Study and Evaluation Scheme

of

M. Pharm Program (Pharmacology)

[Applicable w.e.f. Academic Session - 2021-22]
Choice Based Credit System, (CBCS)

TEERTHANKER MAHAVEER UNIVERSITY
N.H.-24, Delhi Road, Moradabad, Uttar Pradesh-244001 Website: www.tmu.ac.in

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The program of study for **M. Pharm-Choice Based Credit System (CBCS)** 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.

Program/Course credit structure

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.

i. 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.

ii. 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.

iii. 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.

Minimum credit requirements

The minimum credit points required for the award **of M. Pharm. degree is 100.** However, based on the credit points earned by the students under the head of co-curricular activities, a student shall earn a maximum of 105 credit points (Table 1).

Table 1: Semester wise credits distribution

Semester	Credit Points
I	26
II	26
III	26
IV	20
Co-curricular Activities (Attending Conference, Scientific Presentations and Other Scholarly Activities)	**Minimum=02** **Maximum=07***
Total Credit Points	**Minimum=100** **Maximum=105***

*Credit Points for Co-curricular Activities

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Course of study

The course of study for M. Pharm specializations shall include Semester wise Theory & Practical as given in Table – 2.1 to 2.4. The number of hours to be devoted to each theory and practical course in any semester shall not be less than that shown in Table 2.1 to 2.4.

Table 2.1: Course of study for M. Pharm. (Pharmacology)

M. Pharm. (Pharmacology) Semester I						
Category	**Course Code**	**Course**	**Credit Hours**	**Credit Points**	**Hrs./wk**	**Marks**
CC-1	MPL101T	Modern Pharmaceutical Analytical Techniques	4	4	4	100
CC-2	MPL102T	Advanced Pharmacology-I	4	4	4	100
CC-3	MPL103T	Pharmacological and Toxicological Screening Methods-I	4	4	4	100
CC-4	MPL104T	Cellular and Molecular Pharmacology	4	4	4	100
SEC-1	MPL105P	Pharmacology Practical I	12	6	12	150
SEC-2	MPL106	Seminar/Assignment	7	4	7	100
Total			35	26	35	650

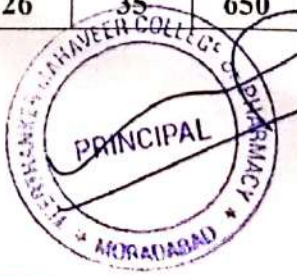
CC- Core Course, SEC-Skill Enhancement Course

Value Added Course (VAC)

Category	Course Code	Course	Credit Hours	Internal	External	Marks
VAC-1	TMUPS-101	Managing Self	00	50	50	100

Semester II						
Category	**Course Code**	**Course**	**Credit Hours**	**Credit Points**	**Hrs./wk**	**Marks**
CC-5	MPL201T	Advanced Pharmacology II	4	4	4	100
CC-6	MPL202T	Pharmacological and Toxicological Screening Methods-II	4	4	4	100
CC-7	MPL203T	Principles of Drug Discovery	4	4	4	100
CC-8	MPL204T	Clinical Research and Pharmacovigilance	4	4	4	100
SEC-3	MPL205P	Pharmacology Practical II	12	6	12	150
SEC-4	MPL206	Seminar/Assignment	7	4	7	100
Total			35	26	35	650

CC- Core Course, SEC-Skill Enhancement Course



Value Added Course (VAC)

Category	Course Code	Course	Credit Hours	Internal	External	Marks
VAC-2	TMUPS-201	Managing work and others	00	50	50	100
VAC-3	TMUPS-202	Introduction to SPSS	00	50	50	100
VAC-4	TMUPS-203	Communication Skills and Technical Writing	00	50	50	100

Table 2.2: Course of study for M. Pharm. (Common for All Specializations)

M. Pharm. III Semester (Common for All Specializations)				
Category	**Course Code**	**Course**	**Credit Hours**	**Credit Points**
	MRM301T	Research Methodology and Biostatistics*	4	4
DSEC-1**	MRM302T	Pharmacoeconomics	3	3
	MRM303T	Blockchain Technology in Pharmaceutical Industry		
	MRM304T	Digital Therapeutics and Curative Therapies		
	MRM305T	Biosimilars		
SEC-5	MRM306	Journal Club	1	1
SEC-6	MRM307	Discussion / Presentation (Proposal Presentation)	2	2
SEC-7	MRM308	Research Work	28	14
GEC-1***	MRM309T	Entrepreneurship Skill Development	2	2
	MRM310T	Intellectual Property Rights		
	MRM311T	Business Model Innovation		
	MRM312T	Principles of Management		
Total			40	26

DSEC-Discipline Specific Elective Course, SEC-Skill Enhancement Course, GEC- General Elective Course

***Non University Examination**

****One course to be opted as electives out of four**

***** One course to be opted as general electives out of four**

Table 2.3: Course of study for M. Pharm. (Common for All Specializations)

M. Pharm. IV Semester				
Category	**Course Code**	**Course**	**Credit Hours**	**Credit Points**
SEC-8	MRM401	Journal Club	1	1
SEC-9	MRM402	Discussion / Presentation (Final Presentation)	3	3
SEC-10	MRM403	Research Work & Colloquium	31	16
	Total		35	20

Table 2.4: Guidelines for Awarding Credit Points for Co-curricular Activities (Attending Conference, Scientific Presentations and Other Scholarly Activities)

Name of the Activity	Maximum Credit Points Eligible / Activity
Participation at National level	1
Participation at International level (Held outside India)	2
Academic Award/Research Award from State Level/National Agencies	1
Academic Award/Research Award from International Agencies	2
Research / Review Publication in National Journals (Indexed in Scopus / Web of Science)	1
Research / Review Publication in International Journals (Indexed in Scopus / Web of Science) [The editorial Board outside India]	2

*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.

Examinations/Assessments

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.

End semester examinations

The End Semester Examinations for each theory and practical course through semesters I to IV shall be conducted by the Teerthanker Mahaveer University except for non-university courses for which examinations shall be conducted by the subject experts at college level and the marks/grades shall be submitted to the university.

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.

Carry forward of marks

In case a student fails to secure the minimum 50% in any Theory or Practical course, 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.

Allowed to keep terms (ATKT)

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.

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 (Table 5). 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.

Table 5: Letter grades and grade points equivalent to Percentage of marks and performances

Percentage of Marks Obtained	Letter Grade	Grade Point	Performance
90.00-100.00	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

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 obtained in 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:

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

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, the SGPA shall then be computed as:

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

Cumulative Grade Point Average (CGPA)

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

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

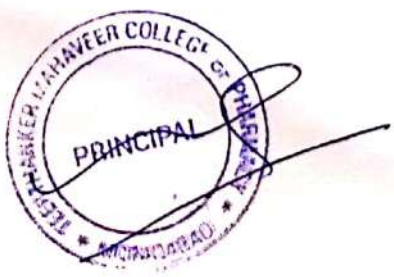
where C1, C2, C3,.... is the total number of credits for semester I,II,III,.... and S1,S2, S3,....is the SGPA of semester I,II,III,.... .

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**

Duration for completion of the program of study



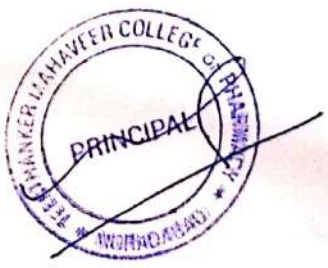
The duration for the completion of the program shall be fixed as double the actual duration of the program and the students have to pass within the said period, otherwise they have to get fresh Registration.

Revaluation/Retotalling of answer papers

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

Re-admission after break of study

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



Syllabus
Master of Pharmacy
(Pharmacology)

[Applicable w.e.f. Academic Session - 2021-22 till revised]
[Framed under the Revised Regulation of the Master of Pharmacy (M. Pharm) Degree Programme regulations 3(a) of 2014 given by PCI]

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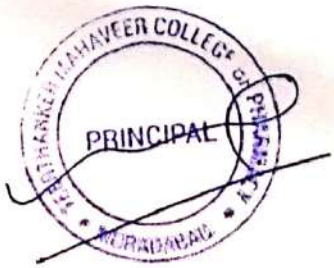


PROGRAM SPECIFIC OUTCOMES: M. PHARM (PHARMACOLOGY)

After completion of the course the students will be

PSO-1: Understanding the application of pharmacological information of active chemical entity (Drug) present in a medicine that is used for diagnosis, prevention, treatment/cure of a disease.

PSO-2: Illustrating pharmacodynamic and pharmacokinetic investigation to evaluate the efficacy and safety of drugs in animal models.

PSO-3: Demonstrating mechanism of action of drug in preclinical research involved in Neurotransmission and Neurohumoral transmission apply in biomedical research.

PSO-4: Practicing animals handling of different species / strains along with their breeding and maintenance as per CPCSEA/international Guidelines/Good laboratory practice (GLP).

PSO-5: Identifying the *in vivo, in vitro*, and other possible animal alternative models for screening of new substances.

PSO-6: Developing the core concept of establishing toxicological profile of a new drug while evaluating during research.

COURSE CODE: MPL101T	M. Pharm- Semester-I Modern Pharmaceutical Analytical Techniques	L-4 T-0 P-0 C-4
Course Outcomes:	On completion of the course, the students will be: **CO1**-Understanding the basic concepts and advances in analytical techniques and theoretical skills of the analytical instruments. **CO2**-Applying advanced analytical instrumental techniques for Identification, characterization and quantification of drugs. **CO3**-Performing quantitative & qualitative analysis of drugs using various analytical instruments in single and combination dosage forms. **CO4**- Evaluating given samples with respect to official standards.	
Course Contents:		
Unit-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 (Characteristics of drugs that can be analysed by fluorimetry), Quenchers, Instrumentation and Applications of fluorescence spectrophotometer. **Flame emission spectroscopy and Atomic absorption spectroscopy:** Principle, Instrumentation, Interferences and Applications	10hr
Unit-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.	10hr
Unit-3:	**Mass Spectroscopy:** Principle, Theory, Instrumentation of Mass Spectroscopy, Different types of ionization like electron impact, chemical, field, FAB and MALDI, APCI, ESI, APPI Analysers of Quadrupole and Time of Flight, Mass fragmentation and its rules, Meta stable ions, Isotopic peaks and Applications of Mass spectroscopy.	10hr
Unit-4:	**Chromatography:** Principle, apparatus, instrumentation, chromatographic parameters, factors affecting resolution, isolation of drug from excipients, data interpretation and applications of the following: a) Thin Layer chromatography b) High Performance Thin Layer Chromatography c) Ion exchange chromatography d) Column chromatography e) Gas chromatography f) High Performance Liquid chromatography	10hr

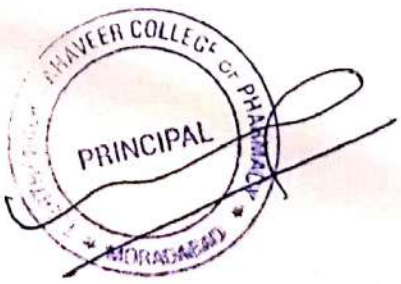
	g) Ultra High Performance Liquid chromatography h) Affinity chromatography i) Gel Chromatography.	
Unit-5:	**Electrophoresis:** Principle, Instrumentation, Working conditions, factors affecting separation and applications of the following: a) Paper electrophoresis b) Gel electrophoresis c) Capillary electrophoresis d) Zone electrophoresis e) Moving boundary electrophoresis f) Iso electric focusing **X ray Crystallography:** Production of X rays, Different X ray methods, Bragg's law, Rotating crystal technique, X ray powder technique, Types of crystals and applications of X-ray diffraction.	**10hr**
Unit-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 conditions, calibration, heating and cooling rates, resolution, source of errors) and their influence, advantage and disadvantages, pharmaceutical applications. **Differential Thermal Analysis (DTA):** Principle, instrumentation and advantage and disadvantages, pharmaceutical applications, derivative differential thermal analysis (DDTA). TGA: Principle, instrumentation, factors affecting results, advantage and disadvantages, pharmaceutical applications.	**10hr**

Text Books:

1. Spectroscopy of Organic Compounds, 2nd edn., P.S/Kalsi, Wiley estern Ltd., Delhi.
2. Textbook of Pharmaceutical Analysis, KA.Connors, 3 rd Edition, John Wiley & Sons, 1982

Reference Books:

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, 5 th edition, Eastern press, Bangalore, 1998.
3. Instrumental methods of analysis – Willards, 7th edition, CBS publishers. 4. Practical Pharmaceutical Chemistry – Beckett and Stenlake, Vol II, 4th edition, CBS Publishers, New Delhi, 1997.
4. Organic Spectroscopy - William Kemp, 3rd edition, ELBS, 1991.
5. Quantitative Analysis of Drugs in Pharmaceutical formulation - P D Sethi, 3rd Edition, CBS Publishers, New Delhi, 1997.
6. Pharmaceutical Analysis - Modern Methods – Part B - J W Munson, Vol 11, Marcel. Dekker Series.



Course Code: MPL102T	M. Pharm- Semester-I ADVANCED PHARMACOLOGY - I (MPL102T)	L-4 T-0 P-0 C-4
Course Outcomes:	On completion of the course, the students will be: CO1-Understanding the basic knowledge in the field of pharmacology pertaining to the drugs and its therapeutic applications for the treatment of various diseases. CO2-Analysing the mechanism of drug actions at cellular and molecular level. CO3 -Evaluating the adverse effects, contraindications and clinical uses of drugs used in treatment of various diseases	
	Course Contents:	
Unit-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.	12hr
Unit-2:	***Neurotransmission*** 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) 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 b) Parasympathomimetics and lytics, sympathomimetics and lytics, agents affecting neuromuscular junction	12hr
Unit-3:	***Central nervous system Pharmacology*** a) General and local anaesthetics b) Sedatives and hypnotics, drugs used to treat anxiety. c) Depression, psychosis, mania, epilepsy, neurodegenerative diseases. d) Narcotic and non-narcotic analgesics.	12hr
Unit-4:	***Cardiovascular Pharmacology*** Diuretics, antihypertensives, antiischemics, anti- arrhythmics, drugs for heart failure and hyperlipidemia. Hematinics, coagulants , anticoagulants, fibrinolytics and anti- platelet drugs	12hr

Unit-5:	***Autocoid Pharmacology*** The physiological and pathological role of Histamine, Serotonin, Kinins Prostaglandins Opioid autocoids. Pharmacology of antihistamines, 5HT antagonists.	**12hr**

Text Books:

1. K D. Tripathi. Essentials of Medical Pharmacology.
2. A Complete Textbook of Medical Pharmacology by Dr. S.K Srivastava published by APC Avichal Publishing Company
3. Basic and Clinical Pharmacology by B.G Katzung.

Reference Books:

1. The Pharmacological Basis of Therapeutics, Goodman and Gillman'sPrinciples of Pharmacology. The Pathophysiologic basis of drug Therapy by David E
2. Golan, Armen H, TashjianJr, Ehrin J, Armstrong, April W, Armstrong, Wolters, Kluwer-Lippincott Williams & Wilkins Publishers.
3. Hand book of Clinical Pharmacokinetics by Gibaldi and Prescott.
4. Applied biopharmaceutics and Pharmacokinetics by Leon Shargel and Andrew
5. B.C.Yu. Graham Smith. Oxford textbook of Clinical Pharmacology. Avery Drug Treatment
6. Dipiro Pharmacology, Pathophysiological approach.
7. Green Pathophysiology for Pharmacists.
8. Robbins &Cortan Pathologic Basis of Disease, 9 th Ed. (Robbins Pathology)
9. Modern Pharmacology with Clinical Applications, Craig Charles R. &Stitzel Robert E., Lippincott Publishers.
10. Clinical Pharmacokinetics & Pharmacodynamics : Concepts and Applications
11. Malcolm Rowland and Thomas N.Tozer, Wolters Kluwer, Lippincott Williams & Wilkins Publishers.
12. Applied biopharmaceutics and Pharmacokinetics, Pharmacodynamics and Drug metabolism for industrial scientists.
13. Modern Pharmacology, Craig CR. &Stitzel RE, Little Brown & Company.

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Course Code: MPL103T	M. Pharm- Semester-I PHARMACOLOGICAL AND TOXICOLOGICAL SCREENING METHODS - I	L-4 T-0 P-0 C-4
Course Outcomes:		
	On completion of the course, the students will be: **CO1**-Understandingandevaluatingtherecent experimental techniques in the drug discovery and development. **CO2**- Understanding the maintenance of laboratory animals as per the guidelines, and various in-vitro and in-vivo preclinical evaluation processes. **CO3**-Applying the various screening methods involved in the drug discovery process	
Course Contents:		
Unit-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 hr**
Unit-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: behavioural and muscle co-ordination, CNS stimulants and depressants, anxiolytics, anti-psychotics, anti-epileptics and nootropics. Drugs for neurodegenerative diseases like Parkinsonism, Alzheimers and multiple sclerosis. Drugs acting on Autonomic Nervous System.	**12hr**
Unit-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, anti-inflammatory and antipyretic agents. Gastrointestinal drugs: anti-ulcer, anti - emetic, anti- diarrheal and laxatives.	**12 hr**
Unit-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.	**12hr**
Unit-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	**12 hr**

Text Books:

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

2. Fundamentals of experimental Pharmacology by M.N.Ghosh
3. Preclinical evaluation of new drugs by S.K. Gupta

Reference Books:

1. Screening methods in Pharmacology by Robert Turner. A
2. Evaluation of drugs activities by Laurence and Bachrach
3. Methods in Pharmacology by Arnold Schwartz.
4. Pharmacological experiment on intact preparations by Churchill Livingstone Drug discovery and Evaluation by Vogel H.G.
5. Experimental Pharmacology by R.K.Goyal.
6. Handbook of Experimental Pharmacology, S. K. Kulkarni Practical Pharmacology and Clinical Pharmacy, SK.Kulkarni, 3 rd Edition.
7. David R.Gross. Animal Models in Cardiovascular Research, 2 nd Edition, Kluwer Academic Publishers, London, UK.
8. Screening Methods in Pharmacology, Robert A.Turner.
9. Rodents for Pharmacological Experiments, Dr.Tapan Kumar chatterjee.
10. Practical Manual of Experimental and Clinical Pharmacology by BikashMedhi (Author), Ajay Prakash (Author)

* Latest editions of all the suggested books are recommended.

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Course Code: MPL104T	M. Pharm- Semester-I CELLULAR AND MOLECULAR PHARMACOLOGY	L-4 T-0 P-0 C-4
Course Outcomes:		
	On completion of the course, the students will be: **CO-1** Understanding the fundamental knowledge on the structure and functions of cellular components. **CO-2** Appreciating the interaction of cellular components with drugs and applying the knowledge in drug discovery process. **CO-3**They would have learnt to explain the molecular pathways affected by drugs. **CO-4** Applying the molecular pharmacology and biomarkers in drug discovery process.	
Course Contents:		
Unit-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 hr**
Unit-2:	***Cell signalling*** Intercellular and intracellular signalling 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 signalling pathways: cyclic AMP signalling pathway, mitogen-activated protein kinase (MAPK) signalling, Janus kinase (JAK)/signal transducer and activator of transcription (STAT) signalling pathway	**12 hr**
Unit-3:	Principles and applications of genomic and proteomic tools DNA electrophoresis, PCR (reverse transcription and real time), micro array technique, SDS page, ELISA and western blotting, Recombinant DNA technology 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 hr**
Unit-4:	***Pharmacogenomics*** Cloning of disease gene. Genetic variation and its role in health/ pharmacology Polymorphisms affecting drug metabolism Genetic variation in drug transporters	**12 hr**

	Genetic variation in G protein coupled receptors Applications of proteomics science: Genomics, proteomics, metabolomics, functionomics, nutrigenomics ***Immunotherapeutics:*** Types of immunotherapeutics, humanisation antibody therapy, Immunotherapeutics in clinical practice.	
Unit-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***	**12**

Text Books:

1. The Cell, A Molecular Approach. Geoffrey M Cooper.
2. Pharmacogenomics: The Search for Individualized Therapies. Edited by J. Licinio and M - L. Wong

Reference Books:

1. Handbook of Cell Signaling (Second Edition) Edited by Ralph A. et.al
2. Molecular Pharmacology: From DNA to Drug Discovery. John Dickenson et.al
3. Basic Cell Culture protocols by CherilD.Helgason and Cindy L.Miller
4. Basic Cell Culture (Practical Approach) by J. M. Davis (Editor)
5. Animal Cell Culture: A Practical Approach by John R. Masters (Editor)
6. Current porotocols in molecular biology vol I to VI edited by Frederick M.Ausuvel et al.

COURSE CODE: MPL105P	M. Pharm- Semester-I PHARMACOLOGY PRACTICAL - I	L-0 T-0 P-12 C-6
Course Outcomes:		
	On completion of the course, the students will be: **CO1:** Understanding the various handling techniques of laboratory animals **CO2:** Practicing the technique of blood Sampling and route of drug administration **CO3:** Analysing drugs and Pharmaceuticals **CO4:** Evaluating drugs in various animal models	
Course Content		
	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.	
	1. Handling of laboratory animals. 2. Various routes of drug administration. 3. Techniques of blood sampling, anaesthesia and euthanasia of experimental animals. 4. Functional observation battery tests (modified Irwin test). 5. Evaluation of CNS stimulant, depressant, anxiogenics and anxiolytic, anticonvulsant activity. 6. Evaluation of analgesic, anti-inflammatory, local anesthetic, mydriatic and miotic activity. 7. Evaluation of diuretic activity. 8. Evaluation of antiulcer activity by pylorus ligation method. 9. Oral glucose tolerance test. 10. Isolation and identification of DNA from various sources (Bacteria, Cauliflower, onion, Goat liver). 11. Isolation of RNA from yeast. 12. Estimation of proteins by Braford/Lowry's in biological samples. 13. Estimation of RNA/DNA by UV Spectroscopy. 14. Gene amplification by PCR. 15. Protein quantification Western Blotting. 16. Enzyme based in-vitro assays (MPO, AChEs, α amylase, α glucosidase). 17. Cell viability assays (MTT/Trypan blue/SRB). 18. DNA fragmentation assay by agarose gel electrophoresis. 19. DNA damage study by Comet assay. 20. Apoptosis determination by fluorescent imaging studies. 21. Pharmacokinetic studies and data analysis of drugs given by different routes of administration using software's. 22. Enzyme inhibition and induction activity. 23. Extraction of drug from various biological samples and estimation of drugs in biological fluids using different analytical techniques (UV.	

	24. Extraction of drug from various biological samples and estimation of drugs in biological fluids using different analytical techniques (HPLC).
Reference Books	
	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 BikashMedhi (Author), Ajay Prakash (Author) Jaypee brothers' medical publishers Pvt. Ltd

COURSE CODE: MPL201T	M. Pharm- Semester-II ADVANCED PHARMACOLOGY – II	L-4 T-0 P-0 C-4
	Course Outcomes:	
	CO1-Understanding the basic knowledge in the field of pharmacology pertaining to the drugs and its therapeutic applications for the treatment of various diseases. **CO2-**Analysing the mechanism of drug actions at cellular and molecular level. **CO3** -Evaluating the adverse effects, contraindications and clinical uses of drugs used in treatment of various diseases.	
	Course Contents:	
Unit-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 hypoglycaemic agents, Oral contraceptives, Corticosteroids. Drugs affecting calcium regulation 2	**12hr**
Unit-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.	**12hr**
Unit-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	**12hr**
Unit-4:	GIT Pharmacology Antiulcer drugs, Prokinetics, antiemetics, anti-diarrheal 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.	**12hr**
Unit-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	**12hr**
	Text Books 1. A Complete Textbook of Medical Pharmacology by Dr. S.K Srivastava published by APC Avichal Publishing Company. 2. KD.Tripathi. Essentials of Medical Pharmacology 3. Principles of Pharmacology. The Pathophysiologic basis of drug Therapy by David E Golan, Armen H, TashjianJr, EhrinJ,Armstrong, April W, Armstrong, Wolters, Kluwer-Lippincott Williams & Wilkins Publishers **References Books** 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, 9 th Ed. (Robbins Pathology)

COURSE CODE: MPL202T	M. Pharm- Semester-II PHARMACOLOGICAL AND TOXICOLOGICAL SCREENING METHODS-II	L-4 T-0 P-0 C-4
	Course Outcomes: On completion of the course, the students will be: **CO1-** Understanding and evaluating the recent experimental techniques in the drug discovery, development and importance of ethical and regulatory requirements for toxicity studies. **CO2-**Understanding the maintenance of laboratory animals as per the guidelines, and various in-vitro and in-vivo preclinical and toxicological evaluation processes. **CO3-**Applying the varjous screening methods involved in the drug discovery process and Demonstrate the practical skills required to conduct the preclinical toxicity studies	
	Course Contents:	
Unit-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	**12hr**
Unit-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	**12hr**
Unit-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	**12hr**
Unit-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	**12hr**
Unit-5:	Toxicokinetics- Toxicokinetic evaluation in preclinical studies, saturation kinetics Importance and applications of toxicokinetic studies. Alternative methods to animal toxicity testing.	**12hr**
	Text Books 1. Drugs from discovery to approval by Rick NG. 2. Animal Models in Toxicology, 3 rd Edition, Lower and Bryan	

References Books

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. OECD test guidelines.
4. Principles of toxicology by Karen E. Stine, Thomas M. Brown.
5. 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)

PRINCIPAL

COURSE CODE: MPL203T	M. Pharm- Semester-II PRINCIPLES OF DRUG DISCOVERY	L-4 T-0 P-0 C-4
	Course Outcomes: **CO1-** Understanding the importance of the role of genomics, proteomics and bioinformatics in drug discovery **CO2-** Understanding and Explain various targets for drug discovery. **CO3** evaluation of various lead seeking method and lead optimization **CO4** Applying the various computer aided drug design in drug discovery	
	Course Contents:	
Unit-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.	**12hr**
Unit-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 modelling methods. Application of NMR and X-ray crystallography in protein structure prediction	**12hr**
Unit-3:	Rational Drug Design Traditional vs rational drug design, Methods followed in traditional drug design, High throughput screening, Concepts of Rational Drug Design, Rational Drug Design Methods: Structure and Pharmacophore based approaches Virtual Screening techniques: Drug likeness screening, Concept of pharmacophore mapping and pharmacophore-based Screening,	**12hr**
Unit-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.	**12hr**
Unit-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	**12hr**
	Text Books 1. Abby L .Parrill. M . Rami Reddy. Rational Drug Design. Novel Methodology and Practical Applications. ACS Symposium Series; American Chemical Society: Washington, DC, 1999. 2. J. Rick Turner. New drug development design, methodology and, analysis. John Wiley & Sons, Inc., New Jersey.	

References Books

1. Mouldy Sioud. Target Discovery and Validation Reviews and Protocols: Volume 2 Emerging Molecular Targetsand Treatment Options. 2007 Humana Press Inc.

2. Darryl León. Scott MarkelIn. Silico Technologies in Drug Target Identification and Validation. 2006 by Taylor and Francis Group, LLC.

3. Johanna K. DiStefano. Disease Gene Identification. Methods and Protocols. Springer New York Dordrecht Heidelberg London.

4. Hugo Kubiny. QSAR: Hansch Analysis and Related Approaches. Methods and Principles in Medicinal Chemistry. Publisher Wiley-VCH

5. Klaus Gubernator, Hans-Joachim Böhm. Structure-Based Ligand Design. Methods and Principles in Medicinal Chemistry. Publisher Wiley-VCH.

COURSE CODE: MPL204T	M. Pharm- Semester-II CLINICAL RESEARCH AND PHARMACOVIGILANCE	L-4 T-0 P-0 C-4
	Course Outcomes: **CO1-** Understanding the regulatory requirements for conducting clinical trial. **CO2-** Understanding the types of clinical trial designs and Explain the responsibilities of key players involved in clinical trials. **CO3-** Applying the safety monitoring, reporting and close-out activities in clinical trials **CO 4-** Evaluation Pharmacovigilance, detect new adverse drug reactions and their assessment, reporting of ADR.	
	Course Contents:	
Unit-1:	Regulatory Perspectives of Clinical Trials: Origin and Principles of International Conference on Harmonization - Good Clinical Practice (ICH-GCP) guidelines Ethical Committee: Institutional Review Board, Ethical Guidelines for Biomedical Research and Human Participant Schedule Y, ICMR Informed Consent Process: Structure and content of an Informed Consent Process Ethical principles governing informed consent process	**12 hr**
Unit-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 hr**
Unit-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 hr**
Unit-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 of Pharmacist, Community Pharmacist and Clinical Pharmacist in Pharmacovigilance	**12 hr**
Unit-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.	**12 hr**

Unit-6:	Pharmacoepidemiology, pharmacoeconomics, safety pharmacology	**12 hr**
	Text books 1. Handbook of clinical Research. Julia Lloyd and Ann Raven Ed. Churchill Livingstone. 2. Principles of Clinical Research edited by Giovanna di Ignazio, Di Giovanna and Haynes. **References Books** 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.	

COURSE CODE: MPL205P	M. Pharm- Semester-II PHARMACOLOGY PRACTICAL – II	L-0 T-0 P-12 C-6
Course outcomes		
	On Completing the Course, the student will be: **CO1:** Understanding the concept of bioassay in experimental pharmacology **CO2:** Applying various techniques to determine the strength of drugs in isolated tissues **CO3:** Predicting the dose toxicity studies **CO4:** Evaluating the various effect of drugs on different animal models	
Course Content		
	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 **Reference Books** 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.	

COURSE CODE: MRM301T	M. Pharm- Semester-III RESEARCH METHODOLOGY & BIOSTATISTICS	L-4 T-0 P-0 C-4
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.	12hr
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.	12hr
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.	12hr
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.	12hr
5	Declaration of Helsinki: History, introduction, basic principles for all medical research, and additional principles for medical research combined with medical care.	12hr
	Text books 1. Cooper & Schindler, Business Research Methods, Tata McGraw Hill. 2. Saunders, Research Methods for Business Students, Pearson Education 3. Allen T Harrell, New Methods in Social Science Researchs, Praeger Publishers, New York 4. Beri, G.C., Statistics for Management, Tata MacGraw-Hill 5. Chandan J. S., Statistics for Business and Economics, Vikas Publications. 6. Broota, K.D., Experimantal Designs in Behavioural Research, New Age International 7. Singh A. K., Test Measurement and Research Methods in Behaviours Sciences, BhartiBhawan 8. Joyce Cox & Polly Urban, Microsoft Office, Galgotia Publishing 9. Sinha P.K., Computer Fundamentals, BPB Publishing. *Latest editions of all the suggested books are recommended.	

COURSE CODE: MRM302T	M. Pharm- Semester-III PHARMACOECONOMICS	L-3 T-0 P-0 C-3
Unit-1	**Basic Concepts** • Introduction to Pharmacoeconomics • History, evolution, objective and importance • Relationship of Pharmacoeconomics to other research • Types of Pharmacoeconomic studies	12 hr
Unit-2	**Pharmacoeconomic evaluation: Basic outline only** • Measuring and estimating cost: Costing terms, timing adjustment cost, resource for cost estimation • Cost minimization analysis (CMA) • Cost effectiveness analysis (CEA): Presentation of cost effective analysis, cost effectiveness grid, cost effectiveness plane, intermediate versus primary outcomes and efficacy versus effectiveness • Cost utility analysis (CUA) • Cost benefit analysis (CBA): Advantages and disadvantages, calculating result of cost and benefits	18 hr
Unit-3	**Application of Pharmacoeconomics** • Case studies • Software	12 hr
	Text books: 1. Pharmacoeconomics-From Theory to Practice. Editor.: Renee J. G. Arnold- 2nd Edition. Pub.: CRC Press, 2021. 2. Essentials of Pharmacoeconomics. Editor.: Karen L. Rascati – 2nd Edition. Pub.: Lippincott Williams & Wilkins, 2014. 3. Pharmacoeconomics. Authors: Tom Walley, Alan Haycox, Angela Boland- 1st Edition. Pub.: Churchill Livingstone (Elsevier), 2003. *Latest editions of all the suggested books are recommended.	

COURSE CODE: MRM303T	M. Pharm- Semester-III BLOCKCHAIN TECHNOLOGY IN PHARMACEUTICAL INDUSTRY	L-3 T-0 P-0 C-3
Unit-1	**Basic concepts of Blockchain technology** Principal & types of Blockchain technology, Advantages of Blockchain technology, rationale of Blockchaintechnology,Key elements in Blockchain technology; Blockchain tools, Blockchain platforms, applications. Importance of Blockchain to India: Indian economy and Blockchain.	12 hr
Unit-2	**Blockchain Technology in Healthcare** Blockchain for management of patient consent and data access permissions, Blockchain for managing medical and pharmaceutical supply chains, Blockchain in inventory management, Blockchain in handling counterfeit drugs, Blockchain in Pharmaceutical R & D, Blockchain in Clinical trials, Policy considerations for deploying Blockchain.Pharma Opportunities with Blockchain, Companies Using a Blockchain Solution in Healthcare and Pharma.	12 hr
Unit-3	**Blockchain Technology in environment protection** Blockchain Technology and Environmental Sustainability, Blockchain in tracking the carbon footprint, recycling program on the Blockchain, Blockchain based energy system, Implications for the European environment, Implications for environmental policy in Europe.	12 hr
Unit-4	**Blockchain Technology for Food & Cosmetics Industry** Blockchain and cosmetic industry, Blockchain and Food Industry.	6 hr
	Text books 1. Blockchain in Healthcare: Innovations that Empower Patients, Connect Professionals and Improve Care. Author: Vikram Dhillon , John Bass, Max Hooper, David Metcalf and Alex Cahana- Ist Edition. Pub.: Productivity Press, 2018. 2. Blockchain for Healthcare Systems. Author: Pankaj Bhatt, Suruchi Singh, Satish Kumar Sharma, Vipin Kumar- 1st Edition. Pub.: CRC Press, 2021. 3. Blockchain Technology and Applications. Editor: Pethuru Raj, KavitaSaini and ChellammalSurianarayanan. - Ist Edition. Pub.: Auerbach Publications, 2021. *Latest editions of all the suggested books are recommended.	

COURSE CODE: MRM304T	M. Pharm- Semester-III DIGITAL THERAPEUTICS AND CURATIVE THERAPIES	L-3 T-0 P-0 C-3
Unit-1	**Digital Therapeutics** Digital drugs/Digital Therapeutics, History of Digital Therapeutics, Digital Health, Relationship between Digital Health, Digital Medicine, and Digital Therapeutics, mechanism of action, regulatory aspects, Barriers in the Adoption of Digital Therapeutics, Digital therapeutics and Practice of Primary Care, Prescription Digital Therapeutics, Non-Prescription Digital Therapeutics, Wellness Apps (technically not a Digital therapeutic), Standalone digital therapeutics, Smart Ancillary Devices, Companion apps. Potential applications of Digital Therapeutics.	18 hr
Unit-2	**Curative Therapies** Curative Therapeutics, Curative Therapy: Gene therapy, Cell Therapy; Curative therapy for Brest Cancer, Colorectal Cancer, Lung Cancer, Sickle Cell Disease, Prostate Cancer.	12 hr
Unit-3	**Precision Interventions** Robotic Surgery, Nanotechnology, 3D printing and tissue engineering	6 hr
Unit-4	**Personalized or customized treatment** Tailored dosing, Tailored drug regims	6 hr
	Text Books: 1. The Digital Health Revolution. Author: Kevin Pereau , Editor: Barry Lenson- Ist Edition. Pub.: Transcendit Health, 2019. 2. Digital Health- Meeting Patient and Professional Needs Online. Author: Barrie Gunter-Ist Edition. Pub.: Taylor & Francis Inc, 2006. 3. Goodman and Gilman's- The Pharmacological Basis of Therapeutics. Author: Laurence Brunton, Bjorn Knollmann and Randa Hilal-Dandan- 13th Edition. Pub.: McGraw Hill, 2017. *Latest editions of all the suggested books are recommended.	

COURSE CODE: MRM305T	M. Pharm- Semester-III BIOSIMILARS	L-3 T-0 P-0 C-3
Unit-1	**Basic Concepts** Biologic Product, Biosimilar Product, Biobetters, Noncomparable biotherapeutics ('intended copies'), difference between Comparability and biosimilarity, Difference between generic drugs and biosimilars, Critical quality attributes of biosimilars, Role of confirmatory clinical studies in biosimilar development, Extrapolation across clinical indications: rationale & scientific justification, Importance of immunogenicity assessment of biosimilars, Interchangeability & switching from reference (originator) products to biosimilars, Practical guidance on the use of biosimilars in clinical practice.	24 hr
Unit-2	**Regulatory Perspectives** Regulatory requirement for biosimilars (EMA, FDA & WHO), Selection of reference products, Manufacturing of Biosimilars, establishment of analytical similarity of biosimilars, the role of comparative *in vivo* non clinical studies, comparative immunogenicity assessment, clinical efficacy and safety similarity.	12 hr
Unit-3	**Important Clinical applications of Biosimilars** Biosimilars in rheumatology, breast cancer, colorectal cancer and nephrology.	6 hr
	Text books 1. Biologics, Biosimilars, and Biobetters: An Introduction for Pharmacists, Physicians and Other Health Practitioners. Editor: Iqbal Ramzan. Pub.: Wiley, 2021. 2. Biosimilars-Design and Analysis of Follow-on Biologics. Editor: Shein-Chung Chow- 1st ed. Pub.: CRC Press, 2019. 3. Biosimilars: Regulatory, Clinical, and Biopharmaceutical Development. Editor: Hiten J. Gutka, Harry Yang and ShefaliKakar- 1st ed.Pub.:Springer, 2018. *Latest editions of all the suggested books are recommended.	

COURSE CODE: MRM309T	M. Pharm-Semester-III ENTREPRENEURSHIP SKILL DEVELOPMENT	L-2 T-0 P-0 C-2
	Course Outcomes:	
	CO1- Recognizing an entrepreneur's DNA and evaluating their strengths and flaws from an entrepreneurial standpoint.	
	CO2-Developing and Inspiring people to start their businesses by highlighting successful entrepreneurs	
Unit-1:	**Introduction to Entrepreneurship:** Meaning and concept of entrepreneurship, the history of entrepreneurship development; the skills/ traits required to be an entrepreneur; Creative and Design Thinking; the entrepreneurial decision process.	14 Hrs
Unit-2:	Entrepreneurial success stories; Role of innovation in entrepreneurship; technical entrepreneurship through incubation; objectives of technology business incubation; Innovative ideas; SWOT analysis.	14 Hrs
	Reference Books	
1	Emiel L. Eijdenberg, Neil_Thompson. Entrepreneurs' Creative Responses to Institutional Challenges. Emerald Publishing Limited.	
2	Michael W.-P. Fortunato, Theodore R. Alter. Entrepreneurship, Community and Community Development. Taylor & Francis Ltd.	

COURSE CODE: MRM310T	M. Pharm-Semester-III INTELLECTUAL PROPERTY RIGHTS	L-2 T-0 P-0 C-2
	Course Outcomes:	
	CO1- Understanding the basic concepts of Intellectual property Rights	
	CO2- Understanding and identifying criteria to fit one's intellectual work in particular IPRs.	
Unit-1:	Introduction to intellectual property rights; acts governing the various IP rights; trademark law in India; industrial designs; trade secret; copyright	14 Hrs
Unit-2:	Role of IPR in pharmaceutical industry growth; patent; IPR of computer software; regulation of pharmaceutical sector; National Pharmaceutical Pricing Authority (NPPA).	14 Hrs
	Reference Books	
1	Rupinder Tewari, Mamta Bhardwaj. Intellectual Property- A Primer for Academia. Publication Bureau, Panjab University Chandigarh-160014, India	
2	Asha Vijay Durafe, Dhanashree K. Toradmalle. Intellectual Property Rights. Wiley.	

COURSE CODE: MRM311T	M. Pharm-Semester-III BUSINESS MODEL INNOVATION	L-2 T-0 P-0 C-2
	Course Outcomes:	
	CO1- Understanding the basic needs to create a business model and building a prototype.	
	CO2- Acquiring the skills and knowledge related to the various phases in the venture creation process.	
Unit-1:	**Preparation of Business model/Plan:** Meaning and significance of a business plan; components of a business plan and feasibility study; MVP (Minimum Viable Product); The importance and diversity of business model; components of an effective business model; core strategy and strategic resources.	14 Hrs
Unit-2:	**Development and validation of Business Processes:** Introduction and importance of ventures; visioning for the venture; digital presence for ventures; Bank Loans and key elements of raising money for a new venture.	14 Hrs
	Reference Books	
1.	Massa, L. and Tucci, C.L., 2013. Business model innovation. *The Oxford handbook of innovation management*, *20*(18), pp.420-441.	
2.	Burgelman, R.A. and Sayles, L.R., 1988. *Inside corporate innovation*. Simon and Schuster.	

COURSE CODE: MRM312T	M. Pharm-Semester-III PRINCIPLES OF MANAGEMENT	L-2 T-0 P-0 C-2
	Course Outcomes:	
	CO1- Understanding the fundamental exposure to the basic concepts of management and demonstrating management's roles, skills, and functions.	
	CO2- Analyze the effective application of management and staffing to diagnose and solve organizational problems and develop an optimal managerial decision.	
Unit-1:	Management: definitions, types of managers; evolution of management thought; principles of management; functions of management; social responsibility of management; challenges of management; managerial ethics. Planning- Nature, purpose and importance of planning; principles of the organization; formal and informal organization; types of organization structure	14 Hrs
Unit-2:	Staffing: Concept, nature, importance of staffing; concept of knowledge worker; Staff directing, concept, nature, importance; Staff control techniques; Leadership concept, nature, importance; decision making.	14 Hrs
	Reference Books	
1.	Koontz & O'Donnel, *Essentials of Management*, Tata McGraw Hill, New Delhi	
2.	Louis A Allen, *Management and Organization*, McGrawHill, New York	
3.	Peter F Drucker, *The Practice of Management*, McGraw Hill, New York	

Examinations/Assessments

Table 3 &3.1 depicts the scheme for internal and external assessment.

Table 3: Schemes for internal assessments and end semester

S .No	Subject Code	Subject Name	Credit hrs./Week	Evaluation Scheme						Total Marks	Credit Points
				Sessional Exams (Marks distribution)				End Semester Examination			
				CT *	Continuous mode		TOTAL	Marks	Duration (hrs.)		
					ST/ PR	At					
SEMESTER I											
1	MPL101T	Modern Pharmaceutical Analytical Techniques	4	15	02	08	25	75	3	100	4
2	MPL102T	Advanced Pharmacology-I	4	15	02	08	25	75	3	100	4
3	MPL103T	Pharmacological and Toxicological Screening Methods-I	4	15	02	08	25	75	3	100	4
4	MPL104T	Cellular and Molecular Pharmacology	4	15	02	08	25	75	3	100	4
5	MPL105P	Pharmacology Practical I	12	30	10	10	50	100	6	150	6
6	MPL106	Seminar /Assignment	7	---	---	---	---	---	---	100	4
		Total	**35**							**650**	**26**
SEMESTER II											
1	MPL201T	Advanced Pharmacology-II	4	15	02	8	25	75	3	100	4
2	MPL202T	Pharmacological and Toxicological Screening Methods-II	4	15	02	8	25	75	3	100	4
3	MPL203T	Principles of Drug Discovery	4	15	02	8	25	75	3	100	4
4	MPL204T	Clinical Research & Pharmacovigilance	4	15	02	8	25	75	3	100	4
5	MPL205P	Pharmacology Practical II	12	30	10	10	50	100	6	150	6
6	MPL206	Seminar /Assignment	7	---	---	---	---	---	---	100	4
		Total	**35**							**650**	**26**

Table 3.1: Schemes for internal assessments and end semester (IIIrd & IVth Semester)

S. No	Subject Code	Subject Name	Credit hrs./Week	Evaluation Scheme						Total Marks	Credit Points
				Sessional Exam (Marks distribution)				End Semester Examination			
				CT#	Continuous mode		TOTAL	Marks	Duration (hrs.)		
					ST	At					
SEMESTER III											
1	MRM301T	Research Methodology and Biostatistics*	4	15	02	08	25	75	3	100	4
2	MRM302T	Pharmacocconomics	3	15	02	08	25	50	2	75	3
	MRM303T	Blockchain Technology in Pharmaceutical Industry									
	MRM304T	Digital Therapeutics and Curative Therapies									
	MRM305T	Biosimilars									
3	MRM306	Journal Club	1	-	-	-	25	-	-	25	1
4	MRM307	Discussion / Presentation (Proposal Presentation)	2	-	-	-	50	-	-	50	2
5	MRM308	Research Work	28	-	-	-	-	350	1	350	14
	MRM309T	Entrepreneurship Skill Development	2	10	01	04	15	35	2	50	2
	MRM310T	Intellectual Property Rights									
	MRM311T	Business Model Innovation									
6	MRM312T	Principles of Management									
		Total	**40**							**650**	**26**
SEMESTER IV											
1	MRM401	Journal Club	1	-	-	-	25	-	-	25	1
2	MRM402	Discussion / Presentation (Final Presentation)	3	-	-	-	75	-	-	75	3
3	MRM403	Research Work & Colloquium	31	-	-	-	-	400	1	400	16
		Total	**35**							**500**	**20**

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PRINCIPAL