# 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**

TEERTHANKER MAHAVEER COLLEGE OF PHARMACY
PRINCIPAL
MORADABAD

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**<br>**Maximum=07*** |
| **Total Credit Points** | **Minimum=100**<br>**Maximum=105*** |

*Credit Points for Co-curricular Activities

# 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. (Pharmaceutics)

| M. Pharm. (Pharmaceutics) Semester I | | | | | | |
|---|---|---|---|---|---|---|
| **Category** | **Course Code** | **Course** | **Credit Hours** | **Credit Points** | **Hrs./ week** | **Marks** |
| CC-1 | MPH101T | Modern Pharmaceutical Analytical Techniques | 4 | 4 | 4 | 100 |
| CC-2 | MPH102T | Drug Delivery System | 4 | 4 | 4 | 100 |
| CC-3 | MPH103T | Modern Pharmaceutics | 4 | 4 | 4 | 100 |
| CC-4 | MPH104T | Regulatory Affair | 4 | 4 | 4 | 100 |
| SEC-1 | MPH105P | Pharmaceutics Practical I | 12 | 6 | 12 | 150 |
| SEC-2 | MPH106 | 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 | MPH201T | Molecular Pharmaceutics (Nano Tech and Targeted DDS) | 4 | 4 | 4 | 100 |
| CC-6 | MPH202T | Advanced Biopharmaceutics & Pharmacokinetics | 4 | 4 | 4 | 100 |
| CC-7 | MPH203T | Computer Aided Drug Delivery System | 4 | 4 | 4 | 100 |
| CC-8 | MPH204T | Cosmetic and Cosmeceuticals | 4 | 4 | 4 | 100 |
| SEC-3 | MPH205P | Pharmaceutics Practical II | 12 | 6 | 12 | 150 |
| SEC-4 | MPH206 | Seminar/Assignment | 7 | 4 | 7 | 100 |
| Total | | | 35 | 26 | 35 | 650 |

CC- Core Course, SEC-Skill Enhancement Course

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**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 |

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**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

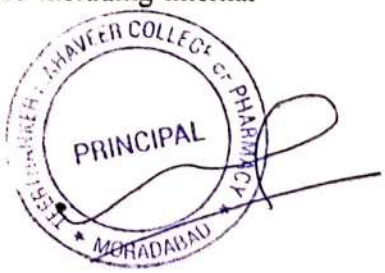
Two sessional exams shall be conducted for each theory / practical course as per the schedule fixed by the college(s). The scheme of question paper for theory and practical sessional examinations is given in the table. The average marks of two sessional exams shall be computed for internal assessment.

## 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 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 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:

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

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:

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

## 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:

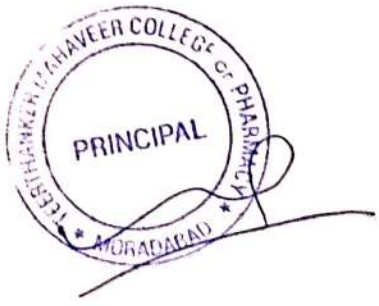
$$SGPA = \frac{C_1S_1 + C_2S_2 + C_3S_3 + C_4S_4}{C_1 + C_2 + C_3 + C_4}$$

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
# (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: Understanding** industrial management with GMP considerations, pilot plant scale-up techniques, stability testing, and packaging of pharmaceutical dosage forms.

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

**PSO-4: Evaluating** drug and pharmaceuticals/cosmeceuticals in its pure as well as dosage forms using modern analytical instrumentation techniques to assure its safety and efficacy.

**PSO-5: Applying pharmaco**-informatics, pharmacokinetic parameters with computational modelling /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<br>**Modern Pharmaceutical Analytical Techniques** | L-4<br>T-0<br>P-0<br>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.<br><br>**b.IR spectroscopy**: Theory, Modes of Molecular vibrations, Sample handling, Instrumentation of Dispersive and Fourier - Transform IR Spectrometer, Factors affecting vibrational frequencies and Applications of IR spectroscopy.<br><br>**c. Spectro flourimetry**: Theory of Fluorescence, Factors affecting fluorescence, Quenchers, Instrumentation and Applications of fluorescence spectrophotometer.<br><br>**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-Spin coupling, Coupling constant, Nuclear magnetic double resonance, Brief outline of principles of FT-NMR and $^{13}C$ NMR. Applications of NMR spectroscopy. | 11 Hrs |
| **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 Analyzers of Quadrupole 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:<br>a) Paper chromatography<br>b) Thin Layer chromatography<br>c) Ion exchange chromatography<br>d) Column chromatography<br>e) Gas chromatography<br>f) High-Performancee Liquid chromatography<br>g) Affinity chromatography<br>h) HPTLC | 11Hrs |
| **Unit-5** | **a. Electrophoresis:** Principle, Instrumentation, Working conditions, factors affecting separation and applications of the following:<br>i) Paper electrophoresis<br>ii) Gel electrophoresis<br>iii) Capillary electrophoresis<br>iv) Zone electrophoresis<br>v) Moving boundary electrophoresis<br>vi) Isoelectric focusing<br>**b. X ray Crystallography:** Production of X-rays, Different X-ray diffraction methods, Bragg's law, Rotating crystal technique, X-ray powder technique, Types of crystals and applications of X-ray diffraction. | 11Hrs |
| **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.<br>**2.** Principles of Instrumental Analysis - Doglas A Skoog, F. James Holler, Timothy A. Nieman, 5th edition, Eastern press, Bangalore, 1998.<br>**3.** Instrumental methods of analysis –Willards, 7th edition, CBS publishers.<br>**4.** Practical Pharmaceutical Chemistry – Beckett and Stenlake, Vol II, 4th edition, CBS Publishers, New Delhi, 1997.<br>**5.** Organic Spectroscopy - William Kemp, 3rd edition, ELBS, 1991.<br>**6.** Quantitative Analysis of Drugs in Pharmaceutical formulation - P D Sethi, 3rd Edition, CBS Publishers, New Delhi, 1997.<br>**7.** Pharmaceutical Analysis- Modern methods – Part B - J W Munson, Volume 11. Marcel Dekker Series | |

| Course Code: MPH102T | M. Pharm- Semester-I<br><br>DRUG DELIVERY SYSTEM | L-4<br>T-0<br>P-0<br>C-4 |
|---|---|---|
| **Course Outcomes:** | On completion of the course, the students will be : | |
| CO1. | Understanding various approaches for the development of novel drug delivery systems. | |
| CO2. | Defining the criteria for selection of drugs and polymers for development 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 & biological approaches for SR/CR formulation, Mechanism of Drug Delivery from SR/CR formulation.<br>**b) Polymers**: Introduction, definition, classification, properties and application.<br>**c) Dosage Forms for Personalized Medicine:** Introduction, Definition,<br>Pharmacogenetics, Categories of Patients for Personalized Medicines:<br>**d) Customized drug delivery systems**, Bioelectronic Medicines, 3D printing of pharmaceuticals, Tele pharmacy. | 10Hrs |
| **Unit-2** | **Rate Controlled Drug Delivery Systems:** Principles & Fundamentals, Types, Activation Modulated Drug Delivery Systems; Mechanically activated, pH activated, Enzyme activated, and Osmotic activated Drug Delivery Systems, Feedback regulated Drug Delivery Systems. Study Rate Controlled Drug Delivery Systems with special reference to marketed formulations. | 10 Hrs |
| **Unit-3** | **Gastro-Retentive Drug Delivery Systems:** Principle, concepts advantages and disadvantages, Modulation of GI transit time approaches to extend GI transit.<br>**Buccal Drug Delivery Systems:**<br>Principle of muco-adhesion, advantages and disadvantages, Mechanism of drug permeation, Methods of formulation and its evaluations. | 10 Hrs |
| **Unit-4** | **Ocular Drug Delivery Systems:** Barriers of ocular permeation, Methods to overcome barriers. Classify ocular drug delivery system and their methods of formulation and evaluations. | 06 Hrs |
| **Unit-5** | **Transdermal Drug Delivery Systems:** Structure of skin and barriers, Penetration enhancers, Transdermal Drug Delivery | 10Hrs |

| | | |
|---|---|---|
| | Systems, Formulation and evaluation. | |
| **Unit-6** | **Protein and Peptide Delivery:** Barriers for protein delivery. Formulation and Evaluation of delivery systems of proteins and other macromolecules and their applications | 8Hrs |
| **Unit-7** | **Vaccine delivery systems:** Vaccines, uptake of antigens, single shot 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.<br>**2.** Robinson, J. R., Lee V. H. L, Controlled Drug Delivery Systems, Marcel Dekker,Inc., New York, 1992.<br>**3.** Encyclopedia of controlled delivery, Editor- Edith Mathiowitz, Published by Wiley Interscience Publication, John Wiley and Sons, Inc, New York! Chichester/Weinheim<br>**4.** N.K. Jain, Controlled and Novel Drug Delivery, CBS Publishers & Distributors, New Delhi, First edition 1997 (reprint in 2001).<br>**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)<br>**2.** Indian drugs (IDMA)<br>**3.** Journal of controlled release (Elsevier Sciences) -Desirable<br>**4.** Drug Development and Industrial Pharmacy (Marcel & Decker)-Desirable | |

| Course Code: MPH103T | M. Pharm- Semester-I<br><br>MODERN PHARMACEUTICS | L-4<br>T-0<br>P-0<br>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. | Analyzing the drugs and pharmaceuticals. | |
| CO4. | Evaluating the given samples with respect to official standards. | |
| Course Contents: | | |
| Unit-I | **a) Pre-formulation Concepts –** Definition, preliminary evaluation, bulk characterization, solubility analysis, Drug Excipient interactions study- kinetics of stability, Stability testing. Theories of dispersion and pharmaceutical Dispersion (Emulsion and Suspension, SMEDDS) preparation and stability Large and small volume parental – physiological and formulation consideration, Manufacturing and evaluation.<br>**b) Optimization techniques in Pharmaceutical Formulation:** Concept and parameters of optimization, Optimization techniques in pharmaceutical formulation and processing. Statistical design, Response surface method, Contour plots, Factorial designs and application in formulation | 10Hrs<br><br>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 of equipments, Validation of specific dosage form, Types of validation. 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.<br>**Production management:** 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 Total Quality Management. | 10 Hrs |
| Unit-4 | **Compression and compaction:** Physics of tablet compression, compression, consolidation, effect of friction, distribution of forces, compaction profi. | 10 Hrs |

| | | |
|---|---|---|
| **Unit-5** | **Study of consolidation parameters:** Diffusion parameters, Dissolution parameters and Pharmacokinetic parameters, Heckelplots, Similarity factors – f2 and f1, Zero order kinetics, first order kinetics, Higuchi and Peppas plot,<br>**Linearity Concept of significance,** Standard deviation, Chi square test, students T-test, ANOVA test. | 10Hrs |
| **Reference Books:** | **1.** Theory and Practice of Industrial Pharmacy By Lachmann and Libermann<br>**2.** Pharmaceutical Dosage forms: Tablets Vol. 1-3 by Leon Lachmann.<br>**3.** Pharmaceutical Dosage forms: Disperse systems, Vol, 1-2; By Leon Lachmann.<br>**4.** Pharmaceutical Dosage forms: Parenteral medications Vol. 1-2; By Leon Lachmann.<br>**5.** Modern Pharmaceutics; By Gillbert and S. Banker.<br>**6.** Remington's Pharmaceutical Sciences.<br>**7.** Advances in Pharmaceutical Sciences Vol. 1-5; By H.S. Bean & A.H. Beckett.<br>**8.** Physical Pharmacy; By Alfred martin<br>**9.** Bentley's Textbook of Pharmaceutics – by Rawlins.<br>**10.** Good manufacturing practices for Pharmaceuticals: A plan for total quality control, Second edition; By Sidney H. Willig.<br>**11.** Quality Assurance Guide; By Organization of Pharmaceutical producers of India.<br>**12.**Drug formulation manual; By D.P.S. Kohli and D.H.Shah. Eastern publishers, New Delhi.<br>**13.** How to practice GMPs; By P.P.Sharma. Vandhana Publications, Agra.<br>**14.** Pharmaceutical Process Validation; By Fra. R. Berry and Robert A. Nash.<br>**15.** Pharmaceutical Preformulations; By J.J. Wells.<br>**16.** Applied production and operations management; By Evans, Anderson, Sweeney and Williams.<br>**17.** Encyclopaedia of Pharmaceutical technology, Vol I – III. | |

| Course Code: MPH104T | M. Pharm- Semester-I<br><br>REGULATORY AFFAIR | L-4<br>T-0<br>P-0<br>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 agencies governing the manufacturing, sales and distribution of pharmaceutical products. | |
| CO3. | Demonstrating regulatory approval process and their registration in Indian and international markets. | |
| CO4. | Evaluating given samples with respect to official standards. | |
| **Course Contents:** | | |
| **Unit-1** | **a) Documentation in Pharmaceutical industry:** Master formula record, DMF (Drug Master File), distribution records. Generic drugs product development Introduction , Hatch-Waxman act and amendments, CFR (CODE OF FEDERALREGULATION) ,drug product performance, in-vitro, ANDA regulatory approval process, NDA approval process, BE and drug product assessment, in –vivo, scale up process approval changes, post marketing surveillance, outsourcing BA and BE to CRO.<br>**b) Regulatory requirement for product approval:** API, biologics, novel, therapies obtaining NDA, ANDA for generic drugs, ways and means of US registration for foreign drugs | 12Hrs |
| **Unit-2** | CMC, post approval regulatory affairs. Regulation for combination products and medical devices. CTD and ECTD format, industry and FDA liaison.<br>ICH - Guidelines of ICH-Q, S E, M.<br>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. Institutional review board/ independent ethics committee, Formulation and working procedures, Informed Consent process and procedures.<br>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<br>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. | |

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| | 3. New Drug Approval Process: Accelerating Global Registrations By Richard AGuarino, MD, 5th edition, Drugs and the Pharmaceutical Sciences, Vol.190.<br>4. Guidebook for drug regulatory submissions / Sandy Weinberg. By John Wiley&Sons.Inc.<br>5. FDA regulatory affairs: a guide for prescription drugs, medical devices, andbiologics/edited By Douglas J. Pisano, David Mantus.<br>6. Clinical Trials and Human Research: A Practical Guide to RegulatoryCompliance by Fay A.Rozovsky and Rodney K. Adams<br>7. www.ich.org/<br>8. www.fda.gov/<br>9. europa.eu/index_en.htm<br>10. https://www.tga.gov.au/tga-basics | |

| Course Code: MPH105P | M. Pharm- Semester-I<br><br>PHARMACEUTICS PRACTICAL I | L-0<br>T-0<br>P-12<br>C-6 |
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| **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 for the 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<br>2. Simultaneous estimation of multi component containing formulations by UVspectrophotometry<br>3. Experiments based on HPLC<br>4. Experiments based on Gas Chromatography<br>5. Estimation of riboflavin/quinine sulphate by fluorimetry<br>6. Estimation of sodium/potassium by flame photometry<br>7. To perform In-vitro dissolution profile of CR/ SR marketed formulation<br>8. Formulation and evaluation of sustained release matrix tablets<br>9. Formulation and evaluation of osmotically controlled DDS<br>10. Preparation and evaluation of Floating DDS- hydro dynamically balancedDDS<br>11. Formulation and evaluation of Muco-adhesive tablets.<br>12. Formulation and evaluation of trans dermal patches.<br>13. To carry out preformulation studies of tablets.<br>14. To study the effect of compressional force on tablets disintegration time.<br>15. To study Micromeritic properties of powders and granulation.<br>16. To study the effect of particle size on dissolution of a tablet.<br>17. To study the effect of binders on dissolution of a tablet.<br>18. To plot Heckal plot, zero order kinetics, first order kinetics, Higuchi and Peppas plot and determine similarity factors. | |

| Course Code: MPH201T | M. Pharm- Semester-II<br>MOLECULAR PHARMACEUTICS (NANO TECH & TARGETED DDS) | L-4<br>T-0<br>P-0<br>C-4 |
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| **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 for development 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 and biological process involved in drug targeting. Tumor targeting and Brain specific delivery. | 12Hrs |
| **Unit-2** | **Targeting Methods:** Introduction preparation and evaluation. Nano Particles & Liposomes: Types, preparation and evaluation. Applications of Nano and targeted drug delivery system | 12 Hrs |
| **Unit-3** | **Micro Capsules / Micro Spheres:** Types, preparation and Evaluation,<br>**Monoclonal Antibodies:** Preparation and application,<br>Preparation and application of **Niosomes, Aquasomes, Phytosomes, Electrosomes.** | 12 Hrs |
| **Unit-4** | **Pulmonary Drug Delivery Systems:** Aerosols, propellants, Containers, Types, preparation and evaluation,<br>**Intra Nasal Route Delivery systems:** Types, preparation and evaluation. | 12 Hrs |
| **Unit-5** | **Nucleic acid based therapeutic delivery system:** Gene therapy, Introduction (ex-vivo & in-vivo gene therapy). Potential target diseases for gene therapy (inherited disorder and cancer). Gene expression systems (viral and nonviral gene transfer). Liposomal gene 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.<br>**2.** S.P.Vyas and R.K.Khar, Controlled Drug Delivery - concepts andadvances, VallabhPrakashan, New Delhi, First edition 2002.<br>**3.** N.K. Jain, Controlled and Novel Drug Delivery, CBS Publishers & Distributors, NewDelhi, First edition 1997 (reprint in 2001). | |

| Course Code: (MPH202T) | M. Pharm- Semester-II<br><br>ADVANCED BIOPHARMACEUTICS & PHARMACOKINETICS | L-4<br>T-0<br>P-0<br>C-4 |
|---|---|---|
| **Course Outcomes:** | On completion of the course, the students will be: | |
| CO1. | Understanding basic concepts in biopharmaceutics and pharmacokinetics and their significance. | |
| CO2. | Describing the concepts of bioavailability and bioequivalence of drug products and their significance. | |
| CO3. | Applying pharmacokinetic parameters in calculation and fixation of dosage regimen. | |
| CO4. | Analyzing plasma drug concentration versus time data to calculate pharmacokinetic parameters and profiles of drug/formulations. | |
| **Course Contents:** | | |
| **Unit-1** | **Drug Absorption from the Gastrointestinal Tract:** Gastrointestinal tract, Mechanism of drug absorption, Factors affecting drug absorption, pH–partition theory of drug absorption. Formulation and physicochemical factors: Dissolution rate, Dissolution process, Noyes–Whitney equation and drug dissolution, Factors affecting the dissolution rate. Gastrointestinal absorption: 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, Dissolution methods, Formulation and processing factors. Transport model: Permeability-Solubility-Charge State and the pH Partition Hypothesis, Properties of the Gastrointestinal Tract (GIT), pH Microclimate, Intracellular pH Environment, Tight-Junction Complex. | 12Hrs |
| **Unit-2** | **Biopharmaceutic considerations in drug product design and In Vitro Drug Product Performance:** Introduction, biopharmaceutic factors affecting drug bioavailability, physicochemical nature of the drug formulation factors affecting drug product performance, in vitro: dissolution and drug release testing, compendial methods of dissolution, alternative methods of dissolution testing, meeting dissolution requirements, problems of variable control in dissolution testing performance of drug products. In vitro–in vivo correlation, dissolution profile comparisons, drug product stability, 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: two compartment- model in brief, Non-linear pharmacokinetics: cause of non-linearity, Michaelis – Menten equation, estimation of Kmax and Vmax.<br>**Drug interactions**: Introduction, the effect of protein binding interactions, the effect of tissue-binding interactions, Cytochrome p450-based drug interactions, and drug interactions linked to transporters. | 12 Hrs |

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| **Unit-4** | **Drug Product Performance, In Vivo: Bioavailability and Bioequivalence:** drug product performance, purpose of bioavailability studies, relative and absolute availability. Methods for assessing bioavailability, bioequivalence studies, design and evaluation 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 and In-vivo methods. Generic biologics (Biosimilardrugproducts), clinical significance of bioequivalence studies, special concerns in bioavailability and bioequivalence studies, generic substitution. | 12 Hrs |
| **Unit-5** | **Application of Pharmacokinetics:** Modified-Release Drug Products, Targeted Drug Delivery Systems and Biotechnological Products.<br>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, 4thEdition, Philadelphia, Lea and Febiger, 1991<br>**2.** Biopharmaceutics and Pharmacokinetics, A. Treatise, D.M. Brahmankar and Sunil B Jaiswal., VallabPrakashan, Pitampura, Delhi<br>**3.** Applied Biopharmaceutics and Pharmacokinetics by Shargel. Land YuABC, 2ndedition, Connecticut Appleton Century Crofts, 1985<br>**4.** Textbook of Biopharmaceutics and Pharmacokinetics, Dr. Shobha Rani R. Hiremath, Prism Book<br>**5.** Pharmacokinetics by Milo Gibaldi and D. Perrier, 2nd edition, Marcel Dekker Inc.,New York, 1982<br>**6.** Current Concepts in Pharmaceutical Sciences: Biopharmaceutics, Swarbrick. J, LeaandFebiger, Philadelphia, 1970<br>**7.** Clinical Pharmacokinetics, Concepts and Applications 3rd edition by MalcolmRowland and Thom~ N. Tozer, Lea and Febiger, Philadelphia, 1995<br>**8.** Dissolution, Bioavailability and Bioequivalence, Abdou. H.M, Mack PublishingCompany, Pennsylvania 1989<br>**9.** Biopharmaceutics and Clinical Pharmacokinetics, An Introduction, 4thEdition,revised and expande by Robert. E. Notari, Marcel Dekker Inc, New York and Basel,1987.<br>**10.** Biopharmaceutics and Relevant Pharmacokinetics by John. G Wagner andM.Pemarowski, 1st edition, Drug Intelligence Publications, Hamilton,Illinois, 1971.<br>**11.** Encyclopedia of Pharmaceutical Technology, Vol 13, James Swarbrick, James. G.Boylan, Marcel Dekker Inc, New York, 1996.<br>**12.** Basic Pharmacokinetics,1stedition,Sunil S Jambhekar and Philip J Breen, Pharmaceutical Press, RPS Publishing,2009.<br>**13.** Absorption and Drug Development- Solubility, Permeability, and Charge State, Alex Avdeef, John Wiley & Sons, Inc,2003. | |

| Course Code: (MPH203T) | M. Pharm- Semester-II<br>COMPUTER AIDED DRUG DELIVERY SYSTEM | L-4<br>T-0<br>P-0<br>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 and pharmacodynamic parameters of drug product using computer simulation | |
| **Course Contents:** | | |
| **Unit-1** | **a) Computers in Pharmaceutical Research and Development:** A General Overview: History of Computers in Pharmaceutical Research and Development. Statistical modeling in Pharmaceutical research and development: Descriptive versus Mechanistic Modeling, Statistical Parameters, Estimation, Confidence Regions, Nonlinearity at the Optimum, Sensitivity Analysis, Optimal Design, Population Modeling<br>**b) Quality-by-Design In Pharmaceutical Development:** Introduction, ICH Q8 guideline, Regulatory and industry views on QbD, Scientifically based QbD - examples of application. | 12Hrs |
| **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.<br>**Computers in Pharmaceutical Formulation:** Development of pharmaceutical emulsions, microemulsion drug carriers Legal Protection of Innovative Uses of Computers in R&D, The Ethics of Computing in 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 vitro in vivo correlation, Biowaiver considerations. | 12 Hrs |

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| | **b) Computer Simulations in Pharmacokinetics and Pharmacodynamics:** Introduction, Computer Simulation: Whole Organism, Isolated Tissues, Organs, Cell, Proteins and Genes.<br>**c) Computers in Clinical Development:** Clinical Data Collection and Management, Regulation of Computer Systems | |
| **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.<br>**2.** Computer-Aided Applications in Pharmaceutical Technology, 1st Edition, JelenaDjuris, Woodhead Publishing<br>**3.** Encyclopedia of Pharmaceutical Technology, Vol 13, James Swarbrick, James. G.Boylan, Marcel Dekker Inc, New York, 1996. | |

| Course Code: (MPH204T) | M. Pharm- Semester-II<br>COSMETIC AND COSMECEUTICALS | L-4<br>T-0<br>P-0<br>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 preparation with desired safety, stability, and efficacy | |
| CO4. | Evaluating different cosmetic preparations. | |
| **Course Contents:** | | |
| **Unit-I** | **Cosmetics – Regulatory:** Definition of cosmetic products as per Indian regulation. Indian regulatory requirements for labelling of Cosmetics, Regulatory provisions relating to import of cosmetics., Misbranded and spurious cosmetics. Regulatory provisions relating to manufacture of cosmetics – Conditions for obtaining license, prohibition of manufacture and sale of certain cosmetics, loan license, offences and penalties. | 12Hrs |
| **Unit-2** | **Cosmetics** - Biological aspects: Structure of skin relating to problems like dry skin, acne, pigmentation, prickly heat, wrinkles and body odor. Structure of hair and hair growth cycle. Common problems associated with oral cavity. Cleansing and care needs for face, eye lids, lips, hands, feet, nail, scalp, neck, body and under-arm. | 12 Hrs |
| **Unit-3** | **Formulation Building blocks:** Building blocks for different product 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 preservative efficacy. Building blocks for formulation of a moisturizing cream, vanishing cream, cold cream, shampoo and toothpaste. Soaps and syndetbars. 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, sunscreens classification 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 by private bodies like cosmos with respect to preservatives,emollients, | 12 Hrs |

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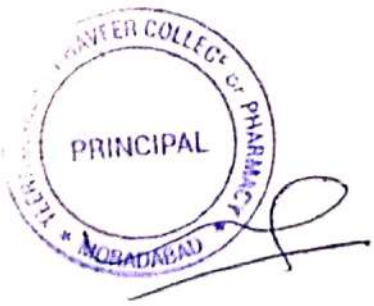
| | foaming agents, emulsifiers and rheology modifiers.Challenges in formulating herbal cosmetics. | |
| **Reference Books:** | **1.** Harry's Cosmeticology. 8th edition.<br>**2.** Poucher'sperfume cosmetics and Soaps,10th edition.<br>**3.** Cosmetics - Formulation, Manufacture and quality control, PP.Sharma,4th edition<br>**4.** Handbook of cosmetic science and Technology A.O.Barel, M.Paye and H.I. Maibach. 3rd edition<br>**5.** CTFA directory. | |

| Course Code: MPH205P | M. Pharm- Semester-II<br><br>PHARMACEUTICS PRACTICAL II | L-0<br>T-0<br>P-12<br>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<br>2. Preparation and evaluation of Alginate beads<br>3. Formulation and evaluation of gelatin /albumin microspheres<br>4. Formulation and evaluation of liposomes/Niosomes<br>5. Formulation and evaluation of spherules<br>6. Improvement of dissolution characteristics of slightly soluble drug by solid dispersion technique.<br>7. Comparison of dissolution of two different marketed products /brands<br>8. Protein binding studies of a highly protein bound drug & poorly protein bound drug<br>9. Bioavailability studies of Paracetamol in animals.<br>10. Pharmacokinetic and IVIVC data analysis by WinnolineR software<br>11. In vitro cell studies for permeability and metabolism<br>12. DoE Using Design Expert® Software<br>13. Formulation data analysis Using Design Expert® Software<br>14. Quality-by-Design in Pharmaceutical Development<br>15. Computer Simulations in Pharmacokinetics and Pharmacodynamics<br>16. Computational Modeling Of Drug Disposition<br>17. To develop Clinical Data Collection manual<br>18. To carry out Sensitivity Analysis, and Population Modeling.<br>19. Development and evaluation of Creams<br>20. Development and evaluation of Shampoo and Toothpaste base<br>21. To incorporate herbal and chemical actives to develop products<br>22. To address Dry skin, acne, blemish, Wrinkles, bleeding gums and dandruff | |

| COURSE CODE: MRM301T | M. Pharm- Semester-III<br>RESEARCH METHODOLOGY & BIOSTATISTICS | L-4<br>T-0<br>P-0<br>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, treatment of family members, sexual relationships, fatality. | 12 hr |
| 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**<br>1. Cooper & Schindler, Business Research Methods, Tata McGraw Hill.<br>2. Saunders, Research Methods for Business Students, Pearson Education<br>3. Allen T Harrell, New Methods in Social Science Researches, Praeger Publishers, New York<br>4. Beri, G.C., Statistics for Management, Tata MacGraw-Hill<br>5. Chandan J. S., Statistics for Business and Economics, Vikas Publications.<br>6. Broota, K.D., Experimental Designs in Behavioural Research, New Age International<br>7. Singh A. K., Test Measurement and Research Methods in Behaviours Sciences, BhartiBhawan<br>8. Joyce Cox & Polly Urban, Microsoft Office, Galgotia Publishing<br>9. Sinha P.K., Computer Fundamentals, BPB Publishing.<br>*Latest editions of all the suggested books are recommended. | |

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



| COURSE CODE: MRM303T | M. Pharm- Semester-III<br>BLOCKCHAIN TECHNOLOGY IN PHARMACEUTICAL INDUSTRY | L-3<br>T-0<br>P-0<br>C-3 |
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| Unit-1 | **Basic concepts of Blockchain technology**<br>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**<br>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**<br>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**<br>Blockchain and cosmetic industry, Blockchain and Food Industry. | 6 hr |
| | **Text books**<br>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.<br>2. Blockchain for Healthcare Systems. Author: Pankaj Bhatt, Suruchi Singh, Satish Kumar Sharma, Vipin Kumar- 1st Edition. Pub.: CRC Press, 2021.<br>3. Blockchain Technology and Applications. Editor: Pethuru Raj, KavitaSaini and ChellammalSurianarayanan. - Ist Edition. Pub.: Auerbach Publications, 2021.<br>*Latest editions of all the suggested books are recommended. | |

| COURSE CODE: MRM304T | M. Pharm- Semester-III<br>DIGITAL THERAPEUTICS AND CURATIVE THERAPIES | L-3<br>T-0<br>P-0<br>C-3 |
|---|---|---|
| Unit-1 | **Digital Therapeutics**<br>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**<br>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**<br>Robotic Surgery, Nanotechnology, 3D printing and tissue engineering | 6 hr |
| Unit-4 | **Personalized or customized treatment**<br>Tailored dosing, Tailored drug regims | 6 hr |
| | **Text books:**<br><br>1. The Digital Health Revolution. Author: Kevin Pereau , Editor: Barry Lenson- Ist Edition. Pub.: Transcendit Health, 2019.<br><br>2. Digital Health- Meeting Patient and Professional Needs Online. Author: Barrie Gunter-Ist Edition. Pub.: Taylor & Francis Inc, 2006.<br><br>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.<br><br>*Latest editions of all the suggested books are recommended. | |

| COURSE CODE: MRM305T | M. Pharm- Semester-III<br><br>BIOSIMILARS | L-3<br>T-0<br>P-0<br>C-3 |
|---|---|---|
| Unit-1 | **Basic Concepts**<br>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**<br>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**<br>Biosimilars in rheumatology, breast cancer, colorectal cancer and nephrology. | 6 hr |
| | **Text books**<br><br>1. Biologics, Biosimilars, and Biobetters: An Introduction for Pharmacists, Physicians and Other Health Practitioners. Editor: Iqbal Ramzan. Pub.: Wiley, 2021.<br>2. Biosimilars-Design and Analysis of Follow-on Biologics. Editor: Shein-Chung Chow- 1st ed. Pub.: CRC Press, 2019.<br>3. Biosimilars: Regulatory, Clinical, and Biopharmaceutical Development. Editor: Hiten J. Gutka, Harry Yang and ShefaliKakar- 1st ed.Pub.:Springer, 2018.<br><br>*Latest editions of all the suggested books are recommended. | |

| COURSE CODE: MRM309T | M. Pharm-Semester-III<br>ENTREPRENEURSHIP SKILL DEVELOPMENT | L-2<br>T-0<br>P-0<br>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<br>INTELLECTUAL PROPERTY RIGHTS | L-2<br>T-0<br>P-0<br>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<br><br>BUSINESS MODEL INNOVATION | L-2<br>T-0<br>P-0<br>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<br>PRINCIPLES OF MANAGEMENT | L-2<br>T-0<br>P-0<br>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.<br>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 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 System | 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 Affair | 4 | 15 | 02 | 08 | 25 | 75 | 3 | 100 | 4 |
| 5 | MPH105P | Pharmaceutics Practical 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] | 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 Delivery System | 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 Practical 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 | **MRM301T** | **Research Methodology and Biostatistics*** | 4 | 15 | 02 | 08 | 25 | 75 | 3 | 100 | 4 |
| 2 | **MRM302T** | Pharmacoeconomics | 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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