SCHEME OF INSTRUCTION, EXAMINATION AND EVALUATION

Program Code: 886 **M. Pharm. (Pharmaceutics)**

2015 – 16

SEMESTER - I

Course Code	Course Title	Hours /Week			Credits	Marks		Duration of Exam
		L	T	P		Internal	End Exam	
PY.09.884.11.T	Pharmaceutical Analytical Techniques	3	0	-	3	25	75	3
PY.09.886.12.T	Pharmaceutical Product Development	4	0	-	4	25	75	3
PY.09.886.13.T	Pharmaceutical Production Technology	4	0	0	4	25	75	3
PY.09.886.14.T	Advanced Physical Pharmaceutics	4	0	0	4	25	75	3
PY.09.885.15.T	Quality Assurance	3	0	0	3	25	75	3
PY.09.884.11.P	Pharmaceutical Analytical Techniques	-	0	4	2	25	75	6
PY.09.886.12.P	Pharmaceutical Product Development	-	0	4	2	25	75	6
					22	175	525	
PY.09.886.10.S	SAIL	1	2	0	2	Grade		
PY.09.886.11.S	Seminar	1	0	2	2	Grade		

SEMESTER - II

Course Code	Course Title	Hours /Week			Credits	Marks		Duration of Exam
		L	T	P		Internal	End Exam	
PY.09.885.21.T	Int. Property Rights & Regulatory Affairs	3	0	-	3	25	75	3
PY.09.886.22.T	Biopharmaceutics and Pharmacokinetics	4	0	-	4	25	75	3
PY.09.886.23.T	Advances in Drug Delivery System	4	0	0	4	25	75	3
PY.09.886.24.T	Process Scale Up and Validation	4	0	0	4	25	75	3
PY.09.88X.25.T	Elective *	3	0	0	3	25	75	3
PY.09.886.22.P	Biopharmaceutics and Pharmacokinetics	-	0	4	2	25	75	6
PY.09.886.23.P	Advances in Drug Delivery System	-	0	4	2	25	75	6
					22	175	525	
PY.09.886.20.S	SAIL	1	2	0	2	Grade		
PY.09.886.21.S	Seminar	1	0	2	2	Grade		

* Discipline Centric – Cosmetic Technology/Drug Polymer Technology;
Open – Pharmaceutical Biotechnology

SEMESTER – III

Course Code	Course Title	Hours /Week	Credits	Marks		Duration in Weeks
				Internal	External	
PY.10.886.31.P	Design Seminar	30	6	50	-	6
PY.10.886.32.P	Progressive Seminar	30	10	50	-	10
		480	16	100		

SEMESTER – IV

Course Code	Course Title	Hours /Week	Credits	Marks		Duration in Weeks
				Internal	External	
PY.10.886.41.P	Pre-Submission Seminar	30	10		50	10
PY.10.886.42.P	Submission and Adjudication	30	12		200	6
PY.10.886.43.P	Final Viva-voce	30	2		50	1
		510	24		300	17

PHARMACEUTICAL ANALYTICAL TECHNIQUES

Scheme of Instruction			Scheme of Examination		
Total Duration	:	60 Hrs.	Max. Marks	:	100
Hours/Week	:	3 Hrs.	Mid Semester	:	20
Credits	:	3	Quiz	:	05
Instruction Mode	:	Lecture	End Semester	:	75
Course Code	:	PY.09.884.11.T	Exam Duration	:	3 Hrs.

Course Objectives:

To familiarize students in conventional and modern techniques of analysis used in different areas of pharmacy.

To understand the experimental concepts, the procedures and safety considerations in a quality control lab.

To give training in use of the technique and its applications in day to day practice.

To build on the basics learned at UG level and give latest advances in the area.

Course Outcomes:

By pursuing this course students are prepared for:

- *Research and Development*
- *Food, Bio and Pharma Industries*
- *Clinical Research and Quality Control Administration*

Unit - I :

UV-Visible Spectroscopy: Basic principles, interaction of electromagnetic radiation with matter and its effects (electronic transitions). Concept of chromophore and Auxo-chrome, effect of conjugation, solvent and pH. Instrumentation (components and their significance). Absorption spectra of organic compounds and complexes illustrating the phenomenon and its utilization in qualitative and quantitative studies of drugs including multicomponent analysis. Woodward-Fieser rules for calculating absorption maximum for unsaturated hydrocarbons. Difference and derivative spectra.

Infra-Red Spectroscopy: Interaction of infrared radiation with organic molecules and it's effects on bonds. Instrumentation- Dispersive IR spectrophotometers and Fourier transform spectrophotometers. Sample handling for IR spectroscopy. Interpretation of IR spectra. Brief note on ATR. (Attenuated Total Reflectance).

Unit - II :

Nuclear Magnetic Resonance Spectroscopy: Fundamental Principles of NMR, Chemical shifts concept, spin-spin coupling, spin-spin decoupling, shielding, de-shielding, shift reagents and solvents. Signal multiplicity phenomena in high resolution PMR. Interpretation of PMR spectra. Brief introduction about Carbon-13 NMR.

Mass Spectrometry: Basic principles Mass Spectrometry. Ionization techniques (EI and CI), Mass spectrum and its characteristics, molecular ion, metastable ions, fragment ions; fragmentation processes, Nitrogen Rules, Relative abundances of isotopes and their contribution to characteristic peaks and molecular formula determination.

Unit - III :

Chromatographic Techniques: General Principles, Classification of Chromatographic Methods Thin Layer Chromatography, Paper Chromatography and Column Chromatography and Methods based on Mechanism .

Gas Chromatography: Instrumentation, Column efficiency parameters, derivatization methods, applications in pharmaceutical analysis.

Liquid Chromatography: Principles of HPLC, Instrumentation, Normal and Reversed Phase Packing Materials, Column Selection, Mobile Phase Selection, Efficiency Parameters, Applications in Pharmaceutical Analysis. Chiral Chromatography, Flash Chromatography, and Supercritical Fluid Chromatography (SFC).

Unit - IV :

Electrophoresis: Principles, Instrumentation and Applications of Moving Boundary Electrophoresis Zone Electrophoresis (ZE), Isoelectric Focusing (IEF), Continuous Electrophoresis (Preparative) and Capillary Electrophoresis. SDS Gel Electrophoresis and Blotting Techniques.

Radio Immunoassay and ELISA: Principle, Instrumentation, Applications and Limitations.

Unit - V :

X-Ray Spectroscopy: Origin of X-rays, basic aspects of crystals, X-ray crystallography, miller indices, rotating crystal technique, single crystal diffraction, powder diffraction, structural elucidation and applications.

Thermal Analytical Techniques: Principles, Theory and Application of Thermal Analysis (DSC, DTA and TGA)

Books and References:

1. Skoog, DA, Holler, FJ, Crouch, SR. Principles of Instrumental Analysis. 6th Ed., Baba Barkha Nath Printers, Haryana, 2007.
2. Silverstein, RM, Webstar, FX. Spectrometric Identification of Organic Compounds. 6th Ed., John Wiley & Sons (Asia) Pvt. Ltd., Singapore, 2005.
3. William Kemp. Organic Spectroscopy, 3rd ed., Palgrave, New York, 2006.
4. Jag Mohan, Organic spectroscopy: Principles and Applications, 2nd ed., Narosa publishing house Pvt Ltd., New Delhi, 2005.
5. Conners KA. A Textbook of Pharmaceutical Analysis, 3rd ed., John Wiley & Sons, Singapore, 2004.
6. Willard HH, Merritt LL, Dean JA, Settle FA. Instrumental Methods of Analysis, 7th Ed., CBS Publishers & Distributors, New Delhi, 1986.
7. Pavia DL, Lampman GM, Kriz GS, Vyvyan JA. Introduction to Spectroscopy. 4th Ed., Brookes Cole Publishers, California, 2008.
8. Sharma BK. Instrumental Methods of Chemical Analysis, 25th Ed., Goel Publishing House, Meerut, 2006.
9. Beckett, AH, Stenlake, JB. Practical Pharmaceutical Chemistry, Part I & II, 4th ed., CBS Publishers & Distributors, New Delhi, 2004.
10. Ewing, GW. Instrumental Methods of Chemical Analysis, 5th Ed., McGraw Hill Book Company, NY, 1985.
11. Schirmer, RE. Modem Methods of Pharmaceutical Analysis, Vol. I & II, 2nd ed., CRC Press, Florida, 2000.

PHARMACEUTICAL PRODUCT DEVELOPMENT

Scheme of Instruction

Total Duration	:	60 Hrs.
Hours/Week	:	4 Hrs.
Credits	:	4
Instruction Mode	:	Lecture
Course Code	:	PY.09.886.12.T

Scheme of Examination

Max. Marks	:	100
Mid Semester	:	20
Quiz	:	05
End Semester	:	75
Exam Duration	:	3 Hrs.

Course Objectives:

This subject imparts overall theoretical knowledge on formulation development of dosage forms and its stability. The student learn about various physical and pharmaceutical parameter/properties of raw materials, drug substances and excipients to be studied and optimized in the pharmaceutical product development.

Course Outcomes:

The students after undergoing their course work shall become thoroughin understanding the influence of various physical and pharmaceutical properties of drug substance, raw material and excipients. They shall become aware of various parameters to be studied and number of experiments to be conducted to develop the optimized formulation of drugs and pharmaceuticals;.

Unit - I :

Pre-formulation (API): Influence of melting point, dissociation constant, pharmaceutical salts and hygroscopicity, physical forms of drugs, Methods of preparation and characterization.

Design of Experiments and Product Specifications: Design, Laying Down and Optimization of Materials and Products Specifications, Process and In-Process Controls;

Unit - II :

Formulation Additives: Study of different types of additives e.g. antioxidants and preservatives, coloring and flavoring agents, emulsifying and suspending agents, basic materials for ointment bases, diluents and pharmaceutical solvents,

Pre-formulation (Excipients Science): Tablet excipients, factors influencing selection of excipients, directly compressible excipients, co-processing of excipients, determination of functionality tests of excipients, flow properties, compression properties, drug-excipient compatibility, methods of evaluations;

Unit - III :

Solubility: Importance, experimental determination, aqueous solubility aspects in pre-formulation, intrinsic solubility, phase-solubility analysis, pH solubility profile, Solubility Improvement; Solubility Techniques, Co-Solvency, Salt-Formation, Complexation, Solid Dispersion;

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 - IV :

Chemical Stability Kinetics: Complex Chemical Reactions – Kinetics, Factors Affecting Chemical Stability, Stability Testing in Pre-formulation;

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). Photo-Stability, Solid state stability and shelf life assignment. Stability Protocols and Reports;

Unit - V :

Generic Drug Products: General Principles, Categories of OUT of Patent Pharmaceuticals, Hatch - Waxman Act, Bolar Amendment, Principles of Exclusivity, Drug Regulations – ANDA, Generic Drug Product Development, Generic Drug Product Approval.

Novel Products Development: Nano-Pharmaceuticals - Generation and Significance of Nano-suspensions, Nano-gels, Nano-carrier Systems;

Books and References:

1. Lachman L, Lieberman HA, Kanig JL. The Theoryand Practice of Industrial Pharmacy, 3rd Ed, Varghese Publishers, Mumbai 1991.
2. Sinko PJ. Martin's Physical Pharmacy& Pharmaceutical Sciences, 5th Ed., B.I. Pub. Pvt. Ltd, Noida, 2006.
3. Lieberman HA, Lachman L, Schwartz JB. Pharmaceutical dosage forms: tablets Vol. I-II, 2nd Ed., CBS Publishers & Distributors, New Delhi, 2005.
4. Conners KA. A Text book of pharmaceutical analysi Wells JI. Pharmaceutical Pre-formulation: The Physicochemical Properties of Drug Substances. Ellis Harwood 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. Saurabh Printer Pvt. Ltd., New Delhi, 2005..
7. Sethi PD. Quantitative Analysis of Drugs in PharmaceuticalFormulations, 3rd edn., CBS Publications, New Delhi, 2008.
8. Carstensen JT, Rhodes CT. Drug StabilityPrinciples 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 GS, Rhodes CT. Modern Pharmaceutics, 4th Ed., Marcel Dekker Inc., New York, 2005.
11. W. Grimm - Stability Testing of Drug Products. Mazzo DJ. International Stability Testing. Eastern Press Pvt. Ltd., Bangalore, 1999.
12. Beckett AH, Stenlake JB. Practical Pharmaceutical Chemistry, Part I & II. 4th Ed., CBS Publishers & Distributors, New Delhi, 2004.
13. Indian Pharmacopoeia. Controller of Publication. Delhi, 1996.
14. British Pharmacopoeia. British Pharmacopoeia Commission Office, London,2008.
15. United States Pharmacopoeia. United States Pharmacopoeial Convention, Inc, USA, 2003.

PHARMACEUTICAL PRODUCTION TECHNOLOGY

Scheme of Instruction			Scheme of Examination		
Total Duration	:	60 Hrs.	Max. Marks	:	100
Hours/Week	:	4 Hrs.	Mid Semester	:	20
Credits	:	4	Quiz	:	05
Instruction Mode	:	Lecture	End Semester	:	75
Course Code	:	PY.09.886.13.T	Exam Duration	:	3 Hrs.

Course Objectives:

The students are given the emphasis on the production activities of pharmaceutical industry with general requirements and special emphasis on the equipment, process problems, including safety and environment concerns.

Course Outcomes:

The students should be able to explain the commercial production activities of different dosage forms of tablets, capsules, disperse systems, describe special requirements for the parenteral products, evaluate the status of safety and pollution, presenting them with specific programs in pharmaceutical industry.

Unit - I :

Improved Tablet Production: Tablet production process, unit operation improvements, granulation and palletization equipment, continuous and batch mixing, rapid mixing granulators, rota granulators, spheronizers and marumerisers, and other specialized granulation and drying equipment. Problems encountered.

Coating Technology: Process, equipment, particle coating, fluidized bed coating, application techniques. Problems encountered.

Unit - II :

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

Lyophilization Technology: Principles, Process, Freeze-drying equipment.

Unit - III :

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 equipment including fine solids dispersion, Problems Encountered.

Unit - IV :

Packaging Technology: The packaging function, types of packaging materials, paper and board based, glass, plastics, metals, films, foils and laminations. Closures and closuresystem, packaging machineryincluding blister strips and sachetpackaging, labeling ofpharmaceutical packages, package printing and decoration, regulatory aspects of packaging.

Unit - V :

Air Handling Systems: Study of AHUs, humidity & temperature control, air filtration systems, dust collectors.
Pharmaceutical Water Systems: Sources, pretreatment, techniques and maintenance; types of waters; water treatment-Ion exchange, reverse osmosis (RO), distillation, ultrafiltration, qualitycontrol, storage & distribution.

Books and 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, Parenteral 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 Harwood's, UK.

ADVANCED PHYSICAL PHARMACEUTICS

Scheme of Instruction			Scheme of Examination		
Total Duration	:	60 Hrs.	Max. Marks	:	100
Hours/Week	:	4 Hrs.	Mid Semester	:	20
Credits	:	4	Quiz	:	05
Instruction Mode	:	Lecture	End Semester	:	75
Course Code	:	PY.09.886.14.T	Exam Duration	:	3 Hrs.

Course Objectives:

The students are given the training on the physical and chemical properties of drugs and polymers, for their judicious application in the design of product and development, which facilitates the effective release of drugs in order to contribute to the development of drugs.

Course Outcomes:

The students should be able to explain the principles and methods for evaluation of particle size including nanoparticles and viscoelastic behavior of raw materials and products. The students should describe the factors and processes involved in compression; explain the physicochemical properties of polymer and their utility in the design, evaluation, and the efficient release of drugs from the novel drug delivery systems.

Unit - I :

Viscoelasticity: Oscillatory testing and behavior analysis, creep testing and behavior analysis, mechanical modeling of viscoelasticity, psycho-rheology

Advanced Methods of Particle Size Distribution: Particle characterization by size, shape and surface of individual particle and for contacted particle.

Drug Delivery Gels: Synthetic hydrogels-their preparation. Diffusion properties of swollen hydrogels;.

Unit - II :

Physics of Tableting: General principles, compression, consolidation, decompression compaction at High Loads Forces Distribution during Compression, compaction profiles, forces in compression – measurement, energy involved in compaction, properties of granules for compression, properties related to machinery for compression, influence of compression force on the properties of tablets

Unit - III :

Surfactant System: Phase behavior of surfactant in binary and ternary systems. Factors affecting phase behavior; Micellization; micelle structure, shape, size factors affecting CMC and micelle size, thermodynamics and kinetics of micelle formation. Pharmaceutical aspects of Solubilization, Solubilization in non-aqueous system, interactions with polymers and oppositely charged species. Hydro trophy in pharmaceuticals, surfactants in emulsions and suspensions. Biological Implications; Effecton: dissolution of drugs, permeability of membranes, drug absorption, antibacterial activity; Cyclodextrin inclusion complexes and co-solvents

Unit - IV :

Polymers – Physicochemical Principles: Polymers/co-polymers - introduction, , classification of polymers, polymerization mechanisms, polymerization methods, behavior in polymer solutions (solvent selection, preparation of solutions, , phase separations, gel formulation, coacervation and microencapsulation, polymer characterization– morphology, molecular weight determination mechanical properties, crystallinity, and morphology.

Polymers – Controlled Drug Delivery Systems: Muco-adhesive polymers, hydro-dynamically Balanced Systems (HBS), activation modulated systems, feedback regulated systems, bio-erodible polymers, drug polymer matrix, rate controlling membrane, covalent linkage with drugs, non-biodegradable polymers, colon drug delivery systems, transdermal drug delivery systems (TDDS), polymer selection.

Unit - V

Drug Release Mechanisms – Models and Modeling: Dissolution release modeling, diffusion mediated release, diffusion methods (Models), drug diffusion release modeling – matrix systems, reservoir systems, swelling matrix systems, osmotic pressure-activated systems, drug release profiles comparison, practical Considerations

Books and References:

1. A. Kitahard and A. Watanabe; Electrical Phenomena at Interfaces; Marcel Dekker.
2. A. Martin, P. Bustamante and A. H. Chun; Physical Pharmacy; Waverly.
3. D. M. Parikh; Handbook of Pharmaceutical Granulation Technology; Marcel Dekker.
4. G. Alderborn and C. Nystrom; Pharmaceutical Powder Compaction Technology; Marcel Dekker.
5. H. G. Brittain; Physical Characterization of Pharmaceutical solids; Marcel Dekker.
6. J. T. Cartensen; Drug Stability; Marcel Dekker.
7. James J. Wells; Pharmaceutical Preformulation, Ellis Harwood Ltd.
8. Lieberman, Rieser and Banker; Pharmaceutical Dosage Forms; Disperse system; Marcel Dekker.
9. M. N. Rubinstein; Pharmaceutical Technology, Drug stability, John Wiley and sons.
10. Martin Rhodes; Principles of Powder Technology, John Wiley and sons.
11. N. G. Stanley – Wooed; Enlargement and compaction of particle solids; Butterworths.
12. P. H. List and P. C. Schmidt; Pharmaceutical Technology, CRS Press.
13. P. J. Tarcha; Polymer for Controlled Drug Delivery, CRC Press.
14. Robinson; Novel Drug Delivery Systems, Marcel Dekker.

QUALITY ASSURANCE

Scheme of Instruction			Scheme of Examination		
Total Duration	:	60 Hrs.	Max. Marks	:	100
Hours/Week	:	3 Hrs.	Mid Semester	:	20
Credits	:	3	Quiz	:	05
Instruction Mode	:	Lecture	End Semester	:	75
Course Code	:	PY.09.885.15.T	Exam Duration	:	3 Hrs.

Course Objectives:

Achieve comprehensive understanding and acquiring professional competency in global quality standards systems and regulatory requirements in the pharmaceutical industry.

Develop and implement a robust quality assurance system in an organization towards quality excellence

Course Outcomes:

This subject is aimed at giving knowledge about concepts of quality assurance,

- *Acquire knowledge on various quality assurance systems, processes and current regulatory guidelines related to manufacturing and distribution.*
- *Address quality issues and provide solutions needed to attain Quality leadership in an environment of continual improvement.*
- *Understand the importance of effective documentation and formula for various operating procedures in Pharmaceutical industry.*

Unit - I :

Basic Quality Assurance Systems: Basic concept of quality control & quality assurance, functions, sources of variation, quality assurance for raw materials, APIs, packing materials & finished products (specifications, receipt, testing, sampling and certificate of analysis), production (change control, aseptic process control, temperature, pressure & humiditycontrol tests, tests for air flow pattern, microbiological monitoring) buildings & facilities (design and construction features, construction materials, lighting, air handling systems, sanitation & maintenance) equipments (construction, cleaning and maintenance, calibration & handling).

Unit - II :

In-Process Quality Control: Importance, inspection, IPQC tests for tablets (weight variation, hardness, thickness, friability, disintegration tests and contentuniformity), suspensions and emulsions (appearance and feel, volume check, viscosity, particle size distribution, electrical conductivity and content uniformity) and parenterals (pH, volume check, clarity, content uniformity, integrity of seals and particulate matter). Problems encountered and trouble shooting.

Unit - III :

Related Quality Systems: ISO- Quality Concepts, Quality Management – Vocabulary, ISO 9000 series-Standards, Guidelines and Selection, Requirements, ISO - Certification Procedure, ISO 14000.

Audits: GMP compliance audit, Definition summary, Audit policy, Internal and External Audits, Second Party Audits, External third party audits.

Unit - IV :

Quality Control Lab: Scope, Organization, Personnel – Desirable Qualities of Analyst, Responsibilities of Key Personnel in the Quality Control Lab. Operation Systems and Procedures in QC Lab, Analytical Worksheet, Test Methods, Evaluation of Test Results. Safety Guidelines in QC Lab.

Documentation - Good Documentation Practices, Route Cause Analysis, Corrective Action Preventive Action (CAPA), Out of Specifications (OOS) and Out of Trend (OOT)

Unit - V:

Impurity Profile: Sources of Impurities, their Effect on Drug Stability and Therapeutic Action. Determinationof Impurities in Bulk Drugs and Formulation - Isolation, Characterization, Analytical Methods and Guidelines as per ICH and WHO for Impurity and Related Substances, Concept of Purity Angle, Threshold and Flag;

Study of Compendia: Evolution, Study of Parts of Compendia like: Policies, General Notices, Monographs, Comparative Picture of IP, USP, BP.

Books and References:

1. Gupta SC. Fundamentals of Statistics. 6th ed., Himalaya Publishing House, Hyderabad, 2004.
2. Sharma PP. How to Practice GMPs, 4th Ed., Vandana Publications Pvt. Ltd., Delhi, 2004.
3. Sharma PP. How to Practice GLP, Vandana Publications, Delhi, 2000.
4. Quality Assurance of Pharmaceuticals (A Compendium of Guidelines and Selected Materials) Vol. I & II, WHO, Geneva, Pharma book syndicate, Hyderabad, 2002.
5. Basic Tests for Pharmaceutical Substances, WHO, Geneva, All India traveler book seller, India, 1990.
6. The International Pharmacopoeia, Vol. I-II, 3rd ed., WHO, Geneva, 1981.
7. Mehra ML. Good Manufacturing Practices (GMP), University Book Agency.
8. Subrahmanyam.CVS, Pharmaceutical Production and Management, 2005, Vallabh Prakashan, NewDelhi.
9. Statistical Design and Analysis in Pharmaceutical Sciences, Marcel Dekker, NY.
10. D.A. Berry, Statistical Methodology in Pharmaceutical Science, Marcel Dekker, NY.
11. DH Shah, Quality Assurance Manual, Business Horizons, New Delhi.
12. Y. Anjaneyulu, R. Marayya, Quality Assurance and Quality Management in Pharmaceutical Industry. Pharma Book Syndicate, Hyderabad

PHARMACEUTICAL ANALYTICAL TECHNIQUES

Scheme of Instruction			**Scheme of Examination**		
Total Duration	:	60 Hrs.	Max. Marks	:	100
Hours/Week	:	4 Hrs.	Mid Semester	:	20
Credits	:	2	Quiz	:	05
Instruction Mode	:	Practical	End Semester	:	75
Course Code	:	PY.09.884.11.P	Exam Duration	:	6 Hrs.

Course Objectives:

To make students familiar with the principles of modern analytical techniques and application of analytical instruments in pharmacy.

Course Outcomes:

At the end of the course, the student will be able to understand the fundamental concept of modern analytical techniques, which is important for qualitative as well as quantitative analysis of drug substances and drug product.

List of Experiments :

1. UV/Visible spectrum scanning of a few organic compounds for UV- absorption and correlations of structures (5 compounds) and isosbestic point in case of mixtures.
2. Effect of solvents and pH on UV spectrum ofdrugs (2 experiments).
3. Estimation of multicomponent formulation byUV- Spectrophotometer in formulations. (2 experiments).
4. Experiments based on the application of derivative spectroscopy. (2 experiments).
5. Experiments based on HPLC (Isocratic and Gradient elution) techniques. (2 experiments).
6. Interpretation of drugs by IR spectra.
7. Workshop of spectroscopy: (UV, IR, NMR, MASS) structural elucidation of at least 5 compounds (4 experiments).
8. Separation of protein drug substances by electrophoresis.
9. Any other relevant experiments based on theory.

Books and References:

PHARMACEUTICL PRODUCT DEVELOPMENT

Scheme of Instruction			**Scheme of Examination**		
Total Duration	:	60 Hrs.	Max. Marks	:	100
Hours/Week	:	4 Hrs.	Mid Semester	:	20
Credits	:	2	Quiz	:	05
Instruction Mode	:	Practical	End Semester	:	75
Course Code	:	PY.09.886.12.P	Exam Duration	:	6 Hrs.

Course Objectives:

To acquaint in analyzing the physical parameters required in pharmaceutical product development.

Course Outcomes:

To develop capacity to explain the differential principles applies to solve the physical parameters associated with product development.

List of Experiments:

1. Effect of surfactants on the solubility of drugs.
2. Effect of pH on the solubility of drugs.
3. Dissolution methods of transdermal drug delivery systems.
4. Dissolution studies of drug in three different bio-relevant dissolution media (2 experiments).
5. Effect of solid dispersion and hydrotropy on the dissolution.
6. Test for degradation of compounds using TLC for any two drugs.
7. Stability testing of solution and solid dosage forms for photo degradation.(2 experiments).
8. Effect of hydrogen peroxide, hydrochloric acid and sodium hydroxide solutions on the stability of drugs in solution at elevated temperatures and room temperature. (2 experiments).
9. Stability studies of drugs in dosage forms at 25 ^{o}C, 60% RH and 40 ^{o}C, 75% RH.
10. Compatibility evaluation of drugs and excipients.
11. Product development and protocol preparation using preformulation data for tablets and capsules.
12. Dissolution of drugs in different pH media for comparison of performance with innovator.

Books and References:

INTELLECTUAL PROPERTY RIGHTS & REGULATORY AFFAIRS

Scheme of Instruction			Scheme of Examination		
Total Duration	:	60 Hrs.	Max. Marks	:	100
Hours/Week	:	3 Hrs.	Mid Semester	:	20
Credits	:	3	Quiz	:	05
Instruction Mode	:	Lecture	End Semester	:	75
Course Code	:	PY.09.885.21.P	Exam Duration	:	3 Hrs.

Course Objectives:

To make students familiar with the fundamental principles of IPR and Drug Regulatory Affairs

Course Outcomes:

On completion of the course the student would understand the principle and importance of IPR and Drug Regulatory Affairs in the Competitive World.

Further to familiarize with Safety and Pollution Control Regulations in addition to Other Product Regulations and Sustainable Development Principles.

Unit - I :

Intellectual Property Rights (IPR): Objectives, types of IPR, Patents-advantages, types, criteria, inventions – patentable, Impact on Pharmaceutical Industry, copyrights-types rights, trademarks-functions, types, geographical indications-significance, types, industrial designs, and trade secrets.

India Patents Act, 1970, Amendments, 1999, 2002, 2005, stages of patenting, patent opposition (Post Grant), maintaining the patent rights – Conditions, patent information – search and sources

Unit - II :

International Patent Filing Procedures – Requirements for patenting, utility, novelty non-obviousness, patent specification & claims, patent infringement and doctrine of equivalents, federal circuit and patent system.

International Organizations and Agreements – IPR: General Agreement on Tariffs and Trade (GATT) - Historical perspectives, objectives and impact, World Trade Organization (WTO) - scope, functions, structure, withdrawal ofmembership, dispute settlement, World Intellectual PropertyOrganization (WIPO) - objectives and programs, Paris Convention – background, scope, impact, Berne Convention, TRIPS Agreement-scope general features, specific features, The Doha Declaration, Patent Cooperation Treaty (PCT), Madrid Protocol.

Unit - III :

ICH – Guidelines: Harmonization Efforts, Basic Principles (Quality, Safety and Efficacy), ICH Q11 (Quality Management Systems); Common Technical Document (CTD) and Generic Drug Products.

WHO – Guidelines: Sampling Operations

PICS Guidelines: Basic Requirements of Medicinal Products and API's

OECD Guidelines: Clinical Studies

US-FDA: Orange Book, FDA Guidelines on Investigational New Drugs (IND), New Drug Applications (NDA).

Unit - IV :

Regulatory Affairs: Indian Context - Drugs and Cosmetics Act 1940 and Rules 1945 with reference to Schedule M, U and Y. Drug Regulatory Controls and Authorities;

Important Regulations: Importand Export of Drugs; Preparation and Submission of Marketing Application of India, US and Europe; Approval and Appeals Present and Issues of Confidentiality.

Unit - V

Industrial Safety Regulations: Industrial Development & Regulation Act 1951, Industrial Hazards – Mechanical, Electrical, Chemical and Pharmaceutical (MSDS Preparation), Industrial Safety - Plant, Gas, Dust, Fire and Explosion, Safety Management. Monitoring & Prevention Systems,

Pollution Control Regulations: Pollution Control Act; Industrial Effluent Testing & Treatment. Control of Environmental Pollution, Water and Solid Waste in Formulation, Synthetic and Fermentation Plants.

Other Product Regulations: Prevention of Food Adulteration Act 1954; Consumer Protection Act

Sustainable Development: 10 Principles Bench Marked against leading International Standards;

Books and References:

1. Guarino RA. New Drug Approval Processes, 4th ed., Vol 139, Marcel Dekker Inc., New York, 2004.
2. Willing SH. Good Manufacturing Practices for Pharmaceuticals. 5th ed., vol 109, Marcel Dekker Inc., New York, 2001.
3. Das P, Das G. Protection of Industrial Property Rights.
4. Treece DJ. Managing Intellectual Capital: Organizational, Strategic and Policy Dimension. Oxford University Press, England. Latest Edition.
5. Wadedhra BL. Law Relating to Patents, Trademarks, Copyright Design and Geographical Indications. Universal Law Publishing, New Delhi. Latest Edition.
6. Bansal P. IPR Handbook for Pharma Students and Researchers, Pharma Book Syndicate, Hyderabad. Latest Edition.
7. Katju SN. Laws and Drugs. Law Publishers.
8. Original Laws Published by Government of India.
9. Hussain. Law of Drugs in India.
10. Regulatory Guidelines Related to GMP by
    a. Australian code of GMPfor medicinal products, 16th Aug. 2002.
    b. 21 Code of Federal Regulation, parts 210, 211 & 58. (US-FDA Guidelines)
    c. MHRA, UK Guidelines on GMP
    d. GMP Guidelines byMedicines Control Council of South Africa
    e. Schedule M of D & C Act
11. WHO Guidelines: QualityAssurance of Pharmaceuticals – A Compendium of Guidelines and Related Materials – Vol. 2; WHO 2007;
12. GMP Guidelines (Websites: www.fda.org; www.wipo.int, www.ich.org, www.cder.org)
13. PICS Guidelines (Website: http://www.picscheme.org/)
14. Information on Orange Book [website: www.fda.gov/cder/ob/default.html].
15. Relevant OECD Guidelines (Website: http://www.ingentaconnect.com/content/oecd/16073/2001/00000001 /00000004
16. Subrahmanyam CVS, Thimma Setty JPharmaceutical Regulatory Affairs, Vallabha Prakashan, Delhi 2012.

BIOPHARMACEUTICS AND PHARMACOKINETICS

Scheme of Instruction			Scheme of Examination		
Total Duration	:	60 Hrs.	Max. Marks	:	100
Hours/Week	:	4 Hrs.	Mid Semester	:	20
Credits	:	4	Quiz	:	05
Instruction Mode	:	Lecture	End Semester	:	75
Course Code	:	PY.09.886.22.T	Exam Duration	:	3 Hrs.

Course Objectives:

To make students familiar with the fundamental principles of drug absorption, distribution, metabolism and excretion of drugs.

To emphasize on bioavailability study and application of biopharmaceuticals.

Course Outcomes:

On completion of the course the student would understand the

- *Drug absorption, distribution, metabolism, and elimination.*
- *Basic mechanisms and concepts of absorption, distribution, metabolism, and elimination.*
- *How to predict the fate of drugs in the body given all the physiological, chemical and physical parameters of the drug and the patient*

Unit - I :

Bioavailability and Bioequivalence: Objectives, bioavailability & variations, measurements of bioavailability, enhancing bioavailability, concepts of equivalents, official bioequivalence protocols & therapeutic equivalence. Methods of determining absorption-*in-vitro*, *in-situ*, and *in-vivo* methods.

Drug Distribution: Factors affecting, protein & tissue binding, kinetics, determination of rate constants & different plots (direct, Scatchard, & reciprocal).

Unit - II :

Pharmacokinetics: Parameters & determination, pharmacokinetic models – one compartment, multi compartment in IV bolus, IV infusion & extra vascular, drug & metabolites levels in blood, urine and other biological fluids. Integration of kinetics; Application of pharmacokinetics in new drug development, design of dosage forms and novel drug delivery systems. Physiological basis for in-vitro modeling.

Unit - III :

Pharmacokinetics of Multiple Dosing: Various terminology, determination, adjustmentofdosage in renal & hepatic impairment, individualization of therapy, therapeutic drug monitoring.

Unit - IV :

Non-linear kinetics: Causes of non-linearity, estimation of various parameters, and bioavailability of drugs that follow non-linear kinetics. Chrono Pharmacokinetics, Population Pharmacokinetics and Pharmacokinetics of Elderly and Infants.

Unit - V :

Drug Disposition and Excretion: Factors affecting biotransformation, Phase I & Phase-II reactions.

Clearance: Concept, renal, non-renal clearance, mechanism, determination, % drug metabolized, different volume of distribution.

Books and References:

1. Biopharmaceutics and Clinical Pharmacokinetics, Mile Gibaldi, Lea and Febriger, Philadelphia.
2. Current concepts in Pharmaceutical Sciences, Swarbrick, Lea and Febriger, Philadelphia.

3. Theory & Practice of Industrial Pharmacy, L.Lachman, Varghese Publ, Bombay.
4. Clinical Pharmacokinetics, Rowland and Tozer, Lea and Febriger, Philadelphia.
5. Biopharmaceutics and Clinical Pharmacokinetics, Niazi, Prentice Hall, London.
6. Remingtons Pharmaceutical Sciences, Mack & Co.
7. Biopharmaceutics & Clinical Pharmacokinetics, DM Brahmankar, Vallabh, Delhi.
8. C.V.S.Subrahmanyam, Textbook of Biopharmaceutics and Pharmacokinetics, 2009, Vallabh Prakashan, Delhi.

ADVANCES IN DRUG DELIVERY SYSTEMS

Scheme of Instruction			Scheme of Examination		
Total Duration	:	60 Hrs.	Max. Marks	:	100
Hours/Week	:	4 Hrs.	Mid Semester	:	20
Credits	:	4	Quiz	:	05
Instruction Mode	:	Lecture	End Semester	:	75
Course Code	:	PY.09.886.23.T	Exam Duration	:	3 Hrs.

Course Objectives:

To get acquainted with applications of New Drug Delivery Systems.

Course Outcomes:

Students can select research based project in subsequent semesters for specific type of delivery systems. The knowledge gained by the students during the study of this course can also help them in research projects and in Pharma industry.

Unit - I :

Concept & Models for NDDS: Classification of rate controlled drug delivery systems (DDS), rate programmed 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.

Unit - II :

Study of Various DDS: Concepts, design, formulation & evaluation of controlled release oral DDS, Muco-adhesive DDS (buccal, nasal, pulmonary).

Unit - III :

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

Advances in Drug Delivery: Pulsatile, colon specific, liquid sustained release systems.

Unit - IV :

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 erythorocytes, microspheres, magnetic microspheres. Specialized pharmaceutical emulsions – multiple emulsions, micro-emulsions.

Unit - V :

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

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

Books and 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, 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.

PROCESS SCALE UP AND VALIDATION

Scheme of Instruction			Scheme of Examination		
Total Duration	:	60 Hrs.	Max. Marks	:	100
Hours/Week	:	4 Hrs.	Mid Semester	:	20
Credits	:	4	Quiz	:	05
Instruction Mode	:	Lecture	End Semester	:	75
Course Code	:	PY.09.886.24.T	Exam Duration	:	3 Hrs.

Course Objectives:

To enable the students acquaint with the scale up techniques, pilot plant design and validation

Course Outcomes:

To apply their knowledge of process scale up and validation for reproducibility

Unit – I :

Scale Up Techniques: Importance and strategies, principles of similarity, dimensional analysis, microspheres (emulsification method) – Dimensional analysis, scale up techniques involved in tablets– mixing, granulation, size reduction, compression, film coating, scale up techniques involved in filling in hard gelatin capsules,

Unit – II

Pharmaceutical Pilot Plant: General principles, scale of batches – product development, layout of pharmaceutical pilot plant, organizational structure, personnel and activities, Pilot Plant- tablets, capsules, solution dosage forms, dispersion systems (suspensions, emulsions, semisolids), parenteral products.

Unit – III :

Validation: General concepts, types, procedures & protocols, documentation, validation master file (VMF).

Analytical Method Validation: General principles, HPLC and dissolution test apparatus.

Unit – IV :

Equipment Qualification: Importance, IQ, OQ, PQ for equipment – autoclave, DHS, membrane filter, rapid mixer granulator, cone blender, FBD, tablet compression machine, liquid filling and sealing machine.

Utilities Validation: Validation of Pharmaceutical Water system, HVAC system, Cleaning Validation.

Unit – V :

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

Inventory Control: Different Systems of inventory control; Import and Export regulations laws and methods to obtain I & E licenses; I and E regulations USA, EU and Japanese perspectives and Vendor Qualification.

Books and References:

1. JR Berry, Nash, Pharmaceutical Process Validation, Vol 57, Marcel Dekker, NY.
2. GC Cole, Pharmaceutical Production Facilities, Design and Applications, Taylor and Francis.
3. T. Kennedy, Pharmaceutical Project Management, Vol 86, Marcel Dekker, NY.
4. L. Lachman, H.A. Lieberman, The Theory& Practice of Industrial Pharmacy, Varghese Publ. Bombay.
5. PR Watt, Tablet Machine Instruments in Pharmaceuticals, John Wiley.
6. L. Lachman, H.A. Lieberman, Pharmaceutical Dosage Forms, Tablets, Vol 1, 2, 3 by Marcel Dekker, NY.
7. K.E. Avis, Pharmaceutical dosage forms, Parenteral Medications, Vol 1, 2 Marcel Dekker, NY.
8. L. Lachman, H.A. Lieberman, Dispersed System Vol 1, 2, 3 Marcel Dekker, NY.
9. Subrahmanyam, CVS, Pharmaceutical Production and Management, 2007, Vallabh Prakashan, Dehli
10. Chary S.N. 'Production and Operative Management" Tata-McGraw Hill, India.

ELECTIVE

COSMETIC TECHNOLOGY

Scheme of Instruction			**Scheme of Examination**		
Total Duration	:	60 Hrs.	Max. Marks	:	100
Hours/Week	:	3 Hrs.	Mid Semester	:	20
Credits	:	3	Quiz	:	05
Instruction Mode	:	Lecture	End Semester	:	75
Course Code	:	PY.09.886.25.T	Exam Duration	:	3 Hrs.

Course Objectives:

To provide the concepts of various parameters involved in the formulation and development of Cosmetics

Course Outcomes:

Understand the formulation concepts and factors influencing the developmentofvarious Cosmetics

Unit – I :

General Raw Materials in CosmeticFormulations: Overview of raw materials-Water, natural & synthetic oils, fats& waxes, inorganic solids, emulsifiers, thickeners, hydrocolloids, polymers, surfactants, antioxidants, humectants, poly-siloxanes, preservatives; Coloring agents used in cosmetics. Quality evaluation of colors, safety, toxicity and regulatory aspects of colors w.r.t. cosmetic products;

Perfumes in cosmetics: Raw materials in perfumery, developing a perfume composition, current trends including emulsified and solid perfumery, analytical and separation techniques of perfumes, sensory analysis, safety and toxicological evaluation of perfumes, manufacturing and packaging of perfumes, legislation and regulations for perfumes in cosmetics.

Unit – II :

Novel Approaches in Cosmetic Formulations: Concepts of micro-emulsions, liposomes, niosomes, nanoparticles, iontophoresis, to enhance functional attributes & delivery of cosmeceuticals.

Therapeutic Ingredients in various Cosmetics: Skin Products, Dentifrices, Hair care and Nail preparations, and performance evaluation of these activities.

Herbal Cosmetics: Current trends in use of herbal materials in cosmetics such as *aloe Vera, henna, tea tree oil, neem in various cosmetic products*

Unit – III :

Physiological Consideration: Skin, Hair, Nail and Eye- in relation to Cosmetic Application.

Rheology of Cosmetics: Rheological additives in cosmetics, rheology of nail products, antiperspirants, deodorants, hair products, creams and lotions.

Manufacturing Techniques: Cosmetic creams, powders, compacts, sticks, liquids, foam and aerosols.

Packaging: Package development and design for cosmetics including aerosol packs.

Unit – IV :

Quality Standards of Cosmetic Products: QualityControl, BIS guidelines for quality of finished products for cosmetics, Microbiological Quality of Cosmetic Products

Evaluation of Cosmetics: Textural Analysis, Performance, Physicochemical, Microbiological and Psychometric evaluation of various cosmetic products such as creams, gels, powders, lipstick, nail lacquer, shampoo, sunscreen products, dentifrices. Design and Assessment of preservative systems for cosmetics, evaluation of preservatives in cosmetic products and factors affecting activity of preservatives.

Unit – V :

Clinical Safety Testing: ; Safety and toxicity evaluation of cosmetic products; Irritation, sensitization, photoirritation, photoallergy, ocular irritation and protocols for the same. Testing of moisturizers, deodorants, antiperspirants, sunscreen and anti-aging products.

Regulatory Requirements: Manufacturing and Sale of Cosmetics.

Books and References:

1. Hilda Butler, Klewer, Poucher's Perfumes, Cosmetics & Soaps, 10th Ed, Academic Publishers, NL, 2000
2. S. Nanda, A. Nanda and R. Khar, Cosmetic Technology, Ed. Birla Publications Pvt. Ltd., New Delhi, 2007
3. M. Paye, A.O. Barel, H. I. Maibach, Handbook of Cosmetic Science and Technology, Informa Healthcare USA, Inc. 2007.
4. James Swarbrick, James C. Boylan, Encyclopedia of Pharmaceutical Technology, Vol. 6, Marcel Dekker Inc., 1992
5. J. Knowlton and S. Rearce; Handbook of Cosmetic Sciences and TechnologyElsevier SciencePublisher.
6. J. B. Wilkinson and R. J. Moore; Harry's Cosmetology; Longman science and Technical.
7. S. N. Katju's; Law of Drugs; Law Publishers (India) Pvt. Ltd.
8. E. G. Thomssen; Modern Cosmetics; Universal Publishing Corporation.
9. M.S. Balsam, E. Sagarin, S.D. Gernon, S.J.Strianse and M.M.Rieger, Cosmetics Science and Technology, Edited Volumes 1,2 and 3.Wiley-Interscience, Wiley India Pvt. Ltd.,2008
10. R. L. Elder; Cosmetic Ingredients, their Safety Assessment; Pathotox.
11. H. R. Moskowitz; Cosmetic Product Testing; Marcel Dekker.
12. W. C. Waggoner; Clinical Safety and Efficacy Testing of Cosmetics; Marcel Dekker.
13. C. G. Gebelein, T. C. Cheng and V. C. Yang; Cosmetic and Pharmaceutical Applications of Polymers; Plenum.
14. L. Appell; The Formulation and Preparation of Cosmetics, Fragrances and Flavors; Micelle Press.
15. W. A. Poucher; Poucher's Perfumes, Cosmetics and Soaps; vol. 3 Chapman and Hall
16. Dr. Laba; 'Rheological Properties of Cosmetics and Toiletries; Marcel Dekker
17. Drugs & Cosmetics Act & Rules, 1940 (with latest amendments)..

ELECTIVE

DRUG POLYMER TECHNOLOGY

Scheme of Instruction			**Scheme of Examination**		
Total Duration	:	60 Hrs.	Max. Marks	:	100
Hours/Week	:	3 Hrs.	Mid Semester	:	20
Credits	:	3	Quiz	:	05
Instruction Mode	:	Lecture	End Semester	:	75
Course Code	:	PY.09.885.25.T	Exam Duration	:	3 Hrs.

Course Objectives:

To know and understand the importance of polymers use in drug development

Course Outcomes:

To acquaint with the knowledge of significance of polymers in drug development.

Unit - I :

General Study of Polymer Science: Classification of polymers, Macromolecules: structure and properties (molecular mass, molecular weight distribution, conformation and configuration), Major strategies for synthesis of polymers, general methods of preparation of polymers like solution bulk, suspension and emulsions, polymerizations with examples. Methods of polymer modification, Solid state properties of polymers, flow characteristics, crystallinity.

Unit - II :

Evaluation of Polymers in Solution: Polymers in solutions: Solubility of polymers, methods of polymer characterization in solution (thermodynamics of polymer solutions), Viscosity and viscoelasticity of polymers, polyelectrolytes and polyampholytes, cross-linked polymers and polymer complexes.

Unit - III :

Therapeutic Applications of Polymers: Polymers for therapeutic applications, biocompatible and biodegradable polymers, biodegradability and biodegradability testing of polymers, applications of biodegradable polymers in parenterals and surgicals, polymer-drug conjugates, self-assembled polymeric carriers (polymeric micelles, polymer-coated liposomes, nanoparticles, microspheres, etc.)

Unit - IV :

Bio interactions of Polymers: Interactions of polymers with tissues and cells, Pharmacokinetics of polymer therapeutics, targeted polymer therapeutics, passive targeting of polymeric drugs, enhanced permeation and retention effect (EPR), functional excipients and biologicalresponsemodifiers, polymeric immune-adjuvants and immune-modulators, stimuli responsive systems and intracellular drug delivery.

Unit - V :

Polymer Drugs and Regulatory Issues: Prospects of Polymer Drugs and Regulatory Challenges in Polymer Therapeutics

Books and References:

1. J. Brandrup, E. H. Immergur; Polymer Handbook ;John wiley and Sons
2. L. H. Sperling, Introduction to Polymer Science, Wiley, NY, 1992.
3. H. Morawetz, Macromolecules in Solution (2nd ed.), Wiley-Interscience, NY, 1975
4. C. Tanford, Physical Chemistry of Macromolecules, John Wiley, NY, 1961.

5. F. W. Billmeyer, Jr. Textbook of Polymer Science, 3rd Ed. John Wiley, New York, 1984.
6. B. D. Ratner, A. S. Hoffman, F. J. Schoen, J. E. Lemons, Biomaterials Science. An Introduction to Materials in Medicine, Academic Press, San Diego, 1996.
7. Biomedical Polymers and Polymer Therapeutics, Eds. E. Chiellini et. al. , KluwerCharles
8. G. Gebelein. T. C. Chin and V. C. Yang; Cosmetic and Pharmaceutical Applications of Polymers; Plenum Press, New work.
9. D. S. Soane; Polymer Applications for Biotechnology; Prentice Hall Inc.
10. J. R. Robinson and V. H. Lee: Controlled Drug Delivery – Fundamentals and Application; Marcel Dekker.
11. N. K. Jain; Controlled and Novel Drug Delivery; CBS publications.
12. P. J. Tarcha; Polymers for Controlled Drug Delivery; CRC Press.
13. A. F. Kydonieus; Controlled Release Technologies: Methods, Theoryand Application, Vol-I & II; CRC Press Inc.
14. Academic/Plenum Publishers, NY, 2001.
15. Self-Assembling Complexes for Gene Delivery. From Laboratory to Clinical Trial. A. V. Kabanov,
16. P. L. Felgner, L. W. Seymour, Eds. John Wiley & Sons: New York, 1998.

ELECTIVE
PHARMACEUTICAL BIOTECHNOLOGY

Scheme of Instruction			**Scheme of Examination**		
Total Duration	:	60 Hrs.	Max. Marks	:	100
Hours/Week	:	3 Hrs.	Mid Semester	:	20
Credits	:	3	Quiz	:	05
Instruction Mode	:	Lecture	End Semester	:	75
Course Code	:	PY.09.886.25.T	Exam Duration	:	3 Hrs.

Course Objectives:

To understand the basics of biotechnology in production ofdrugs and pharmaceuticals

Course Outcomes:

To apply the knowledge of biotechnology in development of Biopharmaceuticals

Unit - I :

Status and Scope of Biotechnology in Pharmacy Enzyme immobilization- Principles and Pharmaceutical applications. Immobilization of enzymes, proteins and their applications – biosensors, enzyme electrodes, immune-sensors, optical sensors

Biotransformation principles and industrial applications in the production ofchemicals and drugs;

Unit - II :

Biotechnology based pharmaceutical using recombinant DNA Technology, interferons and reverse transcriptase.

Production and Control of Biotech derived products: Recombinant DNAproducts – insulin, growth hormone, erythropoietin, cytokines; Vaccines – attenuated virus, genetic alterations of live virus as a vector of other pathogens (recombinant virus or recombinant vaccinia virus); Diagnostic proteins – protein A, protein G, antibodies; Quality control testing of biotech products – determining impurities, contamination -viral, bacterial endotoxin, rabbit pyrogen test, sterility, protein identification, finger prints by electrophoresis, isoelectric focusing, immunogenicity, partial sequence analysis

Unit - III :

Optimization of fermentation processes-Ethyl Alcohol, Antibiotics, Vitamins, Amino-acids and Pharmaceutical solvents-raw materials, process and process validation.

Biotech products through fermentation: Fermentation – batch, continuous fermentation; Role of bioengineering in fermentation – geometry of fermentation tanks, design of impellers, agitation systems and environmental conditions of fermentation; Fermentative production of important secondary metabolites – penicillins, amino glycosides polyene macrolides, macrolides, anthracyclines; Principles of downstream processing of fermentation products; Unit operations and techniques employed inn downstream processing of fermentation; products, microbial strain selection and preservation methods; Genotype and phenotype variation of characters of microbes;

Unit - IV :

Plant biotech products: Substances produced by plant cell culture; Transgenic plants and their application; Biotransformations with plant cell culture;

Bio-technology & GMP- Formulation approaches to protein stabilization. Regulatory aspects of Biotechnology based pharmaceuticals.

Unit - V :

Introduction to Bio-informatics. Information theory and biology, redundancy networking, network access, Internet & E-mail services, use of data base in biology, sequence data base for comparisons. Applications of predictive pharmaceutics, chemico-pharmaceutics, cheminformatics, bioinformatics and data mining.

Books and References:

1. Wiseman A.,ed, Principles of Bio-technology", Chapman & Hall.
2. Antebi E, Fishlock D., "Biotechnology- Strategies for life", Cambridge.
3. Higgins 1.1., Best, DJ & Jones "Biotechnology, Principles & Applications" Blackwell Scientific Pub., Oxford.
4. Stanbary P.F. and Whitaker, "Principles of Fermentation Technology" Pergamon Press, Oxford.
5. Golub E "The Limits of Medicine: How Science Shapes our Hope for the Cure Time Books, New York.
6. Bickerstaff GF. "Enzymes in Industry and Medicine, New Studies in Biology" Edwin Arnold, London.
7. Glick. BR, Pasternak J.I., "Molecular Biotechnology-Principles and Applications of Recombinant DNA" ASM Press Washington.
8. H. J. Rechm, G. Reed, Biotechnology. Vols 1 – 12, A. Pulher, P. Stadler Eds, Weinhelm, New York
9. H. D. Kumar, A text book of Biotechnology, Affiliated, East – West Press Pvt. Ltd.
10. C. Clark, Genetic Engineering Fundamentals, Karl Kammer, Meyer Virginia,.
11. Benjamin Lewin, Genes V, Oxford University Press.
12. Bernard R Glick, John E Thompson, Methods in Plant Molecular Biologyand Biotechnology, CRC Press.
13. Leo C Vining, Colin, Stuttard Butterworth, Genetic and Biochemistryof Antibiotics Production, Heinemann.
14. Paul N Chermisinoff, Robert P Ouellett, Biotechnology-Applications and Research, Technomic Pub. Co. Inc.
15. Meran R. L. Owen, Jan Pen, Transgenic Plants: A production systems for industrial and pharmaceutical proteins, John Wiley and Sons.
16. William R Strohl, Biotechnologyof antibiotics, Marcel Dekker.
17. Sunil Maulik and Salil D Patel, Molecular Biochemistry– Therapeutic Applications and Strategies, John Wiley and Sons,

BIOPHARMACEUTICS AND PHARMACOKINETICS

Scheme of Instruction			**Scheme of Examination**		
Total Duration	:	60 Hrs.	Max. Marks	:	100
Hours/Week	:	4 Hrs.	Mid Semester	:	20
Credits	:	2	Quiz	:	05
Instruction Mode	:	Practical	End Semester	:	75
Course Code	:	PY.09.886.22.P	Exam Duration	:	6 Hrs.

Course Objectives:

To make students familiar with the fundamental principles of drug absorption, distribution, metabolism and excretion of drugs.

Course Outcomes:

Understands the basic mechanisms and concepts of absorption, distribution, metabolism, and elimination.

List of Experiments:

1. Comparative dissolution studies on different dosage forms for drugs.
2. Effect of pH / particle size on dissolution studies.
3. Plasma protein binding studies on different drugs.
4. Estimation of pharmacokinetic parameters in urine / serum samples.
5. Estimation of creatinine clearance.
6. Estimation of pharmacokinetic parameters for the given urinary excretion data.
7. Estimation of pharmacokinetic parameters for the given oral absorption data.

Books and References:

1. Clinical Pharmacokinetics - concept& application - MalcolmRowland&ThomasN.Tozer, Lea & Febiger book.
2. Applied Biopharmaceutics & Pharmacokinetics – LeonShargel.
3. Biopharmaceutics & Pharmacokinetics - Milo Gibaldi , Lea & Febiger book publication
4. Biopharmaceutics & Pharmacokinetics - an introduction - RobertE.Notary.
5. Biopharmaceutics - Swarbrick, Lea & Febiger book publication
6. Biopharmaceutics & Pharmacokinetics. A treatise - D. M. Brahmankar S B. Jasiwal
7. Biopharmaceutics & Pharmacokinetics - P.L.Madan
8. Introduction to Biopharmaceutics. - G.P. -Shriwastav
9. Textbook of Applied Biopharmaceutics and Pharmacokinetics by Shargel.
10. Biopharmaceutics and Clinical Pharmacokinetics by John and Wagner.
11. Biopharmaceutics and Clinical Pharmacokinetics by Milo Gibaldi.
12. Biopharmaceutics and Pharmacokinetics-A Treatise by D.M.Brahmankar and S.B.Jaiswal, VallbahPrakash, New Delhi.
13. Biopharmaceutics by Swabeic.

ADVANCED DRUG DELIVERY SYSTEMS

Scheme of Instruction			**Scheme of Examination**		
Total Duration	:	60 Hrs.	Max. Marks	:	100
Hours/Week	:	4 Hrs.	Mid Semester	:	20
Credits	:	2	Quiz	:	05
Instruction Mode	:	Practical	End Semester	:	75
Course Code	:	PY.09.886.23.P	Exam Duration	:	6 Hrs.

Course Objectives:

To understand the factors influencing the preparation of formulation of advanced drug delivery systems.

Course Outcomes:

Comprehend various classes of excipients involved in formulation of advanced drug delivery systems.

List of Experiments:

1. Preparation and evaluation of albumin microspheres (1 expt)
2. Preparation and evaluation of matrix tablets using various polymers (1 expt)
3. Preparation and in vitro evaluation of buccal mucoadhesive formulations (tablets/films) (2 expts)
4. Preparation and evaluation of hydrodynamically balanced tablets (1 expt)
5. Preparation and evaluation of ocular films (1 expt)

Books and References:

SAIL

SCIENTIFIC AND TECHNICAL WRITING

Scheme of Instruction			**Scheme of Examination**		
Total Duration	:	30 Hrs.	Max. Marks	:	50
Hours/Week	:	2 Hrs.	Assignment	:	20
Credits	:	2	Attendance	:	05
Instruction Mode	:	Tutorial	Seminar	:	25
Course Code	:	PY.09.880.X1.I	Exam Duration	:	1 Hr.

Course Objectives:

To be able to appreciate and understand importance of writing scientifically.

- *To develop competence in writing and abstracting skills.*
- *To write either a draft research proposal or a chapter of dissertation.*

Course Outcomes:

Able to prepare a document with systematic approach

Unit - I :

COLLECTION AND EVALUATION OF INFORMATION: Identification sources, searching information, classifying information under fact/opinion, tabulating information, summarizing a text and presenting sequence of topics in different forms.

WRITING AS A MEANS OF COMMUNICATION: Different forms of scientific and technical writing; Articles in journals, Research notes and reports, Review articles, Monographs, Dissertations, Bibliographies.
How to formulate outlines: The reasons for preparing outlines
(i) as a guide for plan of writing (ii) as skeleton for the manuscript
Outline of topic, concept, sentence and combination of topic and sentence outlines

Unit - II :

DRAFTING TITLES, SUBTITLES, TABLES, ILLUSTRATIONS

- Tables as systematic means of presenting data in rows and columns and lucid way of indicating relationships and results.
- Formatting Tables: Title, Body stab, Stab Column, Column Head, Spanner Head, Box Head
- Appendices: use and guidelines

The Writing process: Getting started, Use outline as a starting device, Drafting, Reflecting and Re-reading
Checking: Organization, Headings, Content, Clarity and Grammar
Brevity and Precision in writing - Drafting and Re-drafting based on critical evaluation

PARTS OF DISSERTATION/RESEARCH REPORT/ARTICLE
Introduction, Review of Literature, Methodology, Results and Discussion
Content, continuity, clarify, validity internal consistency and objectivity during writing each of the above parts.

References:

1. APA (1984): Publication Manual of American Psychological Association 3rd Ed, Washington.
2. Cooper, H.M. (1990): Integrating Research: A Guide for Literature Reviews (2nd Edition). California: Sage.
3. Dunn, F.V & Others. (Ed.) (1984): Disserninating Research: Changing Practice. NY: Sage.

SAIL

RESEARCH METHODOLOGY

Scheme of Instruction			**Scheme of Examination**		
Total Duration	:	30 Hrs.	Max. Marks	:	50
Hours/Week	:	2 Hrs.	Assignment	:	20
Credits	:	2	Attendance	:	05
Instruction Mode	:	Tutorial	Seminar	:	25
Course Code	:	PY.09.880.X2.I	Exam Duration	:	1 Hr.

Course Objectives:

To give exposure on how to do literature survey for the project work.
To develop technical writing skills in the form of a research report.

Course Outcomes:

To able to organize the research in an effective fashion

Unit – I :

Basics of Research: Definition, objectives, motivation, types of research and approaches; Descriptive research, conceptual, theoretical, applied and experimental.

Formation of Research Problem: Research Process: To determine what type of research to be done, plan of research work; Selection of research area, prioritization of research; Literature review: importance and methods, sources; Objectives and scope of work, developing research plan and schedule; Scheduling constraints, steps, problems in scheduling, limitations.

Experimental Modeling: Definition of experimental design, examples, single factor experiments, blocking and Nuisance factors, guidelines for designing experiments; General model of process: Input factors/ variables, Output parameters / variables controllable / uncontrollable variables, dependent / independent variables, experimental validity; Introduction to Risk assessment, reliability, sustainability, and uncertainty.

Unit – II :

Analysis of Data: Types of data: parametric and nonparametric, descriptive and inferential data; Collection of data: normal distribution, calculation of co-relation coefficient; Data processing: analysis, error analysis, meaning, and different methods; analysis of variance, significance of variance, analysis of covariance, multiple regressions, testing linearity/nonlinearity of model, testing adequacy of model; Test to be used in data exploration and their choice; Introduction of software used in data analysis.

Research Deliverables: Various Forms of Publication: T hesis, paper, research proposal; Thesis Writing: Introduction, literature review/state-of-the-art, research approach (methodology), results / findings, discussions, conclusions, scope for future work, references, appendices; Presentation: Poster, thesis, proposal, and paper.

Ethical and Plagiarism issues in research: Historical perspectives, General principles on ethical consideration involving human participation, General ethical evaluation of drugs/ device/ diagnostics/ vaccines/ herbal remedies. Statement of specific principles for human genetics and genomic research. International Conference on Harmonization. Good clinical practices norms, Ethical principles related to animal experiments; Issues related to plagiarism, copyright laws, acknowledging the sources, format for manuscript writing, documentation, organization of reference material, bibliography, end note.

References:

1. C.R. Kothari, 2004. "Research Methodology". 2nd Ed. New Age International (p) Limited, Publishers.
2. D. Montgomary, 2000. "Design of Experiments". 5th Ed. Wiley Interscience.
3. K.P. Willkinsion, L. Bhandarkar, "Formulation of Hypothesis". 3rd ed. Himalaya publishing, Mumbai.
4. Schank Fr, 2008. "Theories of Engineering Experiments". 2nd Ed. Tata McGraw Hill.
5. J.W. Best and J.V. Kahn, 2006. "Research in Education". 10th Ed. PHI publication.

SAIL

TEACHING METHODOLOGY

Scheme of Instruction			**Scheme of Examination**		
Total Duration	:	30 Hrs.	Max. Marks	:	50
Hours/Week	:	2 Hrs.	Assignment	:	20
Credits	:	2	Attendance	:	05
Instruction Mode	:	Tutorial	Seminar	:	25
Course Code	:	PY.09.880.X3.I	Exam Duration	:	1 Hr.

Course Objectives:

To acquaint with the basic tools of teaching to part of teaching profession

Course Outcomes:

Able to practice the teaching techniques for effective dissemination of knowledge

Unit - I :

Learning and Instruction: Principles of Instructional design and learning theory, Merrill's five principles and Gagne's condition of learning. Active learning, group learning, collaborative learning, problem-based learning, team-based learning, Experiential learning model of Kolb.

Curriculum Development: A six step approach- Problem identification and general needs assessment, targeted needs assessment, goals and objectives, educational strategies, implementation, evaluation and feedback. Bloom's Taxonomy, three domains of educational objectives.

Unit - II :

Assessment: Definition and methods, Georges Millers pyramid, assessment, measurement and tests, types of numbers, formative and summative assessment.

Teaching Methods: Activities conducted individually, in pairs and in groups like self-introduction, peer introduction, group poster making, grammar and vocabulary games, etc.
Discussions; Role playactivities; Short presentations; Listening and viewing activities with follow up activities like discussion, filling up worksheets, writing exercises (using language lab wherever necessary/possible) etc.

References:

1. B.D. John, A.L. Brown and R.R. Cocking, 1999."How People Learn: brain, mind, experience and school". Washington, DC: NationalAcademy Press.
2. K.E. David, 2009. Curriculum Developmentfor Medical Education: *A Six-Step Approach,* 2nd Ed. The John Hopkins University Press. ISBN 0-8018-9367-4.

SAIL

ENREPRENEURSHIP DEVELOPMENT

Scheme of Instruction			Scheme of Examination		
Total Duration	:	30 Hrs.	Max. Marks	:	50
Hours/Week	:	2 Hrs.	Assignment	:	20
Credits	:	2	Attendance	:	05
Instruction Mode	:	Tutorial	Seminar	:	25
Course Code	:	PY.09.880.X4.I	Exam Duration	:	1 Hr.

Course Objectives:

To provide conceptual inputs regarding entrepreneurship management.

To sensitize and motivate the students towards entrepreneurship management.

To orient and impart knowledge towards identifying and implementing entrepreneurship opportunities.

Course Outcomes:

To develop management skills for entrepreneurship management

Unit - I :

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;

THE ENTREPRENEUR: Dynamics of Entrepreneurial Motivation; Concepts; Developing Entrepreneurial Competencies; Requirements and understanding the process of entrepreneurship development; self-awareness, interpersonal skills, creativity, assertiveness, achievement, factors affecting entrepreneur'' role.

Unit - II :

LAUNCHING AND ORGANISING 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; Project work – Feasibility report; Planning, resource mobilization and implementation.

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;

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

SAIL

COMPUTATIONAL TECHNIQUES

Scheme of Instruction			**Scheme of Examination**		
Total Duration	:	30 Hrs.	Max. Marks	:	50
Hours/Week	:	2 Hrs.	Assignment	:	20
Credits	:	2	Attendance	:	05
Instruction Mode	:	Tutorial	Seminar	:	25
Course Code	:	PY.09.880.X5.I	Exam Duration	:	1 Hr.

Course Objectives:

Learn the organization of a digital computer.
Learn to think logically and write pseudo code or draw flow charts for problems.

Course Outcomes:

Be familiar with the use of Office software.
Be exposed to presentation and visualization tools.as well as problem solving techniques and flow charts.

Unit - I :

Hardware: Current hardware & their performance, New devices / technology useful in teaching & research like Cameras, Scanner, touch screens, tablets, projection devices etc. Basic idea of computer networking.

Operating systems: Common operating systems used in day to day task & instrumentation like Windows, Linux & Unix (only interface and basic commands).

Language: Evolution of computer languages. Common languages used in scientific fraternity (no specific language detailing is required).

Software: Idea of popular soft ware's like MS Office, structure drawing software's, chemicalstructure visualizing software's, statistical software's & mathematical software, reference managing software's (only introduction).

Unit - II :

Web page design: Need, concept and use of HTML

Databases: Meaning, Need and creating table, record creating and maintenance.

Internet concept: History, creating internet connection, common problems & solutions.

Important Databases of free domain: Patents, Pub med, Pubchem, Science direct, protein database.

References:

1. W. E. Fassett, 1986."Computer Applications in Pharmacy", Lea & Febiger Publisher.
2. C.N. Madu, 2003. "Statistics as easy with Microsoft Excel for Windows", 1st Ed.Chi Pub. Inc.
3. http://pages.stern.nyu.edu/~jsimonof/classes/1305/pdf/excelreg.pdf
4. www.Pubmed.com
5. www.Pubchem.com
6. www.mdl.com
7. http://www.vlifesciences.com
8. http://spdbv.vital-it.ch
9. http://www.winstat.com
10. www.uspto.gov
11. www.esp.gov

SAIL

Laboratory Design, Safety and Management

Scheme of Instruction			**Scheme of Examination**		
Total Duration	:	30 Hrs.	Max. Marks	:	50
Hours/Week	:	2 Hrs.	Assignment	:	20
Credits	:	2	Attendance	:	05
Instruction Mode	:	Tutorial	Seminar	:	25
Course Code	:	PY.09.880.X6.I	Exam Duration	:	1 Hr.

Course Objectives:

To expose them to existing national safety standards
To acquaint with Laboratory Design and Management

Course Outcomes:

On Completion of the course the student will be able to perform the Experiments as per cGLP norms.

Unit - I :

Lab Design Criteria; Codes, Standards and References; Architectural Considerations, Walls, Doors, Windows, Security, Ceiling, Flooring, Cleanability, Sinks, Storage, Exit Paths, Engineering Considerations – Electrical, Plumbing, Utilities – Air, Water, Steam and Gases, Heating, Ventilation, Air Conditioning and Fume Hoods;

Laboratory Furniture Design and Location; General Laboratory Safety Practices; Standard Operating Procedures (SOP's);

Unit - II :

Management of Analytical Laboratory: Organization of Laboratories based on their types, staffing, skill development and training, budgeting and financing, purchase of costly equipment, qualities of laboratory manager and management styles.

Laboratory Inspections: Internal inspection, external audit, concepts, preparing for inspections and audits.

Reference standards: Types, preparation, containers, labeling, storage and use.

Documentation-STPs: Certificate of Analysis (COA.), LaboratoryNote Books: Typical Documents used in a GLP Laboratory including Standard Test Protocols (STP's),

References:

1. Laboratory Design Guidelines – University of North Carolina, USA
2. Laboratory Design Hand Book
3. Designing and Planning of Laboratories (2009)
4. Laboratory Design and Construction Guidelines (2010) – Departmentof Environment, Health and Safety, University of South Carolina, USA
5. Laboratory Safety Design Guide,(2007) – Departmentof Environment, Health and Safety, University of California, USA
6. Laboratory Safety Guidance,(2011) – OSHA, USA
7. Safe Lab (2007) Web site at www.cpsc.gov

SAIL

Creativity and Innovation

Scheme of Instruction			**Scheme of Examination**		
Total Duration	:	30 Hrs.	Max. Marks	:	50
Hours/Week	:	2 Hrs.	Assignment	:	20
Credits	:	2	Attendance	:	05
Instruction Mode	:	Tutorial	Seminar	:	25
Course Code	:	PY.09.880.X7.I	Exam Duration	:	1 Hr.

Course Objectives:

To impart the knowledge of various aspects of Creativity and Innovation

Course Outcomes:

On Completion of the course the student will be able to understand the significance of Creativity and Innovation.

Unit - I :

The process of technological innovation - factors contributing to successful technological innovation - the need for creativity and innovation - creativity and problem solving – brain storming - different techniques.

Unit - II :

Patents - Patent search - Patent laws -International code for patents

References:

1. Twiss, Brian."Managing Technological Innovation", Pitman Publishing Ltd., 1992.
2. Nystrom, Harry "Creativity and Innovation", John Wiley & Sons, 1979.
3. Khandwalla, N.– "Fourth Eye (Excellence through Creativity) - Wheeler Publishing", 1992.
4. I.P.R. Bulletins, TIFAC, New Delhi, 1997.

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Employability Skills

Scheme of Instruction			**Scheme of Examination**		
Total Duration	:	30 Hrs.	Max. Marks	:	50
Hours/Week	:	2 Hrs.	Assignment	:	20
Credits	:	2	Attendance	:	05
Instruction Mode	:	Tutorial	Seminar	:	25
Course Code	:	PY.09.880.X8.I	Exam Duration	:	1 Hr.

Course Objectives:

To enhance the employability skills of learners with a special focus on presentation skills, group discussion and interview skills.
To enable them to improve their soft skills necessary for workplace contexts.
To equip them with effective communicative competence for a global reach.

Course Outcomes:

Participate in conversations both formal and informal, attend phone calls and interviews successfully.
Read different types of texts and Listen to, and understand foreign accents.

Unit - I :

SPEAKING SKILLS: Conversationalskills (formaland informal contexts) - telephonic communication, attending job interviews (responding to FAQs) - taking part in GDs - making presentations.

WRITING SKILLS: Job applications – cover letter – resume – applying online – writing proposals – e-Mails – letters – reports – memos – minutes – blogging – tweeting – writing recommendations and instructions – writing for publications.

READING SKILLS: Vocabularybuilding – speed reading (skimming – scanning) – reading different genres of texts from newspapers to philosophical treatises – criticalreading – effective reading strategies such as reading 'beyond the lines', summarizing, graphic organizers and distinguishing facts from opinions.

Unit - II :

LISTENING/VIEWING SKILLS: Speeches of different nationalities with focus on American and British accent (TED talks, podcasts) – listening to lyrics – lectures – instructions – dialogues – news casting – talk shows – interviews (Hard talk, Devil's Advocate)

SOFT SKILLS: Motivation - persuasive skills – negotiations – time management – emotional intelligence – stress management – creative and critical thinking.

References:

1. Barker, A. Improve Your Communication Skills. New Delhi: Kogan Page India Pvt. Ltd., 2006.
2. Craven, Miles. Listening Extra – A resource book of multi-level skills activities.Cambridge University Press, 2004.
3. Gammidge, Mick. Speaking Extra - A resource book of multi-level skills activities. Cambridge University Press, 2004.
4. Hartley, Peter. Group Communication. London: Routledge, 2004.
5. John Seely. The Oxford Guide to Writing and Speaking. New Delhi: Oxford University Press, 2004.
6. Naterop Jean & Rod Revell. Telephoning in English. Cambridge University Press,1987.
7. Ramesh, Gopalswamy and Mahadevan Ramesh. The ACE of Soft Skills. New Delhi: Pearson, 2010.

Web Sources:

1. www.humanresources.about.com
2. www.careerride.com

SAIL

INFORMATION SEARCH TECHNIQUES

Scheme of Instruction			**Scheme of Examination**		
Total Duration	:	30 Hrs.	Max. Marks	:	50
Hours/Week	:	2 Hrs.	Assignment	:	20
Credits	:	2	Attendance	:	05
Instruction Mode	:	Tutorial	Seminar	:	25
Course Code	:	PY.09.880.X9.I	Exam Duration	:	1 Hr.

Course Objectives:

To learn the types of information searches and know the importance of search preparation
To establish the formulation of search strategies and understand the types of search techniques and also to make use of the search techniques in information retrieval
To identify the search techniques to various search tools

Course Outcomes:

Able to distinguish between simple, advanced and meta searches
Plan for a search session and formulate search strategies
Select the appropriate search tool for the required information
Apply the use of search techniques to various search tools

Unit - I :

Types of Searches:- Simple searching, Advanced searching and Meta searching, Keywords, Search preparation.
Search Strategy: Steps in developing search strategy, advantages of a search strategy

Unit - II :

Search Techniques: Boolean Logic, Parenthesis, Phrase searching, Truncation, Wildcards and Field searching
Application of Search Techniques: Searching from deep web sources eg Medline/PubMed; Searching from directories and search engines; and Searching in subject portals eg: HINARI

References:

1. Eyers John E. Searching bibliographic databases effectively. Health Policyand Planning. 1998. 13(3): 339
2. Finding Information on the Internet: A Tutorial *UC Berkeley - Teaching Library Internet Workshop* (2010)
3. *Steve Lawrence and C. Lee Giles.* Searching the Web: General and Scientific Information Access, *NEC Research Institute.* IEEE Communications Magazine. January1999. 116-122p.

Web Sources:

1. HINARI: Health Internetwork for Access to Research Information. http://www.who.int/hinari/en/(May2010)
2. Indiana University Library: Basic Database Searching Techniques. http://www.libraries.iub.edu/index.php?pageId =1480 (March 2010)
3. National Library of Medicine. Medline/PubMed. PubMed Tutorial. http://www.ncbi.nlm.nih.gov/pubmed/ (2010)
4. Open University. Information skills for researchers. http://www.open.ac.uk/infoskillsresearchers/search-techniques.htm (2010) and http://www.lib.berkeley.edu/TeachingLib/Guides/Internet/FindInfo.html (2010)
5. Reitz, Joan M.(2004). *Online Dictionary for Library and Information Science*. URL:ODLIS - http://lu.com/odlis/
6. T he search manual - Cochrane Libraryhttp://www.thecochranelibrary.com/view/0/SearchManual.html (2010)
7. University Of West England. The Cochrane Library http://www.uwe.ac.uk/library/resources/hea/docs/cochrane.pdf (2010) and Meta searching. http://writing.colostate.edu/activities(2010)