Scheme and Syllabus

M. Pharmacy
Industrial Pharmacy

Batch 2017 onwards

PTU

ਆਈ. ਕੇ. ਗੁਜਰਾਲ ਪੰਜਾਬ ਟੈਕਨੀਕਲ ਯੂਨੀਵਰਸਿਟੀ

By
Board of Studies Pharmacy
Department of Academics

First Semester

Course Code	Course Name	L	P	Marks			Credits
				Internal	External	Total	
MIP101T	Modern Pharmaceutical Analytical Techniques	4	-	25	75	100	4
MIP102T	Pharmaceutical Formulation Development	4	-	25	75	100	4
MIP103T	Novel Drug Delivery Systems	4	-	25	75	100	4
MIP104T	Intellectual Property Rights	4		25	75	100	4
MIP105P	Industrial Pharmacy Practical I	-	12	50	100	150	6
-	Seminar/Assignment#	-	7	-	-	100	4
	Total	**16**	**19**	**150**	**400**	**650**	**26**

- # Minimum five seminar/assignment each of 20 marks per semester

Second Semester

Course Code	Course Name	L	P	Marks			Credits
				Internal	External	Total	
MIP201T	Advanced Biopharmaceutics & Pharmacokinetics	4	-	25	75	100	4
MIP202T	Scale up & Technology Transfer	4	-	25	75	100	4
MIP203T	Pharmaceutical Production Technology	4	-	25	75	100	4
MIP204T	Entrepreneurship Management	4		25	75	100	4
MIP205P	Industrial Pharmacy Practical II	-	12	50	100	150	6
-	Seminar/Assignment#	-	7	-	-	100	4
	Total	**16**	**19**	**150**	**400**	**650**	**26**

- # Minimum five seminar/assignment each of 20 marks per semester

Third Semester

Course Code	Course Name	L	P	Marks			Credits
				Internal	**External**	**Total**	
MRM301T	Research Methodology & Biostatistics*	4	-	25	75	100	4
-	Journal Club	1	-	25	-	25	1
-	Discussion / Presentation (Proposal Presentation)	2	-	50	-	50	2
-	Research Work*	-	28	-	350	350	14
	Total	**7**	**28**	**100**	**425**	**525**	**21**

- *Non -University Exam

Fourth Semester

Course Code	Course Name	L	P	Marks			Credits
				Internal	External	Total	
-	Journal Club	1	-	25	-	25	1
-	Research Work	-	31	-	400	400	16
-	Discussion/Final Presentation	3	-	75	-	75	3
-	Co-curricular Activities	-	-	Satisfactory/Unsatisfactory			2*
	Total	**4**	**31**	**100**	**400**	**500**	**22**

**Note: Required credit points 02 for satisfactory; Less than 02 credit points unsatisfactory*

***Credits not included towards calculation of CGPA**

Semester Wise Credits Distribution

Semester	Credit Points
I	26
II	26
III	21
IV	20
Co-curricular Activities (Attending Conference, Scientific Presentations & Other Scholarly Activities)	02*
Total Credit Points	**93 + 2* = 95**

- *Credit Points for Co-curricular Activities
- *Credits not included towards calculation of CGPA
- *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

Guidelines for Awarding Credit Points for Co-curricular Activities

Name of the Activity	Maximum Credit Points
Participation in National Level Seminar/ Conference/ Workshop/ Symposium/ Training Programs (related to the specialization of the student) OR Academic Award/Research Award from State Level/National Agencies	02
Participation in International Level Seminar/ Conference/ Workshop/ Symposium / Training Programs (related to the specialization of the student) #	02
Academic Award/Research Award from International Agencies	02
Research / Review Publication in National Journals (Indexed in Scopus / Web of Science)*	01
Research / Review Publication in International Journals (Indexed in Scopus / Web of Science)*$	02

- # International Conference held even in India will be considered for award of Credit Points.
- *Only those research / review publications will be considered which have been published during the tenure of M. Pharm. Course.
- $ International Journal: The Editorial Board outside India.

Academic Work

The department / teaching staff of respective courses shall maintain a regular record of attendance in Theory, Practical, Seminar, Assignment, Journal Club, and Discussion with the supervisor, Research work presentation and Dissertation.

Program Committee

1. M. Pharm. Programme shall have a Programme Committee constituted by the Head of the Institution in consultation with all the Heads of the departments.
2. The composition of the Programme Committee shall be as follows:
   a. A teacher at the cadre of Professor shall be the Chairperson
   b. One Teacher from each M. Pharm. Specialization
   c. Four student representatives (two from each academic year), nominated by the Head of the Institution
3. Duties of the Programme Committee:
   a. Periodically review the progress of the classes.
   b. Discuss the problems concerning curriculum, syllabus and the conduct of classes.
   c. Discussing with the course teachers on the nature and scope of assessment for the course and the same shall be announced to the students at the beginning of respective semesters.

Sessional Exams

- Two sessional exams shall be conducted for each theory/practical course
- The average marks of two sessional exams shall be computed for internal assessment
- Sessional exam shall be **conducted for 30 marks** for theory and shall be **computed for 15 marks**.
- Sessional exam for practical shall be **conducted for 40 marks** and shall be **computed for 30 marks**.

Question Paper Pattern for Theory Sessional Examinations

Multiple Choice Questions (MCQs) **OR** Objective Type Questions (5 x 2) (Answer all the questions)	10 x 1 = 10 **OR** 05 x 2 = 10
Short Answers (Answer 2 out of 3)	2 x 5 = 10
Long Answers (Answer 1 out of 2)	1 x 10 = 10
Total	**30 Marks**

Question Paper Pattern for Practical Sessional Examinations

Synopsis	10
Experiments	25
Viva voce	05
Total	**40 Marks**

Internal Assessment

- The internal assessment will have two components i.e. **Continuous Mode** and **Sessional Exams**

1. For Theory Courses having Internal of 25 Marks the scheme of internal award is:
   - Sessional Exams: 15 Marks
   - Continuous Mode: 10 Marks

Continuous Mode Scheme

Criteria	Maximum Marks
*Attendance (as per table given below)	08
Student – Teacher interaction	02
Total	**10**

2. For Practical Courses having Internal of 50 Marks the scheme of internal award is:
   - Sessional Exams: 30 Marks
   - Continuous Mode: 20 Marks

Continuous Mode Scheme

Criteria	Maximum Marks
*Attendance (as per table given below)	10
Based on Practical Records, Regular viva voce, etc.	10
Total	**20**

***Guidelines for the Allotment of Marks for Attendance**

Percentage of Attendance	Theory (Maximum Marks 08)	Practical (Maximum Marks 10)
95 – 100	08	10
90 – 94	06	7.5
85 – 89	04	5
80 – 84	02	2.5
Less than 80	0	0

1st SEMESTER

Course Code	Course Title	Teaching Load		Marks		Exam (hrs)		Credits
		L	P	Int.	Ext.	Int.	Ext.	
MIP101T	Modern Pharmaceutical Analytical Techniques	4	-	25	75	1	3	4

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

Objectives: After completion, of course student is able to know

1. Chemicals and Excipients.
2. The analysis of various drugs in single and combination dosage forms.
3. Theoretical and practical skills of the instruments.

Module 01 **11 Hour**

UV-Visible Spectroscopy

- Introduction, Theory, Laws, and Instrumentation associated with UV-Visible spectroscopy
- Choice of solvents and solvent effect
- Applications of UV- Visible spectroscopy

IR Spectroscopy

- Theory, Modes of Molecular vibrations, Sample handling
- Instrumentation of Dispersive and Fourier - Transform IR Spectrometer
- Factors affecting vibrational frequencies
- Applications of IR spectroscopy

Spectroflourimetry

- Theory of Fluorescence
- Factors affecting fluorescence, Quenchers, Instrumentation
- Applications of fluorescence spectrophotometer

Flame Emission Spectroscopy and Atomic Absorption Spectroscopy

- Principle, Instrumentation, Interferences and Applications

Module 02 **11 Hours**

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

Module 03 **11 Hours**

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
- Applications of Mass spectroscopy

Module 04 **11Hours**

Chromatography

Principle, apparatus, instrumentation, chromatographic parameters, factors affecting resolution and applications of the following:

- Paper chromatography
- Thin Layer chromatography
- Ion exchange chromatography
- Column chromatography
- Gas chromatography
- High Performance Liquid chromatography
- Affinity chromatography

Module 05 **11Hours**

Electrophoresis

Principle, Instrumentation, Working conditions, factors affecting separation and applications of the following:

- Paper electrophoresis
- Gel electrophoresis
- Capillary electrophoresis
- Zone electrophoresis
- Moving boundary electrophoresis
- Isoelectric focusing

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

Module 06 **05 Hours**

Immunological Assays

- RIA (Radio immuno assay)
- ELISA (Theory and practical)
- Knowledge on bioluminescence assays

Recommended Books (Latest editions)

1. Spectrometric Identification of Organic Compounds - Robert M Silverstein, John Wiley & Sons.
2. Principles of Instrumental Analysis - Doglas A Skoog, F. James Holler, Timothy A. Nieman, Eastern press, Bangalore.
3. Instrumental methods of analysis – Willards, CBS publishers.
4. Practical Pharmaceutical Chemistry – Beckett and Stenlake, Vol II, CBS Publishers, New Delhi.
5. Organic Spectroscopy - William Kemp, ELBS.
6. Quantitative Analysis of Drugs in Pharmaceutical formulation - P D Sethi,CBS Publishers, New Delhi.
7. Pharmaceutical Analysis- Modern methods – Part B - J W Munson, Volume 11, Marcel Dekker Series.

Course Code	Course Title	Teaching Load		Marks		Exam (hrs)		Credits
		L	P	Int.	Ext.	Int.	Ext.	
MIP102T	Pharmaceutical Formulation Development	4	-	25	75	1	3	4

Scope: This course is designed to impart knowledge and skills necessary to train the students on par with the routine of Industrial activities in R&D and F&D.

Objectives: Upon completion of the course, student shall be able to understand

1. The scheduled activities in a Pharmaceutical firm.
2. The pre formulation studies of pilot batches of pharmaceutical industry.
3. The significance of dissolution and product stability.

Module 01
12Hours

Preformulation Studies

- Molecular optimization of APIs (drug substances)
- Crystal morphology and variations
- Powder flow
- Structure modification
- Drug-excipient compatibility studies, Methods of determination

Module 02 **12Hours**

Formulation Additives

- Study of different formulation additives
- Factors influencing their incorporation
- Role of formulation development and processing
- New developments in excipient science

Design of Experiments

- Factorial design for product and process development

Module 03 **12Hours**

Solubility

- Importance, experimental determination
- Phase- solubility analysis
- pH-solubility profile
- Solubility techniques to improve solubility

Utilization of Analytical Methods

- Cosolvency, salt formation, complexation, solid dispersion, micellar solubilization and hydrotropy

Module 04 **12Hours**

Dissolution

- Theories, mechanisms of dissolution
- *In-vitro* dissolution testing models: sink and non-sink, factors influencing dissolution and intrinsic dissolution studies
- Dissolution test apparatus: designs, dissolution testing for conventional and controlled release products
- Data handling and correction factor
- Bio-relevant media
- *In-vitro* and *in-vivo* correlations
- Levels of correlations

Module 05 **12Hours**

Product Stability

- Degradation kinetics, mechanisms
- Stability testing of drugs and pharmaceuticals
- Factors influencing-media effects and pH effects
- Accelerated stability studies
- Interpretation of kinetic data (API & tablets)
- Solid state stability and shelf life assignment
- Stability protocols, reports and ICH guidelines

Recommended Books (Latest editions)

1. Lachman L, Lieberman HA, Kanig JL. The Theory and Practice of Industrial Pharmacy, Varghese Publishers, Mumbai.
2. Sinko PJ. Martin's physical pharmacy and pharmaceutical sciences, B.I. Publications Pvt. Ltd, Noida.
3. Lieberman HA, Lachman L, Schwartz JB. Pharmaceutical dosage forms: tablets Vol. I-III, CBS Publishers & distributors, New Delhi.
4. Conners KA. A Text book of pharmaceutical analysis Wells JI. Pharmaceutical preformulation: The physicochemical properties of drug substances. Ellis Horwood Ltd., England.
5. Yalkowsky SH. Techniques of solubilization of drugs, Vol-12, Marcel Dekker Inc., New York.
6. Dressman J, Kramer J. Pharmaceutical dissolution testing. Saurah printer pvt. Ltd., New Delhi.
7. Sethi PD. Quantitative analysis of drugs in pharmaceutical formulations,CBS publications, New Delhi.
8. Carstensen JT, Rhodes CT. Drug stability principles and practices, CBS Publishers & distributors, New Delhi.

9. Yoshioka S, Stella VJ. Stability of drugs and dosage forms, Springer (India) Pvt. Ltd., New Delhi.
10. Banker GS, Rhodes CT. Modern Pharmaceutics, Inc, New York.
11. W. Grimm - Stability testing of drug products. Marcel Dekker.
12. Mazzo DJ. International stability testing. Eastern Press Pvt. Ltd., Bangalore.
13. Beckett AH, Stenlake JB. Practical pharmaceutical Chemistry, Part I & II. CBS Publishers & distributors, New Delhi.
14. Indian Pharmacopoeia. Controller of Publication. Delhi.
15. British Pharmacopoeia. British Pharmacopoeia Commission Office, London.
16. United States Pharmacopoeia. United States Pharmacopeial Convention, Inc, USA.
17. Encyclopaedia of Pharm. Technology, Vol I – III.
18. Wells J. I. Pharmaceutical Preformulation: The physicochemical properties of drug substances, Ellis Horwood Ltd. England.

Course Code	Course Title	Teaching Load		Marks		Exam (hrs)		Credits
		L	P	Int.	Ext.	Int.	Ext.	
MIP103T	Novel Drug Delivery Systems	4	-	25	75	1	3	4

Scope: This course is designed to impart knowledge and skills necessary to train the students in the area of novel drug delivery systems.

Objectives: Upon completion of the course, student shall be able to understand

1. The need, concept, design and evaluation of various customized, sustained and controlled release dosage forms.
2. To formulate and evaluate various novel drug delivery systems.

Module 01 **12 Hours**

Concept and Models for NDDS

- Classification of rate controlled drug delivery systems (DDS)
- Rate programmed release
- Activation modulated and feedback regulated DDS
- Effect of system parameters in controlled drug delivery
- Computation of desired release rate
- Dose for controlled release DDS
- Pharmacokinetic design for DDS: intermittent, zero order and first order release

Carriers for Drug Delivery

- Polymers / co-polymers: introduction, classification, characterization
- Polymerization techniques
- Application in CDDS/NDDS
- Biodegradable and natural polymers

Module 02 **12 Hours**

Study of Various DDS

- Concepts, design, formulation & evaluation of controlled release oral DDS
- Mucoadhesive DDS (buccal, nasal, pulmonary)
- Pulsatile, colon specific, liquid sustained release systems
- Ocular delivery systems

Module 03 **08 Hours**

Transdermal Drug Delivery Systems

- Theory, design, formulation and evaluation including iontophoresis and other latest developments in skin delivery systems

Module 04 **04 Hours**

Sub Micron Cosmeceuticals

- Biology, formulation science and evaluation of various cosmetics for skin, hair, nail, eye etc and it's regulatory aspects

Module 05 **06 Hours**

Targeted Drug Delivery Systems

- Importance, concept, biological process and events involved in drug targeting, design, formulation and evaluation
- Methods in drug targeting – nanoparticles, liposomes, niosomes, pharmacosomes, resealed erythrocytes, microspheres, magnetic microspheres
- Specialized pharmaceutical emulsions – multiple emulsions, micro-emulsions

Module 06 **06 Hours**

Protein / Peptide Drug Delivery Systems

- Concepts, delivery techniques, formulation, stability testing, causes of protein destabilization, stabilization methods

Module 07 **06 Hours**

Biotechnology in Drug Delivery Systems

Brief review of major areas-recombinant DNA technology, monoclonal antibodies, gene therapy

Module 08 **06 Hours**

New Trends for Personalized Medicine

- Introduction, Definition, Pharmacogenetics, Categories of patients for personalized medicines Customized drug delivery systems
- Bioelectronic medicines
- 3D printing of pharmaceuticals
- Telepharmacy

Recommended Books (Latest editions)

1. Novel Drug Delivery System, Y.W. Chein, Vol 50, Marcel Dekker, NY.
2. Controlled Drug Delivery Systems, Robinson, Vol 29, Marcel Dekker, NY.
3. Transdermal Controlled Systemic Medications, YW Chein, Vol 31, Marcel Dekker, NY.
4. Bioadhesive DDS, E. Mathiowitz, Vol 98, Marcel Dekker, NY.
5. Nasal System Drug Delivery, K.S.E. Su, Vol 39, Marcel Dekker, NY.
6. Drug Delivery Devices, Vol 32, P Tyle Marcel Dekker, NY.
7. Polymers for Controlled Drug Delivery, P.J. Tarcha, CRC Press.
8. Pharmaceutical Biotechnology, Vyas, CBS, Delhi.

9. Biotechnology of Industrial Antibiotics, E.J. Vandamme, Marcel Dekker, NY.
10. Protein Formulation & Delivery, E.J. McNally, Vol 99, Marcel Dekker, NY.
11. Drug Targeting, M.H. Rubinstein, John Wiley, NY.

Course Code	Course Title	Teaching Load		Marks		Exam (hrs)		Credits
		L	P	Int.	Ext.	Int.	Ext.	
MIP104T	Intellectual Property Rights	4	-	25	75	1	3	4

Scope: This course is designed to impart knowledge and skills necessary to train the students to be on par with the routine of Industrial activities in drug regulatory affairs.

Objectives: Upon completion of the course, it is expected that the students will be able to

1. Assist in regulatory audit process.
2. Establish regulatory guidelines for drug and drug products.
3. Understand regulatory requirements for contract research organization.

Module 01 **12 Hours**

- Definition, Need for patenting
- Types of Patents
- Conditions to be satisfied by an invention to be patentable
- Introduction to patent search
- Parts of patents
- Filling of patents
- The essential elements of patent
- Guidelines for preparation of laboratory note book
- Non-obviousness in Patent

Module 02 **12 Hours**

- Role of GATT, TRIPS and WIPO

Module 03 **12 Hours**

- Brief introduction to Trademark protection and WHO Patents
- IPR's and its types
- Major bodies regulating Indian Pharmaceutical sector

Module 04 **12 Hours**

- Brief introduction to CDSCO, WHO, USFDA, EMEA, TGA

Module 05 **12 Hours**

- Regulatory requirements for contract research organization
- Regulations for Biosimilars

Recommended Books (Latest editions)

1. Pharmaceutical Process Validation: By Fra R. Berry and Robert A. Nash, Vol 57.
2. Applied Production and Operation Management by Evans, Anderson and Williams.
3. GMP for pharmaceuticals Material Management by K.K. Ahuja Published by CBS publishers.
4. ISO 9000-Norms and explanations.
5. GMP for pharmaceuticals- Willing S.H. Marcel and Dekker

Course Code	Course Title	Teaching Load		Marks		Exam (hrs)		Credits
		L	P	Int.	Ext.	Int.	Ext.	
MIP105P	Industrial Pharmacy Practical - I	-	12	50	100	6	6	6

1. Analysis of pharmacopoeial compounds and their formulations by UV Vis spectrophotometer
2. Simultaneous estimation of multi component containing formulations by UV spectrophotometry
3. Experiments based on HPLC / GC
4. Estimation of riboflavin/quinine sulphate by fluorimetry
5. Estimation of sodium/potassium by flame photometry
6. Effect of surfactants on the solubility of drugs
7. Effect of pH on the solubility of drugs
8. Stability testing of solution and solid dosage forms for photo degradation
9. Stability studies of drugs in dosage forms at 25°C, 60% RH and 40°C, 75% RH
10. Compatibility evaluation of drugs and excipients (DSC & FTIR)
11. Preparation and evaluation of different polymeric membranes
12. Formulation and evaluation of sustained release oral matrix tablet/ oral reservoir system
13. Formulation and evaluation of microspheres / microcapsules
14. Formulation and evaluation of trans-dermal drug delivery systems
15. Design and evaluation of face wash, body- wash, creams, lotions, shampoo, toothpaste, lipstick
16. Electrophoresis of protein solution
17. Preparation and evaluation of Liposome delivery systems

2nd SEMESTER

Course Code	Course Title	Teaching Load		Marks		Exam (hrs)		Credits
		L	P	Int.	Ext.	Int.	Ext.	
MIPH201T	Advanced Biopharmaceutics & Pharmacokinetics	4	-	25	75	1	3	4

Scope: This course is designed to impart knowledge and skills necessary for dose calculations, dose adjustments and to apply Biopharmaceutics theories in practical problem solving.

Objectives: Upon completion of this course students will be able understand

1. The basic concepts in biopharmaceutics and pharmacokinetics.
2. The use raw data and derive the pharmacokinetic models and parameters the best describe the process of drug absorption, distribution, metabolism and elimination.
3. The critical evaluation of biopharmaceutic studies involving drug product equivalency.
4. The design and evaluation of dosage regimens of the drugs using pharmacokinetic and biopharmaceutic parameters.

Module 01 **12 Hours**

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
- Correlation of in vivo data with in vitro dissolution data

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
- Solubility: Experimental methods
- Permeability: *in-vitro*, *in-situ* and *in-vivo* methods

Module 02 **12 Hours**

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 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

Module 03 **12 Hours**

Pharmacokinetics

- Basic considerations, pharmacokinetic models

Compartment Modelling

- One compartment model- IV bolus, IV infusion, extra-vascular
- Multi compartment model: Two compartments - model in brief

Non-Linear Pharmacokinetics

- Cause of non-linearity, Michaelis – Menten equation, estimation of k_{max} and v_{max}

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

Module 04 **12 Hours**

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, evaluation of bioequivalence studies
- Study designs, crossover study designs
- Evaluation of the data, bioequivalence example
- Study submission and drug review process
- Biopharmaceutics classification system
- Generic biologics (biosimilar drug products), clinical significance of bioequivalence studies, special concerns in bioavailability and bioequivalence studies
- Generic substitution

Module 05 **12 Hours**

Application of Pharmacokinetics

- Modified-release drug products
- Targeted Drug Delivery Systems and Biotechnological Products
- Relationship between pharmacokinetics and pharmacodynamics, generation of a pharmacokinetic– pharmacodynamic (PKPD) equation, pharmacokinetic and pharmacodynamic interactions
- Pharmacokinetics and pharmacodynamics of biotechnology drugs: introduction, proteins and peptides, monoclonal antibodies, oligonucleotides, vaccines (immunotherapy)
- Gene therapies

Recommended Books (Latest editions)

1. Biopharmaceutics and Clinical Pharmacokinetics by Milo Gibaldi, Philadelphia, Lea and Febiger.
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, Connecticut Appleton Century Crofts.
4. Textbook of Biopharmaceutics and Pharmacokinetics, Dr. Shobha Rani R. Hiremath, Prism Book.
5. Pharmacokinetics by Milo Gibaldi and D. Perrier, Marcel Dekker Inc.,New York.
6. Current Concepts in Pharmaceutical Sciences: Biopharmaceutics, Swarbrick. J, Leaand Febiger, Philadelphia.
7. Clinical Pharmacokinetics, Concepts and Applications, by MalcolmRowland and Thom N. Tozer, Lea and Febiger, Philadelphia.
8. Dissolution, Bioavailability and Bioequivalence, Abdou. H.M, Mack Publishing Company, Pennsylvania.
9. Biopharmaceutics and Clinical Pharmacokinetics, An Introduction, revised and expanded by Robert. E. Notari, Marcel Dekker Inc, New York and Basel.
10. Biopharmaceutics and Relevant Pharmacokinetics by John. G Wagner and M.Pemarowski, Drug Intelligence Publications, Hamilton, Illinois.
11. Encyclopedia of Pharmaceutical Technology, Vol 13,James Swarbrick, James. G.Boylan, Marcel Dekker Inc, New York.
12. Basic Pharmacokinetics , Sunil S JambhekarandPhilip J Breen,pharmaceutical press, RPS Publishing.
13. Absorption and Drug Development- Solubility, Permeability, and Charge State, Alex Avdeef, John Wiley & Sons, Inc.

Course Code	Course Title	Teaching Load		Marks		Exam (hrs)		Credits
		L	P	Int.	Ext.	Int.	Ext.	
MIP202T	Scale Up & Technology Transfer	4	-	25	75	1	3	4

Scope: This course is designed to impart knowledge and skills necessary to train the students to be on scale up, technology transfer process and industrial safety issues.

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

1. Manage the scale up process in pharmaceutical industry.
2. Assist in technology transfer.
3. Establish safety guidelines, which prevent industrial hazards.

Module 01 **12 Hours**

Pilot Plant Design

- Basic requirements for design, facility, equipment selection, for tablets, capsules, liquid orals, parentral and semisolid preparations

Scale Up

- Importance, Technology transfer from R & D to pilot plant to plant scale
- Process scale up for tablets, capsules, liquid orals, semisolids, parentral
- NDDS products –stress on formula, equipments, product uniformity, stability, raw materials, physical layout, input, in-process and finished product specifications, problems encountered during transfer of technology

Module 02 **12 Hours**

Validation

- General concepts, types, procedures & protocols, documentation, VMF
- Analytical method validation, clearing validation and vender qualification

Module 03 **12 Hours**

Equipment Qualification

- Importance, IQ, OQ, PQ for equipments – autoclave, DHS, membrane filter, rapid mixer granulator, cone blender, FBD, tablet compression machine, liquid filling and sealing machine
- Aseptic room validation

Module 04 **12 Hours**

Process Validation

- Importance, validation of mixing, granulation, drying, compression, tablet coating, liquid filling and sealing, sterilization, water process systems, environmental control

Module 05 **12 Hours**

Industrial Safety

- Hazards – fire, mechanical, electrical, chemical and pharmaceutical
- Monitoring & prevention systems
- Industrial effluent testing & treatment
- Control of environmental pollution

Recommended Books (Latest editions)

1. Pharmaceutical process validation, JR Berry, Nash, Vol 57, Marcel Dekker, NY.
2. Pharmaceutical Production facilities, design and applications, by GC Cole, Taylor and Francis.
3. Pharmaceutical project management, T.Kennedy, Vol 86, Marcel Dekker, NY.
4. The theory & Practice of Industrial Pharmacy, L.Lachman, H.A.Lieberman, Varghese Publ. Bombay.
5. Tablet machine instruments in pharmaceuticals, PR Watt, John Wiloy.
6. Pharmaceutical dosage forms, Tablets, Vol 1, 2, 3 by Lachman, Lieberman, Marcel Dekker, NY.
7. Pharmaceutical dosage forms, Parentral medications, Vol 1, 2 by K.E. Avis, Marcel Dekker, NY.
8. Dispersed system Vol 1, 2, 3 by Lachman, Lieberman, Marcel Dekker, NY.
9. Subrahmanyam, CVS, Pharmaceutical production and Management,Vallabh Prakashan, Dehli.

Course Code	Course Title	Teaching Load		Marks		Exam (hrs)		Credits
		L	P	Int.	Ext.	Int.	Ext.	
MIP203T	Pharmaceutical Production Technology	4	-	25	75	1	3	4

Scope: This course is designed to impart knowledge and skills necessary to train the students to be on par with the routine of Industrial activities in Production.

Objectives: Upon completion of this course, students will be able to

1. Handle the scheduled activities in a Pharmaceutical firm.
2. Manage the production of large batches of pharmaceutical formulations.

Module 01 **12 Hours**

Improved Tablet Production

- Tablet production process, unit operation improvements, granulation and pelletization equipments, continuous and batch mixing, rapid mixing granulators, rota granulators, spheronizers and marumerisers, and other specialized granulation and drying equipments
- Problems encountered

Coating Technology

- Process, equipments, particle coating, fluidized bed coating, application techniques
- Problems encountered

Module 02 **12 Hours**

Parenteral Production

- Area planning and environmental control, wall and floor treatment, fixtures and machineries, change rooms, personnel flow, utilities and utilities equipment location, engineering and maintenance

Module 03 **12 Hours**

Lyophilisation and Spray Drying Technology

- Principles, process, freeze-drying and spray drying equipments

Module 04 **12 Hours**

Capsule Production

Gastrointestinal Absorption Simulation

- Production process, improved capsule manufacturing and filling machines for hard and soft gelatin capsules
- Layout and problems encountered

Disperse Systems Production

- Production processes, applications of mixers, mills, disperse equipments including fine solids dispersion

- Problems encountered

Packaging Technology

- Types of packaging materials, machinery, labeling, package printing for different dosage forms

Module 05 **12 Hours**

Air Handling Systems

- Study of AHUs
- Humidity and temperature control
- Air filtration systems, dust collectors
- Water Treatment Process: techniques and maintenance – RO, DM, ultra – filtration, WFI

Recommended Books (Latest editions)

1. The Theory & Practice of Industrial Pharmacy, L. Lachman, Varghese Publ, Bombay.
2. Modern Pharmaceutics by Banker, Vol 72, Marcel Dekker, NY.
3. Pharmaceutical Dosage Forms, Vol 1, 2, 3 by Lachman, Lieberman, Marcel Dekker, NY.
4. Pharmaceutical Dosage Forms, Parentral medications, Vol 1, 2 by K.E. Avis, Marcel Dekker, NY.
5. Pharmaceutical Production Facilities, design and applications, by G.C. Cole, Taylor and Francis.
6. Dispersed System Vol 1, 2, 3 by Lachman, Lieberman, Marcel Dekker, NY.
7. Product design and testing of polymeric materials by N.P. Chezerisionoff.
8. Pharmaceutical Project Management, T.Kennedy, Vol 86, Marcel Dekker, NY.
9. Packaging Pharmaceutical and Health Care, H.Lockhard.
10. Quality Control of Packaging Materials in Pharmaceutical Industy, Kharburn, Marcel Dekker, NY.
11. Freeze drying / Lyophilization of Pharmaceuticals & Biological Products, L. Ray, Vol 96, Marcel Dekker, NY.
12. Tablet Machine Instrumentation in Pharmaceuticals, PR Watt, Ellis Horwoods, UK.

Course Code	Course Title	Teaching Load		Marks		Exam (hrs)		Credits
		L	P	Int.	Ext.	Int.	Ext.	
MIP204T	Entrepreneurship Management	4	-	25	75	1	3	4

Scope: This course is designed to impart knowledge and skills necessary to train the students on entrepreneurship management.

Objectives: Upon completion of the course, the students shall be able to understand

1. The Role of enterprise in national and global economy.
2. Dynamics of motivation and concepts of entrepreneurship.
3. Demands and challenges of Growth Strategies and Networking.

Module 01 **12 Hours**

Conceptual Frame Work

- Concept need and process in entrepreneurship development
- Role of enterprise in National and global economy
- Types of enterprise – Merits and Demerits
- Government policies and schemes for enterprise development
- Institutional support in enterprise development and management

Module 02 **12 Hours**

Entrepreneur

- Entrepreneurial motivation – dynamics of motivation
- Entrepreneurial competency– concepts
- Developing Entrepreneurial competencies - requirements and understanding the process of entrepreneurship development, self-awareness, interpersonal skills, creativity, assertiveness, achievement
- Factors affecting entrepreneur role

Module 03 **12 Hours**

Launching and Organising an Enterprise

- Environment scanning – Information, sources, schemes of assistance, problems
- Enterprise selection, market assessment, enterprise feasibility study, SWOT Analysis
- Resource mobilisation - finance, technology, raw material, site and manpower
- Costing and marketing management and quality control
- Feedback, monitoring and evaluation

Module 04 **12 Hours**

Growth Strategies and Networking

- Performance appraisal and assessment
- Profitability and control measures, demands and challenges

- Need for diversification
- Future Growth – Techniques of expansion and diversification, vision strategies
- Concept and dynamics, methods, joint venture, co-ordination and feasibility study

Module 05 **12 Hours**

Preparing Project Proposal to Start On New Enterprise

- Project work – feasibility report; planning, resource mobilisation and implementation

Recommended Books (Latest editions)

1. Akhauri, M.M.P: Entrepreneurship for Women in India, NIESBUD, New Delhi.
2. Hisrich, R.D & Brush, C.G. The Women Entrepreneurs, D.C. Health & Co., Toranto.
3. Hisrich, R.D. and Peters, M.P. Entrepreneurship – Starting, Developing and Managing a New Enterprise, Richard D., Inwin, INC, USA.
4. Meredith, G.G. etal. Practice of Entrepreneurship, ILO, Geneva.
5. Patel, V.C. Women Entrepreneurship – Developing New Entrepreneurs, Ahmedabad EDII.

Course Code	Course Title	Teaching Load		Marks		Exam (hrs)		Credits
		L	P	Int.	Ext.	Int.	Ext.	
MIP205P	Industrial Pharmacy Practical - II	-	12	50	100	6	6	6

1. Improvement of dissolution characteristics of slightly soluble drug by Solid dispersion technique
2. Comparison of dissolution of two different marketed products /brands
3. Protein binding studies of a highly protein bound drug & poorly protein bound drug
4. Bioavailability studies of Paracetamol (Animal)
5. Pharmacokinetic and IVIVC data analysis by Winnoline R software
6. In vitro cell studies for permeability and metabolism
7. Formulation and evaluation of tablets
8. Formulation and evaluation of capsules
9. Formulation and evaluation of injections
10. Formulation and evaluation of emulsion
11. Formulation and evaluation of suspension
12. Formulation and evaluation of enteric coating tablets
13. Preparation and evaluation of a freeze-dried formulation
14. Preparation and evaluation of a spray dried formulation

3rd SEMESTER

Course Code	Course Title	Teaching Load		Marks		Exam (hrs)		Credits
		L	P	Int.	Ext.	Int.	Ext.	
MRM301T	Research Methodology & Biostatistics	4	-	25	75	1	3	4

Module 01 **12 Hours**

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

Module 02 **12 Hours**

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

Module 03 **12 Hours**

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

Module 04 **12 Hours**

CPCSEA Guidelines for Laboratory Animal Facility

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

Module 05 **12 Hours**

Declaration of Helsinki

- History, introduction, basic principles for all medical research, and additional principles for medical research combined with medical care

Recommended Books (Latest editions)

1. Basic & Clinical Biostatistics, Beth Dawson and Robert G. Trapp. Lange Medical Books/McGraw-Hill Medical Publishing Division.
2. Research Methdology, R. Panneerselvam, PHI Learning Pvt. Limited, Delhi.
3. Methods in Biostatistics, B.K. Mahajan. JAYPEE Brothers Medical Publishers (P) Ltd.
4. CPCSEA Guidelines.
   A Handbook of Applied Statistics in Pharmacology, Katsumi Kobayashi and K. Sadasivan Pillai. CRC Press, Taylor & Francis Group.