FACULTY OF LIFE SCIENCES

SYLLABUS

For

MASTER OF PHARMACY
(Credit Based Evaluation & Grading System)

(Semester: I-IV)

Examinations: 2019-20

GURU NANAK DEV UNIVERSITY AMRITSAR

MASTER OF PHARMACY (SEMESTER SYSTEM)
(Credit Based Evaluation & Grading System)

Semester I

M. Pharm. (Pharmaceutics)

Course Code	Course	Credit Hours	Credit Points
MPH101T	Modern Pharmaceutical Analytical Techniques	4	4
MPH102T	Drug Delivery System	4	4
MPH103T	Modern Pharmaceutics	4	4
MPH104T	Pharmaceutical Regulatory Affair	4	4
MPH105P	Pharmaceutics Practical I	12	6
MPH301S	Seminar/Assignment	7	4
	Total	**35**	**26**

Semester I

M. Pharm. (Pharmaceutical Chemistry)

Course Code	Course	Credit Hours	Credit Points
MPC101T	Modern Pharmaceutical Analytical Techniques	4	4
MPC102T	Advanced Organic Chemistry -I	4	4
MPC103T	Advanced Medicinal chemistry	4	4
MPC104T	Chemistry of Natural Products	4	4
MPC105P	Pharmaceutical Chemistry Practical I	12	6
MPC301S	Seminar/Assignment	7	4
	Total	**35**	**26**

MASTER OF PHARMACY (SEMESTER SYSTEM)
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Semester I

M. Pharm. (Pharmacology)

Course Code	Course	Credit Hours	Credit Points
MPL101T	Modern Pharmaceutical Analytical Techniques	4	4
MPL102T	Advanced Pharmacology-I	4	4
MPL103T	Pharmacological and Toxicological Screening Methods- I	4	4
MPL104T	Cellular and Molecular Pharmacology	4	4
MPL105P	Pharmacology Practical I	12	6
MPL301S	Seminar/Assignment	7	4
	Total	**35**	**26**

Semester I

M. Pharm. (Pharmacognosy)

Course Code	Course	Credit Hours	Credit Points
MPG101T	Modern Pharmaceutical Analytical Techniques	4	4
MPG102T	Advanced Pharmacognosy-1	4	4
MPG103T	Phytochemistry	4	4
MPG104T	Industrial Pharmacognostical Technology	4	4
MPG105P	Pharmacognosy Practical I	12	6
MPG301S	Seminar/Assignment	7	4
	Total	**35**	**26**

MASTER OF PHARMACY (SEMESTER SYSTEM)
(Credit Based Evaluation & Grading System)

Tables: Scheme for Internal Assessment

Semester-I

(Pharmaceutics- MPH)

Course Code	Course	Internal Assessment				End Semester Exams		Total Marks
		Continuous Mode	Sessional Exams		Total	Marks	Duration	
			Marks	Duration				
		SEMESTER I						
MPH 101T	Modern Pharmaceutical Analytical Techniques	10	15	1 Hr	25	75	3 Hrs	100
MPH 102T	Drug Delivery System	10	15	1 Hr	25	75	3 Hrs	100
MPH 103T	Modern Pharmaceutics	10	15	1 Hr	25	75	3 Hrs	100
MPH 104T	Regulatory Affair	10	15	1 Hr	25	75	3 Hrs	100
MPH 105P	Pharmaceutics Practical I	20	30	6 Hrs	50	100	6 Hrs	150
MPH301S	Seminar /Assignment	-	-	-	-	-	-	100
		Total						**650**

(Pharmaceutical Chemistry-MPC)

Course Code	Course	Internal Assessment				End Semester Exams		Total Marks
		Continuous Mode	Sessional Exams		Total	Marks	Duration	
			Marks	Duration				
		SEMESTER I						
MPC 101T	Modern Pharmaceutical Analytical Techniques	10	15	1 Hr	25	75	3 Hrs	100
MPC 102T	Advanced Organic Chemistry -I	10	15	1 Hr	25	75	3 Hrs	100
MPC 103T	Advanced Medicinal chemistry	10	15	1 Hr	25	75	3 Hrs	100
MPC 104T	Chemistry of Natural Products	10	15	1 Hr	25	75	3 Hrs	100
MPC 105P	Pharmaceutical Chemistry Practical I	20	30	6 Hrs	50	100	6 Hrs	150
MPC301S	Seminar /Assignment	-	-	-	-	-	-	100
		Total						**650**

MASTER OF PHARMACY (SEMESTER SYSTEM)
(Credit Based Evaluation & Grading System)

(Pharmacology-MPL)

Course Code	Course	Internal Assessment				End Semester Exams		Total Marks
		Continuous Mode	Sessional Exams		Total	Marks	Duration	
			Marks	Duration				
		SEMESTER I						
MPL 101T	Modern Pharmaceutical Analytical Techniques	10	15	1 Hr	25	75	3 Hrs	100
MPL 102T	Advanced Pharmacology-I	10	15	1 Hr	25	75	3 Hrs	100
MPL 103T	Pharmacological and Toxicological Screening Methods-I	10	15	1 Hr	25	75	3 Hrs	100
MPL 104T	Cellular and Molecular Pharmacology	10	15	1 Hr	25	75	3 Hrs	100
MPL 105P	Experimental Pharmacology - I	20	30	6 Hrs	50	100	6 Hrs	150
MPL301S	Seminar /Assignment	-	-	-	-	-	-	100
		Total						**650**

(Pharmacognosy-MPG)

Course Code	Course	Internal Assessment				End Semester Exams		Total Marks
		Continuous Mode	Sessional Exams		Total	Marks	Duration	
			Marks	Duration				
		SEMESTER I						
MPG 101T	Modern Pharmaceutical Analytical Techniques	10	15	1 Hr	25	75	3 Hrs	100
MPG 102T	Advanced Pharmacognosy-1	10	15	1 Hr	25	75	3 Hrs	100
MPG 103T	Phytochemistry	10	15	1 Hr	25	75	3 Hrs	100
MPG 104T	Industrial Pharmacognostical Technology	10	15	1 Hr	25	75	3 Hrs	100
MPG 105P	Experimental Pharmacology - II	20	30	6 Hrs	50	100	6 Hrs	150
MPG301S	Seminar /Assignment	-	-	-	-	-	-	100
		Total						**650**

Semester II

M. Pharm. (Pharmaceutics)

Course Code	Course	Credit Hrs.	Credit Points
MPH201T	Molecular Pharmaceutics (Nano Technology and Targeted DDS)	4	4
MPH202T	Advanced Biopharmaceutics & Pharmacokinetics	4	4
MPH203T	Computer Aided Drug Delivery System	4	4
MPH204T	Cosmetic and Cosmeceuticals	4	4
MPH205P	Pharmaceutics Practical II	12	6
MPH302S	Seminar/Assignment	7	4
	Total	**35**	**26**

Semester II

M. Pharm. (Pharmaceutical Chemistry)

Course Code	Course	Credit Hrs.	Credit Points
MPC201T	Advanced Spectral Analysis	4	4
MPC202T	Advanced Organic Chemistry -II	4	4
MPC203T	Computer Aided Drug Design	4	4
MPC204T	Pharmaceutical Process Chemistry	4	4
MPC205P	Pharmaceutical Chemistry Practical II	12	6
MPC302S	Seminar/Assignment	7	4
	Total	**35**	**26**

Semester II

M. Pharm. (Pharmacology)

Course Code	Course	Credit Hours	Credit Points
MPL201T	Advanced Pharmacology II	4	4
MPL202T	Pharmacological and Toxicological Screening Methods- II	4	4
MPL203T	Principles of Drug Discovery	4	4
MPL204T	Clinical Research And Pharmacovigilance	4	4
MPL205P	Pharmacology Practical II	12	6
MPL302S	Seminar/Assignment	7	4
	Total	**35**	**26**

Semester II

M. Pharm. (Pharmacognosy)

Course Code	Course	Credit Hours	Credit Points
MPG201T	Medicinal Plant biotechnology	4	4
MPG202T	Advanced Pharmacognosy-II	4	4
MPG203T	Indian system of medicine	4	4
MPG204T	Herbal cosmetics	4	4
MPG205P	Pharmacognosy Practical II	12	6
MPG302S	Seminar/Assignment	7	4
	Total	**35**	**26**

MASTER OF PHARMACY (SEMESTER SYSTEM)
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Tables: Scheme for Internal Assessment

Semester-II

(Pharmaceutics- MPH)

Course Code	Course	Internal Assessment			Total	End Semester Exams		Total Marks
		Continuous Mode	Sessional Exams			Marks	Duration	
			Marks	Duration				
		SEMESTER II						
MPH 201T	Molecular Pharmaceutics (Nano Technology and Targeted DDS)	10	15	1 Hr	25	75	3 Hrs	100
MPH 202T	Advanced Biopharmaceutics & Pharmacokinetics	10	15	1 Hr	25	75	3 Hrs	100
MPH 203T	Computer Aided Drug Delivery System	10	15	1 Hr	25	75	3 Hrs	100
MPH 204T	Cosmetic and Cosmeceuticals	10	15	1 Hr	25	75	3 Hrs	100
MPH 205P	Pharmaceutics Practical I	20	30	6 Hrs	50	100	6 Hrs	150
MPH302S	Seminar /Assignment	-	-	-	-	-	-	100
			Total					**650**

(Pharmaceutical Chemistry-MPC)

Course Code	Course	Internal Assessment			Total	End Semester Exams		Total Marks
		Continuous Mode	Sessional Exams			Marks	Duration	
			Marks	Duration				
		SEMESTER II						
MPC 201T	Advanced Spectral Analysis	10	15	1 Hr	25	75	3 Hrs	100
MPC 202T	Advanced Organic Chemistry -II	10	15	1 Hr	25	75	3 Hrs	100
MPC 203T	Computer Aided Drug Design	10	15	1 Hr	25	75	3 Hrs	100
MPC 204T	Pharmaceutical Process Chemistry	10	15	1 Hr	25	75	3 Hrs	100
MPC 205P	Pharmaceutical Chemistry Practical II	20	30	6 Hrs	50	100	6 Hrs	150
MPC302S	Seminar /Assignment	-	-	-	-	-	-	100
			Total					**650**

(Pharmacology-MPL)

Course Code	Course	Internal Assessment			Total	End Semester Exams		Total Marks
		Continuous Mode	Sessional Exams			Marks	Duration	
			Marks	Duration				
		SEMESTER II						
MPL 201T	Advanced Spectral Analysis	10	15	1 Hr	25	75	3 Hrs	100
MPL 202T	Pharmacological and Toxicological Screening Methods-II	10	15	1 Hr	25	75	3 Hrs	100
MPL 203T	Principles of Drug Discovery	10	15	1 Hr	25	75	3 Hrs	100
MPL 204T	Clinical Research and Pharmacovigilance	10	15	1 Hr	25	75	3 Hrs	100
MPL 205P	Experimental Pharmacology - II	20	30	6 Hrs	50	100	6 Hrs	150
MPL302S	Seminar /Assignment	-	-	-	-	-	-	100
			Total					**650**

MASTER OF PHARMACY (SEMESTER SYSTEM)
(Credit Based Evaluation & Grading System)

(Pharmacognosy-MPG)

Course Code	Course	Internal Assessment				End Semester Exams		Total Marks
		Continuous Mode	Sessional Exams		Total	Marks	Duration	
			Marks	Duration				
		SEMESTER II						
MPG 201T	Medicinal Plant biotechnology	10	15	1 Hr	25	75	3 Hrs	100
MPG 202T	Advanced Pharmacognosy-II	10	15	1 Hr	25	75	3 Hrs	100
MPG 203T	Indian system of medicine	10	15	1 Hr	25	75	3 Hrs	100
MPG 204T	Herbal cosmetics	10	15	1 Hr	25	75	3 Hrs	100
MPG 205P	Pharmacognosy Practical II	20	30	6 Hrs	50	100	6 Hrs	150
MPG302S	Seminar /Assignment	-	-	-	-	-	-	100
			Total					650

Scheme for awarding internal assessment

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

Guidelines for the allotment of marks for attendance#

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

MASTER OF PHARMACY (SEMESTER SYSTEM)
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M. Pharm. (Pharmaceutics) III Semester			
Course Code	Course	Credit Hours	Credit Points
MRM301T	Research Methodology and Biostatistics*	4	4
MPH303S	Journal club	1	1
MPH304S	Discussion / Presentation (Proposal Presentation)	2	2
MPH305S	Research Work	28	14
Total		35	21
*** Non University Exam**			

M. Pharm. (Pharmaceutical Chemistry) III Semester			
Course Code	Course	Credit Hours	Credit Points
MRM 301T	Research Methodology and Biostatistics*	4	4
MPC303S	Journal club	1	1
MPC304S	Discussion / Presentation (Proposal Presentation)	2	2
MPC305S	Research Work	28	14
Total		35	21
*** Non University Exam**			

M. Pharm. (Pharmacology) III Semester			
Course Code	Course	Credit Hours	Credit Points
MRM301T	Research Methodology and Biostatistics*	4	4
MPL303S	Journal club	1	1
MPL304S	Discussion / Presentation (Proposal Presentation)	2	2
MPL305S	Research Work	28	14
Total		35	21
*** Non University Exam**			

M. Pharm. (Pharmacognosy) III Semester			
Course Code	Course	Credit Hours	Credit Points
MRM301T	Research Methodology and Biostatistics*	4	4
MPG303S	Journal club	1	1
MPG304S	Discussion / Presentation (Proposal Presentation)	2	2
MPG305S	Research Work	28	14
Total		35	21
*** Non University Exam**			

MASTER OF PHARMACY (SEMESTER SYSTEM)
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M. Pharm. (Pharmaceutics) IV Semester			
Course Code -	Course	Credit Hours	Credit Points
MPH401S	Journal Club	1	1
MPH402S	Research Work	31	16
MPH403S	Discussion/Final Presentation	3	3
	Total	35	20
MPH404S	Co-curricular Activities (Attending Conference, Scientific Presentations and Other Scholarly Activities)	-	7* MAXIMUM

M. Pharm. (Pharmaceutical Chemistry) IV Semester			
Course Code -	Course	Credit Hours	Credit Points
MPC401S	Journal Club	1	1
MPC402S	Research Work	31	16
MPC403S	Discussion/Final Presentation	3	3
	Total	35	20
MPC404S	Co-curricular Activities (Attending Conference, Scientific Presentations and Other Scholarly Activities)	-	7* MAXIMUM

M. Pharm. (Pharmacology) IV Semester			
Course Code -	Course	Credit Hours	Credit Points
MPL401S	Journal Club	1	1
MPL402S	Research Work	31	16
MPL403S	Discussion/Final Presentation	3	3
	Total	35	20
MPL404S	Co-curricular Activities (Attending Conference, Scientific Presentations and Other Scholarly Activities)	-	7* MAXIMUM

M. Pharm. (Pharmacognosy) IV Semester			
Course Code -	Course	Credit Hours	Credit Points
MPG401S	Journal Club	1	1
MPG402S	Research Work	31	16
MPG403S	Discussion/Final Presentation	3	3
	Total	35	20
MPG404S	Co-curricular Activities (Attending Conference, Scientific Presentations and Other Scholarly Activities)	-	7* MAXIMUM

MASTER OF PHARMACY (SEMESTER SYSTEM)
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Semester wise credits distribution

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

***Guidelines for Awarding Credit Points for Co-curricular Activities**

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

Note: International Conference: Held Outside India
International Journal: The Editorial Board outside India

MASTER OF PHARMACY (SEMESTER-I)
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MPH101T: MODERN PHARMACEUTICAL ANALYSIS

Max. Marks: 75
Internal Assessment: 25
Total Marks: 100

Scope

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

Objectives

After completion of course student is able to know,

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

THEORY 60 HOURS

11 Hrs

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

   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, Factors affecting fluorescence, Quenchers, Instrumentation and Applications of fluorescence spectrophotometer

   Flame emission spectroscopy and Atomic absorption spectroscopy: Principle, Instrumentation, Interferences and Applications.
2. **NMR spectroscopy**: Quantum numbers and their role in NMR, Principle, Instrumentation, Solvent requirement in NMR, Relaxation process, NMR signals in various compounds, Chemical shift, Factors influencing chemical shift, Spin-Spin coupling, Coupling constant, Nuclear magnetic double resonance, Brief outline of principles of FT-NMR and ^{13}C NMR. Applications of NMR spectroscopy.

11 Hrs

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

11 Hrs

4. **Chromatography**: Principle, apparatus, instrumentation, chromatographic parameters, factors affecting resolution and applications of the following:
   a) Paper chromatography
   b) Thin Layer chromatography
   c) Ion exchange chromatography
   d) Column chromatography
   e) Gas chromatography
   f) High Performance Liquid chromatography
   g) Affinity chromatography

11 Hrs

5. **Electrophoresis**: Principle, Instrumentation, Working conditions, factors affecting separation and applications of the following:
   a) Paper electrophoresis
   b) Gel electrophoresis
   c) Capillary electrophoresis
   d) Zone electrophoresis
   e) Moving boundary electrophoresis
   f) Iso electric focusing

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.

5 Hrs

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

REFERENCES

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

MASTER OF PHARMACY (SEMESTER-I)
(Credit Based Evaluation & Grading System)

MPH102T: DRUG DELIVERY SYSTEM

Max. Marks: 75
Internal Assessment: 25
Total Marks: 100

SCOPE

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

OBJECTIVES

Upon completion of the course, student shall be able to understand the various approaches for development of novel drug delivery systems. The criteria for selection of drugs and polymers for the development of The formulation and evaluation of Novel drug delivery systems..

THEORY **60 Hrs**

10 Hrs

1. **SR/CR formulation:** Introduction & basic concepts, advantages/ disadvantages, factors influencing, Physicochemical & biological approaches for SR/CR formulation, Mechanism of Drug Delivery from SR/CR formulation. Polymers: introduction, definition, classification, properties and application Dosage Forms for Personalized Medicine: Introduction, Definition, Pharmacogenetics, Categories of Patients for Personalized Medicines: Customized drug delivery systems, Bioelectronic Medicines,3D printing of pharmaceuticals, Telepharmacy.

10 HRs

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

10 Hrs

4 **Occular Drug Delivery Systems**: Barriers of drug permeation, Methods to overcome barriers

6 Hrs

5 **Trans Dermal Drug Delivery Systems:** Structure of skin and barriers, Penetration enhancers, Transdermal Drug Delivery Systems, Formulation and evaluation

10 Hrs

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

8 Hrs

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

6 Hrs

REFERENCES

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

JOURNALS

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

MASTER OF PHARMACY (SEMESTER-I)
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MPH103T: MODERN PHARMACEUTICS

Max. Marks: 75
Internal Assessment: 25
Total Marks: 100

Scope

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

Objectives

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

To understand the elements of preformulation studies.

To understand the Active Pharmaceutical Ingredients and Generic drug Product development

To learn Industrial Management and GMP Considerations.

To understand Optimization Techniques & Pilot Plant Scale Up Techniques To study Stability Testing, sterilization process & packaging of dosage forms.

THEORY **60 HRS**

10 Hrs

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

10 Hrs

2. **Optimization techniques in Pharmaceutical Formulation**: Concept and parameters of optimization, Optimization techniques in pharmaceutical formulation and processing. Statistical design, Response surface method, Contour designs, Factorial designs and application in formulation.

10 Hrs

3. **Validation:** Introduction to Pharmaceutical Validation, Scope & merits of Validation, Validation and calibration of Master plan, ICH & WHO guidelines for calibration and validation of equipments, Validation of specific dosage form, Types of validation. Government regulation, Manufacturing Process Model, URS, DQ, IQ, OQ & P.Q. of facilities **10Hrs**
4. **cGMP & Industrial Management**: Objectives and policies of current good manufacturing practices, layout of buildings, services, equipments and their maintenance Production management: Production organization, materials management, handling and transportation, inventory management and control, production and planning control, Sales forecasting, budget and cost control, industrial and personal relationship. Concept of Total Quality Management

5. **Compression and compaction:** Physics of tablet compression, compression, consolidation, effect of friction, distribution of forces, compaction profiles. Solubility enhancement techniques.

10 Hrs

6. **Study of consolidation parameters;** Diffusion parameters, Dissolution parameters and Pharmacokinetic parameters, Heckal plats, Similarity factors – f2 and f1, Higuchi and peppas plot, Linearity Concept of significance, Standard deviation , chi square test , student T-test , Anova test. **10Hrs**

REFERENCES

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

MASTER OF PHARMACY (SEMESTER-I)
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MPH104T: PHARMACEUTICAL REGULATORY AFFAIR

Max. Marks: 75
Internal Assessment: 25
Total Marks: 100

Scope

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

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

Objectives:

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

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

THEORY **60 Hr**

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

   11 Hrs
2. **Regulatory requirement for product approval**: API, biologics, novel, therapies obtaining NDA, ANDA for generic drugs ways and means of US registration for foreign drugs **12Hrs**
3. CMC, post approval regulatory affairs. Regulation for combination products and medical devices.CTD and ECTD format, industry and FDA liaison.
   ICH - Guidelines of ICH-Q,S E,M.
   Regulatory requirements of EU, MHRA, TGA and ROW countries. **12Hrs**

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

5. **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. **12Hrs**

REFERENCES

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

MPH105P: Pharmaceutics Practical I

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

MASTER OF PHARMACY (SEMESTER-I)
(Credit Based Evaluation & Grading System)

MPC 101T: MODERN PHARMACEUTICAL ANALYTICAL TECHNIQUES

Max. Marks: 75
Internal Assessment: 25
Total Marks: 100

Scope

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

Objectives

After completion of course student is able to know about chemicals and excipients
The analysis of various drugs in single and combination dosage forms Theoretical and practical skills of the instruments

THEORY **60 Hrs**

1. a. UV-Visible spectroscopy: Introduction, Theory, Laws, Instrumentation associated with UV-Visible spectroscopy, Choice Hrs of solvents and solvent effect and Applications of UV-Visible spectroscopy, Difference/ Derivative spectroscopy.
   b. IR spectroscopy: Theory, Modes of Molecular vibrations, Sample handling, Instrumentation of Dispersive and Fourier - Transform IR Spectrometer, Factors affecting vibrational frequencies and Applications of IR spectroscopy, Data Interpretation.
   c. Spectroflourimetry: Theory of Fluorescence, Factors affecting fluorescence (Characterestics of drugs that can be analysed by flourimetry), Quenchers, Instrumentation and Applications of fluorescence spectrophotometer.
   d. Flame emission spectroscopy and Atomic absorption spectroscopy: Principle, Instrumentation, Interferences and Applications.

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

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

4 Chromatography: Principle, apparatus, instrumentation, **10 Hrs**

chromatographic parameters, factors affecting resolution, isolation of drug from excipients, data interpretation and applications of the following:

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

5 a. Electrophoresis: Principle, Instrumentation, Working conditions, factors affecting separation and applications of the following: 10 Hrs
a) Paper electrophoresis b) Gel electrophoresis c) Capillary electrophoresis d) Zone electrophoresis e) Moving boundary electrophoresis f) Iso electric focusing

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

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

b. Thermal Techniques: Principle, thermal transitions and

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

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

REFERENCES

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

MASTER OF PHARMACY (SEMESTER-I)
(Credit Based Evaluation & Grading System)

MPC102T: ADVANCED ORGANIC CHEMISTRY-I

Max. Marks: 75
Internal Assessment: 25
Total Marks: 100

Scope

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

Objectives

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

The principles and applications of reterosynthesis

The mechanism & applications of various named reactions

The concept of disconnection to develop synthetic routes for small target molecule. The various catalysts used in organic reactions

The chemistry of heterocyclic compounds

THEORY **60 Hrs**

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

    Addition reactions

    a) Nucleophilic uni- and bimolecular reactions (SN1 and SN2)
    b) Elimination reactions (E1 & E2; Hoffman & Saytzeff's rule)
    c) Rearrangement reaction

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

Ugi reaction, Brook rearrangement, Ullmann coupling reactions, Dieckmann Reaction, Doebner-Miller Reaction, Sandmeyer Reaction, Mitsunobu reaction, Mannich reaction, Vilsmeyer-Haack Reaction, Sharpless asymmetric epoxidation, Baeyer-Villiger oxidation, Shapiro & Suzuki reaction, Ozonolysis and Michael addition reaction

3 Synthetic Reagents & Applications: 12 Hrs

Aluminiumisopropoxide, N-bromosuccinamide, diazomethane,

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

Protecting groups

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

4 Heterocyclic Chemistry: 12 Hrs.

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

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

5 Synthon approach and retrosynthesis applications 12 Hrs.

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

REFERENCES

1. "Advanced Organic chemistry, Reaction, mechanisms and structure", J March, John Wiley and sons, New York.
2. "Mechanism and structure in organic chemistry", ES Gould, Hold Rinchart and Winston, New York.
3. "Organic Chemistry" Clayden, Greeves, Warren and Woihers., Oxford University Press 2001.
4. "Organic Chemistry" Vol I and II. I.L. Finar. ELBS, Sixth ed., 1995.
5. A guide to mechanisms in Organic Chemistry – Peter Skyes (Orient Longman, New Delhi).
6. Reactive intermediates in organic chemistry – Tandom and Gowel.
7. Combinational Chemistry – Synthesis and applications – Stephen R Wilson & Anthony W Czarnik.
8. Carey, Organic chemistry, 5th edition (Viva Books Pvt. Ltd.)
9. Organic synthesis-The disconnection approach, S. Warren, Wily India
10. Principles of organic synthesis, ROC Norman and JM Coxan, Nelson thorns
11. Organic synthesis- Special techniques VK Ahluwalia and R Agarwal, Narosa Publishers
12. Organic reaction mechanisms IV edtn, VK Ahluwalia and RK Parashar, Narosa Publishers

MASTER OF PHARMACY (SEMESTER-I)
(Credit Based Evaluation & Grading System)

MPC103T: ADVANCED MEDICINAL CHEMISTRY

Max. Marks: 75
Internal Assessment: 25
Total Marks: 100

Scope

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

Objectives

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

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

THEORY 60 Hrs

1. **Drug discovery:** Stages of drug discovery, lead discovery; identification, validation and diversity of drug targets. Chemistry of prostaglandins, leukotrienes and thromboxones.
   Biological drug targets: Receptors, types, binding and activation, theories of drug receptor interaction, drug receptor interactions, agonists vs antagonists, artificial enzymes. **12Hrs**
2. **Prodrug Design and Analog design:**
   Prodrug design: Basic concept, Carrier linked prodrugs/ Bioprecursors, Prodrugs of functional group, Prodrugs to improve patient acceptability, Drug solubility, Drug absorption and distribution, site specific drug delivery and sustained drug action. Rationale of prodrug design and practical consideration of prodrug design.
   Combating drug resistance: Causes for drug resistance, strategies to combat drug resistance in antibiotics and anticancer therapy, Genetic principles of drug resistance.
   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. **12Hrs**
3. **Chemistry of Synthetic drugs:** Systematic study, SAR, Mechanism of action and synthesis of new generation molecules of following class of drugs: Anti-hypertensive drugs, Psychoactive drugs, Anticonvulsant drugs, H1 & H2 receptor antagonist, COX1 & COX2 inhibitors, Adrenergic & Cholinergic agents, Antineoplastic and Antiviral agents.
   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.

   12 Hrs

4. **Rational Design of Enzyme Inhibitors:** Enzyme kinetics & Principles of Enzyme inhibitors**,** Enzyme inhibitors in medicine, Enzyme inhibitors in basic research, rational design of non-covalently and covalently binding enzyme inhibitors. **12 Hrs**
5. **Peptidomimetics:** Therapeutic values of Peptidomimetics, design of peptidomimetics by manipulation of the amino acids, modification of the peptide backbone, incorporating conformational constraints locally or globally. **12Hrs**

REFERENCES:

1. Medicinal Chemistry by Burger.
2. Wilson and Gisvold's Text book of Organic Medicinal and Pharmaceutical Chemistry.
3. Comprehensive Medicinal Chemistry – Corwin and Hansch.
4. Computational and structural approaches to drug design edited by Robert M Stroud and Janet. F Moore
5. Introduction to Quantitative Drug Design by Y.C. Martin.
6. Principles of Medicinal Chemistry by William Foye.
7. Drug Design Volumes by Arienes.
8. Principles of Drug Design by Smith.
9. The Organic Chemistry of the Drug Design and Drug action by Richard B.Silverman.
10. An Introduction to Medicinal Chemistry –Graham L.Patrick, (III Edition.)
11. Biopharmaceutics and pharmacokinetics by DM.Brahmankar, Sunil B .Jaiswal.
12. Peptidomimetics in Organic and Medicinal Chemistry by Antonio Guarna and Andrea Trabocchi, First edition, Wiley publishers.

MASTER OF PHARMACY (SEMESTER-I)
(Credit Based Evaluation & Grading System)

MPC104T: CHEMISTRY OF NATURAL PRODUCTS

Max. Marks: 75
Internal Assessment: 25
Total Marks: 100

Scope

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

Objectives

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

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

THEORY **60 Hrs**

1. Study of Natural products as leads for new pharmaceuticals for the following class of drugs:

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))

12Hrs

2 a) Alkaloids **12 Hrs**

General introduction, classification, isolation, purification, molecular modification and biological activity of alkaloids, general methods of structural determination of alkaloids, structural elucidation and stereochemistry of ephedrine, morphine, ergot, emetine and reserpine.

Flavonoids

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

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

3 a) Terpenoids 12 Hrs
Classification, isolation, isoprene rule and general methods of structural elucidation of Terpenoids; Structural elucidation of drugs belonging to mono (citral, menthol, camphor), di(retinol, Phytol, taxol) and tri terpenoids (Squalene,Ginsenoside) carotinoids (β carotene).

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

4 a). Recombinant DNA technology and drug discovery 12 Hrs
rDNA technology, hybridoma technology, New pharmaceuticals derived from biotechnology; Oligonucleotide therapy. Gene therapy: Introduction, Clinical application and recent advances in gene therapy, principles of RNA & DNA estimation

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

5 Structural Characterization of natural compounds 12 Hrs
Structural characterization of natural compounds using IR, 1HNMR, 13CNMR and MS Spectroscopy of specific drugs e.g., Penicillin, Morphine, Camphor, Vit-D, Quercetin and Digitalis glycosides.

REFERENCES

1. Modern methods of plant analysis – Peech and M.V.Tracey.
2. Phytochemistry Vol. I and II by Miller, Jan Nostrant Rein Hld.
3. Recent advances in Phytochemistry Vol. I to IV – Scikel Runeckles.
4. Chemistry of natural products Vol I onwards IWPAC.
5. Natural Product Chemistry Nakanishi Gggolo.
6. Natural Product Chemistry "A laboratory guide" – Rapheal Khan.
7. The Alkaloid Chemistry and Physiology by THF Manske.
8. Introduction to molecular Phytochemistry – CHJ Wells, Chapmannstall.
9. Organic Chemistry of Natural Products Vol I and II by Gurdeep and Chatwall.
10. Organic Chemistry of Natural Products Vol I and II by O.P. Agarwal.
11. Organic Chemistry Vol I and II by I.L. Finar
12. Elements of Biotechnology by P.K. Gupta.
13. Pharmaceutical Biotechnology by S.P.Vyas and V.K.Dixit.
14. Biotechnology by Purohit and Mathoor.
15. Phytochemical methods of Harborne.
16. Burger's Medicinal Chemistry.

MASTER OF PHARMACY (SEMESTER-I)
(Credit Based Evaluation & Grading System)

MPC105P: Pharmaceutical Chemistry Practical I

1. Analysis of pharmacopeial 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

MASTER OF PHARMACY (SEMESTER-I)
(Credit Based Evaluation & Grading System)

MPL 101T: MODERN PHARMACEUTICAL ANALYTICAL TECHNIQUES

Max. Marks: 75
Internal Assessment: 25
Total Marks: 100

Scope

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

Objectives

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

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

THEORY **60 Hrs**

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

e. 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.

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

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

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

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

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

REFERENCES

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

MASTER OF PHARMACY (SEMESTER-I)
(Credit Based Evaluation & Grading System)

MPL102T: ADVANCED PHARMACOLOGY-I

Max. Marks: 75
Internal Assessment: 25
Total Marks: 100

Scope

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

Objectives

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

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

THEORY **60HOURS**

UNIT-I

General Pharmacology **12Hrs**

a. **Pharmacokinetics:** The dynamics of drug absorption, distribution, biotransformation and elimination. Concepts of linear and non-linear compartment models. Significance of Protein binding. 06 hrs

b. **Pharmacodynamics:** Mechanism of drug action and the relationship between drug concentration and effect. Receptors, structural and functional families of receptors, quantitation of drug receptors interaction and elicited effects. 06 hrs

UNIT-II **12 Hrs**

Neurotransmission 6**Hrs**

a. General aspects and steps involved in neurotransmission.

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

c. Neurohumoral transmission in central nervous system (Detailed study about neurotransmitters- histamine, serotonin, dopamine, GABA, glutamate and glycine]. d. Non adrenergic non cholinergic transmission (NANC). Co-transmission

Systemic Pharmacology **06 Hrs**

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

a. Autonomic Pharmacology

Parasympathomimetics and lytics, sympathomimetics and lytics, agents affecting neuromuscular junction

UNIT-III **12 Hrs**

Central nervous system Pharmacology

General and local anesthetics 02 hrs

Sedatives and hypnotics, drugs used to treat anxiety. 02 hrs

Depression, psychosis, mania, epilepsy, neurodegenerative diseases. 05 hrs

Narcotic and non-narcotic analgesics. 03 hrs

UNIT-IV

Cardiovascular Pharmacology **12 Hrs**

Diuretics, antihypertensives, antiischemics, anti- arrhythmics, drugs for heart failure and hyperlipidemia. 07 hrs

Hematinics, coagulants, anticoagulants, fibrinolytics and anti-platelet drugs 05 hrs

UNIT- V

Autocoid Pharmacology **12 Hrs**

The physiological and pathological role of Histamine, Serotonin, Kinins Prostaglandins

Opioid autocoids. 08 hrs

Pharmacology of antihistamines, 5HT antagonists. 04 hrs

REFEERENCES

1 The Pharmacological basis of therapeutics- Goodman and Gill man‘s
2 Principles of Pharmacology. The Pathophysiologic basis of drug Therapy by David E Golan et al.
3 Basic and Clinical Pharmacology by B.G –Katzung
4 Pharmacology by H.P. Rang and M.M. Dale.
5 Hand book of Clinical Pharmacokinetics by Gibaldi and Prescott
6 Text book of Therapeutics, drug and disease management by E T. Herfindal and Gourley.
7 Applied biopharmaceutics and Pharmacokinetics by Leon Shargel and Andrew B.C.Yu.
8 Handbook of Essential Pharmacokinetics, Pharmacodynamics and Drug Metabolism for Industrial Scientists

MASTER OF PHARMACY (SEMESTER-I)
(Credit Based Evaluation & Grading System)

MPL103T: PHARMACOLOGICAL AND TOXICOLOGICAL SCREENING METHODS-I

Max. Marks: 75
Internal Assessment: 25
Total Marks: 100

Scope

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

Objectives

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

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

THEORY **60 HOURS**

Unit-I **12 Hrs**

Laboratory Animals

Common lab animals: Description, handling and applications of different species and strains of animals. 02 hrs
Transgenic animals: Production, maintenance and applications 02 hrs
Anaesthesia and euthanasia of experimental animals. 03 hrs
Maintenance and breeding of laboratory animals. 02 hrs
CPCSEA guidelines to conduct experiments on animals 02 hrs
Good laboratory practice. 01 hrs
Bioassay-Principle, scope and limitations and methods

Unit-II **12 Hrs**

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

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

Unit-III **12 Hrs**

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

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

Unit-IV **12 hrs**

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

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

Unit V **12 hrs**

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

Immunosuppressants and immunomodulators and immunostimulants 02 hrs
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 08 hrs
Limitations of animal experimentation and alternate animal experiments. 01 hr
Extrapolation of *in vitro* data to preclinical and preclinical to humans. 01 hr

REFERENCES

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

MASTER OF PHARMACY (SEMESTER-I)
(Credit Based Evaluation & Grading System)

MPL104T: CELLULAR AND MOLECULAR PHARMACOLOGY

Max. Marks: 75
Internal Assessment: 25
Total Marks: 100

Scope:

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

Objectives:

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

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

Unit I **12 Hrs**

Cell biology

Structure and functions of cell and its organelles

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.

Unit II **12Hrs**

Cell signaling

Intercellular and intracellular signaling pathways.

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

Secondary messengers: cyclic AMP, cyclic GMP, calcium ion, inositol 1,4,5-trisphosphate, (IP3), NO, and diacylglycerol.

Detailed study of following intracellular signaling pathways: cyclic AMP signaling pathway, mitogen-activated protein kinase (MAPK) signaling, Janus kinase (JAK)/signal transducer and activator of transcription (STAT) signaling pathway.

Unit III **12Hrs**

Principles and applications of genomic and proteomic tools **06 hrs**

DNA electrophoresis, PCR (reverse transcription and real time), Gene sequencing, micro array technique, SDS page, ELISA and western blotting,

Recombinant DNA technology and gene therapy **06 hrs**

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

Unit IV **12Hrs**

Pharmacogenomics **08 hrs**

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

04 hrs

Immunotherapeutics

Types of immunotherapeutics, humanisation antibody therapy, Immunotherapeutics in clinical practice

Unit V **12Hrs**

Cell culture techniques

Basic equipments used in cell culture lab. Cell culture media, various types of cell culture, general procedure for cell cultures; isolation of cells, subculture, cryopreservation, characterization of cells and their application.

Principles and applications of cell viability assays, glucose uptake assay, Calcium influx assays

Principles and applications of flow cytometry

Unit VI

Biosimilars

References:

1. The Cell, A Molecular Approach. Geoffrey M Cooper.
2. Pharmacogenomics: The Search for Individualized Therapies. Edited by J. Licinio and M -L. Wong
3. Handbook of Cell Signaling (Second Edition) Edited by Ralph A. et.al
4. Molecular Pharmacology: From DNA to Drug Discovery. John Dickenson et.al
5. Basic Cell Culture protocols by Cheril D.Helgason and Cindy L.Miller
6. Basic Cell Culture (Practical Approach) by J. M. Davis (Editor)
7. Animal Cell Culture: A Practical Approach by John R. Masters (Editor)
8. Current porotocols in molecular biology vol I to VI edited by Frederick M.Ausuvel et la.

Pharmacology Practical I

MPL105P: Experimental Pharmacology- I

1 Analysis of pharmacopeial compounds and their formulations by UV Vis spectrophotometer
2 Simultaneous estimation of multi component containing formulations by UV spectrophotometry
3 Experiments based on HPLC
4 Experiments based on Gas Chromatography
5 Estimation of riboflavin/quinine sulphate by fluorimetry
6 Estimation of sodium/potassium by flame photometry

Handling of laboratory animals.

1. Various routes of drug administration.
2. Techniques of blood sampling, anesthesia and euthanasia of experimental animals.
3. Functional observation battery tests (modified Irwin test)
4. Evaluation of CNS stimulant, depressant, anxiogenics and anxiolytic, anticonvulsant activity.
5. Evaluation of analgesic, anti-inflammatory, local anesthetic, mydriatic and miotic activity.
6. Evaluation of diuretic activity.
7. Evaluation of antiulcer activity by pylorus ligation method.
8. Oral glucose tolerance test.
9. Isolation and identification of DNA from various sources (Bacteria, Cauliflower, onion, Goat liver).
10. Isolation of RNA from yeast
11. Estimation of proteins by Braford/Lowry's in biological samples.
12. Estimation of RNA/DNA by UV Spectroscopy
13. Gene amplification by PCR.
14. Protein quantification Western Blotting.
15. Enzyme based *in-vitro* assays (MPO, AChEs, α amylase, α glucosidase).
16. Cell viability assays (MTT/Trypan blue/SRB).
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)

References

1. CPCSEA, OECD, ICH, USFDA, Schedule Y, EPA guidelines,
2. Fundamentals of experimental Pharmacology by M.N.Ghosh
3. Handbook of Experimental Pharmacology by S.K. Kulkarni.
4. Drug discovery and Evaluation by Vogel H.G.
5. Spectrometric Identification of Organic compounds - Robert M Silverstein,
6. Principles of Instrumental Analysis - Doglas A Skoog, F. James Holler, Timothy A. Nieman,
7. Vogel‘s Text book of quantitative chemical analysis - Jeffery, Basset, Mendham, Denney,
8. Basic Cell Culture protocols by Cheril D. Helgason and Cindy L.Mille
9. Basic Cell Culture (Practical Approach) by J. M. Davis (Editor)
10. Animal Cell Culture: A Practical Approach by John R. Masters (Editor)

MASTER OF PHARMACY (SEMESTER-I)
(Credit Based Evaluation & Grading System)

MPL 101T: MODERN PHARMACEUTICAL ANALYTICAL TECHNIQUES

Max. Marks: 75
Internal Assessment: 25
Total Marks: 100

Scope

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

Objectives

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

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

THEORY **60 Hrs**

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

   h. 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.

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

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

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

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

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

REFERENCES

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

MASTER OF PHARMACY (SEMESTER-I)
(Credit Based Evaluation & Grading System)

MPG102 T: ADVANCED PHARMACOGNOSY-1

Max. Marks: 75
Internal Assessment: 25
Total Marks: 100

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

1. Know the advances in the cultivation and production of drugs
2. Know the various phyto-pharmaceuticals and their source & utilization and medicinal value.
3. Know the various nutraceuticals/herbs and their health benefits

THEORY **60 Hours**

1 **Plant drug cultivation:** General introduction to the importance of Pharmacognosy in herbal drug industry, Indian Council of Agricultural Research, Current good agricultural practices, Current good cultivation practices, Current good collection practices, Conservation of medicinal plants- *Ex-situ* and *In-situ* conservation of medicinal plants. **12 Hr**

2 **Marine natural products:** General methods of isolation and purification, Study of Marine toxins, Recent advances in research in marine drugs, Problems faced in research on marine drugs such as taxonomical identification, chemical screening and their solution. **12Hrs**

3 **Nutraceuticals:** Current trends and future scope, Inorganic mineral supplements, Vitamin supplements, Digestive enzymes, Dietary fibres, Cereals and grains, Health drinks from natural origin, Antioxidants, Polyunsaturated fatty acids, Herbs as functional foods, Formulation and standardization of neutraceuticals, Regulatory aspects, FSSAI guidelines, Sources, name of marker compounds and their chemical nature, medicinal uses and health benefits of following i) Spirulina ii) Soya bean iii) Ginseng iv) Garlic v) Broccoli vi) Green and Herbal Tea vii) Flax seeds viii) Black cohosh ix) Turmeric. **12Hrs**

4 **Phytopharmaceuticals:** Occurrence, isolation and characteristic features (Chemical nature, uses in pharmacy, medicinal and 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 AYUSH guidelines for safety monitoring of natural medicine, Spontaneous reporting schemes for biodrug adverse reactions, bio drug-drug and bio drug-food interactions with suitable examples.

12Hrs

REFERENCES:

1) Cultivation of medicinal and aromatic crops, 1st edition, by AA Farooqui and B.S. Sreeramu. University Press, 2001.
2) Medicinal natural products (a biosynthetic approach), 1st edition, by Paul M. Dewick, John Wiley & Sons Ltd., England, 1998.
3) Natural Products from Plants, 1st edition, by Peter B. Kaufman, CRC Press, New York, 1998
4) Glimpses of Indian Ethano Pharmacology by P. Pushpangadam. Ulf Nyman. V.George Tropical Botanic Garden & Research Institute, 1995.
5) Natural products: A lab guide by Raphael Ikan , 2nd Edition, Academic Press 1991.
6) Pharmacognosy - G. E. Trease and W.C. Evans. 15th Edition W.B. Saunders Edinburgh, New York.
7) Pharmacognosy-Tyler, Brady, Robbers
8) Modem Methods of Plant Analysis- Peach & M.V. Tracey, Vol. I&II
9) Recent Advances in Phytochemistry- Vol. 1&4: Scikel Runeckles- Appleton Century crofts.
10) Chemistry of Marine Natural Products- Paul J. Schewer 1973.
11) Marine Natural Products-Vol.I to IV.
12) Cultivation of Medicinal Plants by C.K. Atal & B.M. Kapoor.
13) Cultivation and Utilization of Aromatic Plants By C.K. Atal & B.M. Kapoor
14) Herbal Drug Industry by RD. Choudhary, 1st edition, Eastern Publisher, New Delhi, 1996.
15) Text book of Pharmacognosy by C.K.Kokate, Purohit, Ghokhale, 4th edition, Nirali Prakasshan, 1996.
16) Pharmacognosy and Pharmacobiotechnology by Ashutoshkar, New Age Publications, New Delhi.
17) Text Book of Pharmacognosy by T.E. Wallis

MASTER OF PHARMACY (SEMESTER-I)
(Credit Based Evaluation & Grading System)

MPG103T: PHYTOCHEMISTRY

Max. Marks: 75
Internal Assessment: 25
Total Marks: 100

Scope:

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

Objectives:

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

1. know the different classes of phytoconstituents and their properties and general process of natural product drug discovery
2. know the process isolation, purification and identification of phytoconstituents

THEORY **60Hrs**

1. **Biosynthetic pathways and Radio tracing techniques:** Constituents & their Biosynthesis, Isolation, Characterization and purification with a special reference to their importance in herbal industries of following phyto-pharmaceuticals containing drugs:

    a) Alkaloids: Ephedrine, Quinine, Strychynine, Piperine, Berberine, Taxol, Vincaalkoloids.
    b) Glycosides: Digitoxin, Glycyrrhizin, Sennosides, Bacosides, Ginsenosides, Quercitin, Rutin.
    c) Steroids: Hecogenin, guggulosterone and withanolides
    d) Coumarin: Umbelliferone.
    e) Terpenoids: Cucurbitacins

    12Hrs

2. **Drug discovery and development:** History of herbs as source of drugs and drug discovery, the lead structure selection process, structure development, product discovery process and drug registration, Selection and optimization of lead compounds with suitable examples from anticancer, CNS cardiovascular drugs, antitubercular drugs and immunomodulators, Clinical studies emphasis on phase of clinical trials, protocol design for lead molecules. **12Hrs**

3. **Extraction and Phytochemical studies:** Recent advances in extractions with emphasis on selection of method and choice of Hrs solvent for extraction, successive and exhaustive extraction and other methods of extraction commonly used like microwave

assisted extraction, Methods of fractionation. Separation of phytoconstituents by latest CCCET, SCFE techniques including preparative HPLC and Flash column chromatography.

4	Phytochemical finger printing: HPTLC and LCMS/GCMS applications in the characterization of herbal extracts. Structure elucidation of phytoconstituents.	12 Hrs
5	Structure elucidation of the following compounds by spectroscopic techniques like UV, IR, MS, NMR (1H, 13C) a. Carvone, Citral, Menthol b. Luteolin, Kaempferol c. Nicotine, Caffeine iv) Glycyrrhizin.	12 Hrs

REFERENCES:

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

MASTER OF PHARMACY (SEMESTER-I)
(Credit Based Evaluation & Grading System)

MPG104T: INDUSTRIAL PHARMACOGNOSTICAL TECHNOLOGY

Max. Marks: 75
Internal Assessment: 25
Total Marks: 100

Scope:

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

Objective:

By the end of the course the student shall be able to:-

1. Know the requirements for setting up the herbal/natural drug industry.
2. To know and understand the guidelines for quality of herbal/natural medicines and regulatory issues.
3. To know patenting/IPR of herbals/natural drugs and trade of raw and finished materials.

THEORY **60Hrs**

1. **Herbal drug industry:** Infrastructure of herbal drug industry involved in production of standardized extracts and various dosage forms. Current challenges in upgrading and modernization of herbal formulations. Entrepreneurship Development, Project selection, project report, technical knowledge, Capital venture, plant design, layout and construction. Pilot plant scale –up techniques, case studies of herbal extracts. Formulation production management. **12Hrs**

2. **Regulatory requirements for setting herbal drug industry:** Global marketing management. Indian and international patent law as applicable herbal drugs and natural products.

   Export –import (EXIM) policy, TRIPS, IPR. Quality assurance in herbal/natural drug products. Concepts of TDM, GMP, GLP, ISO-9000. **12Hrs**

3. **Monographs of herbal drugs:** Study of monographs of herbal drugs and comparative study in IP, USP, Ayurvedic pharmacopoeia, American herbal pharmacopoeia, British herbal pharmacopoeia, Siddha and Unani Pharmacopoeia, WHO guidelines in quality assessment of herbal drugs. **12Hrs**
4. **Testing of natural products and drugs:** Effect of herbal medicines on clinical laboratory testing. Regulation and dispensing of herbal drugs. Stability testing of natural products, protocols. **12 Hrs**

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

REFERENCES:

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

MASTER OF PHARMACY (SEMESTER-I)
(Credit Based Evaluation & Grading System)

Pharmacognosy Practical I

PRACTICALS (MPGI05P)

1. Analysis of pharmacopoeial compounds of natural origin and their formulations by UV Vis spectrophotometer
2. Simultaneous estimation of multi component containing formulations by UV spectrophotometry
3. Analysis of recorded spectra of simple phytoconstituents
4. Experiments based on Gas Chromatography
5. Estimation of sodium/potassium by flame photometry
6. Development of fingerprint of selected medicinal plant extracts commonly used in herbal drug industry viz. ashwagandha, tulsi, bael, amla, ginger, aloe, vidang, senna, lawronia by HPTLC method
7. Method of extraction
8. Phytochemical screening
9. Thin layer chromatography
10. Demonstration of HPLC- estimation of glycyeizin
11. Monograph analysis of clove oil
12. Monograph analysis of castor oil.
13. Identification of bioactive constituents from plant extracts
14. Formulation using qualitative and quantitative methods.

MASTER OF PHARMACY (SEMESTER-II)
(Credit Based Evaluation & Grading System)

MPH201T: MOLECULAR PHARMACEUTICS (NANO TECHNOLOGY & TARGETED DDS)

Max. Marks: 75
Internal Assessment: 25
Total Marks: 100

Scope

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

Objectives

Upon completion of the course student shall be able to understand

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

THEORY **60 Hrs**

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

REFERENCES:

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

Journals

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

MASTER OF PHARMACY (SEMESTER-II)
(Credit Based Evaluation & Grading System)

MPH202T: ADVANCED BIOPHARMACEUTICS & PHARMACOKINETICS

Max. Marks: 75
Internal Assessment: 25
Total Marks: 100

Scope

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

Objectives

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

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

THEORY **60 Hrs**

1. Drug Absorption from the Gastrointestinal Tract: 12 Gastrointestinal tract, Mechanism of drug absorption, Factors Hrs affecting drug absorption, pH–partition theory of drug absorption.

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

MASTER OF PHARMACY (SEMESTER-II)
(Credit Based Evaluation & Grading System)

2	Biopharmaceutic considerations in drug product design and In Vitro Drug Product Performance: Introduction, biopharmaceutic factors affecting drug bioavailability, rate-limiting steps in drug absorption, physicochemical nature of the drug formulation factors affecting drug product performance, in vitro: dissolution and drug release testing, compendial methods of dissolution, alternative methods of dissolution testing,meeting dissolution requirements,problems of variable control in dissolution testingperformance of drug products. In vitro–in vivo correlation, dissolution profile comparisons, drug product stability,considerations in the design of a drug product.	12 Hrs
3	Pharmacokinetics: Basic considerations, pharmacokinetic models, compartment modeling: one compartment model- IV bolus, IV infusion, extra-vascular. Multi compartment model:two compartment - model in brief, non-linear pharmacokinetics: cause of non-linearity, Michaelis – Menten equation, estimation of kmax and vmax. Drug interactions: introduction, the effect of protein-binding interactions,the effect of tissue-binding interactions,cytochrome p450-based drug interactions,drug interactions linked to transporters.	12 Hrs
4	Drug Product Performance, In Vivo: Bioavailability and Bioequivalence: drug product performance, purpose of bioavailability studies, relative and absolute availability. methods for assessing bioavailability, bioequivalence studies, design and evaluation of bioequivalence studies, study designs, crossover study designs, evaluation of the data, bioequivalence example, study submission and drug review process. biopharmaceutics classification system, methods. Permeability: In-vitro, in-situ and In-vivo methods.generic biologics (biosimilar drug products),clinical significance of bioequivalence studies, special concerns in bioavailability and bioequivalence studies, generic substitution.	12 Hrs
5	Application of Pharmacokinetics: Modified-Release Drug Products, Targeted Drug Delivery Systems and Biotechnological Products. Introduction to Pharmacokinetics and pharmacodynamic, drug interactions. Pharmacokinetics and pharmacodynamics of biotechnology drugs. Introduction, Proteins and peptides, Monoclonal antibodies, Oligonucleotides, Vaccines (immunotherapy), Gene therapies.	12 Hrs

REFERENCES:

1. Biopharmaceutics and Clinical Pharmacokinetics by Milo Gibaldi, 4th edition,Philadelphia, Lea and Febiger, 1991
2. Biopharmaceutics and Pharmacokinetics, A. Treatise, D .M. Brahmankar and Sunil B.J aiswal., VallabPrakashan, Pitampura, Delhi
3. Applied Biopharmaceutics and Pharmacokinetics by Shargel. Land YuABC, 2nd edition, Connecticut Appleton Century Crofts, 1985
4. Textbook of Biopharmaceutics and Pharmacokinetics, Dr. Shobha Rani R. Hiremath,Prism Book
5. Pharmacokinetics by Milo Gibaldi and D. Perrier, 2nd edition, Marcel Dekker Inc.,New York, 1982
6. Current Concepts in Pharmaceutical Sciences: Biopharmaceutics, Swarbrick. J, Leaand Febiger, Philadelphia, 1970
7. Clinical Pharmacokinetics, Concepts and Applications 3rd edition by MalcolmRowland and Thom~ N. Tozer, Lea and Febiger, Philadelphia, 1995
8. Dissolution, Bioavailability and Bioequivalence, Abdou. H.M, Mack PublishingCompany, Pennsylvania 1989
9. Biopharmaceutics and Clinical Pharmacokinetics, An Introduction, 4th edition,revised and expande by Robert. E. Notari, Marcel Dekker Inc, New York and Basel,1987.
10. Biopharmaceutics and Relevant Pharmacokinetics by John. G Wagner and M.Pemarowski, 1st edition, Drug Intelligence Publications, Hamilton, Illinois, 1971.
11. Encyclopedia of Pharmaceutical Technology, Vol 13, James Swarbrick, James. G.Boylan, Marcel Dekker Inc, New York, 1996.
12. Basic Pharmacokinetics,1 st edition,Sunil S Jambhekar and Philip J Breen,pharmaceutical press, RPS Publishing,2009.
13. Absorption and Drug Development- Solubility, Permeability, and Charge State, Alex Avdeef, John Wiley & Sons, Inc,2003.

MASTER OF PHARMACY (SEMESTER-II)
(Credit Based Evaluation & Grading System)

MPH203T: COMPUTER AIDED DRUG DELIVERY SYSTEM

Max. Marks: 75
Internal Assessment: 25
Total Marks: 100

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

At 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 **60Hrs**

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

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

   12Hrs

2. **Computational Modeling Of Drug Disposition:** Introduction ,Modeling Techniques: Drug Absorption, Solubility, Intestinal Permeation, Drug Distribution ,Drug Excretion, Active Transport; P-gp, BCRP, Nucleoside Transporters, hPEPT1, ASBT, OCT, OATP, BBB-Choline Transporter.

   12Hrs

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

12Hrs

4. **Computer-aided biopharmaceutical characterization**: Gastrointestinal absorption simulation
   Introduction, Theoretical background, Model construction, Parameter sensitivity analysis, Virtual trial, Fed vs. fasted state, In vitro dissolution and *in vitro-in vivo* correlation, Biowaiver considerations
   Computer Simulations in Pharmacokinetics and Pharmacodynamics:
   Introduction, Computer Simulation: Whole Organism, Isolated Tissues, Organs, Cell, Proteins and Genes.
   Computers in Clinical Development: Clinical Data Collection and Management, Regulation of Computer Systems

12Hrs

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

12Hrs

REFERENCES:

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

MASTER OF PHARMACY (SEMESTER-II)
(Credit Based Evaluation & Grading System)

MPH204T: COSMETICS AND COSMECEUTICALS

Max. Marks: 75
Internal Assessment: 25
Total Marks: 100

Scope

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

Objectives: Upon completion of the course, the students will be able to understand

The key ingredients used in cosmetics and Cosmeceutical.

- The key building blocks for various formulations.
- The current technologies in the market
- The various key ingredients and basic science to develop cosmetics and Cosmeceutical
- The scientific knowledge to develop cosmetics and Cosmeceutical with desired Safety, sensory, stability, and efficacy.

THEORY **60Hrs**

12Hrs

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

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

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

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

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

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

RECOMMENDED BOOKS:

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

MASTER OF PHARMACY (SEMESTER-II)
(Credit Based Evaluation & Grading System)

Pharmaceutics Practical II

PRACTICAL (MPH205P)

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
5. Formulation and evaluation of niosomes
6. Formulation and evaluation of spheruls
7. Improvement of dissolution characteristics of slightly soluble drug by Solid dispersion technique.
8. Comparison of dissolution of two different marketed products /brands
9. Protein binding studies of a highly protein bound drug & poorly protein bound drug
10. Bioavailability studies of Paracetamol.
11. Pharmacokinetic and IVIVC data analysis by Winnoline^{R} software
12. *In vitro* cell studies for permeability and metabolism
13. DoE Using Design Expert® Software
14. Formulation data analysis Using Design Expert® Software
15. Quality-by-Design in Pharmaceutical Development
16. Computer Simulations in Pharmacokinetics
17. Computer Simulations Pharmacodynamics
18. Computational Modeling Of Drug Disposition
19. To develop Clinical Data Collection manual
20. To carry out Sensitivity Analysis, and Population Modeling.
21. Development and evaluation of Creams
22. Development and evaluation of Shampoo and Toothpaste base
23. To Incorprate herbal and chemical actives to develop products
24. To address Dry skin, acne, blemish, Wrinkles, bleeding gums and dandruff

MASTER OF PHARMACY (SEMESTER-II)
(Credit Based Evaluation & Grading System)

MPC201T: ADVANCED SPECTRAL ANALYSIS

Max. Marks: 75
Internal Assessment: 25
Total Marks: 100

Scope

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

Objectives

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

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

THEORY **60Hrs**

1. **UV and IR spectroscopy**: Wood ward – Fiesure rule for 1,3- butadienes, cyclic dienes and α, β-carbonyl compounds and interpretation compounds of enones. ATR-IR, IR Interpretation of organic compounds. **12Hrs**
2. **NMR spectroscopy**: 1-D and 2-D NMR, NOESY and COSY, HECTOR, INADEQUATE techniques, Interpretation of organic compounds. **12Hrs**
3. **Mass Spectroscopy**: Mass fragmentation and its rules, Fragmentation of important functional groups like alcohols, amines, carbonyl groups and alkanes, Meta stable ions, Mc Lafferty rearrangement, Ring rule, Isotopic peaks, Interpretation of organic compounds. **12Hrs**
4. **Chromatography**: Principle, Instrumentation and Applications of the following:
   a. GC-MS
   b. GC-AAS
   c. LC-MS
   d. LC-FTIR
   e. LC-NMR
   f. CE-MS
   g. High Performance Thin Layer chromatography
   h. Super critical fluid chromatography
   i. Ion Chromatography
   j. I-EC (Ion Exclusion Chromatography)
   k. Flash chromatography. **12Hrs**

5. **Thermal methods of analysis** – Introduction, principle, instrumentation and application of DSC, DTA and TGA.
   Raman Spectroscopy: Introduction, Principle, Instrumentation and Applications.
   Radio immuno assay: Biological standardization , bioassay, ELISA, Radioimmuno assay of digitalis and insulin **12Hrs**

REFERENCES

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

MASTER OF PHARMACY (SEMESTER-II)
(Credit Based Evaluation & Grading System)

MPC202T:ADVANCED ORGANIC CHEMISTRY –II

Max. Marks: 75
Internal Assessment: 25
Total Marks: 100

Scope

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

Objectives

Upon completion of course, the student shall able to understand

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

THEORY **60 Hrs**

1. Green Chemistry

a. Introduction, principles of green chemistry
b. Microwave assisted reactions: Merit and demerits of its use, increased reaction rates, mechanism, superheating effects of microwave, effects of solvents in microwave assisted synthesis, microwave technology in process optimization, its applications in various organic reactions and heterocycles synthesis
c. Ultrasound assisted reactions: Types of sonochemical reactions, homogenous, heterogeneous liquid-liquid and liquid-solid reactions, synthetic applications
d. Continuous flow reactors: Working principle, advantages and synthetic applications.

12Hrs

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.

12Hrs

3. Photochemical Reactions

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

Pericyclic reactions

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

12Hrs

4. Catalysis

a. Types of catalysis, heterogeneous and homogenous catalysis, advantages and disadvantages
b. Heterogeneous catalysis – preparation, characterization, kinetics, supported catalysts, catalyst deactivation and regeneration, some examples of heterogeneous catalysis used in synthesis of drugs.
c. Homogenous catalysis, hydrogenation, hydroformylation, hydrocyanation, Wilkinson catalysts, chiral ligands and chiral induction, Ziegler-Natta catalysts, some examples of homogenous catalysis used in synthesis of drugs
d. Transition-metal and Organo-catalysis in organic synthesis: Metal-catalyzed reactions
e. Biocatalysis: Use of enzymes in organic synthesis, immobilized enzymes/cells in organic reaction.
f. Phase transfer catalysis - theory and applications

12Hrs

5. 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.

12Hrs

REFERENCES

1. "Advanced Organic chemistry, Reaction, mechanisms and structure", J March, John Wiley and sons, New York.
2. "Mechanism and structure in organic chemistry", ES Gould, Hold Rinchart and Winston,NewYork.
3. "Organic Chemistry" Clayden, Greeves, Warren and Woihers., Oxford University Press 2001.
4. "Organic Chemistry" Vol I and II. I.L. Finar. ELBS, Sixth ed., 1995.
5. Carey, Organic chemistry, 5th edition (Viva Books Pvt. Ltd.)
6. Organic synthesis-the disconnection approach, S. Warren, Wily India
7. Principles of organic synthesis, ROCNorman and JMCoxan, Nelson thorns
8. Organic synthesis- Special techniques VK Ahluwalia and R Aggarwal, Narosa Publisher
9. Organic reaction mechanisms IV edtn, VK Ahluwalia and RK Parashar, Narosa Publishers

MASTER OF PHARMACY (SEMESTER-II)
(Credit Based Evaluation & Grading System)

MPC203T: COMPUTER AIDED DRUG DESIGN

Max. Marks: 75
Internal Assessment: 25
Total Marks: 100

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

   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 components of cavities, Fragment based drug design.
c. Homology modeling and generation of 3D-structure of protein.

12 Hrs

5. Pharmacophore Mapping and Virtual Screening

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

In Silico Drug Design and Virtual Screening Techniques

Similarity based methods and Pharmacophore based screening, structure based *in silico* virtual screening protocols.

12 Hrs

REFERENCES:

1. Computational and structural approaches to drug design edited by Robert M Stroud and Janet. F Moore
2. Introduction to Quantitative Drug Design by Y.C. Martin.
3. Drug Design by Ariens Volume 1 to 10, Academic Press, 1975.
4. Principles of Drug Design by Smith and Williams.
5. The Organic Chemistry of the Drug Design and Drug action by Richard B. Silverman.
6. Medicinal Chemistry by Burger.
7. An Introduction to Medicinal Chemistry –Graham L. Patrick, (III Edition.)
8. Wilson and Gisvold's Text book of Organic Medicinal and Pharmaceutical Chemistry.
9. Comprehensive Medicinal Chemistry – Corwin and Hansch.
10. Computational and structural approaches to drug design edited by Robert M Stroud and Janet. F Moore

MASTER OF PHARMACY (SEMESTER-II)
(Credit Based Evaluation & Grading System)

MPC204T: PHARMACEUTICAL PROCESS CHEMISTRY

Max. Marks: 75
Internal Assessment: 25
Total Marks: 100

Scope

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

Objectives

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

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

THEORY **60 Hrs**

1. Process chemistry

a. Introduction, Synthetic strategy
b. Stages of scale up process: Bench, pilot and large scale process.
c. In-process control and validation of large scale process.
d. Case studies of some scale up process of APIs.
e. Impurities in API, types and their sources including genotoxic impurities

12 Hrs

2. Unit operations

a. *Extraction:* Liquid equilibria, extraction with reflux, extraction with agitation, counter current extraction.
b. *Filtration*: Theory of filtration, pressure and vacuum filtration, centrifugal filtration,
c. *Distillation*: azeotropic and steam distillation
d. *Evaporation*: Types of evaporators, factors affecting evaporation.
e. *Crystallization*: Crystallization from aqueous, non-aqueous solutions factors affecting crystallization, nucleation. Principle and general methods of Preparation of polymorphs, hydrates, solvates and amorphous APIs. **12 Hrs**

3. Unit Processes

a. **Nitration:** Nitrating agents, Aromatic nitration, kinetics and mechanism of aromatic nitration, process equipment for technical nitration, mixed acid for nitration,
b. **Halogenation:** Kinetics of halogenations, types of halogenations, catalytic halogenations. Case study on industrial halogenation process.

c. **Oxidation**: Introduction, types of oxidative reactions, Liquid phase oxidation with oxidizing agents. Nonmetallic Oxidizing agents such as H_2O_2, sodium hypochlorite, Oxygen gas, ozonolysis. **12 Hrs**

4. Unit Processes

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

b. **Fermentation**: Aerobic and anaerobic fermentation. Production of

i. Antibiotics; Penicillin and Streptomycin,
ii. Vitamins: B2 and B12
iii. Statins: lovastatin, simvastatin

Reaction progress kinetic analysis

a. Streamlining reaction steps, route selection,
b. Characteristics of expedient routes, characteristics of cost-effective routes, reagent selection, families of reagents useful for scale-up.

12 Hrs

5. Industrial Safety

a. MSDS (Material Safety Data Sheet), hazard labels of chemicals and Personal Protection Equipment (PPE)
b. Fire hazards, types of fire & fire extinguishers
c. Occupational Health & Safety Assessment Series 1800 (OHSAS-1800) and ISO-14001(Environmental Management System), Effluents and its management

12 Hrs

REFERENCES:

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

MASTER OF PHARMACY (SEMESTER-II)
(Credit Based Evaluation & Grading System)

Pharmaceutical Chemistry Practical II

PRACTICALS (MPC205P)

1. Synthesis of organic compounds by adapting different approaches involving (3 experiments)
    a. Oxidation
    b. Reduction/hydrogenation
    c. Nitration
2. Comparative study of synthesis of APIs/intermediates by different synthetic routes (2 experiments)
3. Assignments on regulatory requirements in API (2 experiments)
4. Comparison of absorption spectra by UV and Wood ward – Fiesure rule
5. Interpretation of organic compounds by FT-IR
6. Interpretation of organic compounds by NMR
7. Interpretation of organic compounds by MS
8. Determination of purity by DSC in pharmaceuticals
9. Identification of organic compounds using FT-IR, NMR, CNMR and Mass spectra
10. To carry out the preparation of following organic compounds
11. Preparation of 4-chlorobenzhydrylpiperazine. (an intermediate for cetirizine HCl).
12. Preparation of 4-iodotolene from p-toluidine.
13. $NaBH_4$ 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
22. Virtual screening based experiment

MASTER OF PHARMACY (SEMESTER-II)
(Credit Based Evaluation & Grading System)

MPL201T: ADVANCED PHARMACOLOGY-II

Max. Marks: 75
Internal Assessment: 25
Total Marks: 100

Scope

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

Objectives

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

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

UNIT-I **12 Hrs**

Endocrine Pharmacology

Molecular and cellular mechanism of action of hormones such as growth hormone, prolactin, thyroid, insulin and sex hormones

Anti-thyroid drugs, Oral hypoglycemic agents, Oral contraceptives, Corticosteroids. Drugs affecting calcium regulation

UNIT-II **12 Hrs**

Chemotherapy

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

UNIT-III **12 Hrs**

Chemotherapy **06 Hrs**

Drugs used in Protozoal Infections
Drugs used in the treatment of Helminthiasis
Chemotherapy of cancer

Immunopharmacology **06 Hrs**

Cellular and biochemical mediators of inflammation and immune response. Allergic or hypersensitivity reactions. Pharmacotherapy of asthma and COPD.

Immunosuppressants and Immunostimulants

UNIT-IV **08 Hrs**

GIT Pharmacology

Antiulcer drugs, Prokinetics, antiemetics, anti-diarrheals and drugs for constipation and irritable bowel syndrome.

Chronopharmacology **04 Hrs**

Biological and circadian rhythms, applications of chronotherapy in various diseases like cardiovascular disease, diabetes, asthma and peptic ulcer

UNIT-V **04 Hrs**

Free radicals Pharmacology

Generation of free radicals, role of free radicals in etiopathology of various diseases such as diabetes, neurodegenerative diseases and cancer.

Protective activity of certain important antioxidant

Recent Advances in Treatment: **08 Hrs**

Alzheimer ’s disease, Parkinson’s disease , Cancer, Diabetes mellitus

References

1. The Pharmacological basis of therapeutics- Goodman and Gill man‘s
2. Principles of Pharmacology. The Pathophysiologic basis of drug therapy by David E Golan et al.
3. Basic and Clinical Pharmacology by B.G -Katzung
4. Pharmacology by H.P. Rang and M.M. Dale.
5. Hand book of Clinical Pharmacokinetics by Gibaldi and Prescott.
6. Text book of Therapeutics, drug and disease management by E T. Herfindal and Gourley.
7. Applied biopharmaceutics and Pharmacokinetics by Leon Shargel and Andrew B.C.Yu.
8. Handbook of Essential Pharmacokinetics, Pharmacodynamics and Drug Metabolism for Industrial Scientists

MASTER OF PHARMACY (SEMESTER-II)
(Credit Based Evaluation & Grading System)

MPL202T: PHARMACOLOGICAL AND TOXICOLOGICAL SCREENING METHODS

Max. Marks: 75
Internal Assessment: 25
Total Marks: 100

Scope:

The subject imparts knowledge on the preclinical safety and toxicological evaluation of drug & new chemical entity. This knowledge will make the student competent in regulatory toxicological evaluation.

Objectives:

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

- Explain the various types of toxicity studies.
- Appreciate the importance of ethical and regulatory requirements for toxicity studies.
- Demonstrate the practical skills required to conduct the preclinical toxicity studies.

Unit I **12 Hrs**

Basic definition and types of toxicology (general, mechanistic, regulatory and descriptive) Regulatory guidelines for conducting toxicity studies OECD, ICH, EPA and Schedule Y OECD principles of Good laboratory practice (GLP)
History, concept and its importance in drug development

Unit II **12 Hrs**

Acute, sub-acute and chronic- oral, dermal and inhalational studies as per OECD guidelines.
Acute eye irritation, skin sensitization, dermal irritation & dermal toxicity studies.
Test item characterization- importance and methods in regulatory toxicology studies

Unit III **12 Hrs**

Reproductive toxicology studies, Male reproductive toxicity studies, female reproductive studies (segment I and segment III), teratogenecity studies (segment II)
Genotoxicity studies (Ames Test, *in vitro* and *in vivo* Micronucleus and Chromosomal aberrations studies)
In vivo carcinogenicity studies

Unit IV **12 Hrs**

IND enabling studies (IND studies)- Definition of IND, importance of IND, industry perspective, list of studies needed for IND submission.
Safety pharmacology studies- origin, concepts and importance of safety pharmacology. Tier1- CVS, CNS and respiratory safety pharmacology, HERG assay. Tier2- GI, renal and other studies

Unit V **12 Hrs**

Toxicokinetics- Toxicokinetic evaluation in preclinical studies, saturation kinetics
Importance and applications of toxicokinetic studies.
Alternative methods to animal toxicity testing.

REFERENCES

1. Hand book on GLP, Quality practices for regulated non-clinical research and development (http://www.who.int/tdr/publications/documents/glp-handbook.pdf).
2. Schedule Y Guideline: drugs and cosmetics (second amendment) rules, 2005, ministry of health and family welfare (department of health) New Delhi
3. Drugs from discovery to approval by Rick NG.
4. Animal Models in Toxicology, 3rd Edition, Lower and Bryan
5. OECD test guidelines.
6. Principles of toxicology by Karen E. Stine, Thomas M. Brown.
7. Guidance for Industry M3(R2) Nonclinical Safety Studies for the Conduct of Human Clinical Trials and Marketing Authorization for Pharmaceuticals (http://www.fda.gov/downloads/drugs/guidancecomplianceregulatoryinformation/guidances/ucm073246.pdf)

MASTER OF PHARMACY (SEMESTER-II)
(Credit Based Evaluation & Grading System)

MPL203T: PRINCIPLES OF DRUG DISCOVERY

Max. Marks: 75
Internal Assessment: 25
Total Marks: 100

Scope:

The subject imparts basic knowledge of drug discovery process. This information will make the student competent in drug discovery process

Objectives:

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

- Explain the various stages of drug discovery.
- Appreciate the importance of the role of genomics, proteomics and bioinformatics in drug discovery
- Explain various targets for drug discovery.
- Explain various lead seeking method and lead optimization
- Appreciate the importance of the role of computer aided drug design in drug discovery

Unit-I **12 Hrs**

An overview of modern drug discovery process: Target identification, target validation, lead identification and lead Optimization. Economics of drug discovery.

Target Discovery and validation-Role of Genomics, Proteomics and Bioinformatics. Role of Nucleic acid microarrays, Protein microarrays, Antisense technologies, siRNAs, antisense oligonucleotides, Zinc finger proteins. Role of transgenic animals in target validation.

Unit-II **12 Hrs**

Lead Identification- combinatorial chemistry & high throughput screening, in silico lead discovery techniques, Assay development 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

Unit-III **12 Hrs**

Rational Drug Design
Traditional vs rational drug design, Methods followed in traditional drug design, High throughput screening, Concepts of Rational Drug Design, Rational Drug Design Methods: Structure and Pharmacophore based approaches

Virtual Screening techniques: Drug likeness screening, Concept of pharmacophore mapping and pharmacophore based Screening,

Unit-IV **12 Hrs**

Molecular docking: Rigid docking, flexible docking, manual docking; Docking based screening. De novo drug design.

Quantitative analysis of Structure Activity Relationship

History and development of QSAR, SAR versus QSAR, Physicochemical parameters, Hansch analysis, Fee Wilson analysis and relationship between them.

Unit-V **12 Hrs**

QSAR Statistical methods – regression analysis, partial least square analysis (PLS) and other multivariate statistical methods. 3D-QSAR approaches like COMFA and COMSIA

Prodrug design-Basic concept, Prodrugs to improve patient acceptability, Drug solubility, Drug absorption and distribution, site specific drug delivery and sustained drug action. Rationale of prodrug design and practical consideration of prodrug design

References

1. MouldySioud. Target Discovery and Validation Reviews and Protocols: Volume 2 Emerging Molecular Targetsand Treatment Options. 2007 Humana Press Inc.
2. Darryl León. Scott MarkelIn. Silico Technologies in Drug Target Identification and Validation. 2006 by Taylor and Francis Group, LLC.
3. Johanna K. DiStefano. Disease Gene Identification. Methods and Protocols. Springer New York Dordrecht Heidelberg London.
4. Hugo Kubiny. QSAR: Hansch Analysis and Related Approaches. Methods and Principles in Medicinal Chemistry. Publisher Wiley-VCH
5. Klaus Gubernator, Hans-Joachim Böhm. Structure-Based Ligand Design. Methods and Principles in Medicinal Chemistry. Publisher Wiley-VCH
6. Abby L . Parrill. M . Rami Reddy. Rational Drug Design. Novel Methodology and Practical Applications. ACS Symposium Series; American Chemical Society: Washington, DC, 1999.
7. J. Rick Turner. New drug development design, methodology and, analysis. John Wiley & Sons, Inc., Hoboken, New Jeney.

MASTER OF PHARMACY (SEMESTER-II)
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MPL204T: CLINICAL RESEARCH AND PHARMACOVIGILANCE

Max. Marks: 75
Internal Assessment: 25
Total Marks: 100

Scope:

This subject will provide a value addition and current requirement for the students in clinical research and pharmacovigilance. It will teach the students on conceptualizing, designing, conducting, managing and reporting of clinical trials.

This subject also focuses on global scenario of Pharmacovigilance in different methods that can be used to generate safety data. It will teach the students in developing drug safety data in Pre-clinical, Clinical phases of Drug development and post market surveillance.

Objectives:

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

- Explain the regulatory requirements for conducting clinical trial
- Demonstrate the types of clinical trial designs
- Explain the responsibilities of key players involved in clinical trials Execute safety monitoring, reporting and close-out activities
- Explain the principles of Pharmacovigilance
- Detect new adverse drug reactions and their assessment
- Perform the adverse drug reaction reporting systems and communication in Pharmacovigilance

UNIT-I **12Hrs**

Regulatory Perspectives of Clinical Trials:

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

UNIT- II **12 Hrs**

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 its management

UNIT- III **12 Hrs**

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

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

UIT-IV **12 Hrs**

Basic aspects, terminologies and establishment of pharmacovigilance

History and progress of pharmacovigilance, Significance of safety monitoring, Pharmacovigilance in India and international aspects, WHO international drug monitoring programme, WHO and Regulatory terminologies of ADR, evaluation of medication safety, Establishing pharmacovigilance centres in Hospitals, Industry and National programmes related to pharmacovigilance. Roles and responsibilities in Pharmacovigilance

UNIT-V **12 Hrs**

Methods, ADR reporting and tools used in Pharmacovigilance

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

UNIT-VI

Pharmacoepi Dermatology , pharmacoeconomics , safety pharmacology

References

1. Central Drugs Standard Control Organization- Good Clinical Practices, Guidelines for Clinical Trials on Pharmaceutical Products in India. New Delhi: Ministry of Health;2001.
2. International Conference on Harmonization of Technical requirements for registration of Pharmaceuticals for human use. ICH Harmonized Tripartite Guideline. Guideline for Good Clinical Practice.E6; May 1996.
3. Ethical Guidelines for Biomedical Research on Human Subjects 2000. Indian Council of Medical Research, New Delhi
4. Textbook of Clinical Trials edited by David Machin, Simon Day and Sylvan Green, March 2005, John Wiley and Sons.
5. Clinical Data Management edited by R K Rondels, S A Varley, C F Webbs. Second Edition, Jan 2000, Wiley Publications
6. Handbook of clinical Research. Julia Lloyd and Ann Raven Ed. Churchill Livingstone.
7. Principles of Clinical Research edited by Giovanna di Ignazio, Di Giovanna and Haynes.

MPL205P: Pharmacology Practical II

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 PA_2 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.
17. Protocol design for clinical trial.
18. Protocol design for clinical trial.
19. Design of ADR monitoring protocol
20. In silico docking studies.
21. In silico pharmacophore based screening.
22. In silico QSAR studies.
23. ADR reporting
24. In silico docking studies.

References

1. Fundamentals of experimental Pharmacology-by M.N.Ghosh
2. Hand book of Experimental Pharmacology-S.K.Kulakarni
3. Text book of *in-vitro* practical Pharmacology by Ian Kitchen
4. Bioassay Techniques for Drug Development by Atta-ur-Rahman, Iqbal choudhary and William Thomsen
5. Applied biopharmaceutics and Pharmacokinetics by Leon Shargel and Andrew B.C.Yu.
6. Handbook of Essential Pharmacokinetics, Pharmacodynamics and Drug Metabolism for Industrial Scientists.

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MPG201T: MEDICINAL PLANT BIOTECHNOLOGY

Max. Marks: 75
Internal Assessment: 25
Total Marks: 100

Scope

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

Objectives

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

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

THEORY **60Hrs**

1. **Introduction to Plant biotechnology:** Historical perspectives, prospects for development of plant biotechnology as a source of medicinal agents. Applications in pharmacy and allied fields. Genetic and molecular biology as applied to pharmacognosy, study of DNA, RNA and protein replication, genetic code, regulation of gene expression, structure and complicity of genome, cell signaling, DNA recombinant technology. **12Hrs**

2. **Different tissue culture techniques:** Organogenesis and embryogenesis, synthetic seed and monoclonal variation, Protoplast fusion, Hairy root multiple shoot cultures and their applications. Micro propagation of medicinal and aromatic plants. Sterilization methods involved in tissue culture, gene transfer in plants and their applications. **12 Hrs**

3. **Immobilisation techniques & Secondary Metabolite Production:** Immobilization techniques of plant cell and its application on secondary metabolite Production. Cloning of plant cell: Different methods of cloning and its applications. Advantages and disadvantages of plant cell cloning. Secondary metabolism in tissue cultures with emphasis on production of medicinal agents. Precursors and elicitors on production of secondary metabolites. **12Hrs**

4. **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. **12Hrs**
5. **Fermentation technology:** Application of Fermentation technology, Production of ergot alkaloids, single cell proteins, enzymes of pharmaceutical interest. **12 Hrs**

REFERENCES:

1. Plant tissue culture – Bhagwani, Vol 5. (Elsevier)
2. Plant cell and Tissue Culture (Lab. Manual) – J.R.M.M. Yeoman.
3. Elements in biotechnology by P. K. Gupta.
4. An introduction to plant tissue culture by M. K. Razdan.
5. Experiments in plant tissue culture by John H. D and Lorin W. R.
6. Pharmaceutical biotechnology by S. P. Vyas and V. K. Dixit.
7. Plant cell and tissue culture by Jeffrey W. Pollard and John M Walker.
8. Plant tissue culture by Dixon, Oxford Washington DC, 1985
9. Plant tissue culture by Street.
10. Pharmacognosy by G. E. Trease and W. C. Evans.
11. Biotechnology by Purohit and Mathur.
12. Biotechnological applications to tissue culture by Shargool.
13. Pharmacognosy by Virroo E. Tyler, Lynn R. Brady and James E. Robberrt.

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MPG202T: ADVANCED PHARMACOGNOSY-II

Max. Marks: 75
Internal Assessment: 25
Total Marks: 100

Scope:

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

Objectives

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

Know the validation of herbal remedies

Know the methods of detection of adulteration and evaluation techniques for the herbal drugs

To know the methods of screening of herbals for various biological properties

THEORY **60Hrs**

1. **Herbal remedies – Toxicity and Regulations:** Herbals vs Conventional drugs, Efficacy of Herbal medicine products, Validation of herbal therapies, Pharmacodynamic and Pharmacokinetic issues. **12Hrs**

2. **Adulteration and Deterioration:** Introduction, Types of Adulteration/ Substitution of Herbal drugs, Causes and Measures of Adulteration, Sampling Procedures, Determination of Foreign Matter, DNA Finger printing techniques in identification of drugs of natural origin, heavy metals, pesticide residues, phytotoxin, microbial contamination in herbs fruital formulation. **12 Hrs**

3. **Ethnobotany and Ethnopharmacology:** Ethnobotany in herbal drug evaluation, Impact of Ethnobotany in traditional medicine, New development in herbals, Bio-prospecting tools for drug discovery, Role of Ethnopharmacology in drug evaluation, Reverse Pharmacology. **12 Hrs**

4. **Analytical Profiles of herbal drugs:** *Andrographis paniculata, Boswellia serata, Coleus forskholii, Curcuma longa, Embelica officinalis, Psoralea corylifolia.* **12 Hrs**
5. **Biological screening of herbal drugs:** Introduction and Need for Phyto-Pharmacological Screening, New Strategies for evaluating Natural Products, *In vitro* evaluation techniques for Antioxidants, Antimicrobial and Anticancer drugs. In vivo evaluation techniques for Anti-inflammatory, Antiulcer, Anticancer, Wound healing, Antidiabetic, Hepatoprotective, Cardio protective, Diuretics and Antifertility. Toxicity studies as per OECD guidelines. **12Hrs**

REFERENCES:

1. Glimpses of Indian Ethano Pharmacology by P. Pushpangadam. Ulf Nyman. V.George Tropical Botanic Garden & Research Institute, 1995.
2. Natural products: A lab guide by Raphael Ikan , 2nd Edition, Academic Press 1991.
3. Pharmacognosy - G. E. Trease and W.C. Evans. 15th Edition W.B. Saunders Edinburgh, New York.
4. Pharmacognosy-Tyler, Brady, Robbers
5. Modem Methods of Plant Analysis- Peach & M.V. Tracey, Vol. I&II
6. Herbal Drug Industry by RD. Choudhary, 1st edition, Eastern Publisher, New Delhi, 1996.
7. Text book of Pharmacognosy by C.K.Kokate, Purohit, Ghokhale, 4th edition, Nirali Prakasshan, 1996.
8. Text Book of Pharmacognosy by T.E. Wallis
9. Quality control of herbal drugs by Pulok K Mukarjee (2002), Ist Edition, Business Horizons Pharmaceutical Publisher, New Delhi.
10. Indian Herbal Pharmacopoeia (2002), Revised Edition, 1DMA, Mumbai.
11. Text book of Pharmacognosy and Phytochemistry by Vinod D. RangarI (2002), Part I & II, Career Publication, Nasik, India.
12. Plant drug analysis by H.Wagner and S.Bladt, 2nd edition, Springer, Berlin.
13. Standardization of Botanicals. Testing and extraction methods of medicinal herbs by V. Rajpal (2004), Vol.I, Eastern Publisher, New Delhi.
14. Herbal Medicine. Expanded Commission E Monographs by M.Blumenthal, (2004), IST Edition,

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MPG203T: INDIAN SYSTEMS OF MEDICINE

Max. Marks: 75
Internal Assessment: 25
Total Marks: 100

Scope

To make the students understand thoroughly on 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.

Objective

After completion of the course, student is able to

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

THEORY **60Hrs**

1. **Fundamental concepts of Ayurveda, Siddha, Unani, and Homoeopathy systems of medicine:**
Different dosage forms of the ISM-
Ayurveda: Chronological development of Charak Samhita, Sushrut Samhita and Kashyapa Samhita. Ayurvedic Pharmacopoeia Analysis of Ayurvedic Formulations and crude drugs with references to: Identity, purity and quality of crude drugs.
Siddha: Gunapadam (Siddha Pharmacology), raw drugs/Dhatu/Jeevam in siddha system of medicine, Purification process (Suddhi). **12Hrs**
2. **Naturopathy, Yoga and Aromatherapy practices:**

a) Naturopathy - Introduction, basic principles and treatment modalities.
b) Yoga - Introduction and Streams of Yoga. Asanas, Pranayama, Meditations and Relaxation techniques.
c) Aromatherapy – Introduction, aroma oils for common problems, carrier oils.

12 Hrs

3. **Formulation development of various systems of medicine:** Salient features of the techniques of preparation of some of the important class of Formulations as per Ayurveda, Siddha, Homeopathy and Unani Pharmacopoeia and texts. Standardization, Shelf life and Stability studies of ISM formulations. **12 Hrs**
4. **Schedule T – Good Manufacturing Practice of Indian systems of medicine:** Components of GMP (Schedule – T) and its objectives, Infrastructural requirements, working space, storage area, machinery and equipments, standard operating procedures, health and hygiene, documentation and records.
Quality assurance in herbal drug industry of GAP, GMP and GLP in traditional system of medicine. 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. **12Hrs**

5. TKDL, Geographical indication skill, Government skills in AYUSH, ISM, CCRAS, CCRS, CCRH, CCRU. **12 Hrs.**

REFERENCES:

1. Ayurvedic Pharmacopoeia (2004), The Controller of Publications, Civil Lines, Govt. of India, New Delhi.
2. Hand Book on Ayurvedic Medicines by H.Panda National Institute of Industrial Research, New Delhi.
3. Ayurvedic System of Medicine by Kaviraj Nagendranath Sengupata (1998), 2nd Revised Edition, Sri Satguru Publications, New Delhi.
4. Ayurvedic Pharmacopoeia. Formulary of Ayurvedic Medicines (2000), IMCOPS, Chennai.
5. Homeopathic Pharmacopoeia. Formulary of Homeopathic Medicines (2004), IMCOPS, Chennai.
6. Homeopathic Pharmacy An introduction & Hand book by Steven B. Kayne (1997), Churchill Livingstone, New York.
7. Indian Herbal Pharmacopoeia (2002), Revised Edition, 1DMA, Mumbai.
8. British Herbal Pharmacopoeia British (1990), Herbal Medicine Association, UK.
9. GMP for Botanicals - Regulatory and Quality issues on Phytomedicine by Pulok K Mukharjee (2003), First edition, Business Horizons, New Delhi.
10. Indian System of Medicine and Homeopathy in India (2001), Planning and Evaluation Cell, Govt.of India, New Delhi.
11. Essential of Food and Nutrition by Swaminathan (1999), Bappco, Bangalore.
12. Clinical Dietitics and Nutrition by F.P. Antia (1997), 4th Edi, Oxford Universith Press, Delhi.
13. Yoga- The Science of Holistic Living by V.K.Yoga (2005), Vivekananda Yoga Prakashna Publishing, Bangalore.

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MPG204T: HERBAL COSMETICS

Max. Marks: 75
Internal Assessment: 25
Total Marks: 100

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 Drug and cosmetic act.

Objective

After completion of the course, student is 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 **60Hrs**

1. Introduction: Herbal/natural cosmetics, Classification & Economic aspects. 12 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.

2 Commonly used herbal cosmetics, raw materials, preservatives, surfactants, humectants, oils, colors, and some functional herbs, preformulation studies, compatibility studies, possible interactions between chemicals and herbs, design of herbal cosmetic formulation. 12 Hrs

3 Herbal Cosmetics : Physiology and chemistry of skin and pigmentation, hairs, scalp, lips and nail, Cleansing cream, Lotions, Face powders, Face packs, Lipsticks, Bath products, soaps and baby product, Preparation and standardisation of the following :
Tonic, Bleaches, Dentifrices and Mouth washes & Tooth Pastes, Cosmetics for Nails.

4 Cosmeceuticals of herbal and natural origin: Hair growth formulations, Shampoos, Conditioners, Colorants & hair oils, Fairness formulations, vanishing & foundation creams, anti-sun burn preparations, moisturizing creams, deodorants. 12 Hrs

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

REFERENCES:

1. Panda H. 2007. Herbal Cosmetics (Hand book), Edition I, Asia Pacific Business Press Inc, New Delhi.
2. Thomson EG. 2006. Modern Cosmetics, Edition I, Universal Publishing Corporation, Mumbai.
3. P.P.Sharma. 2008. Cosmetics- Formulation, Manufacturing & Quality Control, Edition 4, Vandana Publications, New Delhi.
4. Supriya K B. 2005. Handbook of Aromatic Plants, Edition II(Revised and Enlarged), Pointer Publishers, Jaipur.
5. Skaria P. 2007. Aromatic Plants (Horticulture Science Series Vol. 1) , Edition I, New India Publishing Agency, New Delhi.
6. Kathi Keville and Mindy Green.1995. Aromatheraphy (A Complete Guide to the Healing Art), Edition I, Sri Satguru Publications, New Delhi.
7. Chattopadhyay PK. 2000. Herbal Cosmetics & Ayurvedic Medicines (EOU), Edition I, National Institute of Industrial Research, Delhi.
8. Balsam MS & Edward Sagarin. 2008. Cosmetics Science and Technology, Edition II (Vol-II), Wiley Interscience, New York.

MPG205P: Pharmacognosy Practical II

1. Isolation of nucleic acid from cauliflower heads
2. Isolation of RNA from yeast
3. Quantitative estimation of DNA
4. Immobilization of whole cell
5. Establishment of callus culture
6. Establishment of suspension culture
7. Estimation of aldehyde
8. Estimation of phenolic content in herbal raw materials
9. Estimation of alkaloid content in herbal raw materials
10. Estimation of 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. Herbal cosmetic formulation such as lip balm, lipstick, facial cream, herbal hair and nail care products
14. Evaluation of herbal tablets and capsules
15. Dermatological preparation like sunscreen, UV protection cream, skin care formulations for fungal and dermato reaction
16. Formulation of cough syrup

MRM301T - Research Methodology & Biostatistics

Max. Marks: 75
Internal Assessment: 25
Total Marks: 100

UNIT – I

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

UNIT – II

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

UNIT – III

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

UNIT – IV

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

UNIT – V

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