Study and Evaluation Scheme

of

M. Pharm Program
(Pharmaceutics)

[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

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 101**. However based on the credit points earned by the students under the head of co-curricular activities, a student shall earn a maximum of 104 credit points (Table 1).

Table 1: Semester wise credits distribution

Semester	Credit Points
I	**26**
II	**26**
III	**27**
1V	**20**
Co-curricular Activities (Attending Conference, Scientific Presentations and Other Scholarly Activities)	**Minimum=02** **Maximum=07***
Total Credit Points	**Minimum=101** **Maximum=106***

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 to 2.4.

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

M. Pharm. (Pharmaceutics) Semester I						
Category	**Course Code**	**Course**	**Credit Hours**	**Credit Points**	**Hrs./ week**	**Marks**
CC-1	MPH 101T	Modern Pharmaceutical Analytical Techniques	**4**	**4**	**4**	**100**
CC-2	MPH 102T	Drug Delivery System	**4**	**4**	**4**	**100**
CC-3	MPH 103T	Modern Pharmaceutics	**4**	**4**	**4**	**100**
CC-4	MPH 104T	Regulatory Affair	**4**	**4**	**4**	**100**
SEC-1	MPH 105P	Pharmaceutics Practical I	**12**	**6**	**12**	**150**
SEC-2	MPH 106	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./ week**	**Marks**
CC-5	MPH 201T	Molecular Pharmaceutics (Nano Tech and Targeted DDS)	**4**	**4**	**4**	**100**
CC-6	MPH 202T	Advanced Biopharmaceutics & Pharmacokinetics	**4**	**4**	**4**	**100**
CC-7	MPH 203T	Computer Aided Drug Delivery System	**4**	**4**	**4**	**100**
CC-8	MPH 204T	Cosmetic and Cosmeceuticals	**4**	**4**	**4**	**100**
SEC-3	MPH 205P	Pharmaceutics Practical II	**12**	**6**	**12**	**150**
SEC-4	MPH 206	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**
	MRM 301T	Research Methodology and Biostatistics*	**4**	**4**
DSEC-1**	MRM 302T	Pharmacoeconomics	**4**	**4**
	MRM 303T	Block chain technology in Pharmaceutical Industry		
	MRM 304T	Digital Therapeutics & Curative therapies		
	MRM 305T	Biosimilars		
SEC-5	MRM 306	Journal club	**1**	**1**
SEC-6	MRM 307	Discussion / Presentation (Proposal Presentation)	**2**	**2**
SEC-7	MRM 308	Research Work	**28**	**14**
GEC-1***	MRM 309T	Entrepreneurship Skill Development Intellectual Property Rights Business Model Innovation Principles of Management	**2**	**2**
Total			**41**	**27**

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	Research Work	**31**	**16**
SEC-10	MRM403	Discussion / Presentation (Final Presentation)	**3**	**3**
	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 TeerthankerMahaveer 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.Pharmprogramme if he/she secures at least 50% marks in that particular courseincluding 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 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.

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 (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 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, theSGPA shall then be computed as:

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

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 CGPAshall only reflect the new grade and not the fail grades earned earlier.TheCGPAis calculated as:

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

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.

Syllabus
Master of Pharmacy
(Pharmaceutics)

[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 (PHARMACEUTICS)

After completion of the course the students will be

PSO-1: understanding the novel concepts of design, different approaches to be followed, pre-formulation elements, pharmacokinetic parameters, criteria for selection of polymers/stabilizers and selection of drugs to formulate their stable pharmaceutical dosage forms/cosmeceuticals with its standardization process.

PSO-2: understandingindustrial management with GMP considerations, pilot plant scale-up techniques, stability testing, and packaging of pharmaceutical dosage forms.

PSO-3: understandingregulatory affairs pertaining to manufacturing, distribution and sale of drug and pharmaceuticals.

PSO-4: evaluatingdrug and pharmaceuticals/cosmeceuticals in its pure as well as dosage forms using modern analytical instrumentation techniquesto assure its safety and efficacy.

PSO-5: applyingpharmaco-informatics, pharmacokinetic parameters with computational modeling/approaches, preclinical&clinical development approaches, Artificial Intelligence and Robotics in design and development of conventional as well as novel pharmaceutical dosage forms with fixation of dosage regimen

PSO-6: **creating**solution to the therapeutic requirements emerging out of new disease outbreak or community health problems arising out of practicing existing medications.

Course Code: **MPH101T**	**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	**a.UV-Visible spectroscopy**: Introduction, Theory, Laws, Instrumentation associated with UV-Visible spectroscopy, Choice of solvents and solvent effect and Applications of UV-Visible spectroscopy. **b.IR spectroscopy**: Theory, Modes of Molecular vibrations,Sample handling, Instrumentation of Dispersive and Fourier -Transform IR Spectrometer, Factors affecting vibrationalfrequencies and Applications of IR spectroscopy **c.Spectroflourimetry**: Theory of Fluorescence, Factorsaffecting fluorescence, Quenchers, Instrumentation andApplications of fluorescence spectrophotometer. **d. Flame emission spectroscopy and Atomic absorption spectroscopy:** Principle, Instrumentation, Interferences and Applications.	11Hrs
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-Spincoupling, Coupling constant, Nuclear magnetic double resonance,Brief outline of principles of FT-NMR and ^{13}C NMR. Applicationsof NMR spectroscopy.	11 Hrs
Unit-3	**Mass Spectroscopy:** Principle, Theory, Instrumentation of MassSpectroscopy, Different types of ionization like electron impact,chemical, field, FAB and MALDI, APCI, ESI, APPI AnalyzersofQuadrupole and Time of Flight, Mass fragmentation and its rules,Meta stable ions, Isotopic peaks and Applications of Massspectroscopy	11Hrs
Unit-4	**Chromatography:** Principle, apparatus, instrumentation,chromatographic parameters, factors affecting resolution and applications of the following: a) Paper chromatography b) Thin Layer chromatography c) Ion exchange chromatography d) Column chromatography e) Gas chromatography f) High Performance Liquidchromatography g) Affinity chromatography	11Hrs
Unit-5	**a. Electrophoresis:** Principle, Instrumentation, Working conditions, factors affecting separation and applications of the following: i) Paper electrophoresis ii) Gel electrophoresis iii) Capillary electrophoresis iv) Zone electrophoresis v) Moving boundary electrophoresis vi) Isoelectric focusing **b. X ray Crystallography:** Production of X-rays, Different X-ray	11Hrs

	diffraction methods, Bragg's law, Rotating crystal technique, X-ray powder technique, Types of crystals and applications of X-raydiffraction.	
Unit-6	**Immunological assays:** RIA (Radio immuno assay), ELISA, Bioluminescence assays.	5Hrs
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, 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, 4thedition, 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, 3rdEdition, CBS Publishers, New Delhi, 1997. **7.** Pharmaceutical Analysis- Modern methods – Part B - J W Munson, Volume 11. Marcel Dekker Series	

Course Code: MPH102T	**M.Pharm- Semester-I** **DRUG DELIVERY SYSTEMS**	**L-4** **T-0** **P-0** **C-4**
Course Outcomes:	On completion of the course, the students will be :	
CO1.	Understanding various approaches forthedevelopment of noveldrug delivery systems.	
CO2.	Defining the criteria for selection of drugs and polymers fordevelopment of novel drug delivery systems.	
CO3.	Formulating various novel drug delivery systems.	
CO4.	Evaluating various novel drug delivery systems.	
Course Contents:		
Unit-1	**a) Sustained Release (SR) and Controlled Release (CR) formulations:** Introduction & basic concepts, advantages/disadvantages, factors influencing, Physicochemical &biologicalapproaches for SR/CR formulation, Mechanism of Drug	10Hrs

	Deliveryfrom SR/CR formulation. **b) Polymers**: introduction, definition,classification, properties and application **c) Dosage Forms for Personalized Medicine:** Introduction, Definition, Pharmacogenetics, Categories of Patients for Personalized Medicines: **d) Customized drug delivery systems**, BioelectronicMedicines, 3D printing of pharmaceuticals, Tele pharmacy.	
Unit-2	**Rate Controlled Drug Delivery Systems:** Principles &Fundamentals, Types, Activation; Modulated Drug DeliverySystems; Mechanically activated, pH activated, Enzyme activated,and Osmotic activated Drug Delivery Systems, Feedbackregulated Drug Delivery Systems Principles & Fundamentals.	10 Hrs
Unit-3	**Gastro-Retentive Drug Delivery Systems:** Principle, conceptsadvantages and disadvantages, Modulation of GI transit timeapproaches to extend GI transit. **Buccal Drug Delivery Systems:** Principle of muco-adhesion, advantages anddisadvantages, Mechanism of drug permeation, Methods offormulation and its evaluations.	10 Hrs
Unit-4	**Ocular Drug Delivery Systems:** Barriers of drug permeation, Methods to overcome barriers.	06 Hrs
Unit-5	**Transdermal Drug Delivery Systems:** Structure of skin and barriers, Penetration enhancers, Transdermal Drug Delivery Systems, Formulation and evaluation.	10Hrs
Unit-6	**Protein and Peptide Delivery:** Barriers for protein delivery. Formulation and Evaluation of delivery systems of proteins andother macromolecules.	8Hrs
Unit-7	**Vaccine delivery systems:** Vaccines, uptake of antigens, singleshot vaccines, mucosal and transdermal delivery of vaccines.	6Hrs
Reference Books:	**1.** Y W. Chien, Novel Drug Delivery Systems, 2nd edition, revised and expanded, Marcel Dekker, Inc., New York, 1992. **2.** Robinson, J. R., Lee V. H. L, Controlled Drug Delivery Systems, Marcel Dekker,Inc., New York, 1992. **3.** Encyclopedia of controlled delivery, Editor- Edith Mathiowitz, Published by Wiley Interscience Publication, John Wiley and Sons, Inc, New York! Chichester/Weinheim **4.** N.K. Jain, Controlled and Novel Drug Delivery, CBS Publishers & Distributors, New Delhi, First edition 1997 (reprint in 2001). **5.** S.P.Vyas and R.K.Khar, Controlled Drug Delivery - Concepts and advances, VallabhPrakashan, New Delhi, First edition 2002	
Journals	**1.** Indian Journal of Pharmaceutical Sciences (IPA)	

	2. Indian drugs (IDMA) **3.** Journal of controlled release (Elsevier Sciences) -Desirable **4.** Drug Development and Industrial Pharmacy (Marcel & Decker)-Desirable	

Course Code: MPH103T	**M.Pharm- Semester-I** **MODERN PHARMACEUTICS**	**L-4** **T-0** **P-0** **C-4**
Course Outcomes:	On completion of the course, the students will be :	
CO1.	Understanding the elements of Preformulation study, Drug product development, Physics of tablet compression and compaction profile, Pilot plant scale up techniques, Good Manufacturing Practice (GMP), Stability Testing, Sterilization process, and Packaging of dosage form.	
CO2.	Abled to design Preformulation study, optimize the drug product development process	
CO3.	Analyzingthedrugs and pharmaceuticals.	
CO4.	Evaluating the given samples with respect to official standards.	
Course Contents:		
Unit-1	**a) Pre-formulation Concepts –** Drug Excipient interactions - different methods, kinetics of stability, Stability testing. Theories ofdispersion and pharmaceutical Dispersion (Emulsion	10Hrs

	andSuspension, SMEDDS) preparation and stability Large and small volume parental – physiological and formulation consideration,Manufacturing and evaluation. **b) Optimization techniques in Pharmaceutical Formulation:** Concept and parameters of optimization, Optimization techniques in pharmaceutical formulation and processing. Statistical design, Response surface method, Contour designs, Factorial designs and application in formulation	10Hrs
Unit-2	**Validation:** Introduction to Pharmaceutical Validation, Scope &merits of Validation, Validation and calibration of Master plan,ICH& WHO guidelines for calibration and validation ofequipments, Validation of specific dosage form, Types ofvalidation. Government regulation, Manufacturing Process Model,URS, DQ, IQ, OQ & P.Q. of facilities.	10 Hrs
Unit-3	**cGMP& Industrial Management:** Objectives and policies of current good manufacturing practices, layout of buildings,services, equipments and their maintenance **Productionmanagement:** Production organization, materials management,handling and transportation, inventory management and control,production and planning control, Sales forecasting, budget and cost control, industrial and personal relationship. Concept of TotalQuality Management.	10 Hrs
Unit-4	**Compression and compaction:** Physics of tablet compression,compression, consolidation, effect of friction, distribution offorces, compaction profiles. Solubility.	10 Hrs
Unit-5	**Study of consolidation parameters:**Diffusionparameters,Dissolution parameters and Pharmacokinetic parameters,Heckelplots, Similarity factors – f2 and f1, Higuchi and Peppas plot, **Linearity Concept of significance**, Standard deviation, Chi squaretest, students T-test, ANOVA test.	10Hrs
Reference Books:	**1.** Theory and Practice of Industrial Pharmacy By Lachmann and Libermann **2.** Pharmaceutical Dosage forms: Tablets Vol. 1-3 by Leon Lachmann. **3.** Pharmaceutical Dosage forms: Disperse systems, Vol, 1-2; By Leon Lachmann. **4.** Pharmaceutical Dosage forms: Parenteral medications Vol. 1-2; By Leon Lachmann. **5.** Modern Pharmaceutics; By Gillbert and S. Banker. **6.** Remington's Pharmaceutical Sciences. **7.** Advances in Pharmaceutical Sciences Vol. 1-5; By H.S. Bean & A.H. Beckett. **8.** Physical Pharmacy; By Alfred martin **9.** Bentley's Textbook of Pharmaceutics – by Rawlins.	

	10. Good manufacturing practices for Pharmaceuticals: A plan for total quality control, Second edition; By Sidney H. Willig. **11.** Quality Assurance Guide; By Organization of Pharmaceutical producers of India. **12.**Drug formulation manual; By D.P.S. Kohli and D.H.Shah. Eastern publishers, New Delhi. **13.** How to practice GMPs; By P.P.Sharma. Vandhana Publications, Agra. **14.** Pharmaceutical Process Validation; By Fra. R. Berry and Robert A. Nash. **15.** Pharmaceutical Preformulations; By J.J. Wells. **16.** Applied production and operations management; By Evans, Anderson, Sweeney and Williams. **17.** Encyclopaedia of Pharmaceutical technology, Vol I – III.	

Course Code: MPH104T	**M.Pharm- Semester-I** **REGULATORY AFFAIRS**	**L-4** **T-0** **P-0** **C-4**
Course Outcomes:	On completion of the course, the students will be :	
CO1.	Understanding the concepts of innovator and generic drug, and drug development process, pharmacovigilance, and process of monitoring clinical trials.	
CO2.	Recognizing regulatory authorities and agenciesgoverning the manufacturing, sales and distribution ofpharmaceutical products.	
CO3.	Demonstrating regulatory approval process and theirregistration in Indian and international markets.	
CO4.	Evaluating given samples with respect to official standards.	
Course Contents:		
Unit-1	**a) Documentation in Pharmaceutical industry:**Masterformula record, DMF (Drug Master File), distribution records.Generic drugs product development Introduction , Hatch-Waxman act and amendments, CFR (CODE OF FEDERALREGULATION) ,drug	12Hrs

	product performance, in-vitro, ANDAregulatory approval process, NDA approval process, BE and drugproduct assessment, in –vivo, scale up process approvalchanges, post marketing surveillance, outsourcing BA and BE toCRO. **b) Regulatory requirement for product approval:** API,biologics, novel, therapies obtaining NDA, ANDA for genericdrugs ways and means of US registration for foreign drugs	
Unit-2	CMC, post approval regulatory affairs. Regulation for combinationproducts and medical devices.CTD and ECTD format, industryand FDA liaison. ICH - Guidelines of ICH-Q, S E, M. Regulatory requirements of EU, MHRA, TGA and ROW countries.	10 Hrs
Unit-3	**Non clinical drug development:** Global submission of IND,NDA, ANDA. Investigation of medicinal products dossier, dossier(IMPD) and investigator brochure (IB).	12 Hrs
Unit-4	**Clinical trials:** Developing clinical trial protocols. Institutionalreview board/ independent ethics committee Formulation andworking procedures informed Consent process and procedures. HIPAA- new, requirement to clinical study process,Pharmacovigilance safety monitoring in clinical trials.	12 Hrs
Reference Books:	**1.** Generic Drug Product Development, Solid Oral Dosage forms, Leon ShargelandIsaderKaufer,Marcel Dekker series, Vol.143 **2.** The Pharmaceutical Regulatory Process, Second Edition Edited by Ira R.Berry and Robert P.Martin, Drugs and the Pharmaceutical Sciences,Vol.185,Informa Health care Publishers. **3.** New Drug Approval Process: Accelerating Global Registrations By Richard AGuarino, MD,5th edition, Drugs and the Pharmaceutical Sciences,Vol.190. **4.** Guidebook for drug regulatory submissions / Sandy Weinberg. By John Wiley&Sons.Inc. **5.** FDA regulatory affairs: a guide for prescription drugs, medical devices, andbiologics/edited By Douglas J. Pisano, David Mantus. **6.** Clinical Trials and Human Research: A Practical Guide to RegulatoryCompliance by Fay A.Rozovsky and Rodney K. Adams **7.** www.ich.org/ **8.** www.fda.gov/ **9.** europa.eu/index_en.htm **10.** https://www.tga.gov.au/tga-basics	

Course Code: MPH105P	**M.Pharm- Semester-I** **PHARMACEUTICS PRACTICALS - I**	**L-0** **T-0** **P-12** **C-6**
Course Outcomes:	On completion of the course, the students will be :	
CO1.	Understanding the elements of preformulation study design, basic concepts and advances in analytical techniques, approaches forthe development of drug delivery systems.	
CO2.	Formulating various novel drug delivery systems.	
CO3.	Analyzing drugs and pharmaceuticals.	
CO4.	Evaluating different drug delivery systems.	
Course Contents:	1. Analysis of Pharmacopoeial compounds and their formulations by UV Visible spectrophotometer 2. Simultaneous estimation of multi component containing formulations by UVspectrophotometry 3. Experiments based on HPLC 4. Experiments based on Gas Chromatography 5. Estimation of riboflavin/quinine sulphate by fluorimetry	

	6. Estimation of sodium/potassium by flame photometry 7. To perform In-vitro dissolution profile of CR/ SR marketed formulation 8. Formulation and evaluation of sustained release matrix tablets 9. Formulation and evaluation osmotically controlled DDS 10. Preparation and evaluation of Floating DDS- hydro dynamically balancedDDS 11. Formulation and evaluation of Muco-adhesive tablets. 12. Formulation and evaluation of trans dermal patches. 13. To carry out preformulation studies of tablets. 14. To study the effect of compressional force on tablets disintegration time. 15. To study Micromeritic properties of powders and granulation. 16. To study the effect of particle size on dissolution of a tablet. 17. To study the effect of binders on dissolution of a tablet. 18. To plot Heckal plot, Higuchi and Peppas plot and determine similarityfactors.	

Course Code: MPH201T	**M.Pharm- Semester-II** **MOLECULAR PHARMACEUTICS (NANO TECHNOLOGY & TARGETED DDS) (NTDS)**	**L-4 T-0 P-0 C-4**
Course Outcomes:	On completion of the course, the students will be	
CO1.	Understanding various approaches in development of nano and targeted drug delivery systems.	
CO2.	Defining the criteria for selection of drugs and polymers fordevelopment of nano and targeted drug delivery systems.	
CO3.	Formulating various nano and targeted drug delivery systems.	
CO4.	Evaluating various nano and targeted drug delivery systems.	
Course Contents:		
Unit-1	**Targeted Drug Delivery Systems:** Concepts, Events andbiological process involved in drug targeting. Tumor targeting andBrain specific delivery.	12Hrs
Unit-2	**Targeting Methods:** Introduction preparation and evaluation.Nano Particles & Liposomes: Types, preparation and evaluation.	12 Hrs
Unit-3	**Micro Capsules / Micro Spheres:** Types, preparation	12 Hrs

	andEvaluation, **Monoclonal Antibodies:** Preparation and application, Preparation and application of **Niosomes, Aquasomes, Phytosomes, Electrosomes.**	
Unit-4	**Pulmonary Drug Delivery Systems:** Aerosols, propellants,Containers Types, preparation and evaluation, **Intra Nasal RouteDeliverysystems:**Types, preparation and evaluation.	12 Hrs
Unit-5	**Nucleic acid based therapeutic delivery system:** Gene therapy, Introduction (ex-vivo & in-vivo gene therapy). Potential targetdiseases for gene therapy (inherited disorder and cancer). Geneexpression systems (viral and nonviral gene transfer). Liposomalgene delivery systems.Biodistribution and Pharmacokinetics. Knowledge of therapeutic antisense molecules and aptamers as drugs of future.	12 Hrs
Reference Books:	**1.** Y W. Chien, Novel Drug Delivery Systems, 2nd edition, revised and expanded,Marcel Dekker, Inc., New York, 1992. **2.** S.P.Vyas and R.K.Khar, Controlled Drug Delivery - concepts andadvances, VallabhPrakashan, New Delhi, First edition 2002. **3.** N.K. Jain, Controlled and Novel Drug Delivery, CBS Publishers & Distributors, NewDelhi, First edition 1997 (reprint in 2001).	

Course Code: (MPH 202T)	**M.Pharm- Semester-II** **ADVANCED BIOPHARMACEUTICS & PHARMACOKINETICS**	**L-4 T-0 P-0 C-4**
Course Outcomes:	On completion of the course, the students will be :	
CO1.	Understanding basic concepts in biopharmaceuticsandpharmacokinetics and their significance.	
CO2.	Describing the concepts of bioavailability and bioequivalenceof drug products and their significance.	
CO3.	Applying pharmacokinetic parameters in calculation andfixation of dosage regimen.	
CO4.	Analyzing plasma drug concentration versus time data tocalculate pharmacokinetic parameters and profiles ofdrug/formulations.	
Course Contents:		
Unit-1	**Drug Absorption from the Gastrointestinal Tract:** Gastrointestinal tract, Mechanism of drug absorption, Factorsaffecting drug absorption, pH–partition theory of drug absorption.Formulation and physicochemical	12Hrs

	factors:Dissolutionrate,Dissolution process, Noyes–Whitney equation and drugdissolution, Factors affecting the dissolution rate. Gastrointestinalabsorption: role of the dosage form: Solution (elixir, syrup and solution) as a dosage form,Suspension as a dosage form,Capsule as a dosage form, Tablet as a dosage form ,Dissolutionmethods,Formulation and processing factors, Correlation of invivo data with in vitro dissolution data.Transportmodel:Permeability-Solubility-Charge State and the pH PartitionHypothesis, Properties of the Gastrointestinal Tract (GIT), pHMicroclimate Intracellular pH Environment, Tight-JunctionComplex.	
Unit-2	**Biopharmaceutic considerations in drug product design and In Vitro Drug Product Performance:**Introduction,biopharmaceutic factors affecting drug bioavailability, rate-limiting steps in drug absorption, physicochemical nature of the drugformulation factors affecting drug product performance, in vitro:dissolution and drug release testing, compendial methods ofdissolution, alternative methods of dissolution testing,meetingdissolutionrequirements,problems of variable control in dissolutiontestingperformance of drug products. In vitro–in vivo correlation,dissolution profile comparisons, drug productstability,considerations in the design of a drug product.	12 Hrs
Unit-3	**Pharmacokinetics:**Basic considerations, pharmacokinetic models, compartment modeling: one compartment model- IV bolus, IV infusion, extra-vascular. Multi compartment model:twocompartment - model in brief, Non-linear pharmacokinetics: causeof non-linearity, Michaelis – Menten equation, estimation of KmaxandVmax. **Drug interactions**: introduction, the effect of proteinbindinginteractions,the effect of tissue-bindinginteractions, Cytochrome p450-based drug interactions, and drug interactions linked to transporters.	12 Hrs
Unit-4	**Drug Product Performance**, **In Vivo: Bioavailability and Bioequivalence**: drug product performance, purpose ofbioavailability studies, relative and absolute availability. Methodsfor assessing bioavailability, bioequivalence studies, design andevaluation of bioequivalence studies, study designs, crossover study designs, evaluation of the data, bioequivalence example,study submission and drug review process. Biopharmaceutics Classification System, methods. Permeability: In-vitro, in-situ andIn-vivo methods. Generic biologics (Biosimilardrugproducts),clinical significance of bioequivalence studies, specialconcerns in bioavailability and bioequivalence studies, genericsubstitution.	12 Hrs
Unit-5	**Application of Pharmacokinetics:** Modified-Release Drug Products, Targeted Drug Delivery Systems and Biotechnological Products. Introduction to Pharmacokinetics and pharmacodynamic, drug interactions. Pharmacokinetics and pharmacodynamics of biotechnology drugs. Introduction, Proteins and peptides, Monoclonal antibodies, Oligonucleotides, Vaccines (immunotherapy), Gene therapies.	12 Hrs

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

Course Code: (MPH 203T)	**M.Pharm- Semester-II** **COMPUTER AIDED DRUG DEVELOPMENT**	**L-4** **T-0** **P-0** **C-4**
Course Outcomes:	On completion of the course, the students will be :	
CO1.	Understanding the role of Computer in Preclinical, Clinical, and Post clinical stages of drug product	
CO2.	Recognizing the concept of Computational modeling of drug disposition, optimization technique, and computational fluid dynamics.	
CO3.	Application of computers across the entire drug research and development process.	
CO4.	Evaluating pharmacokinetics andpharmacodynamic parameters of drug product using computer simulation	
Course Contents:		
Unit-1	**a)Computers in Pharmaceutical Research and Development:** A	12Hrs

	General Overview: History of Computers inPharmaceutical Research and Development. Statistical modelingin Pharmaceutical research and development: Descriptive versusMechanisticModeling, Statistical Parameters, Estimation,Confidence Regions, Nonlinearity at the Optimum, SensitivityAnalysis, Optimal Design, Population Modeling **b) Quality-by-Design In Pharmaceutical Development:** Introduction, ICH Q8 guideline, Regulatory and industry views on QbD, Scientifically based QbD - examples of application.	
Unit-2	**Computational Modeling of Drug Disposition:** Introduction, Modeling Techniques**:** Drug Absorption, Solubility, Intestinal Permeation, Drug Distribution, Drug Excretion, Active Transport; P-gp, BCRP, Nucleoside Transporters, hPEPT1, ASBT, OCT, OATP, BBB-Choline Transporter.	12 Hrs
Unit-3	**Computer-aided formulation development::** Concept of optimization, Optimization parameters, Factorial design, Optimization technology & Screening design. **Computers inPharmaceutical Formulation:** Development of pharmaceuticalemulsions, microemulsion drug carriers Legal Protection ofInnovative Uses of Computers in R&D, The Ethics of Computingin Pharmaceutical Research, Computers in Market analysis	12 Hrs
Unit-4	**a) Computer-aided biopharmaceutical characterization:** Gastrointestinal absorption simulation. Introduction, Theoretical background, Model construction, Parameter sensitivity analysis, Virtual trial, Fed vs. fasted state, In vitro dissolution and in vitroin vivo correlation, Biowaiver considerations **b) Computer Simulations in Pharmacokinetics andPharmacodynamics:** Introduction, Computer Simulation: Whole Organism, Isolated Tissues, Organs, Cell, Proteins and Genes. **c) Computers in Clinical Development:** Clinical Data Collection and Management, Regulation of Computer Systems	12 Hrs
Unit-5	Artificial Intelligence (AI), Robotics and Computational fluid dynamics: General overview, Pharmaceutical Automation, Pharmaceutical applications, Advantages and Disadvantages. Current Challenges and Future Directions.	12 Hrs
Reference Books:	**1.** Computer Applications in Pharmaceutical Research and Development, Sean Ekins, 2006, John Wiley & Sons. **2.** Computer-Aided Applications in Pharmaceutical Technology, 1st Edition, JelenaDjuris, Woodhead Publishing **3.** Encyclopedia of Pharmaceutical Technology, Vol 13, James Swarbrick, James. G.Boylan, Marcel Dekker Inc, New York, 1996.	

Course Code: (MPH 204T)	**M.Pharm- Semester-II** **COSMETICS AND COSMECEUTICALS**	**L-4** **T-0** **P-0** **C-4**
Course Outcomes:	On completion of the course, the students will be :	
CO1.	Understanding concepts of cosmetics and cosmeceuticals.	
CO2.	Describing basic requirements for formulation and development of skin care, hair care, oral and dental care cosmetic products.	
CO3.	Formulating different cosmetic preparationwith desired safety, stability, and efficacy	
CO4.	Evaluating different cosmetic preparations.	
Course Contents:		
Unit-1	**Cosmetics – Regulatory:** Definition of cosmetic products as perIndian regulation. Indian regulatory requirements for labelingofCosmetics, Regulatory provisions relating to import of cosmetics.,Misbranded and spurious cosmetics. Regulatory provisionsrelating to manufacture of cosmetics – Conditions for obtaininglicense, prohibition of manufacture and sale of certain	12Hrs

	cosmetics,loan license, offences and penalties.	
Unit-2	**Cosmetics** - Biological aspects: Structure of skin relating toproblems like dry skin, acne, pigmentation, prickly heat, wrinklesand body odor. Structure of hair and hair growth cycle. Commonproblems associated with oral cavity. Cleansing and care needsfor face, eye lids, lips, hands, feet, nail, scalp, neck, body andunder-arm.	12 Hrs
Unit-3	**Formulation Building blocks:**Building blocks for differentproduct formulations of cosmetics/cosmeceuticals. Surfactants – Classification and application. Emollients, rheological additives:classification and application. Antimicrobial used as preservatives,their merits and demerits. Factors affecting microbial preservativeefficacy. Buildingblocks for formulation of a moisturizing cream,vanishing cream, cold cream, shampoo and toothpaste. Soapsandsyndetbars.Perfumes; Classification of perfumes. Perfume ingredients listedas allergens in EU regulation.Controversial ingredients: Parabens, formaldehyde liberators, dioxane.	12 Hrs
Unit-4	**Design of cosmeceutical products:** Sun protection, sunscreensclassification and regulatory aspects. Addressing dry skin, acne,sun-protection, pigmentation, prickly heat, wrinkles, body odor.,dandruff, dental cavities, bleeding gums, mouth odorandsensitive teeth through cosmeceutical formulations.	12 Hrs
Unit-5	**Herbal Cosmetics:** Herbal ingredients used in Hair care, skincare and oral care. Review of guidelines for herbal cosmetics byprivate bodies like cosmos with respect to preservatives,emollients, foaming agents, emulsifiers and rheology modifiers.Challenges in formulating herbal cosmetics.	12 Hrs
Reference Books:	**1.** Harry's Cosmeticology. 8th edition**.** **2.** Poucher'sperfumecosmeticsandSoaps,10th edition. **3.** Cosmetics - Formulation, Manufacture and quality control, PP.Sharma,4th edition **4.** Handbook of cosmetic science and Technology A.O.Barel, M.Paye and H.I. Maibach. 3rd edition **5.** CTFA directory.	

Course Code: MPH205P	**M.Pharm- Semester-II** **PHARMACEUTICS PRACTICALS - II**	**L-0** **T-0** **P-12** **C-6**
Course Outcomes:	On completion of the course, the students will be :	
CO1.	Understanding the concepts of novel drug delivery systems and cosmetics.	
CO2.	Applying various techniques in the development of drug product.	
CO3.	Formulating novel drug delivery system and cosmetics	
CO4.	Evaluating different types of novel drug delivery system and cosmetics preparation.	
Course Contents:	1. To study the effect of temperature change, non-solvent addition,incompatible polymer addition in microcapsules preparation 2. Preparation and evaluation of Alginate beads 3. Formulation and evaluation of gelatin /albumin microspheres 4. Formulation and evaluation of liposomes/Niosomes 5. Formulation and evaluation of spherules 6. Improvement of dissolution characteristics of slightly soluble drug	

	by soliddispersion technique. 7. Comparison of dissolution of two different marketed products /brands 8. Protein binding studies of a highly protein bound drug & poorly proteinbound drug 9. Bioavailability studies of Paracetamol in animals. 10. Pharmacokinetic and IVIVC data analysis by WinnolineR software 11. In vitro cell studies for permeability and metabolism 12. DoE Using Design Expert® Software 13. Formulation data analysis Using Design Expert® Software 14. Quality-by-Design in Pharmaceutical Development 15. Computer Simulations in Pharmacokinetics andPharmacodynamics 16. Computational Modeling Of Drug Disposition 17. To develop Clinical Data Collection manual 18. To carry out Sensitivity Analysis, and Population Modeling. 19. Development and evaluation of Creams 20. Development and evaluation of Shampoo and Toothpaste base 21. To incorporate herbal and chemical actives to develop products 22. To address Dry skin, acne, blemish, Wrinkles, bleeding gums and dandruff	

COURSE CODE: MRM 301T	**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.	**12 hr**
2	Biostatistics: Definition, application, sample size, importance of sample size, factors influencing sample size, dropouts, statistical tests of significance, type of significance tests, parametric tests(students "t" test, ANOVA, Correlation coefficient, regression), non-parametric tests (wilcoxan rank tests, analysis of variance, correlation, chi square test), null hypothesis, P values, degree of freedom, interpretation of P values.	**12 hr**
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,	**12 hr**

	treatment of family members, sexual relationships, fatality.	
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, anaesthesia, euthanasia, physical facilities, environment, animal husbandry, record keeping, SOPs, personnel and training, transport of lab animals.	**12 hr**
5	Declaration of Helsinki: History, introduction, basic principles for all medical research, and additional principles for medical research combined with medical care.	**12 hr**
	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 Researches, 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., Experimental 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: MRM 302T	**M. Pharm- Semester-III** **PHARMACOECONOMICS**	**L-4 T-0 P-0 C-4**
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: MRM 303T	**M. Pharm- Semester-III** **BLOCKCHAIN TECHNOLOGY IN PHARMACEUTICAL INDUSTRY**	**L-4 T-0 P-0 C-4**
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: MRM 304T	**M. Pharm- Semester-III** **DIGITAL THERAPEUTICS AND CURATIVE THERAPIES**	**L-4 T-0 P-0 C-4**
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 regimens	**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: MRM 305T	**M. Pharm- Semester-III** **BIOSIMILARS**	**L-4** **T-0** **P-0** **C-4**
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.	

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 hr/Week	Evaluation Scheme						Total Marks	Credit Points
				Sessional Exams (Marks distribution)				End Semester Examination			
				CT*	Continuous mode		Total	Marks	Duration (hr)		
					ST/PR	At					
SEMESTER I											
1	MPH101T	Modern Pharmaceutical Analytical Techniques	4	15	02	08	25	75	3	100	4
2	MPH102T	Drug Delivery Systems	4	15	02	08	25	75	3	100	4

3	MPH103T	Modern Pharmaceutics	4	15	02	08	25	75	3	100	4
4	MPH104T	Regulatory Affairs	4	15	02	08	25	75	3	100	4
5	MPH105P	Pharmaceutics Practicals I	12	30	10	10	50	100	6	150	6
6	MPH106	Seminar /Assignment	7	---	---	---	---	---	---	100	4
		Total	**35**							**650**	**26**
SEMESTER II											
1	MPH201T	Molecular Pharmaceutics [Nano Tech and Targeted DDS (NTDS)]	4	15	02	8	25	75	3	100	4
2	MPH202T	Advanced Biopharmaceutics & Pharmacokinetics	4	15	02	8	25	75	3	100	4
3	MPH203T	Computer Aided Drug Development	4	15	02	8	25	75	3	100	4
4	MPH204T	Cosmetic and Cosmeceuticals	4	15	02	8	25	75	3	100	4
5	MPH205P	Pharmaceutics Practicals II	12	30	10	10	50	100	6	150	6
6	MPH206	Seminar /Assignment	7	---	---	---	---	---	---	100	4
		Total	**35**							**650**	**26**

CT*: Class Test (duration 1 hr for theory & 6 hr for practical); **At**: Attendance, **ST**: Student-Teacher interaction; **PR**: Practical Records

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	**MRM 301T**	**Research Methodology and Biostatistics***	4	15	02	08	25	75	3	100	4
2	**MRM 302T**	Pharmacoeconomics	4	15	02	08	25	75	3	100	4
	MRM 303T	Block chain technology in Pharmaceutical Industry									
	MRM 304T	Digital Therapeutics & Curative therapies									
	MRM 305T	Biosimilars									
3	**MRM 306**	Journal Club	1	-	-	-	25	-	-	25	1

4	**MRM 307**	Discussion / Presentation (Proposal Presentation)	2	-	-	-	50	-	-	50	2
5	**MRM 308**	**Research Work**	28	-	-	-	-	350	1	350	14
6	**MRM 309T**	Entrepreneurship Skill Development Intellectual Property Rights Business Model Innovation Principles of Management	**2**	15	02	08	25	75	3	100	**2**
		Total	**41**							**725**	**27**
SEMESTER IV											
1	**MRM 401**	Journal Club	1	-	-	-	25	-	-	25	1
2	**MRM402**	Discussion / Presentation (Proposal Presentation)	3	-	-	-	75	-	-	75	3
3	**MRM403**	Research Work& Colloquium	31	-	-	-	-	400	1	400	16
		Total	**35**							**500**	**20**

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