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Course Structure and Syllabus

of

M.Pharm
(Pharmacology)

School of Pharmacy and Life Sciences

2024

COURSE STRUCTURE AND SYLLABI

M. Pharm (Pharmacology)

2024-25 Batch

Centurion UNIVERSITY

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School of Pharmacy and Life Sciences
CENTURION UNIVERSITY OF TECHNOLOGY & MANAGEMENT
Odisha-752050, India

Web Site: - www.cutm.ac.in

CENTURION UNIVERSITY OF TECHNOLOGY AND MANAGEMENT, ODISHA

CERTIFICATE

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This is to certify that the syllabus of the M. Pharm (Pharmacology) Programme of the School of Pharmacy and Life sciences is approved in the 14th Academic Council Meeting held on 22nd November 2024.

Dean
School of Pharmacy and Life Sciences
CUTM, Odisha

SCHOOL OF PHARMACY AND LIFE SCIENCES

SCHEME & SYLLABUS

M.PHARM (PHARMACOLOGY)

FOR

THE MASTER OF PHARMACY (M. PHARM.)
COURSE REGULATION 2014
(BASED ON NOTIFICATION IN THE GAZETTE OF INDIA NO. 362, DATED DECEMBER 11, 2014)

Centurion UNIVERSITY
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CENTURION UNIVERSITY OF TECHNOLOGY AND MANAGEMENT

BHUBANESWAR, ODISHA

2024

VISION:

To be a globally recognized centre for Teaching, Research and Entrepreneurial Training in Pharmaceutical Sciences and to provide Healthcare services for Societal needs.

MISSION:

- To nurture young minds into knowledgeable, skillful and ethical professionals to serve for the society.
- To support research in diverse ways by launching partnerships and collaborations.
- To ensure affordable health care by developing pharmaceutical formulations using in house resources.
- To inculcate the mindset for entrepreneurship and innovativeness to enrich the healthcare system.

Programme Objectives:

1. To develop advanced knowledge and technical expertise in Pharmacy.
2. To cultivate research skills, innovations and professional practice in the Pharmaceutical industry.
3. To Nurture and support an inclination for higher education and entrepreneurship.

PROGRAMME OUTCOMES (POs):

At successfully completing the M. Pharm program, student should have achieved the following program outcomes mentioned below:

POs	
PO 1	**Pharmacy Knowledge:** Possess knowledge and comprehension of the core and basic knowledge associated with the profession of pharmacy, including biomedical sciences; pharmaceutical sciences; behavioral, social, and administrative pharmacy sciences; and manufacturing practices.
PO 2	**Planning Abilities:** Demonstrate effective planning abilities including time management, resource management, delegation skills and organizational skills. Develop and implement plans and organize work to meet deadlines.
PO 3	**Problem analysis:** Utilize the principles of scientific enquiry, thinking analytically, clearly and critically, while solving problems and making decisions during daily practice. Find, analyze, evaluate and apply information systematically and shall make defensible decisions.
PO 4	**Modern tool usage:** Learn, select, and apply appropriate methods and procedures, resources, and modern pharmacy-related computing tools with an understanding of the limitations.
PO 5	**Leadership skills:** Understand and consider the human reaction to change, motivation issues, leadership and team-building when planning changes required for fulfilment of practice, professional and societal responsibilities. Assume participatory roles as responsible citizens or leadership roles when appropriate to facilitate improvement in health and well-being.
PO 6	**Professional Identity:** Understand, analyze and communicate the value of their professional roles in society (e.g. health care professionals, promoters of health, educators, managers, employers, employees).
PO 7	**Pharmaceutical Ethics:** Honour personal values and apply ethical principles in professional and social contexts. Demonstrate behavior that recognizes cultural and personal variability in values, communication and lifestyles. Use ethical

	frameworks; apply ethical principles while making decisions and take responsibility for the outcomes associated with the decisions.
PO 8	**Communication:** Communicate effectively with the pharmacy community and with society at large, such as, being able to comprehend and write effective reports, make effective presentations and documentation, and give and receive clear instructions.
PO 9	**The Pharmacist and society:** Apply reasoning informed by the contextual knowledge to assess societal, health, safety and legal issues and the consequent responsibilities relevant to the professional pharmacy practice.
PO10	**Environment and sustainability:** Understand the impact of the professional pharmacy solutions in societal and environmental contexts, and demonstrate the knowledge of, and need for sustainable development.
PO11	**Entrepreneurship**: Develop entrepreneurship skills that support the growth of Pharmaceutical Industry / Pharmaceutical Services leading to economic development.
PO12	**Life-long learning:** Recognize the need for, and have the preparation and ability to engage in independent and life-long learning in the broadest context of technological change. Self-assess and use feedback effectively from others to identify learning needs and to satisfy these needs on an ongoing basis.

PSO (Program Specific Outcomes)

Sl No.	**Program Specific Outcomes**
PSO1	**Pharmacokinetic and Pharmacodynamic Analysis:** Ability to apply advanced knowledge in pharmacokinetics and pharmacodynamics to assess the absorption, distribution, metabolism, excretion, and therapeutic effects of drugs.
PSO2	**Drug Safety and Efficacy Evaluation:** Expertise in evaluating the safety, efficacy, and potential toxicological effects of drug candidates through preclinical and clinical studies, using appropriate experimental models.
PSO3	**Therapeutic Applications and Drug Interactions:** Proficiency in understanding and analyzing drug interactions, therapeutic uses, and mechanisms of action, as well as providing evidence-based recommendations for clinical pharmacology.

CHAPTER-I: REGULATIONS

1. **Short Title and Commencement**
These regulations shall be called as "The Revised Regulations for the Master of Pharmacy (M. Pharm.)Degree Program - Credit Based Semester System (CBSS) of the Pharmacy Council of India, New Delhi". They shall come into effect from the Academic Year 2016-17. 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 programs 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/extra- curricular 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 23 are distributed semester-wise as shown in Table 5. 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 specializations in M.Pharm program is given in Table 1.

Table – 1: List of M.Pharm. Specializations and their Code

S. No.	Specialization	Code
1.	Pharmaceutics	MPH
2.	Industrial Pharmacy	MIP
3.	Pharmaceutical Chemistry	MPC
4.	Pharmaceutical Analysis	MPA
5.	Pharmaceutical Quality Assurance	MQA
6.	Pharmaceutical Regulatory Affairs	MRA
7.	Pharmaceutical Biotechnology	MPB
8.	Pharmacy Practice	MPP
9.	Pharmacology	MPL
10.	Pharmacognosy	MPG

The course of study for M.Pharm specializations shall include Semester wise Theory & Practical as given in Table – 2. The number of hours to be devoted to each theory and practical course in any semester shall not be less than that shown in Table – 2.

Table – 2: Course of study for M. Pharm. (Pharmacology)

Course Code	Course	Credit Hours	Credit Points	Hrs./k	Marks
Semester I					
MPL101T	Modern Pharmaceutical Analytical Techniques	4	4	4	100
MPL102T	Advanced Pharmacology -I	4	4	4	100
MPL103T	Pharmacological and Toxicological Screening Methods-I	4	4	4	100
MPL104T	Cellular and Molecular Pharmacology	4	4	4	100
MPL105P	Pharmacology Practical I	12	6	12	150
MPL106P	Seminar/Assignment	7	4	7	100
Total		35	26	35	650
Semester II					
MPL201T	Advanced Pharmacology II	4	4	4	100
MPL202T	Pharmacological and Toxicological Screening Methods- II	4	4	4	100
MPL203T	Principles of Drug Discovery	4	4	4	100
MPL204T	Experimental Pharmacology Practical- II	4	4	4	100
MPL205P	Pharmacology Practical II	12	6	12	150
MPL206P	Seminar /Assignment	7	4	7	100
Total		35	26	35	650

Table – 3: Course of study for M. Pharm. III Semester (Common for All Specializations)

Course Code	Course	Credit Hours	Credit Points
MRM301T	Research Methodology Biostatistics*	4	4
MPL302P	Journal Club	1	1
MPL303P	Discussion / Presentation(Proposal Presentation)	2	2
MPL304P	Research Work	28	14
Total		35	21

* Non University Exam

Table – 4: Course of study for M. Pharm. IV Semester (Common for All Specializations)

Course Code	Course	Credit Hours	Credit Points
MPL401P	Journal Club	1	1
MPL402P	Research Work	31	16
MPL403P	Discussion / Final Presentation	3	3
Total		35	20

Table – 5: Semester wise credits distribution

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

Table – 6: 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 colleges 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 eachM.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 sessionalexam and before the end semester exam.

11. Examinations/Assessments

The schemes for internal assessment and end semester examinations are given in Table – 7.

11.1. End semester examinations

The End Semester Examinations for each theory and practical coursethrough semesters I to IVshall beconducted by the respective university except for the subject with asterix symbol (*) in table I and II for which examinations shall be conducted by the subject experts at college level and the marks/grades shall be submitted to the university.

Tables – 7: Schemes for internal assessments and end semester (Pharmacology)

Course Code	Course	Internal Assessment				End Semester Exams		Total Marks
		Continuous Mode	Sessional Exams		Total	Marks	Duration	
			Marks	Duration				
Semester I								
MPL101T	Modern Pharmaceuti cal Analytical Techniques	10	15	1 Hr	25	75	3 Hrs	100
MPL102T	Advanced Pharmacology -I	10	15	1 Hr	25	75	3 Hrs	100
MPL103T	Pharmacological and Toxicological Screening Methods-I	10	15	1 Hr	25	75	3Hrs	100
MPL104T	Cellular and Molecular Pharmacology	10	15	1 Hr	25	75	3 Hrs	100
MPL105P	Pharmacology Practical I	20	30	6 Hrs	50	100	6 Hrs	150
MPL106P	Seminar /Assignment	-	-	-	-	-	-	-
Total								650

Semester II								
MPL201T	Advanced Pharmacology II	10	15	1 Hr	25	75	3 Hrs	100
MPL202T	Pharmacological and Toxicological Screening Methods- II	10	15	1 Hr	25	75	3 Hrs	100
MPL203T	Principles of Drug Discovery	10	15	1 Hr	25	75	3 Hrs	100
MPL204T	Exprimental Pharmacology Practical- II	10	15	1 Hr	25	75	3 Hrs	100
MPL205P	Pharmacology Practical II	20	30	6 Hrs	50	100	6 Hrs	150
MPL206P	Seminar /Assignment	-	-	-	-	-	-	100
Total								650

Tables – 8: Schemes for internal assessments and end semester examinations (Semester III & IV)

Course Code	Course	Internal Assessment				End Semester Exams		Total Marks
		Continuous Mode	Sessional Exams		Total	Marks	Duration	
			Marks	Duration				
Semester III								
MRM 301T	Research Methodology and Biostatistics*	10	15	1 Hr	25	75	3 Hrs	100
MPL302P	Journal Club	-	-	-	25	-	-	25
MPL303P	Discussion / Presentation (Proposal Presentation)	-	-	-	50	-	-	50
MPL304P	Research work	-	-	-	-	350	-	350
Total								525
Semester IV								
MPL401P	Journal club	-	-	-	25	-	-	25
MPL402P	Discussion / Presentation (Proposal Presentation)	-	-	-	75	-	-	75
MPL403P	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 – 9: Scheme for awarding internal assessment: Continuous mode

Theory	
Attendance (Refer Table – 10)	8
Student – Teacher interaction	2
Total	10
Practical	
Attendance (Refer Table – 10)	10
Based on Practical Records, Regular viva voce, etc.	10
Total	20

Table – 10: 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 in the table. The average marks of two sessional exams shall be computed for internal assessment as per the requirements given in tables.

12. Promotion and award of grades

A student shall be declared PASS and eligible for getting grade in a course of M.Pharm. programme 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. Improvement of internal assessment

A student shall have the opportunity to improve his/her performance only once in the sessional exam component of the internal assessment. The re-conduct of the sessional exam shall be completed before the commencement of next end semester theory examinations.

15. Reexamination of end semester examinations

Reexamination of end semester examination shall be conducted as per the schedule given in table 11. The exact dates of examinations shall be notified from time to time.

Table – 11: Tentative schedule of end semester examinations

Semester	For Regular Candidates	For Failed Candidates
I and III	November / December	May / June
II and IV	May / June	November / December

16. 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.

17. Grading of performances

17.1. 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 –12.

Table – 12: Letter grades and grade points equivalent to Percentage of marks and performances

Percentage of Marks Obtained	Letter Grade	Grade Point	Performance
90.00 – 100	0	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.

18. 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:

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

19. 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) theCGPA 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,….

20. 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

21. 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.

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

Total500 Marks

Evaluation of Presentation:

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

Total	250 Marks

22. 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 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.

23. Award of degree

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

24. 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.

25. 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.

26. 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 condo nation fee.

MODERN PHARMACEUTICAL ANALYTICAL TECHNIQUES
(MPL101T)

Course Objective:

- To get fundamental knowledge of advanced analytical instrumental techniques for identification, characterization and quantification of drugs
- To handle instruments like NMR, Mass spectrometer, IR, HPLC, GC, etc.
- To perform analysis of elemental impurities

Course Outcomes: On completion of this course, the successful students should be able to:

CO	Statements	Cos & POs Mapping
CO-1	**Analyze** of various drugs in single and combination dosage forms.	PO1, PO2, PO3, PO11, PO12
CO-2	**Analyze of Chemicals and Excipients**	PO1, PO2, PO3, PO11, PO12
CO-3	**Explain** general principles and theory of spectroscopy	PO1, PO2, PO3, PO4,PO11,PO12
CO-4	**Describe** various separation techniques by employing chromatographic methods.	PO1, PO2, PO3, PO4,PO11,PO12
CO-5	**Understand** basic principles of biological tests and immunoassay.	PO1, PO2, PO3, PO11, PO12

THEORY **60 Hours**

11 Hrs

1. a. UV-Visible spectroscopy: Introduction, Theory, Laws, Instrumentation associated with UV-Visible spectroscopy, Choice of solvents and solvent effect and Applications of UV- Visible spectroscopy.
b. IR spectroscopy: Theory, Modes of Molecular vibrations, Sample handling, Instrumentation of Dispersive and Fourier - Transform IR Spectrometer, Factors affecting vibrational frequencies and Applications of IR spectroscopy.
c. Spectro flourimetry: Theory of Fluorescence, Factors affecting fluorescence, Quenchers, Instrumentation and Applications of fluorescence spectrophotometer.
d. Flame emission spectroscopy and Atomic absorption spectroscopy: Principle, Instrumentation, Interferences and Applications.

11 Hrs

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

11 Hrs

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

11 Hrs

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

11 Hrs

5. a. Electrophoresis: Principle, Instrumentation, Working conditions, factors affecting separation and applications of the following:
a) Paper electrophoresis b) Gel electrophoresis c) Capillary electrophoresis d) Zone electrophoresis e) Moving boundary electrophoresis f) Iso electric focusing
b. X ray Crystallography: Production of X rays, Different X ray diffraction methods, Bragg' s law, Rotating crystal technique, X ray powder technique, Types of crystals and applications of X-ray diffraction.

5 Hrs

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

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

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

d. TGA: Principle, instrumentation, factors affecting results, advantage and disadvantages, pharmaceutical applications.

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ADVANCED PHARMACOLOGY- I(MPL102T)

Course Objective:

- To strengthen the basic knowledge in the field of pharmacology
- To knowledge on recent advances in the drugs used for the treatment of various diseases
- To understand the concepts of drug action and mechanisms involved

Course Outcomes: On completion of this course, the successful students should be able to:

CO	Statements	Cos & POs Mapping
CO-1	***Understand*** *general pharmacology, encompassing pharmacodynamics principles, receptor theories*	PO1, PO2, PO3, PO12
CO-2	***Integrate*** Knowledge of Neurotransmission in Health and Disease	PO1, PO2, PO3, PO12
CO-3	***Describe*** pathophysiology and pharmacotherapy of certain diseases	PO1, PO2, PO3, PO12
CO-4	***Explain*** the mechanism of drug actions at cellular and molecular level	PO1, PO2, PO3, PO12
CO-5	***Identify*** adverse effects, contraindications and clinical uses of drugs used in the treatment of diseases.	PO1, PO2, PO3, PO9,PO12

THEORY **60 Hours**

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). Co- transmission

Systemic Pharmacology: A detailed study on pathophysiology of diseases, mechanism of action, pharmacology and toxicology of existing as well as novel drugs used in the following systems

Autonomic Pharmacology: Parasympathomimetics and lytics, sympathomimetics and lytics, agents affecting neuromuscular junction

12 Hrs

3. Central nervous system Pharmacology

General and local anesthetics, Sedatives and hypnotics, drugs used to treat anxiety.Depression, psychosis, mania, epilepsy, neurodegenerative diseases.Narcotic and non-narcotic analgesics.

12 Hrs

4. Cardiovascular Pharmacology

Diuretics, antihypertensives, antiischemics, anti- arrhythmics, drugs for heart failure and hyperlipidemia.Hematinics, coagulants, anticoagulants, fibrinolytics and anti- platelet drugs

12Hrs

5. Autocoid Pharmacology

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(MPL103T)

Course Objective:

- To impart knowledge on preclinical evaluation of drugs and recent experimental techniques in the drug discovery and development
- To understand the maintenance of laboratory animals as per the guidelines
- To get basic knowledge of various in-vitro and in-vivo preclinical evaluation processes

Course Outcomes: On completion of this course, the successful students should be able to:

CO	Statements	Cos & POs Mapping
CO-1	***Appraise*** the regulations and ethical requirements for the usage of experimental animals.	PO1, PO2, PO3,PO7, PO12
CO-2	***Describe*** the various animals used in the drug discovery process and good laboratory practices in the maintenance and handling of experimental animals	PO1, PO9, PO12
CO-3	***Explain*** the various newer screening methods involved in the drug discovery process	PO1, PO2,PO4, PO12
CO-4	***Appreciate*** and correlate the preclinical data to human	PO1, PO3,PO12
CO-5	***Design and implement*** preclinical screening of new substances for pharmacological activity using alternative animal models	PO1,PO2, PO3, PO12

THEORY **60 Hours**

12 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 anddepressants, anxiolytics,anti-psychotics,anti-epileptics

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.

Iimmunomodulators, Immunosuppressants and immunostimulants

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

Limitations of animal experimentation and alternate animal experiments.

Extrapolation of in vitro data to preclinical and preclinical to humans

REFERENCES

1.Biological standardization by J.H. Burn D.J. Finney and I.G. Goodwin

2.Screening methods in Pharmacology by Robert Turner. A

3.Evaluation of drugs activities by Laurence and Bachrach

4.Methods in Pharmacology by Arnold Schwartz.

5.Fundamentals of experimental Pharmacology by M.N.Ghosh

6.Pharmacological experiment on intact preparations by Churchill Livingstone

7.Drug discovery and Evaluation by Vogel H.G.

8.Experimental Pharmacology by R.K.Goyal.

9.Preclinical evaluation of new drugs by S.K. Guta

10.Handbook of Experimental Pharmacology, SK.Kulkarni

11.Practical Pharmacology and Clinical Pharmacy, SK.Kulkarni, 3rd Edition.

12.David R.Gross. Animal Models in Cardiovascular Research, 2nd Edition, Kluwer Academic Publishers, London, UK.

13.Screening Methods in Pharmacology, Robert A.Turner.

14.Rodents for Pharmacological Experiments, Dr.Tapan Kumar chatterjee.

15.Practical Manual of Experimental and Clinical Pharmacology by Bikash Medhi (Author), Ajay Prakash (Author)

CELLULAR AND MOLECULAR PHARMACOLOGY (MPL 104T)

Course Objective:

- To fundamental knowledge on the structure and functions of cellular components
- To the interaction of cellular components with drugs.
- To get basic knowledge on knowledge in drug discovery process

Course Outcomes: On completion of this course, the successful students should be able to:

CO	Statements	Cos & POs Mapping
CO-1	**Comprehend** understanding of cell structure and function, genome organisation, gene expression regulation their implications in health and disease.	PO1, PO2,PO3, PO12
CO-2	***Describe*** the molecular pathways affected by drugs	PO1, PO2, PO3, PO12
CO-3	***Explain*** the receptor signal transduction processes	PO1, PO2, PO3, PO12
CO-4	***Appreciate*** the applicability of molecular pharmacology and biomarkers in the drug discovery process.	PO1, PO2, PO3, PO12
CO-5	***Demonstrate*** molecular biology techniques as applicable for pharmacology	PO1, PO2, PO3, PO4 PO12

THEORY **60 Hours**

12 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

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.

12 Hrs

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.

Gene therapy- Various types of gene transfer techniques, clinical applications and recent advances in gene therapy.

12 rs

4. Pharmacogenomics

Gene mapping and cloning of disease gene.

Genetic variation and its role in health/ pharmacology Polymorphisms affecting drug metabolism

Genetic variation in drug transporters

Genetic variation in G protein coupled receptors

Applications of proteomics science: Genomics, proteomics, metabolomics, functionomics, nutrigenomics Immunotherapeutics

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

5.a. Cell culture techniques

Basic equipments used in cell culture lab. Cell culture media, 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.

2.Pharmacogenomics: The Search for Individualized Therapies. Edited by J. Licinio and M -L. Wong

3.Handbook of Cell Signaling (Second Edition) Edited by Ralph A. et.al

4.Molecular Pharmacology: From DNA to Drug Discovery. John Dickenson et.al

5.Basic Cell Culture protocols by Cheril D.Helgason and Cindy L.Miller

6.Basic Cell Culture (Practical Approach) by J. M. Davis (Editor)

7.Animal Cell Culture: A Practical Approach by John R. Masters (Editor)

8.Current porotocols in molecular biology vol I to VI edited by Frederick M.Ausuvel et la.

PHARMACOLOGICAL PRACTICAL - I (MPL 105P)

Course Objective:

- To strengthen the basic knowledge in the field of pharmacology
- To the interaction of cellular components with drugs.
- To get basic knowledge on knowledge in drug discovery process

Course Outcomes: On completion of this course, the successful students should be able to:

CO	Statements	Cos & POs Mapping
CO-1	**Design** and analyse drugs using spectroscopy, chromatography , flourimetry	PO1, PO2,PO3, PO4, PO12
CO-2	**Perform** experiment with rodents activity related to diuretics, GI , CNS effects	PO1, PO2,PO3, PO4, PO12
CO-3	**Administer** drugs in the animal, withdraw blood sample and assess efficacy and safety of given unknown compound	PO1, PO2,PO3, PO4, PO12
CO-4	**Handle** molecular techniques to understand molecular biology, including in vitro cell culture techniques	PO1, PO2,PO3, PO4, PO12
CO-5	**Assess** the genetics alternative using molecular techniques	PO1, PO2,PO3, PO4, PO12

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 (PracticalApproach) 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

ADVANCED PHARMACOLOGY - II (MPL 201T)

Course Objective:

- To strengthen the basic knowledge in the field of pharmacology
- To impart recent advances in the drugs used for the treatment of various diseases
- To understand the concepts of drug action and the mechanism involved

Course Outcomes: On completion of this course, the successful students should be able to:

CO	Statements	Cos & POs Mapping
CO-1	***Explain*** the mechanism of drug actions at cellular and molecular level	PO1, PO2,PO3, PO12
CO-2	***Perform*** experiment with rodents activity related to diuretics, GI , CNS effects	PO1, PO2,PO3, PO12
CO-3	***Administer*** drugs in the animal, withdraw blood sample and assess efficacy and safety of given unknown compound	PO1, PO2,PO3, PO12
CO-4	***Handle*** molecular techniques to understand molecular biology, including in vitro cell culture techniques	PO1,PO2,PO3, PO4, PO12
CO-5	***Impart*** knowledge on generation, role, and regulation of free radicals in disease, as well as the protective effects of antioxidants	PO1,PO2, PO3, PO7,PO12

THEORY **60 Hours**

12 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 rs

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

12Hrs

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
Recent Advances in Treatment:
Alzheimer's disease, Parkinson's disease, Cancer, Diabetes mellitus

REFERENCES

1. The Pharmacological basis of therapeutics- Goodman and Gill man's

2. Principles of Pharmacology. The Pathophysiologic basis of drug therapy by David E Golan et al.

3. Basic and Clinical Pharmacology by B.G -Katzung

4. Pharmacology by H.P. Rang and M.M. Dale.

5. Hand book of Clinical Pharmacokinetics by Gibaldi and Prescott.

6. Text book of Therapeutics, drug and disease management by E T. Herfindal and Gourley.

7. Applied biopharmaceutics and Pharmacokinetics by Leon Shargel and Andrew B.C.Yu.

8. Handbook of Essential Pharmacokinetics, Pharmacodynamics and Drug Metabolism for Industrial Scientists

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. KD.Tripathi. Essentials of Medical Pharmacology

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)

Course Objective:

- To imparts knowledge on the preclinical safety and toxicological evaluation of drug
- To make student competent in regulatory toxicological evaluation
- To imparts knowledge preclinical safety and toxicological evaluation of new chemical entity.

Course Outcomes: On completion of this course, the successful students should be able to:

CO	Statements	Cos & POs Mapping
CO-1	**Explain** the various types of toxicity studies	PO1, PO2,PO3,PO12
CO-2	**Appreciate** the importance of ethical and regulatory requirements for toxicity studies.	PO1,PO2,PO3,PO7,PO12
CO-3	**Get** knowledge to demonstrate the practical skills required to conduct the preclinical toxicity studies	PO1,PO2,PO3,PO4,PO12
CO-4	**Describe** various animal used in preclinical experiment	PO1, PO2,PO3,PO12
CO-5	**Describe** good laboratory practices in handling and maintenance of experimental animals	PO1,PO2,PO3,PO4,PO12

THEORY **60 Hours**

12Hrs

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

12Hrs

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

12Hrs

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

12Hrs

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.

12Hrs

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

REFERENCES

1. Hand book on GLP, Quality practices for regulated non-clinical research and development (http://www.who.int/tdr/publications/documents/glp- handbook.pdf).

2. Schedule Y Guideline: drugs and cosmetics (second amendment) rules,

2005, ministry of health and family welfare (department of health) New Delhi

3. Drugs from discovery to approval by Rick NG.

4. Animal Models in Toxicology, 3rd Edition, Lower and Bryan

5. OECD test guidelines.

6. Principles of toxicology by Karen E. Stine, Thomas M. Brown.

7. Guidance for Industry M3(R2) Nonclinical Safety Studies for the Conduct of Human Clinical Trials and Marketing Authorization for Pharmaceuticals (http://www.fda.gov/downloads/drugs/guidancecomplianceregulatoryinformation/guidances/ucm073246.pdf)

PRINCIPLES OF DRUG DISCOVERY (MPL 203T)

Course Objective:

- To impart basic knowledge of the drug discovery process
- To develop a protocol for lead identification and optimization
- To impart knowledge rational on drug discovery and pharmacophore identification through computational techniques.

Course Outcomes: On completion of this course, the successful students should be able to:

CO	Statements	Cos & POs Mapping
CO-1	**Explain** the various stages of drug discovery	PO1,PO2,PO3,PO12
CO-2	**Appreciate** the importance of the role of genomics, proteomics and bioinformatics in drug discovery	PO1,PO2,PO3,PO12
CO-3	Explain various targets for drug discovery.	PO1,PO2,PO3,PO12
CO-4	**Describe** various lead seeking method and lead optimization	PO1,PO2,PO3,PO12
CO-5	**Impart** Knowledge the importance of the role of computer aided drug design in drug discovery	PO1,PO2,PO3,PO4,PO12

THEORY **60 Hours**

12 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.

12Hrs

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 approachesVirtual Screening techniques:

Drug likeness screening, Concept of pharmacophore mapping and pharmacophore based Screening.

12Hrs

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.

12Hrs

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

REFERENCES

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

CLINICAL RESEARCH AND PHARMACOVIGILANCE (MPL 204T)

Course Objective:

- To provide a value addition and current requirement in clinical research and pharmacovigilance
- To conceptualizing, designing, conducting, managing and reporting of clinical trials.
- To develop drug safety data in Pre-clinical, Clinical phases of Drug development and post market surveillance.

Course Outcomes: On completion of this course, the successful students should be able to:

CO	Statements	Cos & POs Mapping
CO-1	**Explain** the regulatory requirements for conducting clinical trial	PO1,PO2,PO3,PO6,PO7,PO12
CO-2	**Demonstrate** the types of clinical trial designs	PO1, PO2,PO3,PO12
CO-3	**Execute** safety monitoring, reporting and close-out activities	PO1, PO2,PO3,PO5,PO12
CO-4	**Describe** the principles of Pharmacovigilance	PO1, PO2,PO3,PO12
CO-5	**Perform** the adverse drug reaction reporting systems and communication in Pharmacovigilance	PO1,PO2,PO3,PO5,PO9,PO12

THEORY **60 Hours**

12Hrs

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

12Hrs

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

12Hrs

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.

12Hrs

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 centres in Hospitals, Industry and National programmes related to pharmacovigilance. Roles and responsibilities in Pharmacovigilance

12Hrs

5. Methods, ADR reporting and tools used in Pharmacovigilance

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

6. 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)

Course Objective:

- To provide value addition and current requirement in clinical research and pharmacovigilance
- To conceptualize, designing, conducting, managing and reporting of clinical trials.
- To develop drug safety data in Pre-clinical and clinical phases of Drug development and post-market surveillance.

Course Outcomes: On completion of this course, the successful students should be able to:

CO	Statements	Cos & POs Mapping
CO-1	**Design and perform** *in vitro* pharmacological experiments using various isolated tissue preparations	PO1,PO2,PO3,PO4,PO12
CO-2	**Estimate** the biological samples using various isolated tissue preparation	PO1,PO2,PO3,PO4,PO12
CO-3	**Describe** the OECD guidelines perform acute toxicity studies for safety evaluations, and interpret the pharmacokinetics profile of a given drug	PO1,PO2,PO3,PO4,PO7,PO12
CO-4	**Understand** cardiovascular responses using proper experimental techniques and drug monitoring and conduct clinical trials and ADR monitoring	PO1,PO2,PO3,PO4,PO9,PO12
CO-5	**Describe the** drug discovery process and develop a new drug through in silico techniques	PO1 PO1,PO2,PO3,PO4,PO12

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.

SEMESTER III

RESEARCH METHODOLOGY & BIOSTATISTICS(MRM301T)

Course Objective:

- To provide knowledge to apply statistical methods for data analysis, interpret results accurately.
- To assess the validity of research findings. By the end of the course, learners will be proficient in developing research proposals.
- To manage datasets and use statistical software to draw meaningful conclusions from empirical data.

Course Outcomes: On completion of this course, the successful students should be able to:

CO	Statements	Cos & POs Mapping
CO-1	**Choose** the appropriate research design and develop the appropriate research hypothesis for a research project	PO1, PO2,PO3, PO7, PO12
CO-2	**Design** experiments, develop research plans, and identify appropriate methodologies and protocols	PO1, PO2,PO3, PO7, PO12
CO-3	**Describe** and criticise research findings and interpret data from scientific articles using different statistical tests.	PO1, PO2,PO3, PO7, PO12
CO-4	**Frame** research hypotheses and present research proposals	PO1, PO2,PO3, PO7, PO12
CO-5	Describe Helsinki principle involving eethical principles for medical research that involves human subjects	PO1, PO2,PO3, PO7, PO12

THEORY **60 Hours**

12 Hrs

1.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.

12Hrs

2.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.

12 Hrs

3.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.

12 Hrs

4.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.

12 Hrs

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

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Paralakhemundi, Dist.- Gajapati
Odisha, India. PIN– 761211

Bhubaneswar Campus
Ramchandrapur
P.O. – Jatni, Bhubaneswar
Dist.- Khurda, Odisha,
India, PIN– 752050

Balangir Campus
Behind BSNL Office
IDCO land, Rajib Nagar
Dist.- Balangir, Odisha
India, PIN-767001

Rayagada Campus
IDCO Industrial Area
Pitamahal, Rayagada
Dist.-Rayagada, Odisha
India, PIN-765001

Balasore Campus
Gopalpur,
P.O.-Balasore
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India, PIN-756044

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