आईएफटीएम विश्वविद्यालय, मुरादाबाद, उत्तर प्रदेश

IFTM University, Moradabad, Uttar Pradesh

NAAC ACCREDITED

SCHOOL OF PHARMACEUTICAL SCIENCES
IFTM UNIVERSITY, MORADABAD.

www.iftmuniversity.ac.in

Study & Evaluation Scheme of Master of Pharmacy

Programme	:	***Master of Pharmacy (Pharmacology)***
Course Level	:	***Post Graduate Degree***
Duration	:	***Four Semester (two academic year) Full Time***
Medium of instruction	:	***English***
Minimum Required Attendance	:	***80%***
Total Credit Points	:	***Minimum=95, Maximum=100***

Programme Outcomes (POs):

On completion of the M. Pharm. program, a student will be able to:

PO1: Explain the knowledge of the basics and advanced pharmaceutical sciences and the ability to acquire, manage and use current information with problem solving approach.

PO2: Perform the synthesis, development of analytical techniques for identification, characterization and quantification of drugs, formulation, pharmacological, pharmacognostical, biotechnological and regulatory aspects of drugs and biomolecules.

PO3: Undergo the applied and interdisciplinary research for betterment of society at national and international level.

PO4: Comply and work on rules and regulations involved in the drug discovery & development, manufacture and other allied area of the field.

PO5: Develop problem-based learning approach and analytical thinking in his/her academic and professional life.

PO6: Apply critical thinking skills, including investigation, application, analysis, creativity, evaluation of information, data and documents related to research at local, regional and global platform.

PO7: Tackle professional challenges through lifelong learning attitude.

PO8: Demonstrate the ability to plan and implement professional activities.

PO9: Act efficiently as a leader in the diverse areas of the profession including writing research papers and articles of contemporary trends.

PO10: Apply the knowledge and skills to gain recognition in professional circle as well as society.

PO11: Make initiatives to create awareness in society about the effective and safe use of medicines.

PO12: Exercise ethical practices and moral values in personal and professional endeavors.

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2016

THE MASTER OF PHARMACY (M. PHARM.)

COURSE REGULATION 2014

(BASED ON NOTIFICATION IN THE GAZETTE OF INDIA NO. 362, DATED DECEMBER 11, 2014)

SCHEME AND SYLLABUS

PHARMACY COUNCIL OF INDIA
Combined Council's Building, Kotla Road,
Aiwan-E-Ghalib Marg, New Delhi-110 002.
Website : www.pci.nic.

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IFTM University, Moradabad

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The Gazette of India

असाधारण

EXTRAORDINARY

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PHARMACY COUNCIL OF INDIA

NOTIFICATION

New Delhi, the 10th December, 2014

The Master of Pharmacy (M.Pharm) Course Regulations, 2014

No. 14-136/ 2014-PCI.—In exercise of the powers conferred by Sections 10 and 18 of the Pharmacy Act, 1948 (8 of 1948), the Pharmacy Council of India, with the approval of the Central Government hereby makes the following regulations, namely–

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 4years of B.Pharm.)

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

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

3. Duration of the program

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

4. Medium of instruction and examinations

Medium of instruction and examination shall be in English.

5. Working days in each semester

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

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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.

Credit assignment

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 betreated 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 ofjournal club, research work presentations and discussions with thesupervisor shall be considered as theory course and multiplied by 1.

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 thehead 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

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are distributed semester-wise as shown in Table 14. 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: M.Pharm. Specialization (Pharmacology) with Code

S. No.	Specialization	Code
1.	Pharmacology	MPL

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 lessthan that shown in Table - 2.

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

Course Code	Course	Credit Hours	Credit Points	Hrs./wk	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
MPL111P	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	Clinical Research And Pharmacovigilance	4	4	4	100
MPL205P	Pharmacology Practical II	12	6	12	150
MPL222P	Seminar/Assignment	7	4	7	100
	Total	35	26	35	650

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Table - 3: Course of study for M. Pharm (Pharmacology). III Semester

Course Code	Course	Credit Hours	Credit Points
MRM 301T	Research Methodology and Biostatistics*	4	4
MPL302	Journal club	1	1
MPL303	Discussion / Presentation (Proposal Presentation)	2	2
MPL304	Research Work	28	14
Total		35	21

* Non University Exam

Table - 4: Course of study for M. Pharm (Pharmacology). IV Semester

Course Code	Course	Credit Hours	Credit Points
MPL 401	Journal Club	1	1
MPL 402	Discussion / Presentation (Proposal Presentation)	3	3
MPL 403	Research Work and Colloquium	31	16
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*

*Credit Points for Co-curricular Activities

MPL- Pharmacology

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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 each M.Pharm specialization and four student representatives (two from each academic year), nominated by the Head of the institution.

3. Duties of the Programme Committee:

i. Periodically reviewing the progress of the classes.
ii. Discussing the problems concerning curriculum, syllabus and the conduct of classes.
iii. Discussing with the course teachers on the nature and scope of assessment for the course and the same shall be announced to the students at the beginning of respective semesters.

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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 forinternal assessment and end semester examinations are given in Table - 7.

End semester examinations

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

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Table – 7: Schemes for internal assessments and end semester (Pharmacology- MPL)

Course Code	Course	Internal Assessment				End Semester Exams		Total Marks
		Continuous Mode	Sessional Exams		Total	Marks	Duration	
			Marks	Duration				
SEMESTER I								
MPL10 1T	Modern Pharmaceutical Analytical Techniques	10	15	1 Hr	25	75	3 Hrs	100
MPL10 2T	Advanced Pharmacology-I	10	15	1 Hr	25	75	3 Hrs	100
MPL10 3T	Pharmacological and Toxicological Screening Methods-I	10	15	1 Hr	25	75	3 Hrs	100
MPL10 4T	Cellular and Molecular Pharmacology	10	15	1 Hr	25	75	3 Hrs	100
MPL10 5P	Pharmacology Practical-I	20	30	6 Hrs	50	100	6 Hrs	150
MPL111P	Seminar /Assignment	-	-	-	-	-	-	100
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	Clinical research and Pharmacovigilance	10	15	1 Hr	25	75	3 Hrs	100
MPL205P	Pharmacology Practical-II	20	30	6 Hrs	50	100	6 Hrs	150
MPL222P	Seminar /Assignment	-	-	-	-	-	-	100
Total								650

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Table – 8: Schemesfor internal assessments and end semester examinations (Semester III&IV)

Course Code	Course	Internal Assessment				End Semester Exams		Total Mark s
		Continuous Mode	Sessional Exams		Total	Mark s	Duration	
			Marks	Duration				
SEMESTER III								
MRM301T	Research Methodology Biostatics*	10	15	1 Hr	25	75	3 Hrs	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	Discussion / Presentation (Proposal Presentation)	-	-	-	75	-	-	75
MPL403	Research work and Colloquium	-	-	-	-	400	1 Hr	400
Total								500

*Non University Examination

MPL- Pharmacology

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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	
Criteria	Maximum Marks
Attendance (Refer Table – 28)	8
Student – Teacher interaction	2
Total	10
Practical	
Attendance (Refer Table – 28	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

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

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shall be carried over and he/she shall be entitled for grade obtained by him/her on passing.

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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 beadmitted 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 IIsemesters 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

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.

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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	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.

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:

$$SGPA = \frac{C_1G_1 + C_2G_2 + C_3G_3 + C_4G_4}{C_1 + C_2 + C_3 + C_4}$$

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:

$$SGPA = \frac{C_1G_1 + C_2G_2 + C_3G_3 + C_4 * ZERO}{C_1 + C_2 + C_3 + C_4}$$

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 statusin case of F grade(s), tillthe course(s) is/are passed. Whenthe course(s) is/are passedby obtaining a passgrade on subsequent examination(s) theCGPA

shall only reflect the new grade and notthe failgrades earned earlier.The CGPA is calculated as:

$$\text{CGPA} = \frac{C_1S_1 + C_2S_2 + C_3S_3 + C_4S_4}{C_1 + C_2 + C_3 + C_4}$$

where C_1, C_2, C_3,.... is the total number of credits for semester I,II,III,.... and S_1,S_2, S_3,....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		50Marks
Methodology adopted		150 Marks
Results and Discussions		250 Marks
Conclusions and Outcomes		50 Marks
	Total	500 Marks

Evaluation of Presentation:

Presentation of work		100 Marks
Communication skills		50 Marks
Question andanswer skills		100 Marks
	Total	250 Marks

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22. Award of Ranks

Ranks and Medals shall be awarded on the basis of final CGPA. However, candidates whofail 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 hasto get the approval from the university by paying a condonation fee.

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PHARMACOLOGY (MPL)

MODERN PHARMACEUTICAL ANALYTICAL TECHNIQUES(MPL101T)

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

Objectives

After completion of course student is able to know about,

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

THEORY 60 Hrs

1	**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.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. **Spectroflourimetry:** Theory of Fluorescence, Factors affecting fluorescence **Flame emission spectroscopy and Atomic absorption spectroscopy:** Principle, Instrumentation, Interferences and Applications.	10 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-Spincoupling, Coupling constant, Nuclear magnetic double resonance, Brief outline of principles of FT-NMR and 13C NMR. Applications of NMR spectroscopy.	10 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	10 Hrs

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	fragmentation and its rules, Metastable ions, Isotopic peaks and Applications of Mass spectroscopy.	
4	**Chromatography:** Principle, apparatus, instrumentation, chromatographic parameters, factors affecting resolution, isolation of drug from excipients, data interpretation and applications of the following: Thin Layer chromatography High Performance Thin Layer Chromatography Ion exchange chromatography Column chromatography Gas chromatography High Performance Liquid chromatography Ultra High Performance Liquid chromatography Affinity chromatography Gel Chromatography	10 Hrs
5	**Electrophoresis:** Principle, Instrumentation, Working conditions, factors affecting separation and applications of the following: Paper electrophoresis Gel electrophoresis Capillary electrophoresis Zone electrophoresis Moving boundary electrophoresis Iso electric focusing **X ray Crystallography**: Production of X rays, Different X ray methods, Bragg's law, Rotating crystal technique, X ray powder technique, Types of crystals and applications of X-ray diffraction.	10 Hrs
6	**Potentiometry:** Principle, working, Ion selective Electrodes and Application of potentiometry. **Thermal Techniques:** Principle, thermal transitions and Instrumentation (Heat flux and power-compensation and designs), Modulated DSC, Hyper DSC, experimental parameters (sample preparation, experimental	10 Hrs

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	conditions, calibration, heating and cooling rates, resolution, source of errors) and their influence, advantage and disadvantages, pharmaceutical applications. **Differential Thermal Analysis** (DTA): Principle, instrumentation andadvantage and disadvantages, pharmaceutical applications, derivative differential thermal analysis (DDTA). **TGA**: Principle, instrumentation, factors affecting results, advantages and disadvantages, pharmaceutical applications.	

Course Outcomes:

Upon completion of this course, the student should be able to:

CO1: Understand theory, instrumentation and applications of various spectroscopic techniques for skill development, entrepreneurship and employability at local, regional and global platform.

CO2: Know about the concept and applications of NMR spectroscopy for skill development, entrepreneurship and employability.

CO3: Learn theory, instrumentation and applications of Mass spectroscopy for skill development, entrepreneurship and employability.

CO4: Understand the principle and instrumentation of various chromatographic methods for skill development, entrepreneurship and employability at national and international level.

CO5: Understand electrophoresis, X-Ray Crystallography, potentiometry, different thermal techniques and/or immunological assay for skill development, entrepreneurship and employability.

PO-CO Mapping (Please write 3, 2, 1 wherever required)

(Note: 3 for highly mapped, 2 for medium mapped and 1 for low mapped)

	PO1	PO2	PO3	PO4	PO5	PO6	PO7	PO8	PO9	PO10	PO11	PO12
CO1	3	2	3	2	3	2	2	2	1	3	1	1
CO2	1	3	2	2	2	1	2	2	2	2	1	1
CO3	1	3	1	2	3	3	2	2	2	2	2	2
CO4	1	1	1	3	3	3	2	2	2	2	1	2
CO5	3	3	3	3	2	2	1	2	1	2	1	2

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CO-Curriculum Enrichment Mapping (Please write 3, 2, 1 wherever required)

(Note: 3 for highly mapped, 2 for medium mapped and 1 for low mapped)

	Skill Development	Employability	Entrepreneurship Development
CO1	3	3	2
CO2	2	3	3
CO3	3	3	3
CO4	3	3	3
CO5	3	2	2

REFERENCES

1. Spectrometric Identification of Organic compounds - Robert M Silverstein, Sixth edition,John Wiley & Sons, 2004.
2. Principles of Instrumental Analysis - Doglas A Skoog, F. James Holler, Timothy A.Nieman, 5th edition, Eastern press, Bangalore, 1998.
3. Instrumental methods of analysis – Willards, 7th edition, CBS publishers.
4. Practical Pharmaceutical Chemistry – Beckett and Stenlake, Vol II, 4th edition, CBS Publishers, New Delhi, 1997.
5. Organic Spectroscopy - William Kemp, 3rd edition, ELBS, 1991.
6. Quantitative Analysis of Drugs in Pharmaceutical formulation - P D Sethi, 3rd Edition,CBS Publishers, New Delhi, 1997.
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ADVANCED PHARMACOLOGY-I(MPL102T)

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, thissubject helps the students to understand the concepts of drug action and mechanisms involved.

Objectives

- Upon completion of the course the student shall be able to
- Discuss the pathophysiology and pharmacotherapy of certain diseases
- Explain the mechanism of drug actions at cellular and molecular level
- Understand the adverse effects, contraindications and clinical uses of drugs used intreatment of diseases

THEORY 60 Hrs

1	**General Pharmacology** **a. Pharmacokinetics**: The dynamics of drug absorption, distribution, biotransformation and elimination. Concepts of linear and non-linear compartment models. Significance of Protein binding. **b. Pharmacodynamics**: Mechanism of drug action and the relationship between drug concentration and effect. Receptors, structural and functional families of receptors, quantitation of drug receptors interaction and elicited effects.	12 Hrs
2	**Neurotransmission** 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]. Non adrenergic non cholinergic transmission (NANC). Co- transmission **Systemic Pharmacology**	12 Hrs

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	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** General and local anesthetics Depression, psychosis, mania, epilepsy, neurodegenerative diseases.Narcotic and non-narcotic analgesics.	12 Hrs
4	**Cardiovascular Pharmacology** Diuretics, antihypertensives, antiischemics, anti-arrhythmic, drugs for heart failure and hyperlipidemia Hematinics, coagulants, anticoagulants, fibrinolytics and anti-platelet drugs	12 Hrs
5	**Autocoid Pharmacology** The physiological and pathological role of Histamine, Serotonin, Kinins Prostaglandins Opioid autocoids. Pharmacology of antihistamines, 5HT antagonists.	12 Hrs

Course Outcomes:

Upon completion of this course, the student should be able to:

CO1: Understand general pharmacology including pharmacokinetics and pharmacodynamics for skill development, entrepreneurship and employability at national and international level.

CO2: Understand the concepts of neurohumoral synthesis, release and transmission of various neurotransmitters along with peripheral nervous system pharmacology for skill development, entrepreneurship and employability.

CO3: Understand the central nervous system and associated diseases with their drug classification and pharmacological activity for skill development, entrepreneurship and employability.

CO4: Understand drug classification and pharmacological actions of cardiovascular and haematopoetic system along with associated diseases for skill development, entrepreneurship and employability.

CO5: Understand the physiology and pharmacology of different autocoids along with their drug

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classification for skill development, entrepreneurship and employability.

PO-CO Mapping (Please write 3, 2, 1 wherever required)

(Note: 3 for highly mapped, 2 for medium mapped and 1 for low mapped)

	PO1	PO2	PO3	PO4	PO5	PO6	PO7	PO8	PO9	PO10	PO11	PO12
CO1	3	1	2	2	2	2	1	2	2	3	3	1
CO2	2	2	2	3	3	2	2	2	3	3	3	2
CO3	2	2	3	2	1	2	2	3	3	2	2	2
CO4	2	3	2	3	3	2	2	2	3	3	3	2
CO5	3	1	2	2	3	3	2	2	2	2	2	2

CO-Curriculum Enrichment Mapping (Please write 3, 2, 1 wherever required)

(Note: 3 for highly mapped, 2 for medium mapped and 1 for low mapped)

	Skill Development	Employability	Entrepreneurship Development
CO1	3	2	2
CO2	3	3	3
CO3	3	3	3
CO4	3	3	3
CO5	3	3	2

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. Handbook of Clinical Pharmacokinetics by Gibaldi and Prescott.
5. Applied biopharmaceutics and Pharmacokinetics by Leon Shargel and Andrew B.C.Yu.

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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 APCAvichal 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.

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PHARMACOLOGICAL AND TOXICOLOGICAL SCREENING METHODS – I(MPL103T)

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 knowledgeof various in-vitro and in-vivo preclinical evaluation processes.

Objectives

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

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

THEORY 60 Hrs

1	**Laboratory Animals** **Common laboratory animals**: Description, handling and 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 depressants, anxiolytics, anti-psychotics, anti-epileptics and nootropics. Drugs for neurodegenerativediseases 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 usingin 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. Anticancer agents. Hepatoprotective screening methods.	12 Hrs
5	Preclinical screening of new substances for the pharmacological activity usingin 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	12 Hrs

Course Outcomes:

Upon completion of this course, the student should be able to:

CO1: Understand various regulations and ethical requirements for the usage of experimental animals and bioassay concept for skill development and employability at national and international level.

CO2: Learn various screening methods involved in the drug discovery process in CNS and ANS for skill development, entrepreneurship and employability.

CO3: Learn screening methods involved in the drug discovery process in respiratory pharmacology, reproductive pharmacology, analgesics, anti-inflammatory and antipyretic agents along with gastrointestinal drugs for skill development, entrepreneurship and employability.

CO4: Describe the various screening methods involved in the drug discovery process in

cardiovascular pharmacology and drugs for metabolic disorders and hepatoprotective agents for skill development and employability at local, regional and global platform.

CO5: Understand general principles of immunoassay along with extrapolation of in vitro data to preclinical and preclinical to humans for skill development, entrepreneurship and employability.

PO-CO Mapping (Please write 3, 2, 1 wherever required)

(Note: 3 for highly mapped, 2 for medium mapped and 1 for low mapped)

	PO1	PO2	PO3	PO4	PO5	PO6	PO7	PO8	PO9	PO10	PO11	PO12
CO1	3	1	3	2	2	3	2	2	1	3	2	1
CO2	1	3	3	2	2	2	1	2	2	2	2	3
CO3	2	3	3	1	2	3	2	2	3	2	2	3
CO4	1	3	2	1	2	3	2	2	2	3	2	2
CO5	3	2	2	3	3	3	3	1	3	1	3	2

CO-Curriculum Enrichment Mapping (Please write 3, 2, 1 wherever required)

(Note: 3 for highly mapped, 2 for medium mapped and 1 for low mapped)

	Skill Development	Employability	Entrepreneurship Development
CO1	2	2	1
CO2	3	2	2
CO3	3	2	2
CO4	3	3	2
CO5	3	3	1

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CELLULAR AND MOLECULAR PHARMACOLOGY(MPL104T)

Scope

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

Objectives

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

- Explain the receptor signal transduction processes.
- Explain the molecular pathways affected by drugs.
- Appreciate the applicability of molecular pharmacology and biomarkers in drug discoveryprocess.
- Dembnstrate 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 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

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

Course Outcomes:

Upon completion of this course, the student should be able to:

CO1: Understand the cell biology for skill development and employability.

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CO2: Understand outline of cells communication and main sequences of events essential for cell-cell communication for skill development and employability at national and international level.

CO3: Understand critical analysis of methods and principles of genome sequencing and genome mapping for skill development and employability at local, regional and global platform.

CO4: Understand the Pharmacogeomics and immunotherapeutics for skill development and employability.

CO5: Learn the cell culture techniques and biosimilars for skill development and employability.

PO-CO Mapping (Please write 3, 2, 1 wherever required)

(Note: 3 for highly mapped, 2 for medium mapped and 1 for low mapped)

	PO1	PO2	PO3	PO4	PO5	PO6	PO7	PO8	PO9	PO10	PO11	PO12
CO1	2	2	2	3	2	2	2	3	3	2	3	2
CO2	2	2	2	3	2	2	2	3	3	2	3	2
CO3	2	2	3	3	2	3	1	3	2	2	2	2
CO4	2	3	3	2	2	3	2	2	3	2	2	2
CO5	2	3	3	2	1	3	2	1	1	3	3	3

CO-Curriculum Enrichment Mapping (Please write 3, 2, 1 wherever required)

(Note: 3 for highly mapped, 2 for medium mapped and 1 for low mapped)

	Skill Development	Employability	Entrepreneurship Development
CO1	3	3	1
CO2	2	3	1
CO3	2	3	1
CO4	3	2	2
CO5	3	1	1

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

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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 protocols in molecular biology vol I to VI edited by Frederick M.Ausuvel et al

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PHARMACOLOGICAL PRACTICAL – I(MPL105P)

1. Analysis of pharmacopoeial compounds and their formulations by UV Vis spectrophotometer
2. Simultaneous estimation of multicomponent 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 photometryHandling 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, anticonvulsantactivity.
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.

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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 ofadministration using softwares
21. Enzyme inhibition and induction activity
22. Extraction of drug from various biological samples and estimation of drugs in biologicalfluids using different analytical techniques (UV)
23. Extraction of drug from various biological samples and estimation of drugs in biologicalfluids 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

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ADVANCED PHARMACOLOGY - II(MPL201T)

Scope

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

Objectives

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

- Explain the mechanism of drug actions at cellular and molecular level
- Discuss the Pathophysiology and pharmacotherapy of certain diseases
- Understand the adverse effects, contraindications and clinical uses of drugs used intreatment 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**	12 Hrs

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	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	
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 antioxidants Recent Advances in Treatment: Alzheimer's disease, Parkinson's disease, Cancer, Diabetes mellitus	12 Hrs

Course Outcomes:

Upon completion of this course, the student should be able to:

CO1: Attain detailed knowledge about Endocrine Pharmacology, Molecular & cellular mechanism of action of hormones, anti-thyroid drugs, oral hypoglycemic agents, oral contraceptives and Corticosteroids for skill development and employability.

CO2: Understand the chemotherapy, molecular and cellular mechanism of action of antimicrobial agents for skill development and employability.

CO3: Understand the drugs used in protozoal infections, helminthiasis. Also, learn about chemotherapy of cancer, immunopharmacology, immunosuppressants and immunostimulants for skill development and employability at national and international level.

CO4: Understand the pharmacology related to GIT and chronopharmacology for skill development and employability.

CO5: Understand Free radical pharmacology and recent advances in treatment such asAlzheimer's disease, Parkinson's disease, Cancer, Diabetes Mellitus for skill development and employability.

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PO-CO Mapping (Please write 3, 2, 1 wherever required)

(Note: 3 for highly mapped, 2 for medium mapped and 1 for low mapped)

	PO1	PO2	PO3	PO4	PO5	PO6	PO7	PO8	PO9	PO10	PO11	PO12
CO1	3	2	3	2	2	2	3	2	3	3	2	2
CO2	2	3	2	2	2	3	2	1	2	2	2	2
CO3	3	2	3	2	2	2	2	2	2	3	3	3
CO4	3	3	2	3	2	2	1	2	2	1	2	2
CO5	2	3	2	2	2	3	2	2	2	2	1	2

CO-Curriculum Enrichment Mapping (Please write 3, 2, 1 wherever required)

(Note: 3 for highly mapped, 2 for medium mapped and 1 for low mapped)

	Skill Development	Employability	Entrepreneurship Development
CO1	3	2	3
CO2	3	2	2
CO3	3	3	2
CO4	3	2	1
CO5	2	3	2

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 Golanet 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 forIndustrial

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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 APCAvichal 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- LippincottWilliams &Wilkins Publishers

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PHARMACOLOGICAL AND TOXICOLOGICAL SCREENING METHODS-II(MPL202T)

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.

Objectives

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

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

THEORY 60 Hrs

1	Basic definition and types of toxicology (general, mechanistic, regulatory and descriptive) Regulatory guidelines for conducting toxicity studies OECD, ICH, EPA and ScheduleY 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), teratogenicity studies (segment II) Genotoxicity studies (Ames Test, in vitro and in vivo Micronucleus and Chromosomal aberrations studies) In vivo carcinogenicity studies	12 Hrs

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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

Course Outcomes:

Upon completion of this course, the student should be able to:

CO1: Learn about the toxicology, OECD, ICH, EPA guidelines, ScheduleY and OECD principlesof good laboratory practice for skill development and employability.

CO2: Attain detailed knowledge about Acute, sub-acute, chronic-oral, dermal, inhalational, acuteeye irritation, skin sensitization, dermal irritation & dermal toxicity studies and test item characterization for skill development and employability.

CO3: Attain detailed knowledge about reproductive toxicology studies, genotoxicity studies and in vivo carcinogenicity studies for skill development and employability at local, regional and global platform.

CO4: Understand the IND enabling studies and safety pharmacology studies for skill development and employability.

CO5: Understand the toxicokinetics and alternative methods to animal toxicity testing for skill development and employability.

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PO-CO Mapping (Please write 3, 2, 1 wherever required)

(Note: 3 for highly mapped, 2 for medium mapped and 1 for low mapped)

	PO1	PO2	PO3	PO4	PO5	PO6	PO7	PO8	PO9	PO10	PO11	PO12
CO1	3	2	3	3	3	2	3	3	2	2	2	2
CO2	3	2	3	3	3	2	3	3	2	2	2	2
CO3	2	3	3	3	3	3	2	2	2	2	2	2
CO4	2	3	1	3	3	3	2	1	1	2	3	2
CO5	1	3	3	2	2	2	2	3	2	3	2	2

CO-Curriculum Enrichment Mapping (Please write 3, 2, 1 wherever required)

(Note: 3 for highly mapped, 2 for medium mapped and 1 for low mapped)

	Skill Development	Employability	Entrepreneurship Development
CO1	3	3	3
CO2	3	3	3
CO3	3	3	3
CO4	3	2	2
CO5	2	2	2

REFERENCES

1. Handbook 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 ofhealth and family welfare (department of health) New Delhi
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4. Animal Models in Toxicology, 3rd Edition, Lower and Bryan
5. OECD test guidelines.
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Trials and marketing Authorization for Pharmaceuticals (http://www.fda.gov/downloads/drugs/guidancecomplianceregulatoryinformation/guidances/ucm073246.pdf)

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PRINCIPLES OF DRUG DISCOVERY(MPL203T)

Scope

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

Objectives

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

- Explain the various stages of drug discovery.
- Appreciate the importance of the role of genomics, proteomics and bioinformatics in drugdiscovery
- Explain various targets for drug discovery.
- Explain various lead seeking methods and lead optimization Appreciate the importanceof 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	12 Hrs

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	Traditional vs rational drug design, Methods followed in traditional drugdesign, High throughput screening, Concepts of Rational Drug Design, RationalDrug Design Methods: Structure and Pharmacophore based approaches Virtual Screening techniques: Drug likeness screening, Concept of pharmacophore mapping and pharmacophore-based Screening	
4	Molecular docking: Rigid docking, flexible docking, manual docking; Docking based screening. De novo drug design. Quantitative analysis of StructureActivity 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

Course Outcomes:

Upon completion of this course, the student should be able to:

CO1: Learn about the modern drug discovery process, target discovery and validation for skill development and employability.

CO2: Attain detailed knowledge about lead identification, combinatorial chemistry, high throughput screening, lead discovery techniques, protein structure and application of NMR & X- ray crystallography in protein structure prediction for skill development and employability.

CO3: Attain detailed knowledge about rational drug design, traditional vs rational drug design, high throughput screening and virtual screening techniques for skill development and employability.

CO4: Understand the molecular docking, QSAR, SAR versus QSAR, Hansch analysis and Fee Wilson analysis for skill development and employability at national and international level.

CO5: Understand the QSAR statistical methods, COMFA, COMSIA and Prodrug design for skill development and employability.

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PO-CO Mapping (Please write 3, 2, 1 wherever required)

(Note: 3 for highly mapped, 2 for medium mapped and 1 for low mapped)

	PO1	PO2	PO3	PO4	PO5	PO6	PO7	PO8	PO9	PO10	PO11	PO12
CO1	3	3	2	3	2	3	2	3	2	3	2	2
CO2	2	3	3	3	3	2	3	3	2	2	2	1
CO3	2	3	3	2	1	2	2	3	3	2	1	3
CO4	2	3	2	3	3	2	3	3	2	2	2	1
CO5	3	3	3	2	1	2	2	3	3	2	1	3

CO-Curriculum Enrichment Mapping (Please write 3, 2, 1 wherever required)

(Note: 3 for highly mapped, 2 for medium mapped and 1 for low mapped)

	Skill Development	Employability	Entrepreneurship Development
CO1	3	3	2
CO2	3	3	2
CO3	2	2	2
CO4	3	3	3
CO5	3	2	1

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2. Darryl León. Scott MarkelIn. Silico Technologies in Drug Target Identification and Validation. 2006 by Taylor and Francis Group, LLC.
3. Johanna K. Di Stefano. Disease Gene Identification. Methods and Protocols. Springer NewYork Dordrecht Heidelberg London.
4. Hugo Kubiny. QSAR: Hansch Analysis and Related Approaches. Methods and Principlesin 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.

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CLINICAL RESEARCH AND PHARMACOVIGILANCE(MPL204T)

Scope

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

Objectives

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

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

THEORY 60 Hrs

1	Regulatory Perspectives of Clinical Trials: Origin and Principles of International Conference on Harmonization - Good Clinical Practice (ICH-GCP) guidelines Ethical Committee: InstitutionalReview 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

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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 centres in Hospitals, Industry and National programmes related to pharmacovigilance. Roles and responsibilities in Pharmacovigilance	12 Hrs
5	Methods,[5]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.	12 Hrs
6	Pharmacoepidemiology, pharmacoeconomics, safety pharmacology	12 Hrs

Course Outcomes:

Upon completion of this course, the student should be able to:

CO1: Learn the regulatory perspectives of clinical trials, ICH-GCP, ethical committee, ICMR and informed consent process for skill development and employability at national and international level.

CO2: Attain detailed knowledge about clinical trials, experimental study, observation study, rolesand responsibilities of clinical trial personnel for skill development and employability.

CO3: Attain detailed knowledge about clinical trial documentation and adverse drug reactions for skill development and employability.

CO4: Understand the basic aspects, terminologies and establishment of pharmacovigilance for skill development and employability.

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CO5: Understand the methods, ADR reporting and tools used in pharmacovigilance. Also, learn pharmacoepidemiology, pharmacoeconomics, safety pharmacology for skill development and employability.

PO-CO Mapping (Please write 3, 2, 1 wherever required)

(Note: 3 for highly mapped, 2 for medium mapped and 1 for low mapped)

	PO1	PO2	PO3	PO4	PO5	PO6	PO7	PO8	PO9	PO10	PO11	PO12
CO1	3	2	3	3	2	2	2	2	2	2	2	3
CO2	3	2	3	3	2	2	2	2	2	2	2	3
CO3	3	2	3	3	2	2	2	2	2	2	2	3
CO4	3	2	3	3	2	3	3	3	3	3	2	2
CO5	3	2	3	3	2	3	3	3	3	3	2	2

CO-Curriculum Enrichment Mapping (Please write 3, 2, 1 wherever required)

(Note: 3 for highly mapped, 2 for medium mapped and 1 for low mapped)

	Skill Development	Employability	Entrepreneurship Development
CO1	3	3	1
CO2	3	2	2
CO3	2	2	2
CO4	3	3	1
CO5	3	3	2

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 GoodClinical Practice.E6; May 1996.
3. Ethical Guidelines for Biomedical Research on Human Subjects 2000. Indian Council of Medical

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Research, New Delhi.

4. Textbook of Clinical Trials edited by David Machin, Simon Day and Sylvan Green, March2005, 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.

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PHARMACOLOGICAL PRACTICAL – II

(MPL 205P)

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

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REFERENCES

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2. Handbook of Experimental Pharmacology-S.K.Kulkarni
3. Text book of in-vitro practical Pharmacology by Ian Kitchen
4. Bioassay Techniques for Drug Development by Atta-ur-Rahman, Iqbal choudhary andWilliam Thomsen
5. Applied biopharmaceutics and Pharmacokinetics by Leon Shargel and Andrew B.C.Yu.
6. Handbook of Essential Pharmacokinetics, Pharmacodynamics and Drug Metabolism forIndustrial Scientists.

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Semester III

MRM301T -Research Methodology & Biostatistics

UNIT – I

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

UNIT – II

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

UNIT – III

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

UNIT – IV

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

UNIT – V

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

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Course Outcomes:

Upon completion of this course, the student should be able to:

CO1: Learn the general research methodology for skill development and employability.

CO2: Learn biostatistics, sample size, statistical tests of significance, parametric tests, non-parametric tests, null hypothesis, P values, degree of freedom and interpretation of P values for skill development and employability at local, regional and global platform.

CO3: Attain detailed knowledge about medical Research for skill development and employability.

CO4: Understand the CPCSEA guidelines for laboratory animal facilities for skill development and employability at national and international level.

CO5: Understand the declaration of Helsinki, basic principles for all medical research andadditional principles for medical research combined with medical care for skill development and employability.

PO-CO Mapping (Please write 3, 2, 1 wherever required)

(Note: 3 for highly mapped, 2 for medium mapped and 1 for low mapped)

	PO1	PO2	PO3	PO4	PO5	PO6	PO7	PO8	PO9	PO10	PO11	PO12
CO1	2	2	1	2	1	2	1	1	2	1	2	1
CO2	1	3	2	1	3	2	2	2	1	2	1	1
CO3	1	2	1	2	2	2	2	1	1	2	1	2
CO4	2	2	1	1	1	3	1	2	2	1	2	1
CO5	1	3	1	2	1	2	1	1	1	2	1	2

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CO-Curriculum Enrichment Mapping (Please write 3, 2, 1 wherever required)

(Note: 3 for highly mapped, 2 for medium mapped and 1 for low mapped)

	Skill Development	Employability	Entrepreneurship Development
CO1	3	3	2
CO2	2	3	2
CO3	3	2	1
CO4	2	3	1
CO5	3	2	2

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