignments from the topics: Open Access Publishing, SHERPA/RoME0 online resource to check publisher copyright; self-archiving policies, Journal finder (like JANE, Elsevier Journal Finder), Publication Misconduct, Databases (Web of Science, Scopus etc.), Impact Factor of journal as per Journal Citation Report, SNIP, SIR,IPP, Cite Score , Metrics: h-index, g index, it() index, altmetrics, Use of plagiarism software like Turnitin. PDS Ouriginal (Urkund), Predatory Journal Identification, clone Journal Identification and other open source software tools etc.

The internal assessment should be spread evenly throughout the course work. Below are the suggestive components for 15 marks. A teacher has a choice to change these components as per the need.

S. No.	Course Assessment Components	Marks/Weightage (%)
1.	Assessment 1 : Class Participation (CP)	10(20%)
2	Assessment 2 : Case Analysis & Presentation	5 (10%)
3	End-Term Examination (EE)	35(70%)
	Total (CP + CAP + EE)	**50(100%)**