Two-Year Post graduate Programme

Master of Pharmacy

INDUSTRIAL PHARMACY

Faculty of Pharmacy

Parul University

Vadodara, Gujarat, India

Faculty of Pharmacy
Master of Pharmacy in Industrial Pharmacy

1. Vision of the Department

To nurture pharmacy aspirants to serve the society with comprehensive subject knowledge, high professional values, excellent skills and outstanding research aptitude.

2. Mission of the Department

M1 Foster humanitarian values, passion for learning and creativity.
M2 Move towards high quality, futuristic educational and research ecosystem.
M3 Develop socially responsible future pharmacists; committed to creating self-reliant India.

3. Program Educational Objectives

PEO 1	Develop pharmaceutical professionals with thorough understanding of production principles, equipments and manufacturing methods in the field of pharmaceutical science.
PEO 2	Impart out of box thinking, problem solving approach and professional values in the students along with equipment handling and formulation development skills.

4. Program Learning Outcomes

Program Learning outcomes are statements conveying the intent of a program of study.

PLO 1	**In-depth Knowledge of Pharmaceutical Science**	Acquire in-depth knowledge of all the theories and principle involved in pharmaceutical science.
PLO 2	**Professional and Interpersonal Skill Development**	Demonstrate necessary skills in pharmaceutical science like working independently, communication, coordination, time management and organizational skills. The students will demonstrate an adaptable, flexible and effective approach towards organizational development.
PLO 3	**Competency Development**	Develop an ability to communicate scientific knowledge in in non-expert/lay term by adopting various modes of scientific
PLO 4	**Technical Expertise**	Enable student handle pharmaceutical instruments in experiments. The student will also learn to draft the protocols and results based on the various research experiments.

PLO 5	**Knowledge Enhancement and Project management abilities**	Gain the knowledge by continue updating of technologies involving management of Pharmaceutical Quality System for continual improvement of Process Performance and Product Quality.
PLO 6	**Innovative Approach for research**	Develop critical thinking quality, which leads to development of the novel ideas in the field of pharmaceutical science
PLO 7	**Individual and Team work**	Function individually as a member or as a leader in diverse team with technical expertise.
PLO 8	**Instrument handling skills**	Understand theoretical and practical skills of the instruments. To apply suitable methods, resources and standard procedures to handle all types of equipment for demonstrating Pharmaceutical activities
PLO 9	**Regulatory Compliance**	Understand the fine regulatory requirements for Pharmacy profession starting from drug discovery to final product marketing.
PLO 10	**Knowledge about Current Affairs and lifelong learning**	Exhibit latest and updated knowledge in the field of pharmacy and will develop the attitude and aptitude for lifelong learning.
PLO 11	**Environment and sustainability**	Understand the impacts of any research in societal and environmental contexts and develop any innovation with a second eye on environment and sustainability.

5. Program Specific Learning Outcomes

PSO 1	**In-depth Knowledge of Pharmaceutical Science and Production**	Post graduate student must possess in-depth knowledge of all the theories and principle involved in pharmaceutical science and pharmaceutical production. The student must master in formulation development, bio-pharmaceutics, production science, regulatory aspects of pharmaceutical industry.
PSO 2	**Innovative Approach & Entrepreneurship**	Post graduate student must develop out of the box thinking quality, which leads to development of the novel ideas in the field of pharmaceutical science. Post graduate student must know various aspects of entrepreneurship like IPR, requirements for the product approvals, production requirements and government policies and schemes for enterprise development.

6. Credit Framework

Semester wise Credit distribution of the programme	
Semester-1	26
Semester-2	26
Semester-3	21
Semester-4	20
Total Credits:	**93**

Category wise Credit distribution of the programme	
Category	**Credit**
Major Core	28
Multidisciplinary	08
Skill Development Courses	20
Research Project/Dissertation	37
Total Credits:	**93**

7. Program Curriculum

Semester 1						
Sr. No.	**Subject Code**	**Subject Name**	**Credit**	**Lect**	**Lab**	**Tut**
1	MIP101T	Modern Pharmaceutical Analytical Techniques	4	4	-	-
2	MIP102T	Pharmaceutical Formulation Development	4	4	-	-
3	MIP103T	Novel drug delivery systems	4	4	-	-
4	MIP104T	Intellectual Property Rights	4	4	-	-
5	MIP105P	Industrial Pharmacy Practical I	6	-	12	-
6		Seminar/Assignment	4	7		
		Total	**26**	**23**	**12**	**-**
Semester 2						
Sr. No.	**Subject Code**	**Subject Name**	**Credit**	**Lect**	**Lab**	**Tut**
1	MIP201T	Advanced Biopharmaceutics and Pharmacokinetics	4	4	-	-
2	MIP202T	Scale up and Technology Transfer	4	4	-	-
3	MIP203T	Pharmaceutical Production Technology	4	4	-	-
4	MIP204T	Entrepreneurship Management	4	4	-	-
5	MIP205P	Industrial Pharmacy Practical II	6	-	12	-
6		Seminar/Assignment	4	7		

		Total	**26**	**23**	**12**	**-**
Semester 3						
Sr. No.	**Subject Code**	**Subject Name**	**Credit**	**Lect**	**Lab**	**Tut**
1	MRM 301T	Research Methodology and Biostatistics	4	4	-	-
2	MIP302P	Pre Dissertation-I	1	-	1	-
3	MIP303P	Pre Dissertation-II	2	-	2	-
4	MIP304P	Pre Dissertation-III	14	-	28	-
		Total	21	**4**	31	**-**
Semester 4						
Sr. No.	**Subject Code**	**Subject Name**	**Credit**	**Lect**	**Lab**	**Tut**
1	MIP401P	Dissertation-I	1	-	1	-
2	MIP402P	Dissertation-II	16	-	31	-
3	MIP403P	Dissertation-III	3	-	3	-
		Total	**20**	**-**	**35**	**-**

ANNEXURE-III
Semester I

a. **Course Name: Modern pharmaceutical analytical techniques**
b. **Course Code: MIP101T**
c. **Prerequisite:** Having basic knowledge of pharmaceutical analysis
d. **Rationale:** 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
e. **Course Learning Objective:**

CLOBJ 1	Analysis of various drugs in single and combination dosage forms.
CLOBJ 2	Theoretical and practical skills of the instruments.

f. **Course Learning Outcomes:**

CLO 1	Apply various Spectroscopic techniques like UV, IR, AAS, Flame Emission and fluorescence spectroscopy.
CLO 2	Construct the concepts of NMR, FT NMR and 13C NMR.
CLO 3	Recognize & build the detail concepts of Mass spectroscopy.
CLO 4	Identify & build the detail concepts of Various Chromatographic Techniques.
CLO 5	Illustrate principles of separation of biomolecules and application of electrophoresis and analyse the crystal nature of compound by X-ray crystallography, learning about potentiometry and various thermal analytical methods.

g. **Teaching & Examination Scheme:**

Teaching Scheme				**Evaluation Scheme**					
L	**T**	**P**	**C**	**Internal Evaluation**			**ESE**		**Total**
				MSE	**CE**	**P**	**Theory**	**P**	
4	**-**	**-**	**4**	**15**	**10**	**-**	**75**	**-**	**100**

L- Lectures; **T**- Tutorial; **P-** Practical; **C**- Credit; **MSE-** Mid-Semester Evaluation, **CE**- Continuous Evaluation, **ESE-** End Semester Examination

h. **Course Content:**

Sr. No.	Content	Weightage (%)	Teaching Hours
1	UV-Visible spectroscopy: Introduction, Theory, Laws, Instrumentation associated with UV-Visible spectroscopy, Choice of solvents and solvent effect and Applications of UV-Visible spectroscopy. 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 Spectrofluorimetric: Theory of Fluorescence, Factors affecting fluorescence, Quenchers, Instrumentation and Applications of fluorescence spectrophotometer. Flame emission spectroscopy and atomic absorption spectroscopy: Principle, Instrumentation, Interferences and Applications.	**18.33**	11
2	NMR spectroscopy: Quantum numbers and their role in NMR, Principle, Instrumentation, Solvent requirement in NMR, Relaxation process, NMR signals in various compounds, Chemical shift, Factors influencing chemical shift, Spin-Spin coupling, Coupling constant, Nuclear magnetic double resonance, Brief outline of principles of FT-NMR and 13C NMR. Applications of NMR spectroscopy.	**18.33**	11
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 Mass spectroscopy.	**18.33**	11
4	Chromatography: Principle, apparatus, instrumentation, chromatographic parameters, factors affecting resolution and applications of the following: a) Paper chromatography b) Thin Layer chromatography c) Ion exchange chromatography d) Column chromatography e) Gas chromatography f) High Performance Liquid chromatography g) Affinity chromatography	**18.33**	11
5	Electrophoresis: Principle, Instrumentation, Working conditions, factors affecting separation and applications of the following: a) Paper electrophoresis b) Gel electrophoresis c) Capillary electrophoresis d) Zone electrophoresis e) Moving boundary electrophoresis f) Iso electric focusing X ray Crystallography: Production of X rays, Different X ray methods, Bragg ‘s law, Rotating crystal technique, X ray powder technique, Types of crystals and applications of X-ray diffraction.	**18.33**	11

6.	Immunological Assays: Radioimmunology assay (RIA), ELISA (Theory & practical) and knowledge on Bioluminescence assays.	**8.33**	5
Total		**100**	**60**

i. Text Book and Reference Book:

1. Spectrometric Identification of Organic compounds - Robert M Silverstein, Sixth edition, John Wiley & Sons, 2004.
2. Principles of Instrumental Analysis - Doglas A Skoog, F. James Holler, Timothy A. Nieman, 5th edition, Eastern press, Bangalore, 1998.
3. Instrumental methods of analysis – Willards, 7th edition, CBS publishers.
4. Practical Pharmaceutical Chemistry – Beckett and Stenlake, Vol II, 4th edition, CBS Publishers, New Delhi, 1997.
5. Organic Spectroscopy - William Kemp, 3rd edition, ELBS, 1991.
6. Quantitative Analysis of Drugs in Pharmaceutical formulation - P D Sethi, 3rd Edition, CBS Publishers, New Delhi, 1997.
7. Pharmaceutical Analysis- Modern methods – Part B - J W Munson, Volume 11, Marcel Dekker

a. **Course Name: Pharmaceutical formulation development**
b. **Course Code: MIP102T**
c. **Prerequisite:** Having basic knowledge of pharmaceutical formulations
d. **Rationale:** 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.
e. **Course Learning Objective:**

CLOBJ 1	Schedule activities in a pharmaceutical firm.
CLOBJ 2	Pre- formulation studies of pilot batches of pharmaceutical industry.
CLOBJ 3	Sketch the significance of dissolution and product stability

f. **Course Learning Outcomes:**

CLO 1	Make use of principles behind various preformulation parameters related to formulation development.
CLO 2	Acquire in depth knowledge of the different formulation Additives used for formulation development & Design of Experiments.
CLO 3	Build concepts of solubility, solubilisation and solubility enhancement techniques.
CLO 4	Illustrate dissolution theories, concept of dissolution and IVIVC.
CLO 5	Relate ICH guideline, Product stability and stability related issues of the formulation.

g. **Teaching & Examination Scheme:**

Teaching Scheme				**Evaluation Scheme**					
L	**T**	**P**	**C**	**Internal Evaluation**			**ESE**		**Total**
				MSE	**CE**	**P**	**Theory**	**P**	
4	**-**	**-**	**4**	**15**	**10**	**-**	**75**	**-**	**100**

L- Lectures; **T**- Tutorial; **P-** Practical; **C**- Credit; **MSE-** Mid-Semester Evaluation, **CE**- Continuous Evaluation, **ESE-** End Semester Examination

h. **Course Content:**

Sr. No.	**Content**	**Weightage (%)**	**Teaching Hours**
1	Preformulation Studies: Molecular optimization of APIs (drug substances), crystal morphology and variations,	**20**	12

	powder flow, structure modification, drug-excipient compatibility studies, methods of determination.		
2	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.	**20**	12
3	Solubility: Importance, experimental determination, phase solubility analysis, pH-solubility profile, solubility techniques to improve solubility and utilization of analytical methods – cosolvency, salt formation, complexation, solid dispersion, micellar solubilisation and hydrotropy.	**20**	12
4	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. Biorelevant media, in-vitro and in-vivo correlations, levels of correlations.	**20**	12
5	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.	**20**	12
Total		**100**	**60**

i. Text Book and Reference Book:

1. Lachman L, Lieberman HA, Kanig JL. The Theory and Practice of Industrial Pharmacy, 3rd ed., Varghese Publishers, Mumbai 1991.
2. Sinko PJ. Martin's physical pharmacy and pharmaceutical sciences, 5 ed., B.I. Publications Pvt. Ltd, Noida, 2006.
3. Lieberman HA, Lachman L, Schwartz JB. Pharmaceutical dosage forms: nd tablets Vol. I-III, 2 ed., CBS Publishers & distributors, New Delhi, 2005.
4. Conners KA. A Text book of pharmaceutical analysis.
5. Wells JI. Pharmaceutical Preformulation: The physicochemical properties of drug substances. Ellis Horwood Ltd., England, 1998.
6. Yalkowsky SH. Techniques of solubilization of drugs. Vol-12. Marcel Dekker Inc., New York, 1981
7. Dressman J, Kramer J. Pharmaceutical dissolution testing. Saurah printer pvt. Ltd., New Delhi,2005.
8. Sethi PD. Quantitative analysis of drugs in pharmaceutical formulations, 3rd ed., CBS publications, New Delhi, 2008.
9. Carstensen JT, Rhodes CT. Drug stability principles and practices, CBS Publishers & distributors, New Delhi, 2005. 3rd ed.

10. Yoshioka S, Stella VJ. Stability of drugs and dosage forms, Springer (India) Pvt. Ltd., New Delhi, 2006.
11. Banker GS, Rhodes CT. Modern Pharmaceutics, 4 Inc, New York, 2005.
12. W. Grimm - Stability testing of drug products. ed., Marcel Dekker
13. Mazzo DJ. International stability testing. Eastern Press Pvt. Ltd., Bangalore, 1999.
14. Beckett AH, Stenlake JB. Practical pharmaceutical th chemistry, Part I & II., 4 2004. ed., CBS Publishers & distributors, New Delhi,
15. Indian Pharmacopoeia. Controller of Publication. Delhi, 1996.
16. British Pharmacopoeia. British Pharmacopoeia Commission Office, London, 2008.
17. United States Pharmacopoeia. United States Pharmacopeial Convention, Inc, USA, 2003.
18. Encyclopaedia of Pharm. Technology, Vol I – III.

a. **Course Name: Novel drug delivery system**
b. **Course Code: MIP103T**
c. **Prerequisite:** Having basic knowledge of drug delivery systems
d. **Rationale:** This course is designed to impart knowledge and skills necessary to train the students in the area of novel drug delivery systems.
e. **Course Learning Objective:**

CLOBJ 1	Recognize the need, concept, design and evaluation of various customized, sustained and controlled release dosage
CLOBJ 2	Formulate and evaluate various novel drug delivery

f. **Course Learning Outcomes:**

CLO 1	Build concept and models of NDDS, CDDS, rate programmed delivery, orders of drug release and carriers for drug delivery.
CLO 2	Classify and illustrate various DDS like ODDS, mucoadhesive DDS, pulsatile, colon specific, liquid sustained release systems and ocular delivery system.
CLO 3	Acquire in depth knowledge of transdermal drug delivery systems, & sub micron cosmeceuticals formulation, evaluation and its regulatory aspects.
CLO 4	Build concept of targeted drug delivery systems: design, development and evaluation, and methods of drug targeting.
CLO 5	Illustrate protein / peptide drug delivery systems, biotechnology in drug delivery systems, personalized medicine.

g. **Teaching & Examination Scheme:**

Teaching Scheme				**Evaluation Scheme**					
L	**T**	**P**	**C**	**Internal Evaluation**			**ESE**		**Total**
				MSE	**CE**	**P**	**Theory**	**P**	
4	**-**	**-**	**4**	**15**	**10**	**-**	**75**	**-**	**100**

L- Lectures; **T**- Tutorial; **P-** Practical; **C**- Credit; **MSE-** Mid-Semester Evaluation, **CE**- Continuous Evaluation, **ESE-** End Semester Examination

h. **Course Content:**

Sr. No.	**Content**	**Weightage (%)**	**Teaching Hours**
1	Concept & Models for NDDS: Classification of rate-controlled drug delivery systems (DDS), rate programmed release, activation modulated & feedback	**20**	**12**

	regulated DDS, effect of system parameters in controlled drug delivery, computation of desired release rate and dose for controlled release DDS, pharmacokinetic design for DDS – intermittent, zero order & first order release. Carriers for Drug Delivery: Polymers / co-polymersintroduction, classification, characterization, polymerization techniques, application in CDDS / NDDS, biodegradable & natural polymers.		
2	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	**20**	**12**
3	Transdermal Drug Delivery Systems: Theory, design, formulation & evaluation including iontophoresis and other latest developments in skin delivery	**13.33**	**8**
4	Sub-Micron Cosmeceuticals: Biology, formulation science and evaluation of various cosmetics for skin, hair, nail, eye etc. and it's regulatory aspects.	**6.66**	**4**
5	Targeted Drug Delivery Systems: Importance, concept, biological process and events involved in drug targeting, design, formulation & evaluation, methods in drug targeting – nanoparticles, liposomes, niosomes, pharmacosomes, resealed erythrocytes, microspheres, magnetic microspheres. Specialized pharmaceutical emulsions – multiple emulsions, micro-emulsions.	**20**	**12**
6.	Protein / Peptide Drug Delivery Systems: Concepts, delivery techniques, formulation, stability testing, causes of protein destabilization, stabilization methods.	**6.66**	**4**
7.	Biotechnology in Drug Delivery Systems: Brief review of major areas-recombinant DNA technology, monoclonal antibodies, gene therapy.	**6.66**	**4**
8.	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.	**6.66**	**4**
Total		**100**	**60**

i. Text Book and Reference Book:

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 Drug Delivery System, 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.

a. **Course Name: Intellectual property rights**
b. **Course Code: MIP104T**
c. **Prerequisite:** Having basic information on patents
d. **Rationale:** 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
e. **Course Learning Objective:**

CLOBJ 1	Assist in Regulatory Audit process.
CLOBJ 2	Establish regulatory guidelines for drug and drug products
CLOBJ 3	The Regulatory requirements for contract research organization

f. **Course Learning Outcomes:**

CLO 1	Build concept of patent, patent filing, patent search methods and related guidelines.
CLO 2	Recognize role of GATT, TRIPS, WIPO.
CLO 3	Extend Trademark, and WHO Patents, other forms of IPRs and major bodies regulating Indian Pharmaceutical sector.
CLO 4	Sketch detail about CDSCO and various regulatory agencies of the world.
CLO 5	Illustrate regulatory requirements for contract research organization and biosimilars.

g. **Teaching & Examination Scheme:**

Teaching Scheme				**Evaluation Scheme**					
L	**T**	**P**	**C**	**Internal Evaluation**			**ESE**		**Total**
				MSE	**CE**	**P**	**Theory**	**P**	
4	**-**	**-**	**4**	**15**	**10**	**-**	**75**	**-**	**100**

L- Lectures; **T-** Tutorial; **P-** Practical; **C-** Credit; **MSE-** Mid-Semester Evaluation, **CE-** Continuous Evaluation, **ESE-** End Semester Examination

h. **Course Content:**

Sr. No.	**Content**	**Weightage (%)**	**Teaching Hours**
1	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.	**20**	**12**

2	Role of GATT, TRIPS, and WIP	**20**	**12**
3	Brief introduction to Trademark protection and WHO Patents. IPR's and its types, Major bodies regulating Indian Pharmaceutical sector	**20**	**12**
4	Brief introduction to CDSCO. WHO, USFDA, EMEA, TGA, MHRA, MCC, ANVISA	**20**	**12**
5	Regulatory requirements for contract research organization. Regulations for Biosimilars	**20**	**12**
		100	**60**

i. **Text Book and Reference Book:**

1. Pharmaceutical Process Validation: By Fra R. Berry and Robert A. Nash, Vol 57, 2nd Edition
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.

ANNEXURE-IV

Semester-I

a. **Course Name: Industrial Pharmacy Practical**-I
b. **Course Code: MIP105P**
c. **Prerequisite:** Having basic knowledge of pharmaceutical practicals
d. **Rationale:** The subject deals with advanced analytical instrumental techniques for identification, characterization and quantification of drugs. Alongside also deals with formulation, evaluation and characterization of various dosage forms.
e. **Course Learning Objective:**

CLOBJ 1	After completion of course student is able to know analytical instrumental techniques for identification, characterization and quantification of drugs
CLOBJ 2	formulation, evaluation and characterization of various dosage forms

f. **Course Learning Outcomes:**

CLO 1	Analyse organic compounds by discussing the principle and methodology of spectroscopic and chromatographic techniques.
CLO 2	Formulate and evaluate various dosage forms.

g. **Teaching & Examination Scheme:**

Teaching Scheme				**Evaluation Scheme**					
L	**T**	**P**	**C**	**Internal Evaluation**			**ESE**		**Total**
				MSE	**CE**	**P**	**Theory**	**P**	
-	**-**	**12**	**6**			**50**		**100**	**150**

L- Lectures; **T**- Tutorial; **P-** Practical; **C**- Credit; **MSE-** Mid-Semester Evaluation, **CE**- Continuous Evaluation, **ESE-** End Semester Examination

h. **Text Book and Reference Book:**
1. Indian Pharmacopoeia 2022.
2. US Pharmacopoeia**2023**

i. **Experiment List:**

Exp. No.	**Name of the Experiment**
1	Analysis of pharmacopoeia 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

Exp. No.	Name of the Experiment
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 RH. ^{o}C, 60% RH and 40 ^{o}C, 75%.
10	Compatibility evaluation of drugs and excipients (DSC)
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 transdermal 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 system.

ANNEXURE-III
Semester II

a. **Course Name: Advanced biopharmaceutics & pharmacokinetics**
b. **Course Code: MIP201T**
c. **Prerequisite:** Having basic knowledge of biopharmaceutics & pharmacokinetics
d. **Rationale:** This course is designed to impart knowledge and skills necessary for dose calculations, and dose adjustments and to apply Biopharmaceutics theories in practical problem solving.
e. **Course Learning Objective:**

CLOBJ 1	Infer basic concepts in Biopharmaceutics and pharmacokinetics.
CLOBJ 2	Use the raw data and derive the pharmacokinetic models and parameters the best describes the process of drug absorption, distribution, metabolism and elimination.
CLOBJ 3	Critically evaluate Biopharmaceutics studies involving drug product equivalency.
CLOBJ 4	Design and evaluate dosage regimens of the drugs using pharmacokinetic and biopharmaceutic parameters.

f. **Course Learning Outcomes:**

CLO 1	Acquire in depth knowledge of mechanism and factors affecting drug absorption from GIT.
CLO 2	Infer biopharmaceutical considerations in drug product design and in-vitro drug product performance.
CLO 3	Acquire in depth knowledge of pharmacokinetic models and drug interactions.
CLO 4	Acquire in depth knowledge of drug product performance *in vivo*, bioavailability and bioequivalence concepts.
CLO 5	Employ applications of pharmacokinetics related to Modified-Release Drug Products, Targeted Drug Delivery Systems & biotechnological products and drug interactions.

g. **Teaching & Examination Scheme:**

Teaching Scheme				**Evaluation Scheme**					
L	**T**	**P**	**C**	**Internal Evaluation**			**ESE**		**Total**
				MSE	**CE**	**P**	**Theory**	**P**	
4	**-**	**-**	**4**	**15**	**10**	**-**	**75**	**-**	**100**

L- Lectures; **T-** Tutorial; **P-** Practical; **C-** Credit; **MSE-** Mid-Semester Evaluation, **CE-** Continuous Evaluation, **ESE-** End Semester Examination

h. **Course Content:**

Sr. No.	Content	Weightage (%)	Teaching Hours
1	Drug Absorption From The Gastrointestinal Tract: Gastrointestinal tract, Mechanism of drug absorption, Factors affecting, pH–partition theory, 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.	**20**	**12**
2	Biopharmaceutic Considerations in Drug Product Design and In Vitro Drug Product Performance: Introduction, Biopharmaceutic Factors Affecting Drug Bioavailability, Rate Limiting Steps in Drug Absorption, Physicochemical Nature of the 12 Hrs 63 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	**20**	**12**
3	Pharmacokinetics: Basic considerations, Pharmacokinetic models, Compartment modelling: 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 Kmax and Vmax. Drug interactions: Introduction, The effect of protein-binding interactions, The effect of tissue-binding interactions, Cytochrome P450-based drug interactions, Drug interactions linked to transporters.	**20**	**12**

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, The Biopharmaceutics Classification System, Generic Biologics (Biosimilar Drug Products),Clinical Significance of Bioequivalence Studies, Special Concerns in Bioavailability and Bioequivalence Studies, Generic Substitution.	**20**	**12**
5	Application of Pharmacokinetics: Modified-Release Drug Products, Targeted Drug Delivery Systems and Biotechnological Products. Relationship between Pharmacokinetics including 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.	**20**	**12**
Total		**100**	**60**

i. **Text Book and Reference Book:**

1. Biopharmaceutics and Clinical Pharmacokinetics by Milo Gibaldi, 4th edition, Philadelphia, Lea and Febiger, 1991
2. Biopharmaceutics and Pharmacokinetics, A. Treatise, D .M. Brahmankar and Sunil B. Jaiswal, Vallab Prakashan, Pitampura, Delhi
3. Applied Biopharmaceutics and Pharmacokinetics by Shargel. Land YuABC, 2nd edition, Connecticut Appleton Century Crofts, 1985
4. Textbook of Biopharmaceutics and Pharmacokinetics, Dr. Shobha Rani R. Hiremath, Prism Book
5. Pharmacokinetics by Milo Gibaldi and D. Perrier, 2nd edition, Marcel Dekker Inc., New York, 1982
6. Current Concepts in Pharmaceutical Sciences: Biopharmaceutics, Swarbrick. J, Lea and Febiger, Philadelphia, 1970
7. Clinical Pharmacokinetics, Concepts and Applications 3rd edition by Malcolm Rowland and Thom~ N. Tozer, Lea and Febiger, Philadelphia, 1995
8. Dissolution, Bioavailability and Bioequivalence, Abdou. H.M, Mack Publishing Company, Pennsylvania 1989
9. Biopharmaceutics and Clinical Pharmacokinetics, An Introduction, 4th edition, revised and expande by Robert. E. Notari, Marcel Dekker Inc, New York and Basel,1987.
10. Biopharmaceutics and Relevant Pharmacokinetics by John. G Wagner and M.Pemarowski, 1st edition, Drug Intelligence Publications, Hamilton, Illinois, 1971.
11. Encyclopedia of Pharmaceutical Technology, Vol 13, James Swarbrick, James. G.Boylan, Marcel Dekker Inc, New York, 1996.

12. Basic Pharmacokinetics,1st edition, Sunil S Jambhekar and Philip J Breen, pharmaceutical press, RPS Publishing, 2009.
13. Absorption and Drug Development- Solubility, Permeability, and Charge State, Alex Avdeef, John Wiley & Sons, Inc, 2003

a. **Course Name: Scale up and technology transfer**
b. **Course Code: MIP202T**
c. **Prerequisite:** Having a basic knowledge of industrial manufacturing
d. **Rationale:** 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.
e. **Course Learning Objective:**

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

f. **Course Learning Outcomes:**

CLO 1	Acquire in depth knowledge of pilot plant design and scale up process for pharmaceutical Formulations.
CLO 2	Build concepts of validation, its types and construct validation protocols.
CLO 3	Extend concept of equipment qualification and validation of various equipment and aseptic area.
CLO 4	Acquire knowledge of process validations and environmental controls.
CLO 5	Infer concepts of industrial safety: hazards, monitoring & prevention, effluent testing, treatment and environmental pollution control.

g. **Teaching & Examination Scheme:**

Teaching Scheme				**Evaluation Scheme**					
L	**T**	**P**	**C**	**Internal Evaluation**			**ESE**		**Total**
				MSE	**CE**	**P**	**Theory**	**P**	
4	**-**	**-**	**4**	**15**	**10**	**-**	**75**	**-**	**100**

L- Lectures; **T**- Tutorial; **P-** Practical; **C**- Credit; **MSE-** Mid-Semester Evaluation, **CE**- Continuous Evaluation, **ESE-** End Semester Examination

h. **Course Content:**

Sr. No.	**Content**	**Weightage (%)**	**Teaching Hours**
1	Pilot plant design: Basic requirements for design, facility, equipment selection, for tablets, capsules, liquid orals, parenteral 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, parenteral, NDDS products – stress on formula,	**20**	**12**

	equipments, product uniformity, stability, raw materials, physical layout, input, in-process and finished product specifications, problems encountered during transfer of technology.		
2	Validation: General concepts, types, procedures & protocols, documentation, VMF. Analytical method validation, cleaning validation and vender qualification.	**20**	**12**
3	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.	**20**	**12**
4	Process validation: Importance, validation of mixing, granulation, drying, compression, tablet coating, liquid filling and sealing, sterilization, water process systems, environmental control.	**20**	**12**
5	Industrial safety: Hazards – fire, mechanical, electrical, chemical and pharmaceutical, Monitoring & prevention systems, industrial effluent testing & treatment. Control of environmental pollution.	**20**	**12**
Total		**100**	**60**

i. Text Book and Reference Book:

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, 2007, Vallabh Prakashan,Dehli.

a. **Course Name: Pharmaceutical production technology**
b. **Course Code: MIP203T**
c. **Prerequisite:** Having a basic knowledge of pharmaceutical production
d. Rationale: 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
e. **Course Learning Objective:**

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

f. **Course Learning Outcomes:**

CLO 1	Acquire in depth knowledge of tablet production, coating technology and various areas of improvement.
CLO 2	Recognize production environment requirement, various utilities and maintenance of parenteral production.
CLO 3	Acquire in depth knowledge of lyophilization and spray drying technology.
CLO 4	Demonstrate capsule production, disperse systems production and packaging technology.
CLO 5	Acquire knowledge of Air Handling Systems, Water Treatment Process, Techniques and maintenance.

g. **Teaching & Examination Scheme:**

Teaching Scheme				**Evaluation Scheme**					
L	**T**	**P**	**C**	**Internal Evaluation**			**ESE**		**Total**
				MSE	**CE**	**P**	**Theory**	**P**	
4	**-**	**-**	**4**	**15**	**10**	**-**	**75**	**-**	**100**

L- Lectures; **T**- Tutorial; **P-** Practical; **C**- Credit; **MSE-** Mid-Semester Evaluation, **CE**- Continuous Evaluation, **ESE-** End Semester Examination

h. Course Content:

Sr. No.	**Content**	**Weightage (%)**	**Teaching Hours**
1	Improved Tablet Production: Tablet production process, unit 1. 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.	**20**	**12**

	Problems encountered. Coating Technology: Process, equipments, particle coating, fluidized bed coating, application techniques. Problems encountered.		
2	Parenteral Production: Area planning & environmental control, wall and floor treatment, fixtures and machineries, change rooms, personnel flow, utilities & utilities equipment location, engineering and maintenance.	**20**	**12**
3	Lyophilization & Spray drying Technology: Principles, process, freeze-drying and spray drying equip	**20**	**12**
4	Capsule Production: 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, labelling, package printing for different dosage form.	**20**	**12**
5	Air Handling Systems: Study of AHUs, humidity & temperature control, air filtration systems, dust collectors. Water Treatment Process: Techniques and maintenance – RO, DM, ultra – filtration, WFI.	**20**	**12**
Total		**100**	**60**

i. Text Book and Reference Book:

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.

a. **Course Name: Entrepreneurship Management**

b. **Course Code: MIP204T**

c. **Prerequisite:** Having a basic knowledge of venture set-up

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

e. **Course Learning Objective:**

CLOBJ 1	Recognize the Role of enterprise in national and global economy
CLOBJ 2	Dynamics of motivation and concepts of entrepreneurship
CLOBJ 3	Demands and challenges of Grow

f. **Course Learning Outcomes:**

CLO 1	Acquire knowledge of entrepreneurship Conceptual frame work, various government policies and schemes for enterprise development.
CLO 2	Categorize various traits of entrepreneur and how to develop entrepreneurial competencies.
CLO 3	Outline launching and organising an enterprise.
CLO 4	Build growth strategies, networking, techniques of expansion and diversification of an enterprise.
CLO 5	Construct project proposal, feasibility report and project planning.

g. **Teaching & Examination Scheme:**

Teaching Scheme				**Evaluation Scheme**					
L	**T**	**P**	**C**	**Internal Evaluation**			**ESE**		**Total**
				MSE	**CE**	**P**	**Theory**	**P**	
4	**-**	**-**	**4**	**15**	**10**	**-**	**75**	**-**	**100**

L- Lectures; **T-** Tutorial; **P-** Practical; **C-** Credit; **MSE-** Mid-Semester Evaluation, **CE-** Continuous Evaluation, **ESE-** End Semester Examination

h. **Course Content:**

Sr. No.	**Content**	**Weightage (%)**	**Teaching Hours**
1	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	**20**	**12**

	development. Institutional support in enterprise development and management.		
2	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.	**20**	**12**
3	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.	**20**	**12**
4	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.	**20**	**12**
5	Preparing Project Proposal To Start On New Enterprise Project work – Feasibility report; Planning, resource mobilisation and implementation.	**20**	**12**
Total		**100**	**60**

i. **Text Book and Reference Book:**

1. Akhauri, M.M.P.(1990): Entrepreneurship for Women in India, NIESBUD, New Delhi.
2. Hisrich, R.D & Brush, C.G.(1996) The Women Entrepreneurs, D.C. Health & Co., Toranto.
3. Hisrich, R.D. and Peters, M.P. (1995): Entrepreneurship – Starting, Developing and Managing a New Enterprise, Richard D., Inwin, INC, USA.
4. Meredith, G.G. etal (1982): Practice of Entrepreneurship, ILO, Geneva.
5. Patel, V.C. (1987): Women Entrepreneurship – Developing New Entrepreneurs, Ahmedabad EDII.

ANNEXURE-IV

Semester-II

a. **Course Name: Industrial Pharmacy practical- II**
b. **Course Code: MIP205P**
c. **Prerequisite:** Having a basic knowledge of pharmaceutical formulations
d. **Rationale:** The subject deals with advanced analytical instrumental techniques for identification, characterization and quantification of drugs. Alongside also deals with formulation, evaluation and characterization of various dosage forms.
e. **Course Learning Objective:**

CLOBJ 1	Sketch the need, concept, design and evaluation of various customized, sustained and controlled release dosage forms.
CLOBJ 2	Formulate and evaluate various novel drug delivery system

f. **Course Learning Outcomes:**

CLO 1	Perform pre-formulation parameters of drug and to formulate various novel dosage forms.
CLO 2	Evaluate various novel dosage forms.

g. **Teaching & Examination Scheme:**

Teaching Scheme				**Evaluation Scheme**					
L	**T**	**P**	**C**	**Internal Evaluation**			**ESE**		**Total**
				MSE	**CE**	**P**	**Theory**	**P**	
-	**-**	**12**	**6**	**-**	**-**	**50**	**-**	**100**	**150**

L- Lectures; **T-** Tutorial; **P-** Practical; **C-** Credit; **MSE-** Mid-Semester Evaluation, **CE-** Continuous Evaluation, **ESE-** End Semester Examination

h. **Text Book and Reference Book:**
1. Indian Pharmacopoeia 2022.
2. US Pharmacopoeia 2023

i. **Experiment List:**

Exp. No.	**Name of the Experiment**
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

Exp. No.	Name of the Experiment
4	Bioavailability studies of Paracetamol (Animal)
5	Pharmacokinetic and IVIVC data analysis by WinnolineR software
6	In vitro cell studies for permeability and metabolism
7	Formulation and evaluation of tablet
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.

ANNEXURE-III
Semester III

a. **Course Name: Research Methodology and Biostatistics**
b. Course Code: MRM301T
c. Prerequisite: Having a basic knowledge of pharmaceutical research and statistics
d. Rationale: The course is designed to study research methodology in terms of basic concepts of statistical analysis, principles of medical research, ethics and patents, maintenance of laboratory animals and design research work.
e. Course Learning Objective:

CLOBJ 1	Analyse the value, scope, objectives and requirements of research
CLOBJ 2	Discuss the basic concepts of statistical analysis
CLOBJ 3	Apply the basic principles of medical research and ethics.
CLOBJ 4	Infer the guidelines for the maintenance of laboratory animals.
CLOBJ 5	Create efficiency in solving practical difficulties and design research work.

f. **Course Learning Outcomes:**

CLO 1	Extend general research methodology to select the appropriate study design and develop appropriate research hypothesis for a research project
CLO 2	Develop the basic concepts of biostatistics and different parametric and non-parametric tests
CLO 3	Recognize the functions of ethics committees in medical research
CLO 4	Outline CPCSEA guidelines for laboratory animal facility
CLO 5	Discuss the genesis of bioethics with special reference to Helsinki declaration

g. **Teaching & Examination Scheme:**

Teaching Scheme				**Evaluation Scheme**					
L	**T**	**P**	**C**	**Internal Evaluation**			**ESE**		**Total**
				MSE	**CE**	**P**	**Theory**	**P**	
4	**-**	**-**	**4**	**15**	**10**	**-**	**75**	**-**	**100**

L- Lectures; **T**- Tutorial; **P-** Practical; **C**- Credit; **MSE-** Mid-Semester Evaluation, **CE**- Continuous Evaluation, **ESE-** End Semester Examination

h. **Course Content:**

Sr. No.	Content	Weightage (%)	Teaching Hours
1	**UNIT – I** General Research Methodology: Research, objective, requirements, practical difficulties, review of literature, study design, types of studies, strategies to eliminate errors/bias, controls, randomization, crossover design, placebo, blinding techniques.	**20**	**12**
2	**UNIT – II** Biostatistics: Definition, application, sample size, importance of sample size, factors influencing sample size, dropouts, statistical tests of significance, type of significance tests, parametric tests(students "t" test, ANOVA, Correlation coefficient, regression), non-parametric tests (wilcoxan rank tests, analysis of variance, correlation, chi square test), null hypothesis, P values, degree of freedom, interpretation of P values.	**20**	**12**
3	**UNIT – III** Medical Research: History, values in medical ethics, autonomy, beneficence, non-maleficence, double effect, conflicts between autonomy and beneficence/non-maleficence, euthanasia, informed consent, confidentiality, criticisms of orthodox medical ethics, importance of communication, control resolution, guidelines, ethics committees, cultural concerns, truth telling, online business practices, conflicts of interest, referral, vendor relationships, treatment of family members, sexual relationships, fatality.	**20**	**12**
4	**UNIT – IV** CPCSEA guidelines for laboratory animal facility: Goals, veterinary care, quarantine, surveillance, diagnosis, treatment and control of disease, personal hygiene, location of animal facilities to laboratories, anesthesia, euthanasia, physical facilities, environment, animal husbandry, record keeping, SOPs, personnel and training, transport of lab animals.	**20**	**12**
5	**UNIT – V** Declaration of Helsinki: History, introduction, basic principles for all medical research, and additional principles for medical research combined with medical care.	**20**	**12**
Total		**100**	**60**

i. Text Book and Reference Book:

1.Research Methodology : Methods & Techniques, C.R. Kothari, Viswa Prakashan,
2. Research Methods- A Process of Inquiry, Graziano, A.M., Raulin, M.L, Pearson Publications.
3. Pharmaceutical Statistics: Practical and Clinical Applications, Sanford Bolton and Charles Bon.
4. Thesis projects in Science & Engineering – Richard M. Davis.
5. Thesis & Assignment – Jonathan Anderson
6. Writing a technical paper- Donald Menzel
7. How to Write a Thesis: Murray, R. Tata McGraw Hill
8. Writing For Academic Journals, Murray, R., McGraw Hill International.
9. A Handbook of Academic Writing, Murray, R. and Moore, S., Tata McGraw Hill International
10. Writing for Publication, Henson, K.T., Allyn & Bacon.
11. Effective Business Report Writing –Leland Brown
12. Manual for evaluation of industrial projects-United Nations
13. Practical Introduction to copyright.- Gavin Mcfarlane
14. Operational research by Dr. S.D.Sharma, Kedarath, Ramnath & Co.
15. Various Guidelines like: ICH – GCP- International Conference on Harmonisation of Technical requirements for registration of pharmaceuticals for human use. ICH Harmonised Tripartite Guideline. Guideline for Good Clinical Practice. E6
16. ICMR Guideline – Ethical Guidelines for Biomedical Research on Human Subjects. Indian GCP – Central Drugs Standard Control Organization.
17. Good Clinical Practices – Guidelines for Clinical Trials on Pharmacuetical Products in India. New Delhi: Ministry of Health; 2001. Schedule Y