गुरू घासीदास विश्वविद्यालय (केन्रीय विश्वविद्यालय अधिन्यम 2009 क्र. 25 के अंतर्गत स्थापित केन्नीय क्षिववेद्यालय) कोनी, बिलासपुर - 495009 (छ.ग.)



Guru Ghasidas Vishwavidyalaya (A Central University Established by the Central Universities Act 2009 No. 25 of 2009) Koni, Bilaspur – 495009 (C.G.)

Dated: 24.07.2020

MINUTES OF THE MEETING OF BOARD OF STUDIES

The meeting of the Board of Studies in Pharmaceutical Sciences, was scheduled on 24.07.2020 at 11:30 AM by online Google meet at Institute of Pharmaceutical Sciences, Guru Ghasidas Vishwavidyalaya, Bilaspur. The following members were present for the online Google meet.

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- 1. Prof. Vinod D. Rangari
- 2. Prof. Moorthy N.S.H.N.
- 3. Dr. K.P. Namdev
- 4. Dr. K.P. Meena

- Chair Person External Expert Member
- Member
- Member
- Agenda: Approval for the adoption of the New PCI syllabus for M. Pharm. Courses: -(1) Pharmaceutics (2) Pharmaceutical Chemistry (3) Pharmacology and
 - (4) Pharmacognosy from Academic Session 2020-21.

Recommendation:

Pharmacy Council of India, New Delhi has made it mandatory to adopt the New M. Pharm. Syllabus for the courses run by all the University Departments, Government & Private Institutions. The committee discussed the issue in details.

The committee recommended the adoption of the New M. Pharm. Syllabus for all the M. Pharm. Courses run by the Pharmacy Department, namely (1) Pharmaceutics (2) Pharmaceutical Chemistry (3) Pharmacology and (4) Pharmacognosy, from the academic session 2020-21 and onward.

The committee further recommended to adopt the changes if any, made in the syllabus of all the above M. Pharm. Courses by Pharmacy Council of India in future and so communicated for their adoption from time to time.

List of New courses introduced for M. Pharm. from the academic year 2020-2021 shall be as follows.

The

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Guru Ghasidas Vishwavidyalaya (A Central University Established by the Central Universities Act 2009 No. 25 of 2009) Koni, Bilaspur – 495009 (C.G.)

Programme Name : *M. Pharm. (Pharmaceutics)*

Academic Year : 2020-21

List of New Courses Introduced

Sr. No.	Course Code	Name of the Course
01.	MPH101T	Modern Pharmaceutical Analytical Techniques
02.	MPH102T	Drug Delivery System
03.	MPH103T	Modern Pharmaceutics
04.	MPH104T	Regulatory Affair
05.	MPH105P	Pharmaceutics Practical I
06.	MPH106P	Seminar/Assignment
07.	MPH201T	Molecular Pharmaceutics (Nano Tech and Targeted DDS)
08.	MPH202T	Advanced Biopharmaceutics & Pharmacokinetics
09.	MPH203T	Computer Aided Drug Delivery System
10.	MPH204T	Cosmetic and Cosmeceuticals
11.	MPH205P	Pharmaceutics Practical II
12.	MPH206P	Seminar/Assignment

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Guru Ghasidas Vishwavidyalaya (A Central University Established by the Central Universities Act 2009 No. 25 of 2009) Koni, Bilaspur – 495009 (C.G.)

Programme Name : *M. Pharm. (Pharmaceutical Chemistry)*

Academic Year : 2020-21

List of New Courses Introduced

Sr. No.	Course Code	Name of the Course
01.	MPC101T	Modern Pharmaceutical Analytical Techniques
02.	MPC1012T	Advanced Organic Chemistry -I
03.	MPC103T	Advanced Medicinal chemistry
04.	MPC104T	Chemistry of Natural Products
05.	MPC105P	Pharmaceutical Chemistry Practical I
06.	MPC106P	Seminar/Assignment
07.	MPC201T	Advanced Spectral Analysis
08.	MPC202T	Advanced Organic Chemistry -II
09.	MPC203T	Computer Aided Drug Design
10.	MPC204T	Pharmaceutical Process Chemistry
11.	MPC205P	Pharmaceutical Chemistry Practical II
12.	MPC206P	Seminar/Assignment

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Guru Ghasidas Vishwavidyalaya (A Central University Established by the Central Universities Act 2009 No. 25 of 2009) Koni, Bilaspur – 495009 (C.G.)

Programme Name : *M. Pharm. (Pharmacology)*

Academic Year : 2020-21

List of New Courses Introduced

Sr. No.	Course Code	Name of the Course
01.	MPL 101T	Modern Pharmaceutical Analytical Techniques
02.	MPL 102T	Advanced Pharmacology-I
03.	MPL 103T	Pharmacological and Toxicological Screening Methods-I
04.	MPL 104T	Cellular and Molecular Pharmacology
05.	MPL 105P	Pharmacology Practical I
06.	MPL 106P	Seminar/Assignment
07.	MPL 201T	Advanced Pharmacology II
08.	MPL 202T	Pharmacological and Toxicological Screening Methods-II
09.	MPL 203T	Principles of Drug Discovery
10.	MPL 204T	Clinical Research and Pharmacovigilance
11.	MPL 205P	Pharmacology Practical II
12.	MPL 206P	Seminar/Assignment

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Guru Ghasidas Vishwavidyalaya (A Central University Established by the Central Universities Act 2009 No. 25 of 2009) Koni, Bilaspur – 495009 (C.G.)

Programme Name : <i>M. Pharm. (Pharmacognosy)</i>						
	Academic Year : <mark>2020-21</mark>					
List of	List of New Courses Introduced					
Sr. No.	Course Code	Name of the Course				
01.	MPG101T	Modern Pharmaceutical Analytical Techniques				
02.	MPG102T	Advanced Pharmacognosy-1				
03.	MPG103T	Phytochemistry				
04.	MPG104T	Industrial Pharmacognostical Technology				
05.	MPG105P	Pharmacognosy Practical I				
06.	MPG106P	Seminar/Assignment				
07.	MPG201T	Medicinal Plant biotechnology				
08.	MPG102T	Advanced Pharmacognosy-II				
09.	MPG203T	Indian system of medicine				
10.	MPG204T	Herbal cosmetics				
11.	MPG205P	Pharmacognosy Practical II				
12.	MPG206P	Seminar/Assignment				

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HEAD S.L.T. Institute of Pharm. Sciences Guru Ghasidas Vishwavidyalaya, Bilaspur (C.G.)

Courses Focus on Employability/Entrepreneurship/Skill Development

Criteria – I (1.1.3)

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Guru Ghasidas Vishwavidyalaya (A Central University Established by the Central Universities Act 2009 No. 25 of 2009) Koni, Bilaspur – 495009 (C.G.)

Programme Name : <i>M. Pharm. (All Specializations)</i>						
	Academic Year : 2021-22					
List of New Courses Introduced						
Sr. No.	Course Code	Name of the Course				
01.	MRM301T	Research Methodology and Biostatistics				
02.	MRM302P	Journal Club				
03.	MRM303P	Discussion/ Presentation (Proposal Presentation)				
04.	MRM304P	Research work				
05.	MRM401P	Journal Club				
06.	MRM402P	Discussion/ Presentation (Proposal Presentation)				
07.	MRM403P	Research Work				

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Courses Focus on Employability/Entrepreneurship/Skill Development

Criteria – I (1.1.3)



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M. Pharm. (Pharmaceutics)

Course Code	Course	Credit Hours	Credit Points	Hrs./w k	Marks				
	I I	nours	1 011105	11					
	Semester I								
MPH101T	Modern	4	4	4	100				
	<mark>Pharmaceutical</mark>								
	Analytical								
	Techniques				100				
MPH102T	Drug Delivery	4	4	4	100				
MDU400	System No. 1	4		4	100				
MPH103T	Modern Pharmaceutics	4	4	4	100				
MPH104T	Regulatory Affair	4	4	4	100				
MPH1041 MPH105P	Pharmaceutics	12	6	12	150				
MI III031	Practical I	12	0	12	150				
MPH106P	Seminar/Assignment	7	4	7	100				
	Total	35	26	35	650				
	I		I						
		Semester	· II						
MPH 201T	<mark>Molecular</mark>	4	4	4	100				
	Pharmaceutics (Nano								
	Tech and Targeted								
	DDS)								
MPH 202T	Advanced	4	4	4	100				
	Biopharmaceutics &								
MDU 202T	Pharmacokinetics	4	4	4	100				
MPH 203T	Computer Aided Drug Delivery	4	4	4	100				
	System								
MPH204T	Cosmetic and	4	4	4	100				
	Cosmeceuticals				100				
MPH 205P	Pharmaceutics	12	6	12	150				
	Practical II								
MPH 206P	Seminar/Assignment	7	4	7	100				
	Total	35	26	35	650				

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PHARMACEUTICS (MPH) FIRST SEMESTER

MODERN PHARMACEUTICAL ANALYTICAL TECHNIQUES (MPH 101T)

<mark>Scope</mark>

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.

<mark>Objectives</mark>

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

1.

60 HOURS

- a. UV-Visible spectroscopy: Introduction, Theory, Laws, Instrumentation 11 associated with UV-Visible spectroscopy. Choice of solvents and solvent Hrs effect and Applications of UV-Visible 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.
 - 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 Interference and Applications.
- 2 NMR spectroscopy: Quantum numbers and their role in NMR, Principle, 11 Instrumentation, Solvent requirement in NMR, Relaxation Hrs 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 11 Spectroscopy, Different types of ionization like electron impact, chemical, Hrs 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, 11 chromatographic parameters, factors affecting resolution and Hrs 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

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5	-	Principle,		Working	11
	conditions, factors affe	ecting separ	ation and application	ns of the	Hrs
	following:				
	a) Paper electrophore	sis b) Gel ele	ectrophoresis c) Capil	llary electrophores	is
	d) Zone electrophores	is e) Moving	g boundary electroph	oresis f) Iso electr	ic
	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.

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

DRUG DELIVERY SYSTEMS (MPH 102T)

SCOPE

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

<mark>OBJECTIVES</mark>

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 & 10 basic concepts, advantages/disadvantages, factors influencing, Physicochemical & Hrs 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.
- 2 Rate Controlled Drug Delivery Systems: Principles & Fundamentals, Types, 10 Activation; Modulated Drug Delivery Systems; Mechanically activated, pH activated, Hrs Enzyme activated, and Osmotic activated Drug Delivery Systems Feedback regulated Drug Delivery Systems; Principles & Fundamentals.
- 3 Gastro-Retentive Drug Delivery Systems: Principle, concepts advantages and 10 disadvantages, Modulation of GI transit time approaches to extend GI transit. Hrs Buccal Drug Delivery Systems: Principle of muco adhesion, advantages and disadvantages, Mechanism of drug permeation, Methods of formulation and its evaluations.

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- 4 Occular Drug Delivery Systems: Barriers of drug permeation, Methods to overcome 06 barriers. 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 08 Evaluation of delivery systems of proteins and other macromolecules. Hrs
- 7 Vaccine delivery systems: Vaccines, uptake of antigens, single shot vaccines, 06 mucosal and transdermal delivery of vaccines. Hrs

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MODERN PHARMACEUTICS (MPH 103T)

<mark>Scope</mark>

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

<mark>Objectives</mark>

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

HRS

- 60
- a. Preformation Concepts Drug Excipient interactions different methods, 10 kinetics of stability, Stability testing. Theories of dispersion and pharmaceutical Hrs Dispersion (Emulsion and Suspension, SMEDDS) preparation and stability Large and small volume parental – physiological and formulation consideration, Manufacturing and evaluation.

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

- 2 Validation: Introduction to Pharmaceutical Validation, Scope & merits of Validation, 10 Validation and calibration of Master plan, ICH & WHO guidelines for calibration and Hrs validation of equipments, Validation of specific dosage form, Types of validation. Government regulation, Manufacturing Process Model, URS, DQ, IQ, OQ & P.Q. of facilities.
- 3 cGMP & Industrial Management: Objectives and policies of current good 10 manufacturing practices, layout of buildings, services, equipments and their Hrs 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.
- 4 Compression and compaction: Physics of tablet compression, consolidation, 10 effect of friction, distribution of forces, compaction profiles. Solubility. Hrs
- 5 Study of consolidation parameters; Diffusion parameters, Dissolution parameters 10 and Pharmacokinetic parameters, Heckel Hrs plots, Similarity factors – f2 and f1, Hrs Higuchi and Peppas plot, Linearity Concept of significance, Standard deviation , Chi square test, students T-test , ANOVA test.

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REGULATORY AFFAIRS (MPH 104T)

<mark>Scope</mark>

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
- reparation 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-
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

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 12 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.
- 3 Non clinical drug development: Global submission of IND, NDA, ANDA. 12 Investigation of medicinal products dossier, dossier (IMPD) and investigator Hrs brochure (IB).
- 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.

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Guru Ghasidas Vishwavidyalaya (A Central University Established by the Central Universities Act 2009 No. 25 of 2009) Koni, Bilaspur – 495009 (C.G.)

Courses Focus on Employability/Entrepreneurship/Skill Development

Criteria – I (1.1.3)

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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 $I_{n-vitro}$ 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.

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PHARMACEUTICS (MPH) SECOND SEMESTER

MOLECULAR PHARMACEUTICS (NANO TECHNOLOGY & TARGETED DDS) (NTDS) (MPH 201T)

<mark>Scope</mark>

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

<mark>Objectives</mark>

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 12 process involved in drug targeting. Tumor targeting and Brain specific delivery. Hrs
- 2 Targeting Methods: introduction preparation and evaluation. Nano Particles & 12 Liposomes: Types, preparation and evaluation. Hrs
- 3 Micro Capsules / Micro Spheres: Types, preparation and evaluation, Monoclonal 12 Antibodies ; preparation and application, preparation and application of Niosomes, Hrs Aquasomes, Phytosomes, Electrosomes.
- 4 Pulmonary Drug Delivery Systems: Aerosols, propellents, Containers Types, 12 preparation and evaluation, Intra Nasal Route Delivery systems; Types, preparation Hrs and evaluation.
- 5 Nucleic acid based therapeutic delivery system: Gene therapy, introduction (ex-vivo 12 & in-vivo gene therapy). Potential target diseases for gene therapy (inherited Hrs 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.

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ADVANCED BIOPHARMACEUTICS & PHARMACOKINETICS (MPH 202T)

<mark>Scope</mark>

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 to 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, 12 Mechanism of drug absorption, Factors affecting drug absorption, pH-Hrs partition theory of drug absorption. Formulation and physicochemical factors: Dissolution rate, Dissolution process, Noves–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 12 and In Vitro Drug Product Performance: Introduction, biopharmaceutic Hrs 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 testing performance 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, 12 compartment modeling: one compartment model- IV bolus, IV infusion, Hrs

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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.

- 4 **Bioavailability** Drug Product Performance, In Vivo: and 12 Bioequivalence: drug product performance, purpose of bioavailability Hrs 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 Biopharmaceutics classification process. system, review methods. Permeability: In-vitro, in-situ and In-vivo methods. generic biologics products), clinical significance of bioequivalence (biosimilar drug studies, special concerns in bioavailability and bioequivalence studies, generic substitution.
- 5 ApplicationofPharmacokinetics:Modified-Release Drug Products, Targeted 12 Drug Delivery Systems and Biotechnological products. Introduction to Hrs pharmacodynamic, drug interactions. Pharmacokinetics and biotechnology Pharmacokinetics pharmacodynamics of and drugs. Introduction, Proteins and peptides, Monoclonal antibodies. Oligonucleotides, Vaccines (immunotherapy), Gene therapies.

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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

a. Computers in Pharmaceutical Research and Development: А General 12 1. Overview: History of Computers in Pharmaceutical Research and Hrs **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.

- 2 Computational Modeling of Drug Disposition: Introduction, Modeling 12 Techniques: Drug Absorption, Solubility, Intestinal Permeation, Drug Hrs Distribution, Drug Excretion, Active Transport; P-gp, BCRP, Nucleoside Transporters, hPEPT1, ASBT, OCT, OATP, BBB-Choline Transporter.
- Computer-aided formulation development:: Concept of optimization, 12
 Optimization parameters, Factorial design, Optimization technology & Hrs
 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
- 4 a. Computer-aided biopharmaceutical characterization: Gastrointestinal 12 absorption simulation. Introduction, Theoretical background, Model Hrs construction, Parameter sensitivity analysis, Virtual trial, Fed vs. fasted state, In vitro dissolution and in vitro- in vivo correlation, Biowaiver

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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

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

COSMETICS AND COSMECEUTICALS (MPH 204T)

<mark>Scope</mark>

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

<mark>Objectives</mark>

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

- Cosmetics Regulatory: Definition of cosmetic products as per Indian 12 regulation. Indian regulatory requirements for labeling of cosmetics Hrs 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.
- 2 Cosmetics Biological aspects: Structure of skin relating to problems like dry 12 skin, acne, pigmentation, prickly heat, wrinkles and body odor. Structure of Hrs 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.
- 3 Formulation Building blocks: Building blocks for different product 12 formulations of cosmetics/cosmeceuticals. Surfactants Classification and Hrs 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.

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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 12 and regulatory aspects. Addressing dry skin, acne, sun-protection, Hrs pigmentation, prickly heat, wrinkles, body odor, dandruff, dental cavities, bleeding gums, mouth odor and sensitive teeth through cosmeceutical formulations.
- 5 Herbal Cosmetics: Herbal ingredients used in Hair care, skin care and oral 12 care. Review of guidelines for herbal cosmetics by private bodies like cosmos Hrs with respect to preservatives, emollients, foaming agents, emulsifiers and rheology modifiers. Challenges in formulating herbal cosmetics.

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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
- Protein binding studies of a highly protein bound drug & poorly protein bound drug
 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



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Scheme and Syllabus

M. Pharm. (Pharmaceutical Chemistry)

Course	Course	Credit	Credit	Hrs./w k	Marks
Code		Hours	Points	,	
		Semester		,	
MPC101T	<mark>Modern</mark>	4	4	4	100
	Pharmaceutical				
	Analytical Analytical				
	Techniques			-	
MPC102T	Advanced Organic	4	4	4	100
	Chemistry – I			-	
MPC103T	Advanced Medicinal	4	4	4	100
	chemistry				100
MPC104T	Chemistry of Natural	4	4	4	100
MDG40FD	Product	4.0	6	10	450
MPC105P	Pharmaceutical Chamistree Dreatical I	12	6	12	150
MPC106P	Chemistry Practical I	7	4	7	100
MPC100P	Seminar/Assignment Total	35	26	35	650
	Total	33	20	35	050
		Semester	II		
MPC201T	Advanced Spectral	4	4	4	100
	Analysis	т	т	т	100
MPC202T	Advanced Organic	4	4	4	100
	Chemistry –II	1	I	1	100
MPC203T	Computer Aided	4	4	4	100
	Drug Design	_	-	_	
MPC204T	Pharmaceutical	4	4	4	100
	Process Chemistry				
MPC205P	Pharmaceutical	12	6	12	150
	Chemistry Practical				
	II				
MPC206P	Seminar/Assignment	7	4	7	100
	Total	35	26	35	650

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PHARMACEUTICAL CHEMISTRY (MPC) FIRST SEMESTER

MODERN PHARMACEUTICAL ANALYTICAL TECHENIQUES (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.

<mark>Objectives</mark>

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 Hrs

1. a. UV-Visible spectroscopy: Introduction, Theory, Laws, Instrumentation 10 associated with UV-Visible spectroscopy, Choice of solvents and solvent Hrs 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 (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, 10 Instrumentation, Solvent requirement in NMR, Relaxation process, NMR Hrs 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 10 Spectroscopy, Different types of ionization like electron impact, chemical, Hrs 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 10 parameters, factors affecting resolution, isolation of drug from excipients, Hrs data interpretation and applications of the following:
 - a) Thin Layer chromatography
 - b) High Performance Thin Layer Chromatography
 - c) Ion exchange chromatography

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- 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, Workingconditions, factors 10 affecting separation and applications of the following: Hrs

a) Paper electrophoresis b) Gel electrophoresis c) Capillary electrophoresisd) 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 10 Application of potentiometry. 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.

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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 retrosynthesis
- 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

1

60 Hrs

- **Basic Aspects of Organic Chemistry:**
 - 12 Organic intermediates: Carbocations, carbanions, free radicals, Hrs carbenes and nitrenes. Their method of formation, stability and synthetic applications.
 - Types of reaction mechanisms and methods of determining them, Detailed knowledge regarding the reactions, mechanisms and their relative reactivity and orientations.

Addition reactions

c)

- Nucleophilic uni- and bimolecular reactions (SN1 and SN2) a)
- Elimination reactions (E1 & E2; Hoffman & Saytzeff'srule) b)
 - **Rearrangement** reaction
- 2 Study of mechanism and synthetic applications of following named 12 **Reactions:** Hrs

Ugi reaction, Brook rearrangement, Ullmann coupling reactions. DieckmannReaction,Doebner-MillerReaction,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 Aluminium isopropoxide, diazomethane. N-bromosuccinamide, Hrs dicyclohexylcarbodimide, Wilkinson reagent, Witting reagent. Osmium tetroxide, titanium chloride, diazopropane, azodicarboxylate, diethyl Triphenylphosphine, Benzotriazol-1-yloxy) tris (dimethylamino) phosphonium hexafluoro-phosphate (BOP).

Protecting groups

- Role of protection in organic synthesis a.
- Protection for the hydroxyl group, including 1,2-and1,3-diols: ethers, b.

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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

Organic Name reactions with their respective mechanism and application Hrs 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 the sehetrocyclic 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

- I. Basic principles, terminologies and advantages of retrosynthesis; Hrs guidelines for dissection of molecules. Functional group interconvertion and addition (FGI and FGA)
- I. C-X disconnections; C-C disconnections alcohols and carbonyl compounds; 1,2-, 1,3-,1,4-, 1,5-, 1,6-difunctionalized compounds
- I. Strategies for synthesis of three, four, five and six-membered ring.

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ADVANCED MEDICINAL CHEMISTRY (MPC 103T)

<mark>Scope</mark>

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.

<mark>Objectives</mark>

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

60Hrs

12

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

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:

- a) Prodrug design: Basic concept, Carrier linked prodrugs/ Hrs 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 a) 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 &



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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.

Rational Design of Enzyme Inhibitors 4

12 Enzyme kinetics & Principles of Enzyme inhibitors, Enzyme inhibitors in Hrs medicine, Enzyme inhibitors in basic research, rational design of noncovalently and covalently binding enzyme inhibitors.

5 **Peptidomimetics**

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

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CHEMISTRY OF NATURAL PRODUCTS (MPC 104T)

<mark>Scope</mark>

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 12 class of drugs 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

General introduction, classification, isolation, purification, molecular hrs 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). गुरू घासीदास विश्वविद्यालय (केंद्रीय विस्तविद्यालय अधिनियम 2008 क. 25 के अंतर्गत खारित केन्द्रीय विश्वविद्यालय) कोनी, बिलासपुर - 495009 (छ.ग.)



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3 a) Terpenoids

Classification, isolation, isoprene rule and general methods of structural hrs 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 rDNA technology, 12 hybridoma technology, New pharmaceuticals derived from biotechnology; hrs 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 – Gymnemasylvestre, Salacia reticulate, Pterocarpus marsupiam, Swertia chirata, Trigonella foenumgraccum; Liver dysfunction – Phyllanthus niruri; Antitumor – Curcuma longa Linn.

5 Structural Characterization of natural compounds Structural characterization 12 of natural compounds using IR, 1HNMR, 13CNMR and MS Spectroscopy of hrs specific drugs e.g., Penicillin, Morphine, Camphor, Vit-D, Quercetin and Digitalis glycosides. गुरू घासीदास विश्वविद्यालय (केन्रीय विश्वविद्यालय अधिनेयम 2009 क्र. 25 के अंतर्गत स्वापित केन्न्रीय विश्वविद्यालय) कोनी, बिलासपर - 495009 (छ.ग.)



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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

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PHARMACEUTICAL CHEMISTRY (MPC) SECOND SEMESTER

ADVANCED SPECTRAL ANALYSIS (MPC 201T)

<mark>Scope</mark>

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.

<mark>Objectives</mark>

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

1.

60Hrs

- UV and IR spectroscopy: 12 Wood ward – Fieser rule for 1,3- butadienes, cyclic dienes and α , β -carbonyl Hrs compounds and interpretation compounds of enones. ATR-IR, IR Interpretation of organic compounds.
- 2 NMR spectroscopy: 12 1-D and 2-D NMR, NOESY and COSY, HECTOR, INADEQUATE techniques, Hrs Interpretation of organic compounds.
- 3 Mass Spectroscopy

12 Hrs

- 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 4 Chromatography: Principle, Instrumentation and Applications of the following:a) GC-MS b) GC-Hrs AAS c) LC-MS d) LC-FTIR e) LC-NMR f) CE- MS g) High Performance Thin Layer fluid chromatography h) Super critical chromatography i) Ion Chromatography j) I-EC (Ion-Exclusion Chromatography) k) Flash chromatograph
- 5 1. Thermalmethods of analysis 12 Introduction, principle, instrumentation and application of DSC, DTA and Hrs TGA.
 - 2. Raman Spectroscopy Introduction, Principle, Instrumentation and Applications.

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3. Radio immuno assay

Biological standardization, bioassay, ELISA, Radioimmunoassay of digitalis and insulin.

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ADVANCED ORGANIC CHEMISTRY – II (MPC 202T)

<mark>Scope</mark>

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

Hrs

- 1. Green Chemistry:
 - 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 sonochemicalreactions, homogenous, heterogeneous liquid-liquid and liquid-solid reactions, synthetic applications
 - d. Continuous flow reactors: Working principle, advantages and synthetic applications

2 Chemistry of peptides

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

Pericyclic reactions

Mechanism, Types of pericyclic reactions such as cyclo addition, electrocyclic

12

Hrs

12

Hrs

Criteria – I (1.1.3)

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reaction and sigmatrophic rearrangement reactions with examples.

4 Catalysis:

5

12

12

Hrs

- a. Types of catalysis, heterogeneous and homogenous catalysis, advantages Hrs 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: Metalcatalyzed reactions
- e. Biocatalysis: Use of enzymes in organic synthesis, immobilized enzymes/cells in organic reaction.
- f. Phase transfer catalysis theory and applications
- Stereochemistry & Asymmetric Synthesis
 - 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.
 b. Methods of asymmetric synthesis using chiral pool, chiral auxiliaries and catalytic asymmetric synthesis, enantiopure separation and Stereo selective synthesis with examples.

Courses Focus on Employability/Entrepreneurship/Skill Development

Criteria – I (1.1.3)

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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) 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.	12 Hrs
2	Quantitative Structure Activity Relationships: Applications Hansch analysis, Free Wilson analysis and relationship between them, Advantages and disadvantages; Deriving 2D-QSAR equations. 3D-QSAR approaches and contour map analysis. Statistical methods used in QSAR analysis and importance of statistical parameters.	12 Hrs
3	 Molecular Modeling and Docking 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) 	12 Hrs
4	 Molecular Properties and Drug Design 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 	12 Hrs

Courses Focus on Employability/Entrepreneurship/Skill Development

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components of cavities, Fragment based drug design.

- c) Homology modeling and generation of 3D-structure of protein.
- 5 Pharmacophore Mapping and Virtual Screening Concept of pharmacophore, pharmacophore mapping, ju

12

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

In Silico Drug Design and Virtual Screening Techniques

Similarity based methods and Pharmacophore base screening, structure based In-silico virtual screening protocols.

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PHARMACEUTICAL PROCESS CHEMISTRY (MPC 204T)

<mark>Scope</mark>

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	
	Process chemistry Introduction, Synthetic strategy	12 Hrs
	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
	a) Extraction: Liquid equilibria, extraction with reflux, extraction with agitation, counter current extraction.	Hrs
	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
;	a) Nitration: Nitrating agents, Aromatic nitration, kinetics and mechanism of aromatic nitration, process equipment for technical nitration, mixed acid for nitration,	Hrs
	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 H ₂ O ₂ , sodium hypochlorite, Oxygen gas, ozonolysis.	

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4	Unit Processes - II a) Reduction: Catalytic hydrogenation, Heterogeneous and homogeneous	12 Hrs
	catalyst; Hydrogen transfer reactions, Metal hydrides. Case study on industrial reduction process.	1115
	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
5	a) MSDS (Material Safety Data Sheet), hazard labels of chemicals and Personal	Hrs
		1115
	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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PHARMACEUTICAL CHEMISTRY PRACTICALS – II

<mark>(MPC 205P)</mark>

1. Synthesis of organic compounds

by

- adaptingdifferentapproachesinvolving (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 Massspectra
- 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



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Scheme and Syllabus

M. Pharm. (Pharmacology)

Course	Course	Credit	Credit	Hrs./w k	Marks			
Code		Hours	Points	-				
Semester I								
MPL 101T	<mark>Modern</mark>	4	4	4	100			
	Pharmaceutical							
	Analytical							
	Techniques							
MPL 102T	Advanced	4	4	4	100			
	Pharmacology-I							
MPL 103T	Pharmacological and	4	4	4	100			
	Toxicological							
	Screening Methods-I			-				
<mark>MPL 104T</mark>	Cellular and	4	4	4	100			
	Molecular							
	Pharmacology	4.0		10	450			
MPL 105P	Pharmacology	12	6	12	150			
	Practical I			7	100			
MPL 106P	Seminar/Assignment	<u>7</u> 35	4	7 35	100			
	Total		26	35	650			
		Semeste	F 11					
MPL 201T	Advanced	4	4	4	100			
	Pharmacology II	7	т	т	100			
MPL 202T	Pharmacological and	4	4	4	100			
	Toxicological	Т	т	т	100			
	Screening Methods-							
	II							
MPL 203T	Principles of Drug	4	4	4	100			
	Discovery							
MPL 204T	Clinical Research	4	4	4	100			
	and							
	Pharmacovigilance							
MPL 205P	Pharmacology	12	6	12	150			
	Practical II							
MPL 206P	Seminar/Assignment	7	4	7	100			
	Total	35	26	35	650			

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PHARMACOLOGY (MPL) FIRST SEMESTER

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.

<mark>Objectives</mark>

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 HOURS

60

- 1. e. UV-Visible spectroscopy: Introduction, Theory, Laws, 10 Instrumentation associated with UV-Visible spectroscopy. Choice of solvents and solvent effect and Applications of UV- Hrs Visible spectroscopy.
 - f. 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.
 - g. Spectroflourimetry: Theory of Fluorescence, Factors affecting fluorescence, Quenchers, Instrumentation and Applications of fluorescence spectrophotometer.
 - h. Flame emission spectroscopy and Atomic absorption spectroscopy: Principle, Instrumentation Interference and Applications.
 i.
- 2 NMR spectroscopy: Quantum numbers and their role in NMR, Principle, 10 Instrumentation, Solvent requirement in NMR, Relaxation Hrs process, NMR signals in various compounds, Chemical shift, Factors influencing chemical shift, Spin-Spin coupling, Coupling constant, Brief outline of principles of FT-Nuclear magnetic double resonance, NMR and 13C NMR. Applications of NMR spectroscopy.
- 3. Mass Spectroscopy: Principle, Theory, Instrumentation of Mass 10 Spectroscopy, Different types of ionization like electron impact, Hrs chemical, field, FAB and MALDI, APCI, ESI, APPI Analyzers of Ouadrupole and Time of Flight, Mass fragmentation and its rules, Meta stable ions, Isotopic peaks and Applications of Mass



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spectroscopy

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

following:

- j) Thin Layer chromatography
- k) High Performance Thin Layer Chromatography
- l) Ion exchange chromatography
- m) Column chromatography
- n) Gas chromatography
- o) High Performance Liquid chromatography
- p) Ultra High Performance Liquid chromatography
- q) Affinity chromatography
- r) Gel Chromatography
- 5 Electrophoresis: Principle, Instrumentation, Working conditions, 10 factors affecting separation and applications of the following: 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 diffraction 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 10Hr Application of potentiometry. s

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 गुरू घासीदास विश्वविद्यालय (केंद्रीय विश्वविद्यालय) कोनी, बिलासपुर - 495009 (छ.ग.)



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results, advantage and

disadvantages, pharmaceutical applications.

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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, 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

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

2 Neurotransmission

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

12

12

Hrs

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	Parasympathomimetics and lytics, sympathomimetics and lytics, agents affecting	-
	neuromuscular junction	
	Central nervous system Pharmacology	12
	General and local anesthetics	Hrs
	Sedatives and hypnotics, drugs used to treat anxiety.	
	Depression, psychosis, mania, epilepsy, neurodegenerative	
	diseases. Narcotic and non-narcotic analgesics.	
•	Cardiovascular Pharmacology	12
	Diuretics, antihypertensives, antiischemics, anti- arrhythmics, drugs for heart failure and hyperlipidemia.	Hrs
	Hematinics, coagulants , anticoagulants, fibrinolytics and anti- platelet drugs	
	Autocoid Pharmacology	12
	The physiological and pathological role of Histamine, Serotonin, Kinins Prostaglandins Opioid autocoids.	Hrs
	Pharmacology of antihistamines, 5HT antagonists.	

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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

<mark>Objectives</mark>

Upon completion of the course, 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 Common laboratory animals: Description, handling and 12 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 12 vivo, in vitro, and other possible animal alternative models.

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. गुरू घासीदास विश्वविद्यालय (केंद्रीय विस्तविद्यालय अधिनियम 2009 क्र. 25 के अंतर्गत स्वापित केन्द्रीय विश्ववेद्यालय) कोनी, बिलासपर - 495009 (छ.ग.)

ulcer, anti -emetic, anti-diarrheal and laxatives.



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

Hrs

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

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

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

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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.

<mark>Objectives:</mark>

Upon completion of the course, it is expected that the students 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

THE	DRY 60 Hrs	
1.	Cell biology	12
	Structure and functions of cell and its organelles	Hrs
	Genome 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
	Intercellular and intracellular signaling pathways.	Hrs
	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.	
0		10

3 Principles and applications of genomic and proteomic tools DNA 12 electrophoresis, PCR (reverse transcription and real time), Gene sequencing,

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micro array technique, SDS page, ELISA and western blotting,

Hrs

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.

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

5 a. Cell culture techniques

Basic equipments used in cell culture lab. Cell culture media, general procedure for cell cultures; various types of cell culture, 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

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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)
- 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).
- 17. DNA fragmentation assay by agarose gel electrophoresis.
- 18. DNA damage study by Comet assay.
- 19. Apoptosis determination by fluorescent imaging studies.
- 20. Pharmacokinetic studies and data analysis of drugs given by different routes of administration using softwares
- 21. Enzyme inhibition and induction activity
- 22. Extraction of drug from various biological samples and estimation of drugs in biological fluids using different analytical techniques (UV)
- 23. Extraction of drug from various biological samples and estimation of drugs in biological fluids using different analytical techniques (HPLC)

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<u>PHARMACOLOGY (MPL)</u> <u>FIRST SEMESTER</u>

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

<mark>Objectives</mark>

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, Hrs prolactin, thyroid, insulin and sex hormones

Anti-thyroid drugs, Oral hypoglycemic agents, Oral contraceptives, Corticosteroids.

Drugs affecting calcium regulation

2 Chemotherapy

Cellular and molecular mechanism of actions and resistance of antimicrobial agents Hrs such as ß-lactams, aminoglycosides, quinolones, Macrolide antibiotics. Antifungal, antiviral, and anti-TB drugs.

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.

Courses Focus on Employability/Entrepreneurship/Skill Development

12

12

12 Hrs



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	Immunosuppressants and Immunostimulants						
4	GIT Pharmacology					12 Hrs	
	Antiulcer drugs and irritable bo		antiemetics, anti e.	-diarrheals an	d drugs for c	onstipation	
	Chronopharmad	cology					
	Biological and c like	circadian rhyt	hms, applications	s of chronothe	erapy in vario	us diseases	
	cardiovascular o	disease, diabe	tes, asthma and p	eptic ulcer			
5	Free radicals Ph	narmacology					12
Generation of free radicals, role of free radicals in etiopathology of various diseases such as diabetes, neurodegenerative diseases and cancer.					Hrs		
	Protective activ	ity of certain i	important antioxi	dant			
	Recent Advance	es in Treatmer	nt:				
	Alzheimer's mellitus	disease,	Parkinson's	disease,	Cancer,	Diabetes	

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PHARMACOLOGICAL AND TOXICOLOGICAL SCREENING METHODS-II (MPL 202T)

<mark>Scope</mark>

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.

<mark>Objectives</mark>

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, 12 regulatory and descriptive)

Hrs

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

2 Acute, sub-acute and chronic- oral, dermal and inhalational studies as per 12 OECD guidelines.

Hrs

Acute eye irritation, skin sensitization, dermal irritation & dermal toxicity studies.

Test item characterization- importance and methods in regulatory

toxicology

Reproductive toxicology studies, Male reproductive toxicity studies, female 12 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

4 IND enabling studies (IND studies)- Definition of IND, importance of IND, 12



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industry perspective, list of studies needed for IND submission.

Hrs

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

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

<mark>Objectives</mark>

Upon completion of this course it is expected that students will 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 discoverv process: Target 12 identification. target validation. lead identification and lead Hrs Optimization. Economics of drug discovery.

Discovery and validation-Role of Genomics. **Proteomics** Target 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 12 screening, in silico lead discovery techniques, Assay development Hrs for hit identification. 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 Traditional vs rational drug design, Methods followed in traditional 12 Hrs drug design, High throughput screening, Concepts of Rational गुरू घासीदास विश्वविद्यालय (केन्रीय विश्वविद्यालय अधिनेयम 2009 क्र. 25 के अंतर्गत खातित केन्नीय विश्वविद्यालय) कोनी, बिलासपुर - 495009 (छ.ग.)



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	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.	12 Hrs
	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.

5 QSAR Statistical methods – regression analysis, partial least 12 square analysis (PLS) and other multivariate statistical methods. 3D-QSAR Hrs 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

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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.

<mark>Objectives</mark>

Upon completion of the course, the students 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

1.

60 Hrs Regulatory Perspectives of Clinical Trials:

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

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

12

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its management

Clinical Trial Documentation-Guidelines 3 to the preparation of 12 Case Hrs documents. Preparation of protocol, Investigator Brochure. Report Forms, Clinical Study Report Clinical Trial Monitoring Safety Monitoring in CT

Definition Adverse Drug Reactions: and types. Detection and reporting methods. Severitv and seriousness assessment.Predictability and preventability assessment. Management of adverse drug reactions; Terminologies of ADR.

4 Basic aspects, terminologies and establishment of 12 pharmacovigilance Hrs

History and progress of pharmacovigilance, Significance of safety monitoring, Pharmacovigilance in India and international aspects, monitoring WHO international drug 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

5 Methods, ADR reporting and tools used in 12 Pharmacovigilance Hrs

classification diseases. International International of Nondrugs, Passive surveillance. proprietary names for and Active Comparative observational studies, Targeted clinical investigations and surveillance. **Spontaneous** reporting Vaccine safety system authorities, Guidelines and Reporting to regulatory for **ADRs** Pharmacovigilance, reporting. Argus, Aris G VigiFlow, Statistical methods for evaluating medication safety data.

6 Pharmacoepidemiology, pharmacoeconomics, safety 12 pharmacology Hrs गुरू घासीदास विश्वविद्यालय (केन्रीय विश्वविद्यात्य अधिनियम 2008 ज्ञ. 25 के अंतर्गत स्वापित केन्न्रीय विश्वविद्यात्य) कोनी, बिलासपर - 495009 (छ.ग.)



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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



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Scheme and Syllabus

M. Pharm. (Pharmacognosy) Course of study for M. Pharm. (Pharmacognosy)

Course	Course	Credit	Credit	Hrs./w k	Marks			
Code	course	Hours	Points	1113./ W IX	Marias			
		nouro	1 011100	11				
Semester I								
MPG101T	<mark>Modern</mark>	4	4	4	100			
	Pharmaceutical							
	Analytical							
	Techniques							
MPG102T	Advanced	4	4	4	100			
	Pharmacognosy-I							
MPG103T	Phytochemistry	4	4	4	100			
MPG104T	<mark>Industrial</mark>	4	4	4	100			
	Pharmacognostical							
	Technology							
MPG105P	<mark>Pharmacognosy</mark>	12	6	12	150			
	Practical I							
MPG106P	Seminar/Assignment	7	4	7	100			
	Total	35	26	35	650			
		Semester			100			
MPG201T	Medicinal Plant	4	4	4	100			
N C C C C C C C C C C C C C C C C C C C	biotechnology				100			
MPG102T	Advanced	4	4	4	100			
N CD	Pharmacognosy-II				100			
MPG203T	Indian system of	4	4	4	100			
	medicine				400			
MPG204T	Herbal cosmetics	4	4	4	100			
MPG205P	Pharmacognosy	12	6	12	150			
	Practical II				100			
MPG206P	Seminar/Assignment	7	4	7	100			
	Total	35	26	35	650			

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Scheme and Syllabus

PHARMACOGNOSY (MPG) FIRST SEMESTER

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.

<mark>Objectives</mark>

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

HOURS

1.

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

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.

Spectroflourimetry: Theory of Fluorescence, Factorsaffectingfluorescence,Quenchers,Instrumentationandof fluorescence spectrophotometer.Applications

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

- NMR spectroscopy: Quantum numbers 2 and their role in NMR, Principle, 11 Instrumentation, Solvent requirement NMR, Relaxation in Hrs compounds, Chemical shift, Factors process, NMR signals in various 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 11 Spectroscopy, Different types of ionization like electron impact,

60

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chemical, field, FAB and MALDI, APCI, ESI, APPI Analyzers of Hrs Quadrupole and Time of Flight, Mass fragmentation and its rules, Isotopic Meta stable ions. peaks and **Applications** of Mass spectroscopy

- 4 Chromatography: Principle, apparatus, instrumentation, 11 chromatographic parameters, factors affecting resolution and Hrs 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 Electrophoresis: Principle, Instrumentation, Working conditions, 11 factors affecting separation and applications of the following: 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 diffraction 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 5Hrs 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. calibration. heating and cooling rates, resolution, source of errors) and their influence, advantage and disadvantages, pharmaceutical applications.

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

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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. cultivation: General introduction Plant drug to the importance of 12 Pharmacognosy Indian of Hrs in herbal drug industry. Council Agricultural Agricultural Research. Current Good Practices. Current Good Cultivation Practices. Current Good Collection Conservation Practices. of medicinal plants-Ex-situ and Insitu conservation of medicinal plants
- 2 products: General methods of isolation and 12 Marine natural purification, Study of Marine toxins. Recent advances in research Hrs faced in marine drugs, Problems in research on marine drugs such as taxonomical identification. chemical screening and their solution.
- 3 Nutraceuticals: Current trends and future Inorganic 12 scope, enzymes, Hrs mineral supplements. Vitamin supplements, Digestive fibres. Cereals and Health drinks of natural origin, Dietarv grains, Antioxidants, Polyunsaturated fatty acids. Herbs functional as foods. Formulation and standardization of neutraceuticals. FSSAI Regulatory aspects. guidelines, Sources. name of marker compounds and their chemical medicinal and health nature, uses benefits of following

i) Spirulina ii) Soya bean iii) Ginseng iv) Garlic v) Broccoli vi) Flax seeds Green and Herbal Tea vii) viii) Black cohosh ix) Turmeric.

4 Phytopharmaceuticals: Occurrence, isolation and characteristic 12 features (Chemical nature, uses in pharmacy, medicinal and Hrs



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health benefits) of following.

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

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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 phytoconstituents

OBJECTIVES

Upon completion of the course, 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: Constituents & their 12 Biosynthesis, Isolation, Characterization and purification with a special reference Hrs to their importance in herbal industries of following phytopharmaceuticals 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: Cucurbitacin
- 2 Drug discovery and development: History of herbs as source of drugs and drug 12 discovery, the lead structure selection process, structure development, product Hrs discovery process and drug registration, Selection and optimization of lead compounds with suitable examples from the following source : artemesin, and rographolides. Clinical studies emphasising on phases of clinical trials, protocol design for lead molecules.
- 3 Extraction and Phytochemical studies: Recent advances in extractions with 12 emphasis on selection of method and choice of solvent for extraction, successive and Hrs 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
- 4 Phytochemical finger printing: HPTLC and LCMS/GCMS applications in the 12 characterization of herbal extracts. Structure elucidation of phytoconstituents. Hrs
- 5 Structure elucidation of the following compounds by spectroscopic techniques like 12 UV, IR, MS, NMR (1H, 13C) Hrs

Courses Focus on Employability/Entrepreneurship/Skill Development

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- a. Carvone, Citral, Menthol
- b. Luteolin, Kaempferol
- c. Nicotine, Caffeine iv) Glycyrrhizin.

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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

<mark>Objectives:</mark>

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

THEORY 60 Hrs

- 1. Herbal drug industry: Infrastructure of herbal drug industry involved in 12 production of standardized extracts and various dosage forms. Current Hrs 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.
- 2 Regulatory requirements for setting herbal drug industry: Global marketing 12 management. Indian and international patent law as applicable herbal drugs Hrs and natural products. Export - Import (EXIM) policy, TRIPS.

Quality assurance in herbal/natural drug products.

Concepts of TQM, GMP, GLP, ISO-9000

- 3 Monographs of herbal drugs: General parameters of monographs of herbal 12 drugs and comparative study in IP, USP, Ayurvedic Pharmacopoeia, Siddha and Hrs Unani Pharmacopoeia, American herbal pharmacopoeia, British herbal pharmacopoeia, WHO guidelines in quality assessment of herbal drugs.
- of natural products Herbal medicines 4 Testing and drugs: clinical laboratory Stability testing. testing of natural products, protocols.
- 5 Patents: Indian and international patent laws, 12 proposed amendments herbal/natural as applicable to products and Hrs

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Copyright, process. Geographical indication, Patentable subject novelty, utility, maters, non obviousness, enablement and best mode, procedure for Indian patent filing, patent processing, grant patents, opposition and rights of patents, cases of of patents, revocation of patents, patent search and literature, Controllers of patents

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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
- 11. Formulation of different dosage forms and their standardisation.

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PHARMACOGNOSY (MPG) SECOND SEMESTER

MEDICINAL PLANT BIOTECHNOLOGY (MPG 201T)

Scope

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

<mark>Objectives</mark>

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 12 development of plant biotechnology as a source of medicinal agents. Applications in Hrs pharmacy and allied fields. Genetic and molecular biology as applied to pharmacognosy, study of DNA, RNA and protein replication, genetic code, expression. structure regulation of gene and complicity of genome, cell signaling, DNA recombinant technology.
- Different tissue culture techniques: Organogenesis and embryogenesis, synthetic 15 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.
- 3 Immobilisation techniques & Secondary Metabolite Production: Immobilization 15 Hrs 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.
- Biotransformation and Transgenesis: Biotransformation, bioreactors for pilot and large scale cultures of plant cells and retention of biosynthetic potential in cell culture. Transgenic plants, methods used in gene identification, localization and sequencing of genes. Application of PCR in plant genome analysis.

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ADVANCED PHARMACOGNOSY - II (MPG 202T)

<mark>Scope</mark>

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, 12 Efficacy of Herbal medicine products, Validation of herbal therapies, Pharmacodynamic and Pharmacokinetic issues Hrs
- Adulteration and Deterioration: Introduction, Types of Adulteration/ 12
 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.
- 3 Ethnobotany and Ethnopharmacology: Ethnobotany in herbal drug 12 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.
- 4 Analytical Profiles of herbal drugs: Andrographis paniculata, Boswellia 12 serata, Coleus forskholii, Curcuma longa, Embelica officinalis, Psoralea corylifolia. Hrs
- 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
 Hrs Anticancer drugs. In vivo evaluation techniques for Anti-inflammatory, Antiulcer, Anticancer, Wound healing, Antidiabetic, Hepatoprotective, Cardio protective, Diuretics and Antifertility, Toxicity studies as per OECD

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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.

<mark>Objectives</mark>

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 12 Homoeopathy systems of medicine Hrs

Different dosage forms of the ISM.

Avurveda: Avurvedic Pharmacopoeia, Analysis formulations of and bio crude drugs with references to: Identity, purity and quality. Siddha: Gunapadam (Siddha Pharmacology), raw drugs/Dhatu/Jeevam in Siddha medicine, Purification system of process (Suddhi).

2 Naturopathy, Yoga and Aromatherapy practices

12 Hrs

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.

Formulation development 3 of various systems of medicine 12 Salient features of the techniques of preparation of some of the Hrs class of Formulations Ayurveda, important as per Siddha. Homeopathy and Unani Pharmacopoeia and texts.

Standardization,

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Shelf life and Stability studies of ISM formulations

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

Components of GMP (Schedule T) and its objectives. _ Infrastructural requirements, working space, storage area, machinerv equipments, and 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 ISM, CCRAS, CCRS, CCRH, CCRU Hrs गुरू घासीदास विश्वविद्यालय (केन्रीय विश्वविद्यालय अधिनियम 2009 क्र. 25 के अंतर्गत खावित केन्न्रीय विश्वविद्यालय) कोनी, बिलासपुर - 495009 (छ.ग.)



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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, the students 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/naturalcosmetics,Classification& 12Economic aspects.Hrs

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.

- Commonly used herbal cosmetics. materials. 2 raw preservatives, 12 surfactants. humectants. oils, colors, and functional herbs. Hrs some preformulation studies, compatibility possible studies. interactions between chemicals and herbs, design of herbal cosmetic formulation.
- 3 Herbal Cosmetics Physiology and chemistrv skin and 12 : of pigmentation, hairs. scalp, lips and nail. Cleansing cream. Hrs Lotions. Face powders. Face Lipsticks. packs, Bath baby product. Preparation products. soaps and and standardisation of the following :

Tonic, Bleaches, Dentifrices and Mouth washes & Tooth Pastes, Cosmetics for Nails.

- Cosmeceuticals of 4 herbal and natural origin: Hair growth 12 formulations. Shampoos. Conditioners. Colorants & hair oils. Hrs foundation formulations, vanishing Fairness & creams, anti-sun burn preparations, moisturizing creams, deodorants.
- 5 Analysis of Cosmetics, Toxicity screening and test methods: 12 Quality control and toxicity studies as per Drug and Cosmetics Hrs Act.

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HERBAL COSMETICS PRACTICALS

<mark>(MPG 205P)</mark>

- 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 Ayurvedic, 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.



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M. Pharm. (All Specializations)

Course Code	Course	Credit Hours	Credit Points	Hrs./wk	Marks				
	Semester I								
MRM301T	Research Methodology and Biostatistics	4	4	4	100				
MRM302P	<mark>Journal club</mark>	1	1	1	25				
MRM303P	Discussion / Presentation (Proposal Presentation)	2	2	2	50				
MRM304P	Research work	28	14	28	350				
	Total	35	21	35	525				
		Semester	· II						
MRM401P	Journal club	1	1	1	25				
MRM402P	Discussion / Presentation (Proposal Presentation)	3	3	3	50				
MRM403P	Research work	31	16	31	400				
	Total	35	20	35	475				

Courses Focus on Employability/Entrepreneurship/Skill Development

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MRM301T - Research Methodology & Biostatistics

UNIT – I

Methodology: General Research Research. objective, requirements, practical difficulties. review of design, studies. literature. study types of eliminate errors/bias. controls. randomization. design. strategies to crossover 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 correlation. chi square test), null hypothesis, Р values, variance. degree of freedom, interpretation of P values.

UNIT – III

Medical Research: History, values in medical ethics, autonomy, beneficence, nonmaleficence, 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 of animal facilities laboratories. hygiene, location to 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.