M. PHARM. I YEAR

INDUSTRIAL PHARMACY

SEMESTER – I

I M. PHARM. SCHEME
(INDUSTRIAL PHARMACY)

SEMESTER 'I'

S. No.	Sub. Code	Subject	L	T	P	Th. Credit	Pr. Credit	Maximum Marks				
								TH	CW	SW	Pr.	Total
1.	PY90003	Modern Pharmaceutical Analytical Techniques	4	-	-	4	-	75	25	-	-	100
2.	PY98005	Pharmaceutical Formulation Development	4	-	-	4	-	75	25	-	-	100
3.	PY98006	Novel Drug Delivery Systems	4	-	-	4	-	75	25	-	-	100
4.	PY98007	Intellectual Property Rights	4	-	-	4	-	75	25	-	-	100
5.	PY98455	Industrial Pharmacy Practical I	-	-	12	-	6	-	-	50	100	150
6.	PY98583	Seminar/Assignment	-	-	7	-	4	-	-	25	75	100
Total			**16**	**0**	**19**	**16**	**10**	**300**	**100**	**75**	**175**	**650**

PY90003: MODERN PHARMACEUTICAL ANALYTICAL TECHNIQUES

L	T	P	Th. Credit	Pr. Credit	Maximum Marks				
					TH	CW	SW	Pr.	Total
4	-	-	4	-	75	25	-	-	100

Course objectives:

- To develop the basic knowledge of spectra generation and factors affecting the spectra.
- To correlate structure of drug with its spectra.
- To understand the thermal behavior of materials.
- To provide the fundamental of separation in chromatographic techniques
- To provide a knowledge of Atomic spectroscopy.

Course Outcomes:

After completion of course student should be able to:

CO-1: Explain general principles and theory of Spectroscopy.
CO-2: Explain thermal techniques like TGA, DSC.
CO-3: Understand the basic concepts and instrumentation of chromatographic techniques.
CO-4: Learn various separation techniques by chromatographic methods
CO-5: Understand the basic principles and instrumentation of atomic absorption spectrometer.

THEORY **DURATION(LECTURES)**

UNIT-I **11 Hrs**

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

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

c. **Spectroflourimetry:** Theory of Fluorescence, Factors affecting fluorescence, Quenchers, Instrumentation and Applications of fluorescence spectrophotometer.

d. **Flame emission spectroscopy and Atomic absorption spectroscopy:** Principle, Instrumentation, Interferences and Applications .

UNIT-II **11**

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

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

UNIT-III **11 Hrs**

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

UNIT-IV **11 Hrs**

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) lso-electric focusing

UNIT-V **11 Hrs**

X ray Crystallo-graphy: 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.

Immunological Assays: Radioimmunology assay (RIA), ELISA (Theory & practical) and knowledge on Bioluminescence assays.

REFERENCES

1. Spectrometric Identification of Organic compounds - Robert M Silverstein, 6th 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 Series

PY98005: PHARMACEUTICAL FORMULATION DEVELOPMENT

L	T	P	Th. Credit	Pr. Credit	Maximum Marks				
					TH	CW	SW	Pr.	Total
4	-	-	4	-	75	25	-	-	100

Course Objectives

To impart knowledge and skills necessary to train the students on par with the routine of Industrial activities in R&D and F&D.

To understand the scheduled activities in a Pharmaceutical firm.

To impart knowledge of preformulation studies for pilot batches of pharmaceutical industry.

The significance of dissolution and product stability.

Course Outcomes

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

CO-1: Learn and identify importance of formulation development in pharmaceutical industry.
CO-2: Understand importance of preformulation in formulation development and their importance in pilot batches.
CO-3: Screen suitable excipients for dosage form development on the basis of physicochemical properties of excipients, drug, and the dosage form.
CO-4: Point out the stability studies in accessing the shelf life of drug products.
CO-5: Develop understanding theories and mechanism of dissolution studies and to apply them in-vitro and in-vivo correlation.

THEORY **DURATION(LECTURES)**

UNIT-I **12 Hrs**

Preformulation Studies: Molecular optimization of APIs (drug substances), crystal morphology and variations, powder flow, structure modification, drug-excipient compatibility studies, methods of determination.

UNIT-II **12 Hrs**

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.

UNIT-III **12 Hrs**

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 solubilization and hydrotropy.

UNIT-IV **12 Hrs**

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.

UNIT-V **12 Hrs**

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.

REFERENCE

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, 5th ed., B.I. Publications Pvt. Ltd, Noida, 2006.
3. Lieberman HA, Lachman L, Schwartz JB. Pharmaceutical dosage forms : tablets Vol. I-III, 2nd ed., CBS Publishers & distributors, New Delhi, 2005.
4. Conners KA. A Text book of pharmaceutical analysis, Wells JI. Pharmaceutical preformulation : The physicochemical properties of drug substances . Ellis Horwood Ltd., England , 1998.
5. Yalkowsky SH. Techniques of solubilization of drugs. Vol-12. Marcel Dekker Inc., New York, 1981
6. Dressman J, Kramer J. Pharmaceutical dissolution testing. Saurah printer pvt. Ltd., New Delhi,2005 .
7. Sethi PD. Quantitative analysis of drugs in pharmaceutical formulations, 3rd ed. , CBS publications, New Delhi, 2008 .
8. Carstensen J T, Rhodes CT. Drug stability principles and practices, 3rd ed., CBS Publishers & distributors, New Delhi, 2005.
9. Yoshioka S, Stella VJ. Stability of drugs and dosage forms, Springer (India) Pvt. Ltd., New Delhi, 2006.
10. Banker G S, Rhodes CT. Modern Pharmaceutics, 4th ed., Marcel Dekker Inc, New York, 2005.
11. W. Grimm - Stability testing of drug products.
12. Mazzo DJ. International stability testing. Eastern Press Pvt. Ltd., Bangalore, 1999.
13. Beckett A H, Stenlake JB. Practical pharmaceutical chemistry, Part I & II., 4th ed., CBS Publishers & distributor s, New Delhi,2004.
14. Indian Pharmacopoeia. Controller of Publication. Delhi, 1996.
15. British Pharmacopoeia. British Pharmacopoeia Commission Office, London, 2008.
16. United States Pharmacopoeia. United States Pharmacopeial Convention, Inc, USA, 2003.
17. Encyclopedia of Pharm. Technology, Vol I - III.
18. Wells J. I. Pharmaceutical Preformulation: The physicochemical properties of drug substances, Ellis Horwood Ltd. England, 1988.

PY98006: NOVEL DRUG DELIVERY SYSTEMS

L	T	P	Th. Credit	Pr. Credit	Maximum Marks				
					TH	CW	SW	Pr.	Total
4	-	-	4	-	75	25	-	-	100

Course Objectives

- To impart knowledge and skills in the area of novel drug delivery system.
- To develop understanding of sustained release of drug for better therapeutic action.
- To develop understanding about approaches of drug targeting to desired site.
- To understand the principles of achieving maximum therapeutic efficacy.
- To learn and apply concepts of biological processes involved in ligand-receptors pathways and biomaterials in development of NDDS.

Course Outcomes

Upon completion of the course, the student will be able to:

CO-1: Describe the concepts of different novel drug delivery systems.

CO-2: Explain the formulation and evaluation various controlled drug delivery systems.

CO-3: Illustrate technologies involved in formulation of TDDS and various Cosmeceuticals.

CO-4: Determine concepts and events involved in targeted drug delivery systems, protein peptide drug delivery system.

CO-5: Design personalized medicine as per new trends in pharmacy.

THEORY **DURATION(LECTURES)**

UNIT-I **12 Hrs**

Concept & Models for NDDS: Classification of rate controlled drug delivery systems (DDS), rateprogrammed release, activation modulated & feedback 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-polymers- introduction, classification, characterization, polymerization techniques, application in CDDS / NDDS, biodegradable & natural polymers.

UNIT-II **12 Hrs**

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

UNIT-III **12 Hrs**

Transdermal Drug Delivery Systems: Theory, design, formulation & evaluation including iontophoresis and other latest developments in skin delivery systems.

Sub Micron Cosmeceuticals: Biology, formulation science and evaluation of various cosmetics for skin, hair, nail, eye etc and it's regulatory aspects.

UNIT-IV **12 Hrs**

Targeted Drug Delivery System: 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.

UNIT-V **12 Hrs**

Purification of nano-carrier based formulations, Design of Experiments (DoE) based optimization of NDDS based formulations.

Protein / Peptide Drug Delivery Systems: Concepts, delivery techniques, formulation, stability testing, causes of protein destabilization, stabilization methods.

Biotechnology in Drug Delivery Systems: Brief review of major areas-recombinant DNA technology, monoclonal antibodies, gene therapy.

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.

REFERENCES

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, PJ . Tarcha, CRC Press .
8. . Pharmaceutical Biotechnology, Vyas, CBS, Delhi.
9. Biotechnology of Industrial Antibiotics , EJ. Vandamme , Marcel Dekker, NY.
10. Protein Formulation & Delivery, EJ. McNally, Vol 99, Marcel Dekker, NY.
11. Drug Targeting, M.H. Rubinstein , J ohn Wiley, NY.

PY98007: INTELLECTUAL PROPERTY RIGHTS

L	T	P	Th. Credit	Pr. Credit	Maximum Marks				
					TH	CW	SW	Pr.	Total
4	-	-	4	-	75	25	-	-	100

Course Objectives

- To make understanding, defining and differentiating different types of Intellectual Properties.
- To understand the importance, drafting and process of filling of patent.
- To explain the international agreements which gave importance to research activities.
- To contrast the importance of trademark in pharmaceutical sector.
- To analyze and develop the interface between Intellectual Property Rights and Regulatory affairs.

Course Outcomes

Upon completion of the course, the student will be able to:

CO-1: Identify different types of Intellectual Properties (IPs), the right of ownership, scope of protection.

CO-2: Be able to draft patent and thoroughly understand the process of patent filing.

CO-3: Recognize the crucial role of IP in Pharmaceutical sector for the purposes of product and technology development.

CO-4: Identify the role of trademark in business development.

CO-5: Develop the interface between various IPs and regulatory affairs.

THEORY **DURATION(LECTURES)**

UNIT-I **12 Hrs**

Introduction to Intellectual Property Rights (IPR), Basic concept and need of IPR. Definition, Need for patenting, Types of Patents, Conditions to be satisfied by an invention to be patentable, Introduction to patent search. Parts of patents. The essential elements of patent; Non-obviousness in Patent.

UNIT-II **12 Hrs**

Drafting of patent, Type of patent applications, filing of patents, Role of GATT, TRIPS, WIPO and Patent cooperation treaty; Guidelines for preparation of laboratory note book.

UNIT-III **12 Hrs**

IPR's and its types, brief introduction to Trademark protection and copyrights.

UNIT-IV **12 Hrs**

Brief introduction to CDSCO. WHO, USFDA, EMEA, TGA, MHRA, MCC, ANVISA, Major bodies regulating Indian Pharmaceutical sector.

UNIT-V **12 Hrs**

Regulatory requirements for contract research organization. Regulations for Biosimilars.

REFERENCES:

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

PY98455: INDUSTRIAL PHARMACY PRACTICAL - I

L	T	P	Th. Credit	Pr. Credit	Maximum Marks				
					TH	CW	SW	Pr.	Total
-	-	12	-	6	-	-	50	100	150

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 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.

PY98583: SEMINAR/ASSIGNMENT

L	T	P	Th. Credit	Pr. Credit	Maximum Marks				
					TH	CW	SW	Pr.	Total
-	-	7	-	4	-	-	25	75	100

Course Objectives

- To identify any contemporary topic from the thrust area of pharmaceutical technology, formulation development, novel drug delivery system, regulatory affairs, quality assurance & current affairs and any other field beyond the syllabus of interest of pharmaceutical industry.
- To do exhaustive research of literature and information reported in the area of seminar topic.
- To develop in-depth understanding on seminar topic and preparation of power point presentation.
- To develop the skills of scientific presentation in front of scientific community.

Course Outcomes

On completion of this activity, students are expected to be able to:

CO-1: Know different sources of scientific literature and current pharmaceutical news/information.

CO-2: Collect information/subject knowledge and identify the relevant topic in thrust area of interest of pharmaceutical field beyond the syllabus contents.

CO-3: Develop skills and confidence of seminar presentation and extempore discussion with scientific fraternity.

M. PHARM. I YEAR

INDUSTRIAL PHARMACY

SEMESTER – II

I M. PHARM. SCHEME
(INDUSTRIAL PHARMACY)

SEMESTER 'II'

S. No.	Sub. Code	Subject	L	T	P	Th. Credit	Pr. Credit	Maximum Marks				
								TH	CW	SW	Pr.	Total
1.	PY98505	Advanced Biopharmaceutics and Pharmacokinetics	4	-	-	4	-	75	25	-	-	100
2.	PY98506	Scale up and Technology Transfer	4	-	-	4	-	75	25	-	-	100
3.	PY98507	Pharmaceutical Production Technology	4	-	-	4	-	75	25	-	-	100
4.	PY98508	Entrepreneurship Management	4	-	-	4	-	75	25	-	-	100
5.	PY98855	Industrial Pharmacy Practical-II	-	-	12	-	6	-	-	50	100	150
6.	PY98883	Seminar/Assignment	-	-	7	-	4	-	-	25	75	100
Total			**16**	**0**	**19**	**16**	**10**	**300**	**100**	**75**	**175**	**650**

PY98505: ADVANCED BIOPHARMACEUTICS & PHARMACOKINETICS

L	T	P	Th. Credit	Pr. Credit	Maximum Marks				
					TH	CW	SW	Pr.	Total
4	-	-	4	-	75	25	-	-	100

Course objectives:

- To provide knowledge of biopharmaceutical considerations of drug products.
- To understand pharmacokinetic models and pharmacokinetic parameters.
- To provide hands-on experience on calculations involved in pharmacokinetic parameters using drug concentration in biological fluids, describe, and interpret pharmacokinetic models.
- To understand principles of dosage regimen designing and dose adjustment.
- To understand significance of bioavailability and bioequivalence studies and related regulatory aspects.

Course Outcomes

On completion of this course, it is expected that students will be able to,

CO-1: Understand the basic concepts in biopharmaceutics and pharmacokinetics.

CO-2: The use of raw data and derive the pharmacokinetic models and parameters the best describe the process of drug absorption, distribution, metabolism and elimination.

CO-3: Critically evaluate biopharmaceutics studies involving drug product equivalency .

CO-4: Design and evaluate dosage regimens of the drugs using pharmacokinetic and biopharmaceutic parameters.

THEORY **DURATION(LECTURES)**

UNIT-I **12 Hrs**

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 (GID, pH Microclimate Intracellular pH Environment, Tight-Junction Complex. Solubility: Experimental methods. Permeability: In-vitro, in-situ and In-vivo methods.

UNIT-II **12 Hrs**

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, compendia! 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.

UNIT-III **12 Hrs**

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 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.

UNIT-IV **12 Hrs**

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.

UNIT-V **12 Hrs**

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.

REFERENCES

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., Vallabh Prakashan, Pitampura, Delhi
3. Applied Biopharmaceutics and Pharmacokinetics by Shargel. Land Yu ABC, 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 lnc.,New York, 1982
6. Current Concepts in Pharmaceutical Sciences: Biopharmaceutics, Swarbrick. J, Lea and Febiger, Philadelphia, 1 970
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 expanded 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, Ist 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, lnc,2003.

PY98506: SCALE UP AND TECHNOLOGY TRANSFER

L	T	P	Th. Credit	Pr. Credit	Maximum Marks				
					TH	CW	SW	Pr.	Total
4	-	-	4	-	75	25	-	-	100

Course objectives:

- To provide knowledge and skills necessary for scale up, technology transfer process and industrial safety issues.
- To demonstrate concept of validation necessary for analytical method development
- To explain the importance of equipment qualification during the purchase, installation and performance of machines.
- To identify the critical parameters involved in process validation and their importance in technology transfer.
- To establish safety guidelines, which prevent industrial hazards.

Course Outcomes

On completion of this course it is expected that students will be able to,

CO-1: To identify the necessary steps involved in scale up, technology transfer process and industrial safety issues.

CO-2: To explain the concept of validation necessary for analytical method development.

CO-3: To prepare equipment qualification protocols for installation and performance machines.

CO-4: To illustrate the critical parameters involved in process validation and their importance in technology transfer.

CO-5: To plan safety guidelines for preventing industrial hazards and controlling environmental pollution.

THEORY **DURATION(LECTURES)**

UNIT-I **12 Hrs**

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, equipments, product uniformity, stability, raw materials, physical layout, input, in-process and finished product specifications, problems encountered during transfer of technology

UNIT-II **12 Hrs**

Validation: General concepts, types, procedures & protocols, documentation, VMF. Analytical method validation, cleaning validation and vender qualification.

UNIT-III **12 Hrs**

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.

UNIT-IV **12 Hrs**

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

UNIT-V **12 Hrs**

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

REFERENCES

1. Pharmaceutical process validation, JR Berry, Nash, 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, Delhi.

PY98507: PHARMACEUTICAL PRODUCTION TECHNOLOGY

L	T	P	Th. Credit	Pr. Credit	Maximum Marks				
					TH	CW	SW	Pr.	Total
4	-	-	4	-	75	25	-	-	100

Course objectives:

- To provide basic understanding of the technologies involved in the pharmaceutical manufacturing.
- To provide hands-on training in troubleshooting of problems encountered during pharmaceutical manufacturing.
- To provide basic theoretical knowledge and practical training of in-process quality control of pharmaceutical dosage forms.
- To impart knowledge about the advanced pharmaceutical technologies and their marketed products.

Course outcomes:

On completion of this subject, students are expected to be able to:

CO-1: Understand the manufacturing technologies of solid, semi-solid, liquid, sterile dosage forms, nasal and pulmonary drug delivery systems.

CO-2: Perform the troubleshooting encountered during manufacture of pharmaceutical products.

CO-3: Understand the design and functioning of equipments and processes employed in pharmaceutical manufacturing.

CO-4: Perform in-process quality control testing of pharmaceutical products.

CO-5: Understand the principles and applications of advanced technologies like supercritical fluid technology, lyophilization, spray drying, pelletization and PEGylation technologies, etc.

THEORY **DURATION(LECTURES)**

UNIT-I **12 Hrs**

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.

UNIT-II **12 Hrs**

Parenteral Production: Area planning & environmental control, wall and floor treatment, fixtures and machineries, change rooms, personnel flow, utilities & utilities equipment location, engineering and maintenance.

UNIT-III **12 Hrs**

Lyophilization & Spray drying Technology: Principles, process, freeze-drying and spray drying equipments.

UNIT-IV **12 Hrs**

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.

UNIT-V **12 Hrs**

Packaging Technology: Types of packaging materials, machinery, labeling, and package printing for different dosage forms.

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.

REFERENCES

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 industry, 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.

PY98508: ENTREPRENEURSHIP MANAGEMENT

L	T	P	Th. Credit	Pr. Credit	Maximum Marks				
					TH	CW	SW	Pr.	Total
4	-	-	4	-	75	25	-	-	100

Course Objectives

1. To develop acquaintance about entrepreneurship in pharmaceutical sector.
2. To illustrate managerial skills in various segments of a pharmaceutical organization.
3. To understand role of enterprise in national and global economy.
4. To enable them to analyze and understand the environment of the organization.
5. To develop well structure project proposals for the success of organization.

Course Outcome

On completion of this course it is expected that students will be able to

CO-1: Outline the role of enterprise in national and global economy.

CO-2: Demonstrate the scope of entrepreneurship in pharmaceutical business.

CO-3: Identify the problem associated in organizing an enterprise with regards to resource mobilization and marketing management.

CO-4: Identify the challenges involved in developing growth strategies for pharmaceutical organization.

CO-5: Develop a project proposal that includes a detailed, practical and effective implementation strategy.

THEORY **DURATION(LECTURES)**

UNIT-I **12 Hrs**

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.

UNIT-II **12 Hrs**

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.

UNIT-III **12 Hrs**

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

UNIT-IV **12 Hrs**

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.

UNIT-V **12 Hrs**

Preparing project proposal to start on new enterprise project work – Feasibility report; Planning, resource mobilization and implementation.

REFERENCES

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. et al. (1982): Practice of Entrepreneurship, ILO, Geneva.
5. Patel, V.C. (1987): Women Entrepreneurship – Developing New Entrepreneurs, Ahmedabad EDII.

PY98855: INDUSTRIAL PHARMACY PRACTICAL – II

L	T	P	Th. Credit	Pr. Credit	Maximum Marks				
					TH	CW	SW	Pr.	Total
-	-	12	-	6	-	-	50	100	150

List of practical to be conducted:

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.

PY98883: SEMINAR/ASSIGNMENT

L	T	P	Th. Credit	Pr. Credit	Maximum Marks				
					TH	CW	SW	Pr.	Total
-	-	7	-	4	-	-	25	75	100

Course Objectives

- To identify any contemporary topic from the thrust area of pharmaceutical technology, formulation development, novel drug delivery system, regulatory affairs, quality assurance & current affairs and any other field beyond the syllabus of interest of pharmaceutical industry.
- To do exhaustive research of literature and information reported in the area of seminar topic.
- To develop in-depth understanding on seminar topic and prepare the power point presentation.
- To develop the skills of scientific presentation in front of scientific community.

Course Outcomes

On completion of this activity, students are expected to be able to:

CO-1: Know different sources of scientific literature and current pharmaceutical news/information.

CO-2: Collect information/subject knowledge and identify the relevant topic in thrust area of interest of pharmaceutical field beyond the syllabus contents.

CO-3: Develop skills and confidence of seminar presentation and extempore discussion with scientific fraternity.

M. PHARM. II YEAR

INDUSTRIAL PHARMACY

SEMESTER – III

II M. PHARM. SCHEME
(INDUSTRIAL PHARMACY)

SEMESTER 'III'

S. No.	Sub. Code	Subject	L	T	P	Th. Credit	Pr. Credit	Maximum Marks				
								TH	CW	SW	Pr.	Total
1.	PY98902	Research Methodology & Biostatistics	4	-	-	4	-	75	25	-	-	100
2.	PY98931	Journal Club	1	-	-	1	-	-	25	-	-	25
3.	PY98932	Discussion/ Presentation (Proposal Presentation)	2	-	-	2	-	-	50	-	-	50
4.	PY98940	Research Work	-	-	28	-	14	-	-	-	350	350
Total			**7**	**0**	**28**	**7**	**14**	**75**	**100**	**-**	**350**	**525**

PY98902: Research Methodology & Biostatistics

L	T	P	Th. Credit	Pr. Credit	Maximum Marks				
					TH	CW	SW	Pr.	Total
4	-	-	4	-	75	25	-	-	100

Course Objectives

- To outline the role of research methodology solving the practical difficulties arising during the research work.
- To know about various statistical tests, design and analysis of experiments.
- To explain the software used for statistical analysis.
- To outline the medical ethics in pharmaceutical research work
- To learn about various CPCSEA guidelines for conducting animal studies.

Course Outcomes:

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

CO-1: Develop understanding of various statistical methodologies and data analysis tools with respect to pharmaceutical sciences.

CO-2: Understand the basic utility and operations of statistical tests.

CO-3: Apply reasoning for design of research projects and prepare work plan for assigned research problem.

CO-4: Outline the medical ethics in pharmaceutical research work

CO-5: To prepare protocols for conducting animal studies.

UNIT – I **12 Hrs**

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.

UNIT – II **12 Hrs**

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.

UNIT – III **12 Hrs**

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.

UNIT – IV **12 Hrs**

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.

UNIT – V **12 Hrs**

Declaration of Helsinki: History, introduction, basic principles for all medical research, and additional principles for medical research combined with medical care.

M. PHARM. II YEAR

INDUSTRIAL PHARMACY

SEMESTER – IV

II M. PHARM. SCHEME
(INDUSTRIAL PHARMACY)

SEMESTER 'IV'

S. No.	Sub. Code	Subject	L	T	P	Th. Credit	Pr. Credit	Maximum Marks				
								TH	CW	SW	Pr.	Total
1.	PY98953	Journal Club	1	-	-	1	-	-	25	-	-	25
2.	PY98952	Discussion/ Presentation (Proposal Presentation)	3	-	-	3	-	-	75	-	-	75
3.	PY98985	Research Work & Colloquium	-	-	32	-	16	-	-	-	400	400
4.	PY98999	Co-curricular Scholastic Activities*	-	-	-	-	2*	-	-	-	-	-
Total			**4**	**0**	**32**	**4**	**18**	**-**	**100**	**-**	**400**	**500**

Credits of co-curricular scholastic activities (minimum 2 and maximum 7 credits) shall be earned during the course. Refer minutes of 27th meeting of Academic council 22/07/2022

PY98985: RESEARCH WORK & COLLOQUIUM

L	T	P	Th. Credit	Pr. Credit	Maximum Marks				
					TH	CW	SW	Pr.	Total
-	-	31	-	16	-	-	-	400	400

Objectives:

- To pursue advanced concepts, emerging research methodologies and recent experimental tools for carrying out the planned research work.
- To carry on the planned experimental work & optimize methodology.
- To pursue the experimental findings & draw conclusion.
- To establish correlation of results obtained & publication of research.
- To develop research orientation and aptitude in the area of pharmaceutical technology, formulation development, novel drug delivery system, regulatory affairs, quality assurance & current affairs and any other field beyond the syllabus of interest of pharmaceutical industry.

Outcome:

Upon completion of this course, students should be able to:

CO-1: Understand advanced concepts and recent experimental tools in the area of research completed.

CO-2: Develop themselves as upcoming researcher in the emerging area of pharmaceutical technology, formulation development, novel drug delivery system, regulatory affairs, quality assurance & current affairs and any other field beyond the syllabus of interest of pharmaceutical industry.

CO-3: Do value addition to the existing knowledge in the research field through scientific presentation & publications.

CO-4: Complete the planned work in the stipulated time, correlate the findings after compilation and submit the dissertation for evaluation.