UTTAR PRADESH UNIVERSITY OF MEDICAL SCIENCES, SAIFAI

FACULTY OF PHARMACY

REGULATIONS, EXAMINATION SCHEME AND SYLLABUS FOR M. PHARMACY (Pharmacology)

Adapted from Master of Pharmacy
(M. Pharm- Pharmacology)
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-Pharmacology 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-Pharmacology 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.-Pharmacology degree is 95. However based on the credit points earned by the students under the head of co-curricular activities; a student shall earn a maximum of 100 credit points. These credits are divided into Theory courses, Practical, Seminars, Assignments, Research work, Discussions with the supervisor, Journal club and Co-Curricular activities over the duration of four semesters. The credits are distributed semester wise as shown in Table 4. Courses generally progress in sequence, building competencies and their positioning indicates certain academic maturity on the part of the learners. Learners are expected to follow the semester wise schedule of courses given in the syllabus.

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. – Pharmacology 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 1-3.

Table – 1: 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 –2: Course of study for M. Pharm-Pharmacology III Semester

Course Code	Course	Credit Hours	CreditPoints
MRL 301T	Research Methodology and Biostatistics*	4	4
MPL 302	Journal club	1	1
MPL303	Discussion / Presentation (Proposal Presentation)	2	2
MPL304	Research Work	28	14
	Total	35	21

* Non University Exam

Table – 3: Course of study for M. Pharm-Pharmacology IV Semester

Course Code	Course	Credit Hours	Credit Points
MPL401	Journal club	1	1
MPL402	Research Work	31	16
MPL403	Discussion / Final Presentation	3	3
	Total	35	20

Table – 4: 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 – 5: Guidelines for Awarding Credit Points for Co-curricular Activities

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

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-Pharmacology 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 6-7.

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 – 6: 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	100	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	100	6Hrs	150
	Seminar/ Assignment							100
Total								650

Tables – 7: 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								
MPL 301T	Research Methodology and Biostatistics*	10	15	1 Hr	25	75	3Hrs	100
MPL302	Journal club				25			25
MPL303	Discussion / Presentation (Proposal Presentation)				50			50
MPL304	Research work*					350	1 hr	350
Total								525
SEMESTER IV								
MPL401	Journal club				25			25
MPL402	Research work					400	1 hr	400
MPL403	Discussion / Final Presentation				75			75
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 – 8: 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 – 9: 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 6 - 9.

Question paper pattern for theory Sessional examination

I.	Multiple Choice Questions (MCQs)	= 10 x 1 = 10
	OR	
	Very short Type Questions (05 x 2) (Answer all the questions)	= 05 x 2 = 10
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

Question paper pattern for Theory End semester examinations

I.	Very short Type Questions (10 x 2) (Answer all the questions)	= 10 x 2 = 20
II.	Short Answers (Answer 5 out of 7)	= 5 x 7 = 35
III.	Long Answers (Answer 2 out of 3)	= 2 x 10 = 20

	Total	**= 75 Marks**

12. Promotion and award of grades

A student shall be declared PASS and eligible for getting grade in a course of M. Pharm (Pharmacology) 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 10. The exact dates of examination shall be notified from time to time.

Table – 10: 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 – 11.

Table –11: Letter grades and grade points equivalent to Percentage of marks and performances

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

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

17. The Semester grade point average (SGPA)

The performance of a student in a semester is indicated by a number called 'Semester Grade Point Average' (SGPA). The SGPA is the weighted average of the grade points obtainedin all the courses by the student during the semester. For example, if a student takes five courses (Theory/Practical) in a semester with credits C1, C2, C3 and C4 and the student's grade points in these courses are G1, G2, G3 and G4, respectively, and then students' SGPA is equal to:

$$SGPA = \frac{C1G1 + C2G2 + C3G3 + C4G4}{C1 + C2 + C3 + C4}$$

The SGPA is calculated to two decimal points. It should be noted that, the SGPA for any semester shall take into consideration the F and ABS grade awarded in that semester. For example if a learner has a F or ABS grade in course 4, theSGPA shall then be computed as:

$$SGPA = \frac{C1G1 + C2G2 + C3G3 + C4* ZERO}{C1 + C2 + C3 + C4}$$

18. Cumulative Grade Point Average (CGPA)

The CGPA is calculated with the SGPA of all the IV semesters to two decimal points and is indicated in final grade report card/final transcript showing the grades of all IV semesters and their courses. The CGPA shall reflect the failed status in case of F grade(s), till the course(s) is/are passed. When the course(s) is/are passed by obtaining a pass grade on subsequent examination(s) the CGPA shall only reflect the new grade and not the fail grades earned earlier. The CGPA is calculated as:

$$CGPA = \frac{C1S1 + C2S2 + C3S3 + C4S4}{C1 + C2 + C3 + C4}$$

where C1, C2, C3,…. is the total number of credits for semester I,II,III,…. and S1,S2, S3,….is the SGPA of semester I,II,III,…. .

19. Declaration of class

The class shall be awarded on the basis of CGPA as follows:

First Class with Distinction	= CGPA of. 7.50 and above
First Class	= CGPA of 6.00 to 7.49
Second Class	= CGPA of 5.00 to 5.99

20. Project work

All the students shall undertake a project under the supervision of a teacher in Semester III to IV and submit a report. 4 copies of the project report shall be submitted (typed & bound copy not less than 75 pages).

The internal and external examiner appointed by the University shall evaluate the project at the time of the Practical examinations of other semester(s). The projects shall be evaluated as per the criteria given below.

21. Evaluation of Dissertation Book:

Objective(s) of the work done	50 Marks
Methodology adopted	150 Marks
Results and Discussions	250 Marks
Conclusions and Outcomes	50 Marks

Total	500 Marks

22. Evaluation of Presentation:

Presentation of work	100 Marks
Communication skills	50 Marks
Question and answer skills	100 Marks

Total	250 Marks

23. Award of Ranks

Ranks and Medals shall be awarded on the basis of final CGPA. However, candidates who fail in one or more courses during the M.Pharm (Pharmacology) program shall not be eligible for award of ranks. Moreover, the candidates should have completed the M. Pharm program in minimum prescribed number of years, (two years) for the award of Ranks.

24. Award of degree

Candidates who fulfill the requirements mentioned above shall be eligible for award of degree during the ensuing convocation.

25. Duration for completion of the program of study

The duration for the completion of the program shall be fixed as double the actual duration of the program and the students have to pass within the said period, otherwise they have to get fresh Registration.

26. Revaluation I Retotaling of answer papers

There is no provision for revaluation of the answer papers in any examination. However, the candidates can apply for retotaling by paying prescribed fee.

27. Re-admission after break of study

Candidate who seeks re-admission to the program after break of study has to get the approval from the university by paying a condonation fee.

M.PHARM - PHARMACOLOGY
(MPL)

PROGRAM OUTCOMES (POs)
M. PHARM (Pharmacology)

PO 1. Apply fundamentals of Pharmacology to elucidate and regulate drug discovery, drug development and care practice.

PO 2. Design and conduct experiments, as well as to analyze and interpret data of appropriate pharmaceutical system or process.

PO 3.Design and isolate a drug system, component, or drug use process to meet desired needs within realistic constraints such as economic, environmental, social, political, ethical, health and safety.

PO 4. Create an ability to function in multidisciplinary teams, at different organizational levels of academic, industry, research and health care.

PO 5. Develop an ability to identify, formulate, and solve health problems to meet the professional challenges.

PO 6. Understand pharmacy professional values and ethical responsibility in discharging professional obligations at society, national and global perspectives.

PO 7. Develop an ability to comprehend the impact of practice of Pharmacy in a global, economic, environmental, and societal context.

PO 8. Can relate knowledge of contemporary issues on the research, development and use of pharmaceutical products in population.

PO 9. Develop an ability to employ the techniques, skills, and modern tools necessary for professional practice, research and development.

PROGRAM SPECIFIC OUTCOMES (PSOs)
M PHARM (Pharmacology)

PSO 1. Knowledge: Enable post graduates to understand the core and basic knowledge in subject of pharmacology as per the requirement of pharmaceutical sectors.

PSO 2. Employment and Entrepreneurship: Enable post graduates to succeed in technical or professional careers in Research / Academic institutes or in health care system.

PSO 3. Professional Practice: Enable post graduates to practice profession and adapt themselves to the constantly developing global pharmacological trends.

PSO 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 - PHARMACOLOGY
(MPL)
PROGRAM OUTCOMES (POs)
M. PHARM (Pharmacology)

PHARMACOLOGY (MPL)
MODERN PHARMACEUTICAL ANALYTICAL TECHNIQUES
(MPL 101T)

Scope

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

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

CO1: Apply fundamentals of Pharmacology to elucidate and regulate drug discovery, drug development and care practice..

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

CO3: Professional Practice: Enable post graduates to practice profession and adapt themselves to the constantly developing global pharmacological trends.

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 pharmacological problems meeting professional challenges.

THEORY **60 Hrs**

Unit 1 **12 Hrs**

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 **10 Hrs**

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.

Unit 3 **10 Hrs**

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 4 **10 Hrs**

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 5 **10 Hrs**

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 6 **10 Hrs**

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.

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

REFERENCES

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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: Know about the pathophysiology and pharmacotherapy of certain diseases

CO2: Understand Clarify the mechanism of drug actions at cellular and molecular level

CO3: Know the adverse effects, contraindications and clinical uses of drugs used in treatment of diseases.

THEORY **60 Hrs**

1. General Pharmacology **12 Hrs.**

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

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

2. Neurotransmission **12 Hrs**

a. General aspects and steps involved in neurotransmission.

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

c. Neurohumoral transmission in central nervous system (Detailed study about neurotransmitters- histamine, serotonin, dopamine, GABA, glutamate and glycine).

d. Non adrenergic non cholinergic transmission (NANC). 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 Hrs**

General and local anesthetics

Sedatives and hypnotics, drugs used to treat anxiety.

Depression, psychosis, mania, epilepsy, neurodegenerative diseases.

Narcotic and non-narcotic analgesics.

4. Cardiovascular Pharmacology: **12 Hrs**

Diuretics, antihypertensives, antiischemics, antiarrhythmics, drugs for heart failure and hyperlipidemia. Hematinics, coagulants, anticoagulants, fibrinolytics and antiplatelet Drugs

5. Autocoid Pharmacology: **12 Hrs**

The physiological and pathological role of histamine, serotonin, kinins prostaglandins opioid autocoids. Pharmacology of antihistamines, 5HT 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: Discus the regulations and ethical requirement for the usage of experimental animals.

CO2: Identify various animals used in the drug discovery process and good laboratory practices in maintenance and handling of experimental animals

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

CO4: Understand to appreciate and correlate the preclinical data to humans.

THEORY	**60 Hrs**
1. 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	**12 Hrs**
2. 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.	**12 Hrs**
3. 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.	**12 Hrs**
4. 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.	**12 Hrs**

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

General principles of immunoassay: theoretical basis and optimization of immunoassay, heterogeneous and homogenous immunoassay systems. Immunoassay methods evaluation; protocol outline, objectives and preparation. Immunoassay for digoxin and insulin. 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: Recognize 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: Validate molecular biology techniques as applicable for pharmacology.

THEORY **60 Hrs**

1. 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. **12 Hrs**

2. Cell Signaling **12 Hrs.**

Intercellular and intracellular signaling pathways.
Classification of receptor family and molecular structure ligand gated ion channels; G-protein coupled receptors, tyrosine kinase receptors and nuclear receptors.
Secondary messengers: cyclic AMP, cyclic GMP, calcium ion, inositol 1,4,5-trisphosphate, (IP3), NO, and diacylglycerol.
Detailed study of following intracellular signaling pathways: cyclic AMP signaling pathway, mitogen-activated protein kinase (MAPK) signaling, Janus kinase (JAK)/signal transducer and activator of transcription (STAT) signaling pathway

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

4. Pharmacogenomics **12Hrs**

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

5. a. Cell Culture Techniques: Basic equipments used in cell culture lab. Cell culture media, 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. **12 Hrs**

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 Cheril D.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

PHARMACOLOGICAL PRACTICAL - I
(MPL 105P)

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

Handling of laboratory animals:

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

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: Differentiate 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 Hrs**

1. Endocrine Pharmacology: Molecular and cellular mechanism of action of hormones such as growth hormone, prolactin, thyroid, insulin and sex hormones, anti-thyroid drugs, oral hypoglycemic agents, oral contraceptives, corticosteroids. Drugs affecting calcium regulation **12 Hrs**

2. Chemotherapy: Cellular and molecular mechanism of actions and resistance of antimicrobial agents such as ß-lactams, aminoglycosides, quinolones, macrolide antibiotics. Antifungal, antiviral, and anti-TB drugs. **12 Hrs**

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

4. GIT Pharmacology: 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. **12 Hrs**

5. 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. **12 Hrs**

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 & 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: Describe 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.

THOERY **60 Hrs**

1. Basic definition and types of toxicology (general, mechanistic, regulatory and descriptive) Regulatory guidelines for conducting toxicity studies OECD, ICH, EPA and Schedule Y OECD principles of good laboratory practice (GLP). History, concept and its importance in drug development. **12 Hrs**

2. Acute, sub-acute and chronic- oral, dermal and inhalational studies as per OECD guidelines. Acute eye irritation, skin sensitization, dermal irritation & dermal toxicity studies. Test item characterization- importance and methods in regulatory toxicology studies. **12 Hrs**

3. Reproductive toxicology studies, male reproductive toxicity studies, female reproductive studies (segment I and segment III), teratogenecity studies (segment II) . Genotoxicity studies (Ames test, in vitro and in vivo micronucleus and chromosomal aberrations studies). In vivo carcinogenicity studies. **12 Hrs**

4. IND enabling studies (IND studies)- Definition of IND, importance of IND, industry perspective, list of studies needed for IND submission. Safety pharmacology studies- Origin, concepts and importance of safety pharmacology. Tier1- CVS, CNS and respiratory safety pharmacology, HERG assay. Tier2- GI, renal and other studies. **12 Hrs**

5. Toxicokinetics- Toxicokinetic evaluation in preclinical studies, saturation kinetics. Importance and applications of toxicokinetic studies. Alternative methods to animal toxicity testing. **12 Hrs**

REFERENCES

1. Hand book on GLP, Quality practices for regulated non-clinical research and development (http://www.who.int/tdr/publications/documents/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/ucm 07324
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 Outcome: After completion of the course, the student shall be able to

CO1: Learn the various stages of drug discovery.

CO2: Explain the importance of the role of genomics, proteomics and bioinformatics in drug discovery.

CO3: Discus various targets for drug discovery.

CO4: Describe various lead seeking method and lead optimization.

CO5: Remonstrate the importance of the role of computer aided drug design in drug discovery.

THEORY	**60 Hrs**
1. An Overview of Modern Drug Discovery Process: Target identification, target validation, lead identification and lead optimization. Economics of drug discovery. 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	**12 Hrs**
2. Lead Identification: combinatorial chemistry & high throughput screening, in silico lead discovery techniques. Assay development for hit identification. Protein structure: Levels of protein structure, domains, motifs, and folds in protein structure. Computational prediction of protein structure: Threading and homology modeling methods. Application of NMR and X-ray crystallography in protein structure prediction.	**12 Hrs**
3. 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.	**12 Hrs**
4. Molecular Docking: Rigid docking, flexible docking, manual docking: Docking based screening. De novo drug design. Quantitative analysis of structure activity relationship: History and development of QSAR, SAR versus QSAR, physicochemical parameters, Hansch analysis, Fee-Wilson analysis and relationship between them.	**12 Hrs**
5. QSAR Statistical Methods: Regression analysis, partial least square analysis (PLS) and other multivariate statistical methods. 3D-QSAR approaches like COMFA and COMSIA. Prodrug design: Basic concept, prodrugs to improve patient acceptability, drug solubility, drug absorption and distribution, site specific drug delivery and sustained drug action. Rationale of prodrug design and practical consideration of prodrug design.	**12 Hrs**

REFERENCES

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

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 Outcome: After completion of the course, the student shall be able to

CO1: Elucidate the regulatory requirements for conducting clinical trial.

CO2: Validate the types of clinical trial designs.

CO3: Discus the responsibilities of key players involved in clinical trials.

CO4: Understand to execute safety monitoring, reporting and close-out activities.

CO5: Apply the principles of pharmacovigilance.

CO6: Determine new adverse drug reactions and their assessment.

CO7: Recognize the adverse drug reaction reporting systems and communication in pharmacovigilance.

THOERY **60 Hrs**

1. 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. **12 Hrs**

2. Clinical Trials: Types and design experimental study- RCT and non RCT, observation study: Cohort, case control, cross sectional clinical trial study team roles and responsibilities of clinical trial personnel: Investigator, study coordinator, sponsor, contract research organization and its management. **12 Hrs**

3. Clinical Trial Documentation: Guidelines to the preparation of documents, preparation of protocol, investigator brochure, case report forms, clinical study report. Clinical trial monitoring: Safety monitoring in CT. Adverse drug reactions: Definition and types, detection and reporting methods. Severity and seriousness assessment. Predictability and preventability assessment, management of adverse drug reactions: Terminologies of ADR. **12 Hrs**

4. Basic Aspects, Terminologies and Establishment of Pharmacovigilance: History and progress of pharmacovigilance, significance of safety monitoring, pharmacovigilance in India and international aspects, WHO international drug monitoring programme, WHO and regulatory terminologies of ADR, evaluation of medication safety, establishing pharmacovigilance centers in hospitals, industry and national programmes related to pharmacovigilance. Roles and responsibilities in pharmacovigilance **12 Hrs**

5. Methods, ADR reporting and tools used in pharmacovigilance international

classification of diseases, international 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.

PHARMACOLOGICAL PRACTICAL - II
(MPL 205P)

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

REFERENCES

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

Syllabus for
III and IV Semester
M. Pharm. Pharmacology (MPL)

M. Pharm III Sem

MPL301T - 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.

MPL 302 - 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

MPL 303 - 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

MPL 304 - 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

MPL 401 - 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

MPL 402 - 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

MPL 403 - 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