UTTAR PRADESH UNIVERSITY OF MEDICAL SCIENCES, SAIFAI

FACULTY OF PHARMACY

REGULATIONS, EXAMINATION SCHEME AND SYLLABUS FOR M.PHARMACY

Adapted from Master of Pharmacy (M. Pharm)
COURSE REGULATIONS 2014 as per PCI Regulations

Regulations

1. Short Title and Commencement

These regulations shall be called as "The Regulations for the Master of Pharmacy Degree Program - Credit Based Semester System (CBSS)". The regulations framed are subject to modifications from time to time by the authorities of the university.

2. Minimum qualification for admission

A Pass in the following examinations

a) B. Pharm Degree examination of an Indian university established by law in India from an institution approved by Pharmacy Council of India and has scored not less than 55 % of the maximum marks (aggregate of 4 years of B. Pharm.)

b) Every student, selected for admission to post graduate pharmacy program in any PCI approved institution should have obtained registration with the State Pharmacy Council or should obtain the same within one month from the date of his/her admission, failing which the admission of the candidate shall be cancelled.

Note: It is mandatory to submit a migration certificate obtained from the respective university where the candidate had passed his/her qualifying degree (B. Pharm.)

3. Duration of the program

The program of study for M. Pharm shall extend over a period of four semesters (two academic years). The curricula and syllabi for the program shall be prescribed from time to time by Pharmacy Council of India, New Delhi.

4. Medium of instruction and examinations

Medium of instruction and examination shall be in English.

5. Working days in each semester

Each semester shall consist of not less than 100 working days. The odd semesters shall be conducted from the month of June/July to November/December and the even semesters shall be conducted from the month of December/January to May/June in every calendar year.

6. Attendance and progress

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

7. Program/Course credit structure

As per the philosophy of Credit Based Semester System, certain quantum of academic work viz. theory classes, practical classes, seminars, assignments, etc. are measured in terms of credits. On satisfactory completion of the courses, a candidate earns credits. The amount of credit associated with a course is dependent upon the number of hours of instruction per week in that course.

Similarly the credit associated with any of the other academic, co/extracurricular activities is dependent upon the quantum of work expected to be put in for each of these activities per week/per activity.

7.1. Credit assignment

7.1.1. Theory and Laboratory courses

Courses are broadly classified as Theory and Practical. Theory courses consist of lecture (L) and Practical (P) courses consist of hours spent in the laboratory. Credits (C) for a course is dependent on the number of hours of instruction per week in that course, and is obtained by using a multiplier of one (1) for lecture and a multiplier of half (1/2) for practical (laboratory) hours. Thus, for example, a theory course having four lectures per week throughout the semester carries a credit of 4. Similarly, a practical having four laboratory hours per week throughout semester carries a credit of 2.

The contact hours of seminars, assignments and research work shall be treated as that of practical courses for the purpose of calculating credits. i.e., the contact hours shall be multiplied by 1/2. Similarly, the contact hours of journal club, research work presentations and discussions with the supervisor shall be considered as theory course and multiplied by 1.

7.2. Minimum credit requirements

The minimum credit points required for the award of M. Pharm. degree is 95.However based on the credit points earned by the students under the head of co-curricular activities; a student shall earn a maximum of 100 credit points. These credits are divided into Theory courses, Practical, Seminars, Assignments, Research work, Discussions with the supervisor, Journal club and Co-Curricular activities over the duration of four semesters. The credits are distributed semester wise as shown in Table 7. Courses generally progress in sequence, building competencies and their positioning indicates certain academic maturity on the part of the learners. Learners are expected to follow the semester wise schedule of courses given in the syllabus.

8. Academic work

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

9. Course of study

The course of study for M. Pharm shall include Semester wise Theory & Practical as given in Tables 1-4. The number of hours to be devoted to each theory and practical course in any semester shall not be less than that shown in Tables 1-4.

Table – 1: Course of study for M. Pharm. (Pharmaceutics)

Course Code	Course	Credit Hours	Credit Points	Hrs./wk	Marks
MPH 101T	Modern Pharmaceutical Analytical Techniques	4	4	4	100
MPH 102T	Drug Delivery System	4	4	4	100
MPH 103T	Modern Pharmaceutics	4	4	4	100
MPH 104T	Regulatory Affairs	4	4	4	100
MPH 105P	Pharmaceutics Practical-I	12	6	12	150
Seminar/ Assignment		7	4	7	100
Total		35	26	35	650
MPH201T	Molecular Pharmaceutics (Nano Tech and Targeted DDS)	4	4	4	100
MPH202T	Advanced Biopharmaceutics & Pharmacokinetics	4	4	4	100
MPH203T	Computer Aided Drug Delivery System	4	4	4	100
MPH204T	Cosmetic and Cosmeceuticals	4	4	4	100
MPH205P	Pharmaceutics Practical-II	12	6	12	150
Seminar/ Assignment		7	4	7	100
	Total	35	26	35	650

Table – 2: Course of study for M. Pharm. (Pharmaceutical Chemistry) Sem I & II

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

Table – 3: Course of study for M. Pharm. (Pharmacognosy)

Course Code	Course	Credit Hours	Credit Points	Hrs./wk	Marks
MPG 101T	Modern Pharmaceutical Analytical Techniques	4	4	4	100
MPG 101T	Advanced Pharmacognosy-1	4	4	4	100
MPG 101T	Phytochemistry	4	4	4	100
MPG 101T	Industrial Pharmacognostical Technology	4	4	4	100
MPG 101T	Pharmacognosy Practical I	12	6	12	150
Seminar/ Assignment		7	4	7	100
Total		35	26	35	650
MPG 201T	Medicinal Plant biotechnology	4	4	4	100
MPG 201T	Advanced Pharmacognosy-II	4	4	4	100
MPG 201T	Indian system of medicine	4	4	4	100
MPG 201T	Herbal cosmetics	4	4	4	100
MPG 201T	Pharmacognosy Practical II	12	6	12	150
Seminar/ Assignment		7	4	7	100
	Total	35	26	35	650

Table – 4: Course of study for M. Pharm. (Pharmacology) Semester I & II

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

Table –5: Course of study for M. Pharm. III Semester

Course Code	Course	Credit Hours	CreditPoints
MPC 301T	Research Methodology and Biostatistics*	4	4
-	Journal club	1	1
-	Discussion / Presentation (Proposal Presentation)	2	2
-	Research Work	28	14
	Total	35	21

* Non University Exam

Table – 6: Course of study for M. Pharm. IV Semester

Course Code MPC 401	Course	Credit Hours	Credit Points
-	Journal club	1	1
-	Research Work	31	16
	Discussion / Final Presentation	3	3
	Total	35	20

Table – 7: Semester wise credit distribution

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

*Credit Points for Co-curricular Activities

Table – 8: Guidelines for Awarding Credit Points for Co-curricular Activities

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

Note: International Conference: Held Outside India

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

10. Program Committee

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

11. Examinations/Assessments

The schemes for internal assessment and end semester examinations are given in Table – 6.

11.1. End semester examination

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

Tables – 9: Schemes for internal assessments and end semester for I and II Sem for M. Pharm (Pharmaceutics).

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

Tables – 10: Schemes for internal assessments and end semester for I and II Sem for M. Pharm (Pharmaceutical Chemistry).

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

Tables – 11: Schemes for internal assessments and end semester for I and II Sem for M. Pharm (Pharmacognosy).

Course Code	Course	Internal Assessment				End Semester Exam		Total Marks
		Continuous Mode	Sessional Exam		Total	Marks	Duration	
			Marks	Duration				
SEMESTER I								
MPG 101T	Modern Pharmaceutical Analytical Techniques	10	15	1 Hr	25	75	3Hrs	100
MPG 101T	Advanced Pharmacognosy-1	10	15	1 Hr	25	75	3Hrs	100
MPG 101T	Phytochemistry	10	15	1 Hr	25	75	3 Hrs	100
MPG 101T	Industrial Pharmacognostical Technology	10	15	1 Hr	25	75	3 Hrs	100
MPG 101T	Pharmacognosy Practical I	20	30	6 Hrs	50	150	6 Hrs	150
	Seminar /Assignment							100
Total								650
SEMESTER II								
MPG 201T	Medicinal Plant Biotechnology	10	15	1 Hr	25	75	3Hrs	100
MPG 201T	Advanced Pharmacognosy-II	10	15	1 Hr	25	75	3Hrs	100
MPG 201T	Indian system of Medicine	10	15	1 Hr	25	75	3Hrs	100
MPG 201T	Herbal cosmetics	10	15	1 Hr	25	75	3Hrs	100
MPG 201T	Pharmacognosy Practical II	20	30	6 Hrs	50	150	6Hrs	150
	Seminar/Assignment							100
Total								650

Tables – 12: Schemes for internal assessments and end semester for I and II Sem for M. Pharm (Pharmacology).

Course Code	Course	Internal Assessment				End Semester Exam		Total Marks
		Continuous Mode	Sessional Exam		Total	Marks	Duration	
			Marks	Duration				
SEMESTER I								
MPL 101T	Modern Pharmaceutical Analytical Techniques	10	15	1 Hr	25	75	3Hrs	100
MPL 102T	Advanced Pharmacology-I	10	15	1 Hr	25	75	3Hrs	100
MPL 103T	Pharmacological and Toxicological Screening	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	Pharmacology Practical-I	20	30	6 Hrs	50	150	6 Hrs	150
	Seminar /Assignment							100
Total								650
SEMESTER II								
MPL 201T	Advanced Pharmacology II	10	15	1 Hr	25	75	3Hrs	100
MPL 202T	Pharmacological and Toxicological Screening	10	15	1 Hr	25	75	3Hrs	100
MPL 203T	Principles of Drug Discovery	10	15	1 Hr	25	75	3Hrs	100
MPL 204T	Experimental Pharmacology practical- II	10	15	1 Hr	25	75	3Hrs	100
MPL 205P	Pharmacology Practical-II	20	30	6 Hrs	50	150	6Hrs	150
	Seminar/Assignment							100
Total								650

Tables – 13: Schemes for internal assessments and End semester Examination for III and IV Sem.

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

*Non University Examination

11.2. Internal assessment: Continuous mode

The marks allocated for Continuous mode of Internal Assessment shall be awarded as per the scheme given below.

Table – 14: Scheme for awarding internal assessment: Continuous mode

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

Table – 15: 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

11.2.1. Sessional Exams

Two sessional exams shall be conducted for each theory / practical course as per the schedule fixed by the college(s). The scheme of question paper for theory and practical sessional examinations is given below. The average marks of two sessional exams shall be computed for internal assessment as per the requirements given in Tables 9-12.

Question paper pattern for theory Sessional examination

I.	Multiple Choice Questions (MCQs)	= 10 x 1 = 10
	OR	
	Objective Type Questions (10 x 1)	= 10 x 1 = 10
	(Answer all the questions)	
II.	Short Answers (Answer 2 out of 3)	= 2 x 5 = 10
III.	Long Answers (Answer 1 out of 2)	= 1 x 10 = 10
	Total	= 30 marks

Question paper pattern for practical sessional examination

I. Experiment(s)	= 20
II. Viva voce	= 10
Total	= 30 marks

12. Promotion and award of grades

A student shall be declared PASS and eligible for getting grade in a course of M. Pharm. program if he/she secures at least 50% marks in that particular course including internal assessment.

13. Carry forward of marks

In case a student fails to secure the minimum 50% in any Theory or Practical course as specified in 12, then he/she shall reappear for the end semester examination of that course. However his/her marks of the Internal Assessment shall be carried over and he/she shall be entitled for grade obtained by him/her on passing.

14. End Semester Examination

End semester examination shall be conducted as per the schedule given in Table 16. The exact dates of examination shall be notified from time to time.

Table – 16: Tentative schedule of end semester examinations

Semester	For Regular/Carry over Candidates
I and III	December/January
II and IV	May / June

15. Allowed to keep terms (ATKT):

No student shall be admitted to any examination unless he/she fulfills the norms given in 6. ATKT rules are applicable as follows: A student shall be eligible to carry forward all the courses of I and II semesters till the III semester examinations. However, he/she shall not be eligible to attend the courses of IV semester until all the courses of I, II and III semesters are successfully completed.
A student shall be eligible to get his/her CGPA upon successful completion of the courses of I to IV semesters within the stipulated time period as per the norms.
Note: Grade AB should be considered as failed and treated as one head for deciding ATKT. Such rules are also applicable for those students who fail to register for examination(s) of any course in any semester.

16. Grading of performances

16.1. Letter grades and grade points allocations:

Based on the performances, each student shall be awarded a final letter grade at the end of the semester for each course. The letter grades and their corresponding grade points are given in Table – 17.

Table –17: Letter grades and grade points equivalent to Percentage of marks and performances

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

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

PROGRAM OUTCOMES – M. PHARM

1. Apply fundamentals of Pharmaceutics, Pharmaceutical chemistry, Pharmacology and Pharmacognosy to elucidate and regulate drug discovery, drug development and care practice.
2. Design and conduct experiments, as well as to analyze and interpret data of appropriate pharmaceutical system or process.
3. Design, synthesize and isolate a drug and drug formulation system, component, or drug use process to meet desired needs within realistic constraints such as economic, environmental, social, political, ethical, health and safety, manufacturability, and sustainability,
4. Create an ability to function in multidisciplinary teams, at different organizational levels of academic, industry, research and health care.
5. Develop an ability to identify, formulate, and solve pharmaceutical problems to meet the professional challenges.
6. Understand pharmacy professional values and ethical responsibility in discharging professional obligations at society, national and global perspectives.
7. Develop an ability to comprehend the impact of practice of Pharmacy in a global, economic, environmental, and societal context.
8. Can relate knowledge of contemporary issues on the research, development and manufacturing technology and use of pharmaceutical products in population.
9. Develop an ability to employ the techniques, skills, and modern tools necessary for professional practice, research and development.

PROGRAM SPECIFIC OUTCOMES – M PHARM

1. Knowledge: Enable post graduates to understand the core and basic knowledge in different subjects of pharmaceutical sciences as per the requirement of pharmaceutical sectors.
2. Employment and Entrepreneurship: Enable post graduates to succeed in technical or professional careers in pharmaceutical industry/ Academic institutes or in health care system.
3. Professional Practice: Enable post graduates to practice profession and adapt themselves to the constantly developing global pharmaceutical trends.
4. Lifelong Learning & Professional Ethics: Enable the post graduates to be a lifelong learner in terms of personal and professional growth with ethics and self esteem

Syllabus

M.PHARM PHARMACEUTICS (MPH)

Semester I and II

M. Pharm First Semester

MODERN PHARMACEUTICAL ANALYTICAL TECHNIQUES (MPH 101T)

Scope

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

Course Outcome: After completion of course student is able to

CO1: Apply fundamentals of pharmaceutical chemistry, Pharmaceutics, Pharmaceutical technology, Pharmacy practice, Pharmacology, Pharmacognosy and Quality assurance to elucidate and regulate drug discovery, drug development care practice.

CO2: Design and conduct experiments, as well as analyze and interpret data of appropriate pharmaceutical system or process.

CO3 : Design, synthesize, isolate a drug and drug formulation system, component, or drug use process to meet desired needs within realistic constraints such as economic, environmental, social, political, ethical, health and safety, manufacturability, and sustainability.

CO4 : Develop an ability to function on multidisciplinary teams, at different organizational levels of academic, industry, research and health care.

CO5 : Identify, formulate and solve pharmaceutical problems meeting professional challenges.

THEORY **60 Hours**

Unit 1 **12 Hours**

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

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

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

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

Unit 2 **12 Hours**

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

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.

Unit 3 **12 Hours**

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

a) Thin Layer chromatography

b) High Performance Thin Layer Chromatography

c) Ion exchange chromatography

d) Column chromatography
e) Gas chromatography
f) High Performance Liquid chromatography
g) Ultra High Performance Liquid chromatography
h) Affinity chromatography
i) Gel Chromatography

Unit 4 **12 Hours**

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.

Unit 5 **12 hours**

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

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DRUG DELIVERY SYSTEMS (MPH 102T)

Scope

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

Course Outcome: After completion of course student is able to

CO1 : Explain vaccine delivery and different mode of application approach for clinical use.

CO2 : Demonstrate about Drug delivery systems and give a detailed information regarding transporting a pharmaceutical compound in the body as needed to safely achieve its desired therapeutic effect.

CO3 : Utilize the different types of Drug carrier used in the process of drug delivery which serves to improve the selectivity, effectiveness, and/or safety of drug administration.

CO4 : Discover recent developments in protein and peptide for parenteral delivery approaches which will give new dimension of drug deliver for antibiotics, insulin, etc.

THEORY **60 Hours**

Unit 1 **12 Hours**

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

Unit 2 **12 Hours**

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.

Unit 3 **12 Hours**

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 mucoadhesion, advantages and disadvantages, Mechanism of drug permeation, Methods of formulation and its evaluations.

Unit 4 **12 Hours**

Ocular Drug Delivery Systems: Barriers of drug permeation, Methods to overcome barriers.
Transdermal Drug Delivery Systems: Structure of skin and barriers, Penetration enhancers, Transdermal Drug Delivery Systems, Formulation and evaluation.

Unit 5 **12 Hours**

Protein and Peptide Delivery: Barriers for protein delivery, Formulation and Evaluation of delivery systems of proteins and other macromolecules.
Vaccine delivery systems: Vaccines, uptake of antigens, single shot vaccines, mucosal and transdermal delivery of vaccines.

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 Wiley Interscience Publication, John Wiley and Sons, Inc, New York! Chichester/Weinheim
4. N.K. Jain, Controlled and Novel Drug Delivery, CBS Publishers & Distributors, New Delhi, First edition 1997 (reprint in 2001).
5. S.P. Vyas and R.K. Khar, Controlled Drug Delivery - concepts and advances, Vallabh Prakashan, New Delhi, First edition 2002

JOURNALS

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

MODERN PHARMACEUTICS (MPH 103T)

Scope

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

Course Outcomes: After completion of course the student is able to

CO1 : Apply the knowledge of preformulation studies for the dosage form development.
CO2 : Apply the knowledge of optimization techniques to formulation processing and development.
CO3 : Utilize the knowledge of validation techniques as per internationally accepted guidelines.
CO4 : Demonstrate the principles of cGMP and industrial management during planning of industrial Quality management.

THEORY **60 Hours**

Unit 1 **12 Hours**

a. Preformulation 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 parenterals – physiological and formulation consideration, Manufacturing and evaluation.

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

Unit 2 **12 Hours**

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.

Unit 3 **12 Hours**

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

Unit 4 **12 Hours**

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

Unit 5 **12 Hours**

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

REFERENCES

1. Theory and Practice of Industrial Pharmacy By Lachmann and Libermann
2. Pharmaceutical dosage forms: Tablets Vol. 1-3 by Leon Lachmann.
3. Pharmaceutical Dosage forms: Disperse systems, Vol, 1-2; By Leon Lachmann.
4. Pharmaceutical Dosage forms: Parenteral medications Vol. 1-2; By Leon Lachmann.
5. Modern Pharmaceutics; By Gillbert and S. Banker.

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

REGULATORY AFFAIRS (MPH 104T)

Scope

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

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

Course Outcome: After completion of course student is able to

CO1 : Explain the Concepts of innovator and generic drugs, drug development process.

CO2 : Understand the Regulatory guidance's and guidelines for filing and approval process

CO3 : Plan the preparation of Dossiers and their submission to regulatory agencies in different countries

CO4 : Outline Post approval regulatory requirements for actives and drug products

CO5 : Organize submission of global documents in CTD/eCTD formats

THEORY **60 Hours**

Unit 1 **12 Hours**

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.

Unit 2 **12 Hours**

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

Unit 3 **12 Hours**

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.

Unit 4 **12 Hours**

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

Unit 5 **12 Hours**

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.

REFERENCES

1. Generic Drug Product Development, Solid Oral Dosage forms, Leon Shargel and Isader Kaufer, Marcel Dekker series, Vol.143
2. The Pharmaceutical Regulatory Process, Second Edition Edited by Ira R. Berry and Robert P.Martin, Drugs and the Pharmaceutical Sciences,Vol.185, Informa Health care Publishers.

3. New Drug Approval Process: Accelerating Global Registrations By Richard A Guarino, MD, 5th edition, Drugs and the Pharmaceutical Sciences,Vol.190.
4. Guidebook for drug regulatory submissions / Sandy Weinberg. By John Wiley & Sons.Inc.
5. FDA regulatory affairs: a guide for prescription drugs, medical devices, and biologics/edited By Douglas J. Pisano, David Mantus.
6. Clinical Trials and Human Research: A Practical Guide to Regulatory Compliance By Fay A. Rozovsky and Rodney K. Adams
7. www.ich.org/
8. www.fda.gov/
9. europa.eu/index_en.htm
10. https://www.tga.gov.au/tga-basics

PHARMACEUTICS PRACTICALS – I (MPH 105P)

Scope
This course is designed to provide hand-on practice for analysis of pharmacopoeial compounds and reactions of synthetic importance. It also includes performing preformulation studies, formulating and evaluating various novel drug delivery systems.

Course Outcomes: After completion of course student is able to
CO1: Outline the principles involved in pharmaceutical analysis
CO2: Apply appropriate techniques for the qualitative and quantitative analysis of chemicals in laboratories.
CO3: Organize separation of organic mixture by chromatographic methods.
CO4: Find practical aspects of performing preformulation studies of various drug molecules
CO5: Develop practical aspects of formulating and evaluating various Controlled/sustained release formulations

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 Mucoadhesive tablets.
12. Formulation and evaluation of transdermal 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 Heckel plot, Higuchi and Peppas plot and determine similarity factors.

Seminar/Assignment-I

This course provides path to acquire skills and focuses on work in a professional digital format online/offline towards specific job goals and so forth. It also provides an opportunity to re-address previous projects, assignments for inclusion in their portfolios.

Course Outcomes: Through this course students should be able to

CO1: Analyze the knowledge gained during degree program to generate new skills and present it in a scientific manner

CO2: Develop the presentation proficiency

CO3: Develop specific communication skills associated with reporting technical information

CO4: Apply substantive argumentation, utilizing personal views that are based on critical analysis of works of various field of analysis

CO5: Outline how to cite the different information sources and previous reports related to specific area of the study

CO6: Develop good scientific and writing skills in paper presentation

M. Pharm Second Semester

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

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

Course Outcome: After completion of course student is able to
CO1: Understand the various approaches for development of novel drug delivery systems.
CO2: Identify the criteria for selection of drugs and polymers for the development of NTDS
CO3: Develop the formulation and evaluation of novel drug delivery systems.

THEORY **60 Hours**

Unit 1 **12 Hours**

Targeted Drug Delivery Systems: Concepts, Events and biological process involved in drug targeting. Tumor targeting and Brain specific delivery.

Unit 2 **12 Hours**

Targeting Methods: introduction preparation and evaluation. Nano Particles & Liposomes: Types, preparation and evaluation.

Unit 3 **12 Hours**

Micro Capsules / Micro Spheres: Types, preparation and evaluation , Monoclonal Antibodies; preparation and application, preparation and application of Niosomes, Aquasomes, Phytosomes, Electrosomes.

Unit 4 **12 Hours**

Pulmonary Drug Delivery Systems: Aerosols, propellents, Containers: Types, preparation and evaluation, Intra Nasal Route Delivery systems; Types, preparation and evaluation.

Unit 5 **12 Hours**

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 non-viral gene transfer). Liposomal gene delivery systems, Biodistribution and pharmacokinetics. Knowledge of therapeutic antisense molecules and aptamers as drugs of future.

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, Vallabh Prakashan, New Delhi, First edition 2002.
3. N.K. Jain, Controlled and Novel Drug Delivery, CBS

ADVANCED BIOPHARMACEUTICS & PHARMACOKINETICS (MPH 202T)

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

Course Outcome: After completion of course student is able to
CO1: Understand the basic concepts in biopharmaceutics and pharmacokinetics
CO2: Understand the use of raw data and derive the pharmacokinetic models and parameters which best describe the process of drug absorption, distribution, metabolism and elimination
CO3: Examine the critical evaluation of biopharmaceutical studies involving drug product equivalency
CO4: Design and evaluate dosage regimens of the drugs using pharmacokinetic and biopharmaceutical parameters
CO5: Understand the potential clinical pharmacokinetic problems and application of basics of pharmacokinetics

THEORY **60 Hours**

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

Unit 2 **12 Hours**
Biopharmaceutical considerations in drug product design and In Vitro Drug Product Performance: Introduction, biopharmaceutical factors affecting drug bioavailability, rate-limiting steps in drug absorption, physicochemical nature of the drug formulation factors affecting drug product performance, in vitro: dissolution and drug release testing, compendial methods of dissolution, alternative methods of dissolution testing, meeting dissolution requirements, problems of variable control in dissolution testing performance of drug products. In vitro–in vivo correlation, dissolution profile comparisons, drug product stability, considerations in the design of a drug product.

Unit 3 **12 Hours**
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.

Unit 4 **12 Hours**
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. Biopharmaceutical classification system, 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.

Unit 5 **12 Hours**

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

REFERENCES

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

COMPUTER AIDED DRUG DEVELOPMENT (MPH 203T)

Scope

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

Course Outcome: After completion of course student is able to

CO1: Apply the concepts of computers in pharmaceutical research and development and QBD

CO2: Understand the basic concepts of computational modeling of drug disposition and introduction to modeling techniques including drug absorption, solubility, permeation, ADME, Active transport.

CO3: Apply the knowledge of computer aided formulation development and to know the optimization parameters and factorial design.

CO4: Understand the aspects of biopharmaceutical characterization through computer aided techniques.

CO5: Understand the advantages and disadvantages of artificial intelligence and robotics and to understand the basics of fluid dynamics and the challenges and opportunities.

THEORY **60 Hours**

Unit 1 **12 Hours**

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

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

Unit 2 **12 Hours**

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.

Unit 3 **12 Hours**

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

Unit 4 **12 Hours**

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

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

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

Unit 5 **12 Hours**

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

REFERENCES

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

COSMETICS AND COSMECEUTICALS (MPH 204T)

Scope

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

Course Outcomes: After completion of course student is able to

CO1: Find regulatory requirements relating to manufacture of cosmetics, import of cosmetics and misbranded and spurious cosmetics.

CO2: Understand the biological aspects of structure of skin relating problems and structure of hair and hair growth cycle and common problems associated with oral cavity.

CO3: Explain and understand building blocks for different product formulations of cosmetics and cosmeceuticals

CO4: Understand and design the different cosmetic products addressing skin, hair and oral cavity

THEORY **60 Hours**

Unit 1 **12 Hours**

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.

Unit 2 **12 Hours**

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.

Unit 3 **12 Hours**

Formulation Building blocks: Building blocks for different product formulations of cosmetics /cosmeceuticals. Surfactants – Classification and application. Emollients, rheological additives: classification and application. Antimicrobial used as preservatives, their merits and demerits. Factors affecting microbial preservative efficacy. Building blocks for formulation of a moisturizing cream, vanishing cream, cold cream, shampoo and toothpaste. Soaps and syndet bars.
Perfumes; Classification of perfumes, Perfume ingredients listed as allergens in EU regulation. Controversial ingredients: Parabens, formaldehyde liberators, dioxane.

Unit 4 **12 Hours**

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.

Unit 5 **12 Hours**

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.

REFERENCES

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. 3rd edition
5. Cosmetic and Toiletries recent suppliers catalogue. CTFA directory.

PHARMACEUTICS PRACTICALS – II (MPH 205P)

Scope
This course is designed to provide hand-on practice for formulating and evaluating various novel drug delivery systems as well as the implementation of various softwares for data analysis.

Course Outcomes: After completion of course student is able to
CO1: Develop the formulation and evaluation of various drug delivery systems
CO2: Improve the solubility of slightly soluble drugs by different techniques.
CO3: Perform the Pharmacokinetic study and analyze data using software.
CO4: Utilize application of design software for optimization of dosage forms.
CO5: Develop the formulation and evaluation of various kinds of cosmetics and cosmeceuticals.

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

Seminar Assignment-II

This course provides path to acquired skills and focuses on work in a professional digital format online/offline towards specific job goals and so forth. It also provides an opportunity to re-address previous projects, assignments for inclusion in their portfolios.

Course Outcomes: Through this course students should be able to

CO1: Discuss the methods in the major subject/field of study
CO2: Apply substantive argumentation, utilizing personal views that are based on critical analysis of works from various fields of knowledge
CO3: Assess and critically analyze different solutions
CO4: Demonstrate professional competence by identifying and analyzing emerging issues
CO5: Prioritize professional competence by identifying and analyzing emerging issues
CO6: Apply foundational research skills to address a research question

Syllabus

M.PHARM PHARMACEUTICAL CHEMISTRY (MPC)

Semester I and II

Semester I

MODERN PHARMACEUTICAL ANALYTICAL TECHNIQUES (MPC 101T)

Scope

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

Course Outcomes: Through this course students should be able to

CO1: Demonstrate the principle, techniques and applications of chromatographic techniques
CO2: Illustrate the fundamentals of Fourier transform infrared spectroscopy and its convergence.
CO3: Outline the principle and working of the thermal analytical techniques
CO4: Apply NMR, IR, MS, UV-Vis spectroscopic techniques in solving structure of organic molecules and in determination of their stereochemistry
CO5: Interpret the spectroscopic data of unknown compounds to solve structure elucidation problems.
CO6: Compare the role of different separation techniques

Theory: 60 Hrs

Unit 1 **12 hours**

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

Unit 2 **12 hours**

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

Unit 3 **12 hours**

Chromatography: Principle, apparatus, instrumentation, chromatographic parameters, factors affecting resolution, isolation of drug from excipients, data interpretation and applications of the following:
a) Thin Layer chromatography
b) High Performance Thin Layer Chromatography
c) Ion exchange chromatography
d) Column chromatography
e) Gas chromatography
f) High Performance Liquid chromatography
g) Ultra High Performance Liquid chromatography
h) Affinity chromatography

i) Gel Chromatography

Unit 4 **12 hours**

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.

Unit 5 **12 hours**

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 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 Eastern Ltd., Delhi.
9. Textbook of Pharmaceutical Analysis, KA. Connors, 3rd Edition, John Wiley & Sons, 1982.

ADVANCED ORGANIC CHEMISTRY – I (MPC 102T)

This course 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.

Course Outcomes: Through this course students should be able to

CO1: Analyze the generation and stability of various synthetic process intermediates.
CO2: Understand the concepts of substitution, elimination and rearrangement reactions.
CO3: Define to understand and implement suitable role of name reactions during chemical synthesis.
CO4: Apply the disconnection strategy to develop synthetic routes for small target molecule.
CO5: Examine and demonstrate the practical application of several synthetic reagents and protecting groups.

Theory: 60 Hrs

Unit 1 **12 hours**

1. Basic aspects of organic chemistry:
1. Organic intermediates: Carbocations, carbanions, free radicals, carbenes and nitrenes. Their method of formation, stability and synthetic applications
2. Types of reaction mechanisms and methods of determining them,
3. Detailed knowledge regarding the reactions, mechanisms and their relative reactivity and orientations.
Addition reactions
a) Nucleophilic uni- and bimolecular reactions (SN1 and SN2)
b) Elimination reactions (E1 & E2; Hoffman & Saytzeff's rule)
c) Rearrangement reaction

Unit 2 **12 hours**

Study of mechanism and synthetic applications of following named reactions:
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 Aluminium isopropoxide, 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).

Unit 3 **12 hours**

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

Unit 4 **12 hours**

Heterocyclic Chemistry:
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.

Unit 5 **12 hours**

Synthon approach and retrosynthesis applications

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

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

ADVANCED MEDICINAL CHEMISTRY (MPC 103T)

Scope: This course 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.

Course Outcomes: Through this course students should be able to

CO1: Understand the fundamental concepts of drug discovery and development
CO2: Understand various strategies to design and develop a new drug like molecules for biological targets
CO3: Explain drug receptor concept
CO4: Analyze the structural activity relationship of the important class of drugs
CO5: Discuss the enzyme kinetics and fundamentals of rational design of enzyme inhibitors
CO6: Determine the chemistry of peptidomimetics design and eicosanoids

Theory: 60 Hrs

Unit 1 **12 hours**

Drug discovery: Stages of drug discovery, lead discovery; identification, validation and diversity of drug targets. Biological drug targets: Receptors, types, binding and activation, theories of drug receptor interaction, drug receptor interactions, agonists versus antagonists, artificial enzymes.

Unit 2 **12 hours**

Prodrug Design and Analog design:

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

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

c) Analog Design: Introduction, Classical & Non classical, Bioisosteric replacement strategies, rigid analogs, position isomers, design of stereo isomers and geometric isomers, fragments of a lead molecule, variation in inter atomic distance.

Unit 3 **12 hours**

a) Medicinal chemistry aspects of the following class of drugs Systematic study, SAR, Mechanism of action and synthesis of new generation molecules of following class of drugs:

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

Unit 4 **12 hours**

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

Rational design of enzyme inhibitors 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

Unit 5 **12 hours**

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.

Chemistry of prostaglandins, leukotrienes and thromboxones.

REFERENCES

1. Medicinal Chemistry by Burger, Vol I –VI.

2. Wilson and Gisvold's Text book of Organic Medicinal and Pharmaceutical Chemistry, 12th Edition, Lppincott Williams & Wilkins, Woltess Kluwer (India) Pvt. Ltd, New Delhi.
3. Comprehensive Medicinal Chemistry – Corwin and Hansch.
4. Computational and structural approaches to drug design edited by Robert M Stroud and Janet F Moore.
5. Introduction to Quantitative Drug Design by Y.C. Martin.
6. Principles of Medicinal Chemistry by William Foye, 7th Edition, Lippincott Williams & Wilkins, Wolters Kluwer (India) Pvt.Ltd, New Delhi.
7. Drug Design Volumes by Arienes, Academic Press, Elsevier Publishers, Noida, Uttar Pradesh.
8. Principles of Drug Design by Smith.
9. The Organic Chemistry of the Drug Design and Drug action by Richard B.Silverman, II Edition, Elsevier Publishers, New Delhi.
10. An Introduction to Medicinal Chemistry, Graham L. Patrick, III Edition, Oxford University Press, USA.
11. Biopharmaceutics and Pharmacokinetics, DM. Brahmankar, Sunil B. Jaiswal II Edition, 2014, Vallabh Prakashan, New Delhi.
12. Peptidomimetics in Organic and Medicinal Chemistry by Antonio Guarna and Andrea Trabocchi, First edition, Wiley publishers.

CHEMISTRY OF NATURAL PRODUCTS (MPC 104T)

Scope: This course 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.

Course Outcomes: Through this course students should be able to

CO1: Understand the importance of natural compounds as lead molecules for new drug discovery.
CO2: Explain the isolation, purification and characterization of simple chemical constituents from natural source.
CO3: Identify the medicinal importance of various natural compounds with their chemistry.
CO4: Outline the general methods of structural elucidation for compounds of natural origin.
CO5: Examine the active constituent of certain crude drugs used in Indigenous system.
CO6: Apply the concept of DNA technology tool for new drug discovery

Theory: 60 Hrs

Unit 1 **12 hours**

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 macrolide antibiotics (Erythromycin, Azithromycin, Roxithromycin, and Clarithromycin) and β-Lactam antibiotics (Cephalosporins and Carbapenem)

Unit 2 **12 hours**

a) Alkaloids: General introduction, classification, isolation, purification, molecular modification and biological activity of alkaloids, general methods of structural determination of alkaloids, structural elucidation and stereochemistry of ephedrine, morphine, ergot, emetine and reserpine.
b) Flavonoids: Introduction, isolation and purification of flavonoids, General methods of structural determination of flavonoids; Structural elucidation of quercetin.
c) Steroids: General introduction, chemistry of sterols, sapogenin and cardiac glycosides. Stereochemistry and nomenclature of steroids, chemistry of contraceptive agents male & female sex hormones (Testosterone, Estradiol, Progesterone), adrenocorticoids (Cortisone), contraceptive agents and steroids (Vitamin D).

Unit 3 **12 hours**

a) Terpenoids: 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.

Unit 4 **12 hours**

a) Recombinant DNA technology and drug discovery 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(s) 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.

Unit 5 **12 hours**

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

REFERENCES

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

PHARMACEUTICAL CHEMISTRY PRACTICAL – I (MPC 105P)

This course is designed to provide hand-on practice for analysis of pharmacopoeial compounds and reactions of synthetic importance. It also includes performing isolation, purification and characterization of medicinal compounds.

Course Outcomes: Through this course students should be able to

CO1: Outline the principles involved in pharmaceutical analysis
CO2: Apply appropriate techniques for the qualitative and quantitative analysis of chemicals in laboratories and in industries
CO3: Assess the separation of organic mixture by chromatographic methods.
CO4: Illustrate both basics and practical aspects of separation techniques
CO5: Interpret NMR, IR, MS, UV-Vis spectroscopic techniques in solving structure of organic molecules and in determination of their stereochemistry

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

To perform the following reactions of synthetic importance

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

Seminar/Assignment-I

This course provides path to acquire skills and focuses on work in a professional digital format online/offline towards specific job goals and so forth. It also provides an opportunity to re-address previous projects, assignments for inclusion in their portfolios.

Course Outcomes: Through this course students should be able to

CO1: Analyze the knowledge gained during degree program to generate new skills and present it in a scientific manner
CO2: Develop the presentation proficiency
CO3: Develop specific communication skills associated with reporting technical information
CO4: Apply substantive argumentation, utilizing personal views that are based on critical analysis of works of various field of analysis
CO5: Outline how to cite the different information sources and previous reports related to specific area of the study
CO6: Develop good scientific and writing skills in paper presentation

M. Pharm II Sem

ADVANCED SPECTRAL ANALYSIS (MPC 201T)

This course 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.

Course Outcomes: Through this course students should be able to

CO1: Discuss various theoretical aspects of hyphenated analytical instrumental techniques
CO2: Develop practical skills of the different hyphenated analytical instruments
CO3: Interpret the NMR, Mass and IR spectrum of various organic compounds
CO4: Identify characterize and quantify the drugs using various spectroscopy and chromatography techniques
CO5: Distinguish different thermal analytical methods for the estimation of compounds
CO6: Understand the biological standardization and Radio Immuno Assay (RIA) method for drug estimation

THEORY: 60Hrs

Unit 1 **12 hours**

1. UV and IR spectroscopy:
Wood ward – Fieser rule for 1, 3- butadienes, cyclic dienes and α, β-carbonyl compounds and interpretation compounds of enones. ATR-IR, IR Interpretation of organic compounds.

Unit 2 **12 hours**

NMR spectroscopy:
1-D and 2-D NMR, NOESY and COSY, HECTOR, INADEQUATE techniques, Interpretation of organic compounds

Unit 3 **12 hours**

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.

Unit 4 **12 hours**

Chromatography:
Principle, Instrumentation and Applications of the following:
a) GC-MS b) GC-AAS c) LC-MS d) LC-FTIR e) LC-NMR f) CEMS
g) High Performance Thin Layer chromatography h) Super critical fluid chromatography i) Ion Chromatography j) I-EC (Ion-Exclusion Chromatography) k) Flash chromatography

Unit 5 **12 hours**

a) Thermal methods of analysis: Introduction, principle, instrumentation and application of DSC, DTA and TGA.
b) Raman Spectroscopy: Introduction, Principle, Instrumentation and Applications.
c) Radio immuno assay: Biological standardization, bioassay, ELISA, Radioimmuno assay of digitalis and insulin.

REFERENCES

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

ADVANCED ORGANIC CHEMISTRY – II (MPC 202T)

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

Course Outcomes: Through this course students should be able to

CO1: Discuss the principles and applications of Green chemistry
CO2: Explain the concept of peptide chemistry
CO3: Determine the various catalysts used in organic reactions
CO4: Analyze the concept of stereochemistry
CO5: Examine the concept of photochemical and pericyclic reactions
CO6: Develop the knowledge of carrying out asymmetric synthesis

THEORY: 60 Hrs

Unit 1 **12 hours**

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.

Unit 2 **12 hours**

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, overactivation and side reactions of individual amino acids.

Unit 3 **12 hours**

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, electrocyclic reaction and sigmatrophic rearrangement reactions with examples

Unit 4 **12 hours**

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

Unit 5 **12 hours**

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.

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. Carey, Organic chemistry, 5th edition (Viva Books Pvt. Ltd.)
6. Organic synthesis-the disconnection approach, S. Warren, Wily India
7. Principles of organic synthesis, ROC Norman and JM Coxan, Nelson thorns
8. Organic synthesis- Special techniques VK Ahluwalia and R Aggarwal, Narosa Publishers.
9. Organic reaction mechanisms IV edtn, VK Ahluwalia and RK Parashar, Narosa Publishers.

COMPUTER AIDED DRUG DESIGN (MPC 203T)

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

Course Outcomes: Through this course students should be able to

CO1: Illustrate the role of computer aided drug design in drug discovery
CO2: Determine the ADMET properties of new molecules
CO3: Develop and understand the concept of Quantitative Structure Activity Relationships
CO4: Evaluate the importance of statistical parameters in QSAR
CO5: Define the concept of molecular mechanics and docking in drug design
CO6: Identify in silico drug design and virtual screening techniques

Theory: 60 Hrs

Unit 1 **12 hours**

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.

Unit 2 **12 hours**

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.

Unit 3 **12 hours**

Molecular modeling and docking
a) Molecular and Quantum Mechanics in drug design.
b) Energy Minimization Methods: comparison between global minimum conformation and bioactive conformation
c) Molecular docking and drug receptor interactions: Rigid docking, flexible docking and extra-precision docking. Agents acting on enzymes such as DHFR, HMG-CoA reductase and HIV protease, cholinesterase (AchE & BchE)

Unit 4 **12 hours**

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.

Unit 5 **12 hours**

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.

REFERENCES

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

PHARMACEUTICAL PROCESS CHEMISTRY (MPC 204T)

This course 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.

Course Outcomes: Through this course students should be able to

CO1: Analyze the synthetic strategies on large scale production of APIs
CO2: Demonstrate the extraction procedures and their applications
CO3: Interpret reaction methods and their mechanisms
CO4: Illustrate the reduction methods and their applications
CO5: Apply the reaction progress and kinetic analysis
CO6: Understand the industrial safety and process chemistry

Theory : 60 Hrs

Unit 1 **12 hours**

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

Unit 2 **12 hours**

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.

Unit 3 **12 hours**

Unit Processes - I
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. Non-metallic oxidizing agents such as H_2O_2, sodium hypochlorite,
Oxygen gas, ozonolysis.

Unit 4 **12 hours**

Unit Processes - II
a) Reduction: Catalytic hydrogenation, Heterogeneous and homogeneous catalyst; Hydrogen transfer reactions, Metal hydrides. Case study on industrial reduction process.
b) Fermentation: Aerobic and anaerobic fermentation. Production of
i. Antibiotics; Penicillin and Streptomycin,
ii. Vitamins: B2 and B12
iii. Statins: Lovastatin, Simvastatin
c) Reaction progress kinetic analysis
i. Streamlining reaction steps, route selection,

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

Unit 5 **12 hours**

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

REFERENCES

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

PHARMACEUTICAL CHEMISTRY PRACTICALS – II (MPC 205P)

This course is designed to provide hand-on practice for synthesis of APIs/intermediates by different synthetic routes and interpretation of organic compounds by spectroscopic techniques.

Course Outcomes: Through this course students should be able to

CO1: Analyze the drug-protein interactions using molecular docking software
CO2: Relate the conventional and advanced synthetic methods of organic synthesis
CO3: Interpret the spectra of different organic compounds
CO4: Determine the purity of pharmaceuticals by differential scanning calorimetry
CO5: Make use of different routes for synthesis of organic compounds
CO6: Utilize various software's of drug design

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

Seminar Assignment-II

This course provides path to acquired skills and focuses on work in a professional digital format online/offline towards specific job goals and so forth. It also provides an opportunity to re-address previous projects, assignments for inclusion in their portfolios.

Course Outcomes: Through this course students should be able to

CO1: Discuss the methods in the major subject/field of study
CO2: Apply substantive argumentation, utilizing personal views that are based on critical analysis of works from various fields of knowledge
CO3: Assess and critically analyze different solutions
CO4: Demonstrate professional competence by identifying and analyzing emerging issues
CO5: Prioritize professional competence by identifying and analyzing emerging issues
CO6: Apply foundational research skills to address a research question

Syllabus

M. PHARM PHARMACOGNOSY (MPG)

SEMESTER I and II

MODERN PHARMACEUTICAL ANALYTICAL TECHNIQUES (MPG 101T)

Scope

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

Course Outcomes: After completion of course student is able to
CO1: Demonstrate the principle, techniques and applications of chromatographic techniques
CO2: Illustrate the fundamentals of Fourier transform infrared spectroscopy and its convergence.
CO3: Outline the principle and working of the thermal analytical techniques
CO4: Apply NMR, IR, MS, UV-Vis spectroscopic techniques in solving structure of organic molecules and in determination of their stereochemistry
CO5: Interpret the spectroscopic data of unknown compounds to solve structure elucidation problems.
CO6: Compare the role of different separation techniques

THEORY: **60 Hours**

Unit 1 **12 Hours**

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

Unit 2 **12 Hours**

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

Unit 3 **12 Hours**

Chromatography: Principle, apparatus, instrumentation, chromatographic parameters, factors affecting resolution, isolation of drug from excipients, data interpretation and applications of the following:
a) Thin Layer chromatography
b) High Performance Thin Layer Chromatography
c) Ion exchange chromatography
d) Column chromatography
e) Gas chromatography
f) High Performance Liquid chromatography
g) Ultra High Performance Liquid chromatography
h) Affinity chromatography
i) Gel Chromatography

Unit 4 **12 Hours**

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.

Unit 5 **12 Hours**

Potentiometry: Principle, working, Ion selective Electrodes and Application of potentiometry
Thermal Techniques: Principle, thermal transitions and Instrumentation (Heat flux and power-compensation and designs), Modulated DSC, Hyper DSC, experimental parameters (sample preparation, experimental conditions, 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. 2. Principles of Instrumental Analysis - Doglas A Skoog, F. James Holler, Timothy A. Nieman, 5 th edition, Eastern press, Bangalore, 1998.
3. Instrumental methods of analysis – Willards, 7th edition, CBS publishers.
4. Practical Pharmaceutical Chemistry – Beckett and Stenlake, Vol II, 4th edition, CBS Publishers, New Delhi, 1997.
5. Organic Spectroscopy - William Kemp, 3rd edition, ELBS, 1991.
6. Quantitative Analysis of Drugs in Pharmaceutical formulation - P D Sethi, 3rd Edition, CBS Publishers, New Delhi, 1997.
7. Pharmaceutical Analysis - Modern Methods – Part B - J W Munson, Vol 11, Marcel. Dekker Series
8. Spectroscopy of Organic Compounds, 2nd Edn., P.S Kalsi, Wiley estern Ltd., Delhi.

ADVANCED PHARMACOGNOSY - I (MPG 102T)

SCOPE

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

Course Outcomes: After completion of course student is able to
CO1: Understand the advances in drug cultivation and production
CO2 : Understand various phytopharmaceuticals along with their sources, its utilization and medicinal value
CO3 : Summarize knowledge about various nutraceuticals or herbs and their health benefits
CO4 : Outine about the drugs of marine origin
CO5 : Examine the Pharmacovigilance of natural origin drugs

Theory : 60 Hours

Unit 1 **12 Hours**

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.

Unit 2 **12 Hours**

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

Unit 3 **12 Hours**

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

Unit 4 **12 Hours**

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

Unit 5 **12 Hours**

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

REFERENCES (Latest Editions of)

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

PHYTOCHEMISTRY (MPG 103T)

SCOPE

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

Course Outcomes: After completion of course student is able to

CO1: Knowledge about the various classes/categories of phytoconstituents along with their biosynthesis, isolation and characterization techniques

CO2: Understand the process of drug discovery from plants and acquire knowledge about various steps involved in drug development

CO3: Categorize different methods of extraction and fractionation of phytoconstituents

CO4:Relate about phytochemical fingerprinting of extracts by chromatography techniques

CO5: Determine in vitro and in vivo screening techniques for detection of bioactive phytoconstituents

THEORY **60 Hours**

Unit 1 **12 Hours**

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 phytopharmaceuticals containing drugs:

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

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

c) Steroids: Hecogenin, guggulosterone and withanolides

d) Coumarin: Umbelliferone

e) Terpenoids: Cucurbitacins

Unit 2 **12 Hours**

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

Unit 3 **12 Hours**

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

Unit 4 **12 Hours**

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

Unit 5 **12 Hours**

Structure elucidation of the following compounds by spectroscopic techniques like UV, IR, MS, NMR (^{1}H, ^{13}C)

a. Carvone, Citral, Menthol

b. Luteolin, Kaempferol

c. Nicotine, Caffeine

d. Glycyrrhizin

REFERENCES (Latest Editions of)

1. Organic chemistry by I.L. Finar Vol.II
2. Pharmacognosy by Trease and Evans, ELBS.
3. Pharmacognosy by Tylor and Brady.
4. Text book of Pharmacognosy by Wallis.
5. Clark's isolation and Identification of drugs by A.C. Mottal.
6. Plant Drug Analysis by Wagner & Bladt.
7. Wilson and Gisvold's text book of Organic Medicinal 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
13. Medicinal Natural products – a biosynthetic approach, Dewick PM, John Wiley & Sons, Toronto, 1998.
14. Chemistry of Natural Products, Bhat SV, Nagasampagi BA, Meenakshi S, Narosa Publishing House, New Delhi.
15. Pharmacognosy & Phytochemistry of Medicinal Plants, 2nd edition, Bruneton J, Interceptt Ltd., New York, 1999.

INDUSTRIAL PHARMACOGNOSTICAL TECHNOLOGY (MPG 104T)

SCOPE

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

Course Outcomes: After completion of course student is able to

CO1: Propose about starting up of new herbal drug industry

CO2: Develop knowledge about regulatory requirements or documentation for starting a new herbal drug industry

CO3: Find information about Export and import policies in herbal industry sector

CO4: Understand the concept of ISO documentation, GMP / GLP in Herbal drug sector and Monograph preparation

CO5: Develop different testing protocols of herbal drugs and acquire knowledge about Intellectual Property Rights and Patenting

THEORY **60 Hours**

Unit 1 **12 Hours**

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

Unit 2 **12 Hours**

Regulatory requirements for setting herbal drug industry: Global marketing management, Indian and international patent law as applicable herbal drugs and natural products, Export - Import (EXIM) policy, TRIPS, Quality assurance in herbal/natural drug products. Concepts of TQM, GMP, GLP, ISO-9000

Unit 3 **12 Hours**

Monographs of herbal drugs: General parameters of monographs of herbal drugs and comparative study in IP, USP, Ayurvedic Pharmacopoeia, Siddha and Unani Pharmacopoeia, American herbal pharmacopoeia, British herbal pharmacopoeia, WHO guidelines in quality assessment of herbal drugs

Unit 4 **12 Hours**

Testing of natural products and drugs: Herbal medicines - clinical laboratory testing. Stability testing of natural products, protocols.

Unit 5 **12 Hours**

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.

REFERENCES (Latest Editions of)

1. Herbal drug industry by R.D. Choudhary (1996), Eastern Publisher, New Delhi.
2. GMP for Botanicals - Regulatory and Quality issues on Phytomedicine by Pulok K Mukharjee (2003), Ist Edition, Business horizons Robert Verpoorte, New Delhi.
3. Quality control of herbal drugs by Pulok K Mukherjee (2002), Business Horizons Pharmaceutical Publisher, New Delhi.

4. PDR for Herbal Medicines (2000), Medicinal Economic Company, NewJersey.
5. Indian Herbal Pharmacopoeia (2002), IDMA, Mumbai.
6. Text book of Pharmacognosy by C.K. Kokate, Purohit, Gokhlae (1996), Nirali Prakashan, New Delhi.
7. Text book of Pharmacognosy and Phytochemistry by Vinod D. Rangari (2002), Part I & II, Career Publication, Nasik, India.
8. Plant drug analysis by H. Wagner and S. Bladt, Springer, Berlin.
9. Standardization of Botanicals. Testing and extraction methods of medicinal herbs by V. Rajpal (2004), Vol. I, Eastern Publisher, New Delhi
10. Phytochemical Dictionary. Handbook of Bioactive Compounds from Plants by J.B. Harborne, (1999), IInd Edition, Taylor and Francis Ltd, UK
11. Herbal Medicine. Expanded Commission E Monographs by M. Blumenthal, (2004), IST Edition
12. Drug Formulation Manual by D.P.S. Kohli and D.H. Shah (1998), Eastern Publisher, New Delhi.

PHARMACOGNOSY PRACTICAL - I (MPG I05P)

This course is designed to provide hand-on practice for analysis of Pharmacopoeial compounds of natural origin and their formulations. It also includes performing isolation, purification and characterization of natural compounds through chromatography and spectroscopy.

Course Outcomes: After completion of course student is able to
CO1: Outline the principles involved in analysis of phytoconstituents
CO2: Apply appropriate techniques for the qualitative and quantitative analysis of phytochemicals in laboratory
CO3: Interpret spectra of unknown phyotconstituents using various spectral approaches
CO4: Illustrate separation of phytoconstituents by chromatographic methods.
CO5: Illustrate both basics and practical aspects of separation techniques
CO6: Interpret NMR, IR, MS, UV-Vis spectroscopic techniques for structure elucidation

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

Seminar/Assignment-I

This course provides path to acquire skills and focuses on work in a professional digital format online/offline towards specific job goals and so forth. It also provides an opportunity to re-address previous projects, assignments for inclusion in their portfolios.

Course Outcomes: Through this course students should be able to

CO1: Analyze the knowledge gained during degree program to generate new skills and present it in a scientific manner

CO2: Develop the presentation proficiency

CO3: Develop specific communication skills associated with reporting technical information

CO4: Apply substantive argumentation, utilizing personal views that are based on critical analysis of works of various field of analysis

CO5: Outline how to cite the different information sources and previous reports related to specific area of the study

CO6: Develop good scientific and writing skills in paper presentation

SEMESTER II

MEDICINAL PLANT BIOTECHNOLOGY (MPG 201T)

SCOPE

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

Course Outcomes: After completion of course student is able to

CO1: Relate the role of plant biotechnology and rDNA technology in the field of pharmacy

CO2: Understand different techniques of plant tissue culture and their applications

CO3: Apply the process like genetic engineering in medicinal plants for higher yield of Phytopharmaceuticals

CO4- Utilize the biotechnological techniques for obtaining and improving the quality of natural products/medicinal plants

THEORY **60 Hours**

Unit 1 **12 Hours**

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

Unit 2 **15 Hours**

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.

Unit 3 **15 Hours**

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

Unit 4 **13 Hours**

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

Unit 5 **5 Hours**

Fermentation technology: Application of Fermentation technology, Production of ergot alkaloids, single cell proteins, enzymes of pharmaceutical interest

REFERENCES (Latest Editions of)

1. Plant tissue culture, Bhagwani, vol 5, Elsevier Publishers.
2. Plant cell and Tissue Culture (Lab. Manual), JRMM. Yeoman.
3. Elements in biotechnology by PK. Gupta, Rastogi Publications, New Delhi.
4. An introduction to plant tissue culture by MK. Razdan, Science Publishers.
5. Experiments in plant tissue culture by John HD and Lorin WR., Cambridge University Press.
6. Pharmaceutical biotechnology by SP. Vyas and VK. Dixit, CBS Publishers.
7. Plant cell and tissue culture by Jeffrey W. Pollard and John M Walker, Humana press.

8. Plant tissue culture by Dixon, Oxford Press, Washington DC, 1985
9. Plant tissue culture by Street.
10. Pharmacognosy by G. E. Trease and WC. Evans, Elsevier.
11. Biotechnology by Purohit and Mathur, Agro-Bio, 3 rd revised edition.
12. Biotechnological applications to tissue culture by Shargool, Peter D, Shargoal, CKC Press.
13. Pharmacognosy by Varo E. Tyler, Lynn R. Brady and James E. Robberrt, That Tjen, NGO.
14. Plant Biotechnology, Ciddi Veerasham.

ADVANCED PHARMACOGNOSY - II (MPG 202T)

SCOPE

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

Course Outcomes: After completion of course student is able to

CO1: Recall about validation of herbal remedies
CO2- Demonstrate about drug adulteration and evaluation techniques
CO3- Develop Analytical Profiles of herbal drugs
CO4- Understand about different methods of screening of herbals for various biological properties

THEORY **60 Hours**

Unit 1 **12 Hours**

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

Unit 2 **12 Hours**

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

Unit 3 **12 Hours**

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

Unit 4 **12 Hours**

Analytical Profiles of herbal drugs: Andrographis paniculata, Boswellia serata, Coleus forskholii, Curcuma longa, Embelica officinalis, Psoralea corylifolia

Unit 5 **12 Hours**

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.

REFERENCES (Latest Editions of)

1. Glimpses of Indian Ethano Pharmacology by P. Pushpangadam. Ulf Nyman. V.George Tropical Botanic Garden & Research Institute
2. Natural products: A lab guide by Raphael Ikan, Academic Press
3. Pharmacognosy - G. E. Trease and W.C. Evans. WB. Saunders Edinburgh, New York
4. Pharmacognosy-Tyler, Brady, Robbers, Lee & Fetiger
5. Modem Methods of Plant Analysis- Peach & M.V. Tracey, Vol. I & II, Springer Publishers
6. Herbal Drug Industry by RD. Choudhary, Eastern Publishers, New Delhi
7. Text book of Pharmacognosy by C.K.Kokate, Purohit, Ghokhale, Nirali Prakashan
8. Text Book of Pharmacognosy by T.E. Wallis, J & A Churchill Ltd., London
9. Quality control of herbal drugs by Pulok K Mukherjee, Business Horizons Pharmaceutical Publishers, New Delhi
10. Indian Herbal Pharmacopoeia, IDMA, Mumbai

11. Text book of Pharmacognosy and Phytochemistry by Vinod D. Rangari, Part I & II, Career Publication, Nasik, India
12. Plant drug analysis by H. Wagner and S. Bladt, 2nd edition, Springer, Berlin
13. Standardization of Botanicals. Testing and extraction methods of medicinal herbs by V. Rajpal (2004), Vol. I, Eastern Publisher, New Delhi
14. Herbal Medicine. Expanded Commission E Monographs, M.Blumenthal

INDIAN SYSTEMS OF MEDICINE (MPG 203T)

SCOPE

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

Course Outcomes: After completion of course student is able to

CO1: Understand the basic principles of various Indian systems of medicine

CO2: Find salient features of the techniques of preparation of some of the important class of Formulations as per Ayurveda, Siddha, Homeopathy and Unani Pharmacopoeia

CO3: Make use of the clinical research of traditional medicines, Current Good Manufacturing Practice in Indian systems of medicine and their formulations

THEORY **60 Hours**

Unit 1 **12 Hours**

Fundamental concepts of Ayurveda, Siddha, Unani and Homoeopathy systems of medicine Different dosage forms of the ISM.

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

Unit 2 **12 Hours**

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.

Unit 3 **12 Hours**

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

Unit 4 **12 Hours**

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 ISM formulation industry - GAP, GMP and GLP, Preparation of documents for new drug application and export registration, Challenges in monitoring the safety of herbal medicines: Regulation, quality assurance and control, National/Regional Pharmacopoeias.

Unit 5 **12 Hours**

TKDL, Geographical indication Bill, Government bills in AYUSH, ISM, CCRAS, CCRS, CCRH, CCRU

REFERENCES (Latest Editions of)

1. Ayurvedic Pharmacopoeia, The Controller of Publications, Civil Lines, Govt. of India, New Delhi.
2. Hand Book on Ayurvedic Medicines, H. Panda, National Institute of Industrial Research, New Delhi.
3. Ayurvedic System of Medicine, Kaviraj Nagendranath Sengupata, Sri Satguru Publications, New Delhi.
4. Ayurvedic Pharmacopoeia. Formulary of Ayurvedic Medicines, IMCOPS, Chennai.

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

HERBAL COSMETICS (MPG 204T)

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

Course Outcomes: After completion of course student is able to
CO1: Understand the basic principles of various herbal/natural cosmetic preparations
CO2 Demonstrate Current Good Manufacturing Practices of herbal/natural cosmetics as per the regulatory authorities
CO3- Analysis of Cosmetics, Toxicity screening and testing methods
CO4- Explain Quality control and toxicity studies as per Drug and Cosmetics Act

THEORY **60 Hours**

Unit 1 **12 Hours**
Introduction: Herbal/natural cosmetics, Classification & Economic aspects. Regulatory Provisions relation to manufacture of cosmetics: - License, GMP, offences & Penalties, Import & Export of Herbal/natural cosmetics, Industries involved in the production of Herbal/natural cosmetics.

Unit 2 **12 Hours**
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

Unit 3 **12 Hours**
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

Unit 4 **12 Hours**
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.

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

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

HERBAL COSMETICS PRACTICALS (MPG 205P)

Scope- This course is designed to provide knowledge of different techniques involved in isolation technique of nucleic acid, immobilization and plant tissue culture. It also includes preparation and standardization study of various herbal products.

Course Outcomes: After completion of course student is able to
CO1: Outline the principles involved in isolation of nucleic acid
CO2: Apply appropriate estimation techniques for nucleic acid and phytoconstituents
CO3: Acquire knowledge about preparation and standardization of herbal products
CO4: Demonstrate about manufacturing process of aromatherapy formulations.
CO5: Explain more about preparation of Herbal cosmetics

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

Seminar Assignment-II

This course provides path to acquired skills and focuses on work in a professional digital format online/offline towards specific job goals and so forth. It also provides an opportunity to re-address previous projects, assignments for inclusion in their portfolios.

Course Outcomes: Through this course students should be able to

CO1: Discuss the methods in the major subject/field of study
CO2: Apply substantive argumentation, utilizing personal views that are based on critical analysis of works from various fields of knowledge
CO3: Assess and critically analyze different solutions
CO4: Demonstrate professional competence by identifying and analyzing emerging issues
CO5: Prioritize professional competence by identifying and analyzing emerging issues
CO6: Apply foundational research skills to address a research question

Syllabus for

M. Pharm Pharmacology (MPL)

Semester I and II

Semester I

MODERN PHARMACEUTICAL ANALYTICAL TECHNIQUES (MPL 101T)

Scope

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

Course Outcomes: Through this course students should be able to

CO1: Demonstrate the principle, techniques and applications of chromatographic techniques
CO2: Illustrate the fundamentals of Fourier transform infrared spectroscopy and its convergence.
CO3: Outline the principle and working of the thermal analytical techniques
CO4: Apply NMR, IR, MS, UV-Vis spectroscopic techniques in solving structure of organic molecules and in determination of their stereochemistry
CO5: Interpret the spectroscopic data of unknown compounds to solve structure elucidation problems.
CO6: Compare the role of different separation techniques

Theory: 60 Hrs

Unit 1 **12 hours**

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

Unit 2 **12 hours**

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

Unit 3 **12 hours**

Chromatography: Principle, apparatus, instrumentation, chromatographic parameters, factors affecting resolution, isolation of drug from excipients, data interpretation and applications of the following:
a) Thin Layer chromatography
b) High Performance Thin Layer Chromatography
c) Ion exchange chromatography
d) Column chromatography
e) Gas chromatography
f) High Performance Liquid chromatography
g) Ultra High Performance Liquid chromatography
h) Affinity chromatography
i) Gel Chromatography

Unit 4 **12 hours**

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.

Unit 5 **12 hours**

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 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 Eastern Ltd., Delhi.
9. Textbook of Pharmaceutical Analysis, KA. Connors, 3rd Edition, John Wiley & Sons, 1982.

REFERENCES

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

ADVANCED PHARMACOLOGY – I (MPL 102T)

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

Course Outcome: After completion of the course the student shall be able to
CO1: Discuss the pathophysiology and pharmacotherapy of certain diseases
CO2: Explain the mechanism of drug actions at cellular and molecular level
CO3: Relate the adverse effects, contraindications and clinical uses of drugs in the treatment of diseases.

THEORY **60 Hours**

1. General Pharmacology **12 Hours**
a. Pharmacokinetics: The dynamics of drug absorption, distribution, biotransformation and elimination. Concepts of linear and non-linear compartment models, Significance of protein binding.
b. Pharmacodynamics: Mechanism of drug action and the relationship between drug concentration and effect. Receptors, structural and functional families of receptors, quantitation of drug receptors interaction and elicited effects.

2. Neurotransmission **12 Hours**
a. General aspects and steps involved in neurotransmission.
b. Neurohumoral transmission in autonomic nervous system (Detailed study about neurotransmitters- adrenaline and acetylcholine).
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). Cotransmission.
Systemic Pharmacology: A detailed study on pathophysiology of diseases, mechanism of action, pharmacology and toxicology of existing as well as novel drugs used in the following systems: -
Autonomic Pharmacology
Parasympathomimetics and lytics, sympathomimetics and lytics, agents affecting neuromuscular junction.

3. Central nervous System Pharmacology: **12 Hours**
General and local anesthetics
Sedatives and hypnotics, drugs used to treat anxiety.
Depression, psychosis, mania, epilepsy, neurodegenerative diseases.
Narcotic and non-narcotic analgesics.

4. Cardiovascular Pharmacology: **12 Hours**
Diuretics, antihypertensives, antiischemics, antiarrhythmics, drugs for heart failure and hyperlipidemia. Hematinics, coagulants, anticoagulants, fibrinolytics and antiplatelet drugs

5. Autocoid Pharmacology **12 Hours**
The physiological and pathological role of histamine, serotonin, kinins, prostaglandins, opioid autocoids. Pharmacology of antihistamines, 5-HT antagonists.

REFERENCES
1. The Pharmacological Basis of Therapeutics, Goodman and Gillman‘s

2. Principles of Pharmacology. The Pathophysiologic basis of drug Therapy by David E Golan, Armen H, Tashjian Jr, Ehrin J,Armstrong, April W, Armstrong, Wolters, Kluwer-Lippincott Williams & Wilkins Publishers.
3. Basic and Clinical Pharmacology by B.G Katzung.
4. Hand book of Clinical Pharmacokinetics by Gibaldi and Prescott.
5. Applied biopharmaceutics and Pharmacokinetics by Leon Shargel and Andrew B.C.Yu.
6. Graham Smith. Oxford textbook of Clinical Pharmacology.
7. Avery Drug Treatment
8. Dipiro Pharmacology, Pathophysiological approach.
9. Green Pathophysiology for Pharmacists
10. Robbins &Cortan Pathologic Basis of Disease, 9th Ed. (Robbins Pathology).
11. A Complete Textbook of Medical Pharmacology by Dr. S.K Srivastava published by APC Avichal Publishing Company.
12. KD.Tripathi. Essentials of Medical Pharmacology.
13. Modern Pharmacology with Clinical Applications, Craig Charles R. & Stitzel Robert E., Lippincott Publishers.
14. Clinical Pharmacokinetics &Pharmacodynamics : Concepts and Applications – Malcolm Rowland and Thomas N. Tozer, Wolters Kluwer, Lippincott Williams & Wilkins Publishers.
15. Applied biopharmaceutics and Pharmacokinetics, Pharmacodynamics and Drug metabolism for industrial scientists.
16. Modern Pharmacology, Craig CR. & Stitzel RE, Little Brown & Company.

PHARMACOLOGICAL AND TOXICOLOGICAL SCREENING METHODS – I (MPL 103T)

Scope

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

Course outcome: After completion of the course the student shall be able to

CO1: Explain the regulations and ethical requirement for the usage of experimental animals.

CO2: Make use of various animals in the drug discovery process and apply good laboratory practices in maintenance and handling of experimental animals

CO3: Discuss the various newer screening methods involved in the drug discovery process

CO4: Develop understanding to appreciate and correlate the preclinical data to humans

THEORY **60 Hours**

Unit I **12 Hours**

Laboratory Animals

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

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

Bioassay-Principle, scope and limitations and methods

Unit II **12 Hours**

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 coordination, CNS stimulants and nootropics. Drugs for neurodegenerative diseases like Parkinsonism, Alzheimers and multiple sclerosis. Drugs acting on Autonomic Nervous System.

Unit III **12 Hours**

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 Hours**

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, antidyslipidemic agents. Anti-cancer agents. Hepatoprotective screening methods.

Unit V **12 Hours**

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

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

experimentation and alternate animal experiments. Extrapolation of in vitro data to preclinical and preclinical to humans.

REFERENCES

1. Screening Methods in Pharmacology by Turner R.A., Hebborn P., Academic Press, Cambridge.
2. Evaluation of drugs activities by Laurence D.R., Bacharach A.L., Academic Press, Cambridge.
3. Methods in Pharmacology by Arnold S., Springer, New York.
4. Fundamentals of Experimental Pharmacology by Ghosh M.N. Scientific Book Agency, Calcutta.
5. Pharmacological Experiment on Intact Preparations by Mcleod, L.J., Churchill Livingstone, London.
6. Drug discovery and Evaluation by Vogel H.G., Springer-Verlag, Heidelberg.
7. Practicals in Pharmacology by Goyal R.K., B.S. Shah Prakashan, Ahmadabad.
8. Preclinical Evaluation of New Drugs by Gupta S.K., Jaypee Brothers Medical Publishers Private Limited, New Delhi.
9. CPCSEA, OECD, ICH, USFDA, Schedule Y, EPA Guidelines.
10. Biological standardization by J.H. Burn D.J. Finney and I.G. Goodwin.
11. Handbook of Experimental Pharmacology, S.K..Kulkarni.
12. Practical Pharmacology and Clinical Pharmacy, S.K..Kulkarni, 3rd Edition.
13. David R. Gross. Animal Models in Cardiovascular Research, 2nd Edition, Kluwer Academic Publishers, London, UK.
14. Screening Methods in Pharmacology, Robert A. Turner.
15. Rodents for Pharmacological Experiments, Tapan Kumar Chatterjee.
16. Practical Manual of Experimental and Clinical Pharmacology by Bikash Medhi (Author), Ajay Prakash (Author).

CELLULAR AND MOLECULAR PHARMACOLOGY (MPL 104T)

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

Course Outcome: After completion of the course, the student shall be able to
CO1: Explain the receptor signal transduction processes.
CO2: Identify the molecular pathways affected by drugs.
CO3: Develop ability to appreciate the applicability of molecular pharmacology and biomarkers in drug discovery process.
CO4: Support molecular biology techniques as applicable for pharmacology.

THEORY **60 Hours**

Unit I **12 Hours**
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 **12 Hours**
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 **12 Hours**
Principles and applications of genomic and proteomic tools DNA electrophoresis, PCR (reverse transcription and real time), Gene sequencing, micro array technique, SDS page, ELISA and western blotting, recombinant DNA technology and gene therapy. Basic principles of recombinant DNA technology-Restriction enzymes, various types of vectors. Applications of recombinant DNA technology.
Gene therapy- Various types of gene transfer techniques, clinical applications and recent advances in gene therapy.

Unit IV
4. Pharmacogenomics
Gene mapping and cloning of disease gene.
Genetic variation and its role in health/ pharmacology.
Polymorphisms affecting drug metabolism.
Genetic variation in drug transporters.
Genetic variation in G protein coupled receptors.
Applications of proteomics science: Genomics, proteomics, metabolomics, functionomics, nutrigenomics.
Immunotherapeutics: Types of immunotherapeutics, humanisation antibody therapy, Immunotherapeutics in clinical practice

Unit V
a. Cell Culture Techniques: Basic equipments used in cell culture lab. Cell culture

media, various types of cell culture, general procedure for cell cultures: Isolation of cells, subculture, cryopreservation, characterization of cells and their application. Principles and applications of cell viability assays, glucose uptake assay, calcium influx assays. Principles and applications of flow cytometry.

b. Biosimilars

REFERENCES:

1. The Cell, A Molecular Approach. Geoffrey M Cooper, Sinauer Publisher, USA.
2. Pharmacogenomics: The Search for Individualized Therapies. Edited by J. Licinio and M -L. Wong, Wiley-VCH, Weinheim.
3. Handbook of Cell Signaling by Bradshaw R.A., Denis E.A., Academic Press, Cambridge (Second Edition) Edited by Ralph A. et.al.
4. Molecular Pharmacology: From DNA to Drug Discovery. John Dickenson et.al., Wiley, Colorado.
5. Basic Cell Culture protocols by CherilD.Helgason and Cindy L.Miller, Springer, New York.
6. Basic Cell Culture (Practical Approach) by J. M. Davis (Editor), Oxford University Press, Oxford
7. Animal Cell Culture: A Practical Approach by John R. Masters (Editor), Oxford University Press, Oxford.
8. Current porotocols in molecular biology, Vol I to VI edited by Frederick M. Ausuvel et al., Wiley, New Jersey

PHARMACOLOGY PRACTICAL – I (MPL 105P)

Course Outcome: After completion of course, student is able to

CO1: Remember various routes of drug administration.
CO2: Understand techniques of blood sampling, anesthesia and euthanasia of experimental animals
CO3: Analyze CNS stimulant, depressant, anxiogenics and anxiolytic, anticonvulsant activity
CO4: Evaluate analgesic, anti-inflammatory, local anesthetic, mydriatic and miotic activity, diuretic activity, antiulcer activity by pylorus ligation method.
CO5: Evaluate Protein quantification Western Blotting.

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

Handling of laboratory animals:

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

Seminar/Assignment-I

This course provides path to acquire skills and focuses on work in a professional digital format online/offline towards specific job goals and so forth. It also provides an opportunity to re-address previous projects, assignments for inclusion in their portfolios.

Course Outcomes: Through this course students should be able to

CO1: Analyze the knowledge gained during degree program to generate new skills and present it in a scientific manner
CO2: Develop the presentation proficiency
CO3: Develop specific communication skills associated with reporting technical information
CO4: Apply substantive argumentation, utilizing personal views that are based on critical analysis of works of various field of analysis
CO5: Outline how to cite the different information sources and previous reports related to specific area of the study
CO6: Develop good scientific and writing skills in paper presentation

SECOND SEMESTER

ADVANCED PHARMACOLOGY – II (MPL 201T)

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

Course Outcome: After completion of the course the student shall be able to
CO1: Understand the mechanism of drug actions at cellular and molecular level.
CO2: Distinguish the pathophysiology and pharmacotherapy of certain diseases.
CO3: Understand the adverse effects, contraindications and clinical uses of drugs used in treatment of diseases.

THEORY **60 Hours**

Unit I **12 Hours**
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
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
Chemotherapy: Drugs used in protozoal infections Drugs used in the treatment of helminthiasis Chemotherapy of cancer Immunopharmacology Cellular and biochemical mediators of inflammation and immune response. Allergic or hypersensitivity reactions. Pharmacotherapy of asthma and COPD. Immunosuppressants and immunostimulants

Unit IV
GIT Pharmacology: Antiulcer drugs, prokinetics, antiemetics, anti-diarrheals and drugs for constipation and irritable bowel syndrome. Chronopharmacology Biological and circadian rhythms, applications of chronotherapy in various diseases like cardiovascular disease, diabetes, asthma and peptic ulcer.

Unit V
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: Alzheimer's disease, Parkinson's disease, Cancer, Diabetes Mellitus.

REFERENCES
1. Goodman and Gill man's-The Pharmacological Basis of Therapeutics- by Hardman J.G., Limbird Le, Molinoss P.B., Ruddon R.W. and Gil A.G.,
2. Principles of Pharmacology. The Pathophysiologic Basis of Drug Therapy by David E Golan et al., Wolters Kluwer, Alphen aan den Rijn.
3. Basic and Clinical Pharmacology by B.G –Katzung, Prentice Hall International, New Jersey.
4. Pharmacology by H.P. Rang and M.M. Dale, Churchill Livingstone, London.
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, Williams and Wilkins, Philadelphia.
7. Applied Biopharmaceutics and Pharmacokinetics by Leon Shargel and Andrew B.C. Yu.
8. Handbook of Essential Pharmacokinetics, Pharmacodynamics and Drug Metabolism for Industrial Scientists.
9. Robbins & Cortan Pathologic Basis of Disease, 9th Ed. (Robbins Pathology).
10. A Complete Textbook of Medical Pharmacology by Dr. S.K Srivastava published by APC Avichal Publishing Company.
11. Essentials of Medical Pharmacology, K.D. Tripathi.
12. Principles of Pharmacology. The Pathophysiologic Basis of Drug Therapy by David E Golan, Armen H, Tashjian Jr, Ehrin J, Armstrong, April W, Armstrong, Wolters, Kluwer-Lippincott Williams & Wilkins Publishers.

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

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

Course outcome: After completion of the course, the student shall be able to
CO1: Explain various types of toxicity studies.
CO2: Understand to appreciate the importance of ethical and regulatory requirements for toxicity studies.
CO3: Develop knowledge to determine the practical skills required to conduct the preclinical toxicity studies.

THEORY **60 Hours**

Unit I **12 Hours**
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 Hours**
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 Hours**
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 Hours**
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 Hours**
Toxicokinetics- Toxicokinetic evaluation in preclinical studies, saturationkinetics. 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/glphandbook.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/ucm07324 6.pdf)

PRINCIPLES OF DRUG DISCOVERY (MPL 203T)

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

Course Outcomes: After completion of the course, the student shall be able to
CO1: Find the various stages of drug discovery.
CO2: Assess the importance of the role of genomics, proteomics and bioinformatics in drug discovery.
CO3: Outline various targets for drug discovery.
CO4: Demonstrate various lead seeking method and lead optimization.
CO5: Evaluate the importance of the role of computer aided drug design in drug discovery.

THEORY **60 Hours**

Unit I **12 Hours**

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 Hours**

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. Applications of NMR and X-ray crystallography in protein structure prediction.

Unit III **12 Hours**

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 Hours**

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 Hours**

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. Mouldy Sioud. Target Discovery and Validation Reviews and Protocols: Volume 2 Emerging Molecular Targets and Treatment Options. 2007 Humana Press Inc.
2. Darryl León. Scott MarkelIn. Silico Technologies in Drug Target Identification and Validation. 2006 by Taylor and Francis Group, LLC.

3. Johanna K. DiStefano. Disease Gene Identification. Methods and Protocols. Springer New York Dordrecht Heidelberg London.
4. Hugo Kubiny. QSAR: Hansch Analysis and Related Approaches. Methods and Principles in Medicinal Chemistry. Publisher Wiley-VCH.
5. Klaus Gubernator, Hans-Joachim Böhm. Structure-Based Ligand Design. Methods and Principles in Medicinal Chemistry. Publisher Wiley-VCH.
6. Abby L. Parrill. M. Rami Reddy. Rational Drug Design. Novel Methodology and Practical Applications. ACS Symposium Series; American Chemical Society: Washington, DC, 1999. 7. J. Rick Turner. New drug development design methodology and analysis. John Wiley & Sons, Inc., New Jersey.

CLINICAL RESEARCH AND PHARMACOVIGILANCE (MPL 204T)

Scope
This subject will provide a value addition and current requirement for the students in clinical research and pharmacovigilance. It will teach the students on conceptualizing, designing, conducting, managing and reporting of clinical trials. This subject also focuses on global scenario of pharmacovigilance in different methods that can be used to generate safety data. It will teach the students in developing drug safety data in pre-clinical, clinical phases of drug development and post market surveillance.

Course Outcomes: After completion of the course, the student shall be able to
CO1: Analyze the regulatory requirements for conducting clinical trial.
CO2: Evaluate the types of clinical trial designs.
CO3: Understand the responsibilities of key players involved in clinical trials.
CO4: Understand to execute safety monitoring, reporting and close-out activities.
CO5: Outline the principles of pharmacovigilance.
CO6: Find new adverse drug reactions and their assessment.

THEORY **60 Hours**

Unit I **12 Hours**

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 Hours**

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 Hours**

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.

Unit IV **12 Hours**

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 centers in hospitals, industry and national programmes related to pharmacovigilance. Roles and responsibilities in pharmacovigilance

Unit V **12 Hours**

Methods, ADR reporting and tools used in pharmacovigilance international classification of diseases, international nonproprietary 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. Pharmacoepidemiology, 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.

PHARMACOLOGY PRACTICAL – II (MPL 205P)

Course Outcomes: After completion of course, student is able to

CO1: Apply the DRC of agonist using suitable isolated tissues preparation.
CO2: Understand antagonist/potentiating agents on DRC of agonist using suitable isolated tissue preparation.
CO3: Understand the strength of unknown sample by matching bioassay, interpolation bioassay, bracketing bioassay and multiple point bioassays by using suitable tissue preparation.
CO4: Evaluate PA2 values of various antagonists using suitable isolated tissue preparations.
CO5: Evaluate dose toxicity studies- Serum biochemical, hematological, urine analysis, functional observation tests and histological studies.
CO6: Remember acute oral toxicity & acute dermal toxicity studies as per OECD guidelines.
CO7: Create ADR monitoring protocol.

1. To record the DRC of agonist using suitable isolated tissues preparation.
2. To study the effects of antagonist/potentiating agents on DRC of agonist using suitable isolated tissue preparation.
3. To determine to the strength of unknown sample by matching bioassay by using suitable tissue preparation.
4. To determine to the strength of unknown sample by interpolation bioassay by using suitable tissue preparation.
5. To determine to the strength of unknown sample by bracketing bioassay by using suitable tissue preparation.
6. To determine to the strength of unknown sample by multiple point bioassay by using suitable tissue preparation.
7. Estimation of PA2 values of various antagonists using suitable isolated tissue preparations.
8. To study the effects of various drugs on isolated heart preparations
9. Recording of rat BP, heart rate and ECG.
10. Recording of rat ECG.
11. Drug absorption studies by averted rat ileum preparation.
12. Acute oral toxicity studies as per OECD guidelines.
13. Acute dermal toxicity studies as per OECD guidelines.
14. Repeated dose toxicity studies- Serum biochemical, haematological, urine analysis, functional observation tests and histological studies.
15. Drug mutagenicity study using mice bone-marrow chromosomal aberration test.
16. Protocol design for clinical trial (3 Nos.).
17. Design of ADR monitoring protocol.
18. In-silico docking studies (2 Nos.).
19. In-silico pharmacophore-based screening.
20. In-silico QSAR studies.
21. ADR reporting.

REFERENCES

1. Fundamentals of experimental Pharmacology -by M.N. Ghosh
2. Hand book of Experimental Pharmacology- S.K. Kulkarni
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.

Seminar Assignment-II

This course provides path to acquired skills and focuses on work in a professional digital format online/offline towards specific job goals and so forth. It also provides an opportunity to re-address previous projects, assignments for inclusion in their portfolios.

Course Outcomes: Through this course students should be able to

CO1: Discuss the methods in the major subject/field of study
CO2: Apply substantive argumentation, utilizing personal views that are based on critical analysis of works from various fields of knowledge
CO3: Assess and critically analyze different solutions
CO4: Demonstrate professional competence by identifying and analyzing emerging issues
CO5: Prioritize professional competence by identifying and analyzing emerging issues
CO6: Apply foundational research skills to address a research question

Syllabus for
III and IV Semester

M. Pharm. Pharmaceutics (MPH)
M. Pharm. Pharmaceutical Chemistry (MPC)
M. Pharm. Pharmacognosy (MPG)
M. Pharm. Pharmacology (MPG)

M. Pharm III Sem

MRM301T - Research Methodology & Biostatistics

The subject trains the user in statistical methods to see the significance in the data derived from research experiments.

Course Outcomes: Through this course students should be able to

CO1: Apply different parametric and non parametric tests in research
CO2: Apply different research design required in research
CO3: Make use of different statistical tools required for research
CO4: Formulate and test hypothesis based on the nature of the research problem
CO5: Adapt with the ethics of medical research
CO6: Understand the purpose of control and supervision of experiments on animals

Unit 1 **12 Hours**

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 2 **12 Hours**

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 3 **12 Hours**

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 4 **12 Hours**

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 5 **12 Hours**

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

REFERENCES

1. Kothari C.R., Research Methodology Methods and Techniques, Vishwa Prakashan, New Delhi.
2. Lokesh K., Methodology of Educational research, Vikash Publishing House Pvt. Ltd., New Delhi.
3. Kumar R., Research Methodology, Dorling Kindersley (India) Pvt. Ltd., New Delhi.
4. Rao G.N., Research Methodology and Qualitative Methods, B.S. Publications, Hyderabad.

5. Saunders M., Lewis P. and Thornhill A., Research Methods for Business Students, Dorling Kindersley (India) Pvt. Ltd., New Delhi.
6. Bolton S. and Bon C., Pharmaceutical Statistics: Practical and Clinical Applications, Marcel Dekker, New York.
7. Garg, B.L., Karadia, R., Agarwal, F. and Agarwal, An introduction to Research Methodology, RBSA Publishers, Jaipur.
8. Fisher R.A. Statistical Methods for Research Works, Oliver and Boyd, Edinburgh.
9. Chow S.S. and Liu J.P., Statistical Design and Analysis in Pharmaceutical Sciences, Marcel Dekker, New York.
10. Buncher C.R., Statistics in the Pharmaceutical Industry, Marcel Dekker, New York.

Journal Club

It provides a platform to enhance the research aptitude, reading capabilities and presenting capabilities of researcher by using various published articles.

Course Outcomes: Through this course students should be able to
CO1: Create substantive argumentation, utilizing personal views that are based on critical analysis of works from various fields of knowledge
CO2: Identify the various recent studies in the field of research
CO3: Demonstrate different tools employed in arranging references in manuscripts
CO4: Illustrate professional competence by identifying and analyzing emerging issues
CO5: Analyze ability of self-learning and professional development
CO6: Develop a capacity to communicate research results clearly, comprehensively and persuasively

Discussion/Presentation

This course helps the students to analyze the research done and search its future perspective

Course Outcomes: Through this course students should be able to
CO1: Explore the methods in the major subject/field of study
CO2: Outline possible strategies to deal with field problems
CO3: Analyze the problem and evaluate alternative solutions
CO4: Propose scientific argumentation based on critical analysis of work
CO5: Integrate their knowledge and practical skills during problem solving
CO6: Develop the key skills required to facilitate a scientific discussion

Research Work

This course involves the students to use rigorous methods to solve problems related to a substantive area of the study.

Course Outcomes: Through this course students should be able to

CO1: Identify the recent studies in the field of research
CO2: Create substantive argumentation, utilizing personal views that are based on critical analysis of works from various fields of knowledge
CO3: Find skills of planning and execution of work
CO4: Illustrate professional competence by identifying and analyzing emerging issues
CO5: Apply foundational research skills to address a research issue
CO6: Demonstrate different tools employed in arranging references in manuscripts

M. Pharm IV Sem

Journal Club-II

It provides a platform to enhance the research aptitude, reading capabilities and presenting capabilities of researcher by using various published articles.

Course Outcomes: Through this course students should be able to
CO1: Analyze the recent studies in the field of research
CO2: Apply substantive argumentation, utilizing personal views that are based on critical analysis of works from various fields of knowledge
CO3: Prioritize on keeping up-to-date with literature & promoting evidence-based practice
CO4: Summarize the outcomes of a study with the existing literature
CO5: Determining the importance of valid research findings into regular practice at individual or community level
CO6: Recommend his/her knowledge in design and development of novel compounds

Research Work

This course involves the students to use rigorous methods to solve problems related to a substantive area of the study.

Course Outcomes: Through this course students should be able to

CO1: Understand and appreciate the relevance of the specific research area to current developments in drug discovery
CO2: Examine a research problem and critically categorize relevant papers retrieved from various sources for the study.
CO3: Demonstrate reflective learning skills based on their research work
CO4: Outline and present an overview of the proposed topic of interest, as well as the findings from the investigation of various parameters.
CO5: Find novel strategies for resolving identified problems and examine the outcomes of interventions adopted
CO6: Evaluate the usefulness of various research methods for the study of a specific problem by selecting one of the options and justifying your choice

Discussion/Presentation

This course helps the students to analyze the research done and search its future perspective
Course Outcomes: Through this course students should be able to
CO1: Identify the research gap and review the methods in the major subject/field of study
CO2: Find the relevant research methodology to solve the given problem
CO3: Propose possible solution to the given problem based on the outcomes
CO4: Analyze the usefulness of various anthropological research methods for the study of a specific problem by selecting one of the options and justifying your choice.
CO5: Demonstrate presentation skill of his /her work effectively and accurately
CO6: Evaluate his/her capacity to communicate research results clearly, comprehensively and persuasively