SCHEME OF INSTRUCTION, EXAMINATION AND EVALUATION
Program Code: 885 M. Pharm. (Pharmaceutical Analysis & Quality Assurance)
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.09.885.13.T	Quality Controlof Health Related Products	4	0	0	4	25	75	3
PY.09.885.14.T	Instrumental Methods of Analysis	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.09.885.10.S	SAIL	1	2	0	2	Grade		
PY.09.885.11.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	IPR & Regulatory Affairs	3	0	-	3	25	75	3
PY.09.885.22.T	Analytical Method Validation	4	0	-	4	25	75	3
PY.09.885.23.T	Quality Control Methods	4	0	0	4	25	75	3
PY.09.885.24.T	Biological Standardization	4	0	0	4	25	75	3
PY.09.88X.25.T	Elective *	3	0	0	3	25	75	3
PY.09.885.22.P	Analytical Method Validation	-	0	4	2	25	75	6
PY.09.885.23.P	Quality Control Methods	-	0	4	2	25	75	6
					22	175	525	
PY.09.885.20.S	SAIL	1	2	0	2	Grade		
PY.09.885.21.S	Seminar	1	0	2	2	Grade		

* Discipline Centric –Pharmaceutical Packaging Technology / Drug Polymer Technology;
Open – Quality Assurance & Management.

SEMESTER – III

Course Code	Course Title	Hours /Week	Credits	Marks		Duration in Weeks
				Internal	External	
PY.10.885.31.P	Design Seminar	30	6	50	-	6
PY.10.885.32.P	Report on 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.10.885.41.P	Pre-Submission Seminar	30	10		50	10
PY.10.885.42.T	Submission and Adjudication	30	12		200	6
PY.10.885.43.T	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 laboratory.

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 Spectroscopy.

Mass Spectrometry: Basic principles Mass Spectrometry. Ionization techniques (EI and CI), Mass spectrum and its characteristics, molecular ion, metastable ions, fragment ions; fragmentation processes and Mc-Lafferty Rearrangement, 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 Immuno Assay (RIA) and ELISA: RIA- General Principles, Scope of Limitations of Insulin and Digitalis, ELISA - Instrumentation, Principle and Application for Analysis of Drugs

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, Webster, 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. Connors KA. A Text book 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., Brookescole 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, New York, 1985.
11. Schirmer, RE. Modem methods of pharmaceutical analysis, Vol. I & II, 2nd ed., CRC Press, Florida, 2000.

PHARMACEUTICAL PRODUCT DEVELOPMENT

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.09.886.12.T	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.

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,

Dissolution: Theories, mechanisms of dissolution, *in-vitro* dissolution testing models – sink and non-sink. Factors influencingdissolution and intrinsic dissolutionstudies. 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). 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 Drug Products: Nano-Pharmaceuticals - Generation and Significance of Nano-suspensions, Nano-gels, Nano-carrier Systems;

Books and References:

1. Lachman L, LiebermanHA, 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, SchwartzJB. Pharmaceutical Dosage Forms: Tablets Vol. I-II, 2nd Ed., CBS Publishers & Distributors, New Delhi, 2005.
4. Conners KA. A Textbook of Pharmaceutical Analysis 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 Pharmaceutical Formulations, 3rd Ed. 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 Pharmacopeial Convention, Inc, USA, 2003.

QUALITY CONTROL OF HEALTH RELATED PRODUCTS

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.09.885.13.T	Exam Duration	:	3 Hrs.

Course Objectives:

This subject is aimed at giving knowledge about different quality control tests for analysis of cosmetics, Herbal products, Biological products, food constituents and Nutraceuticals. This knowledge will be helpful in evaluation/ quality control of prepared finished products. Students know about procedures and different guidelines used for analysis of health related products.

Course Outcomes:

After the students have undergone the course work, they shall become acquainted with application of principles of pharmaceutical analysis for quality control of various products as mentioned in the above units.

Unit - I :

Quality Control of Cosmeceuticals: Hair care products (shampoo and hair dyes), baby care products (Oils, Creams, Powders and Shampoos), Personal HygieneProducts (shaving creams, after shave lotions and soaps), eye care products (eye shadows, eye liners, and eye brow pencils)

Unit - II :

Quality Controlof Herbal Products: Qualitycontrol of crude drugs (WHO guidelines) - Determination of Ash value and extractive matter, foreign matter, bitter value, haemolytic activity, swelling index, foaming index, pesticide residues and MO's, UV and fluorescence analysis of powdered drugs, and micro-chemical tests.

Unit - III :

Quality Control of Biological Products: Biological assays of the following.

1. Vaccines: Diphtheria, Tetanus, Rabies.
2. Enzymes: Streptokinase, Urokinase.
3. Antitoxins: Diphtheria, Tetanus.
4. Hormones: Chronic Gonadotropin, Oxytocin, Insulin.

Unit - IV :

Quality Control of Nutraceuticals: Vitamins (A, B_1, B_2, B_{12}, C, D, E and K), Micro Nutrients and Health Supplements.

Unit - V :

Quality Control of Food Constituents: Carbohydrates, Proteins and Fats with Special Emphasis in the Determination of Moisture, Ash, Nitrogen and Physical Constituents. General Analytical Methods for Milk and Milk Products (Milk Powder, Margarine, Tea and Coffee).

Books and References:

1. Commercial's Manual on Drugs & Cosmetics. 2nd Ed., Commercial Law Publishers (India) Pvt. Ltd., Delhi, 2004.

2. Sharma PP. Cosmetics-Formulation, Manufacturing andQualityControl. 3rd Ed., Vandana Publications Pvt. Ltd., Delhi, 2005.
3. Kokare CR. Pharmaceutical Microbiology and Biotechnology. 2nd Ed., Nirali Prakashan, Pune, 2006.
4. Nanda S, Nanda A, Khar RK. Cosmetic Technology. Birla Publications Pvt. Ltd., Delhi, 2007.
5. Mukherjee PK. Quality Control of Herbal Drugs: An Approach to Evaluation of Botanicals. Business Horizons, New Delhi, 2007.
6. Evans WC. Trease and Evans Pharmacognosy. 15th ed., Saunders, China, 2004.
7. Lachman L, Lieberman HA, Kanig JL. The Theoryand Practice of Industrial Pharmacy, 3rd Ed., Varghese Publishers, Bombay, 1991.
8. Remington: The Scienceand Practiceof Pharmacy. 21st Ed., Vol. I & II, Lippincott Williams & Wilkins, Noida, 2006.
9. Agrawal SS, Paridhavi M. Herbal Drug Technology. Universities Press (India) Pvt. Ltd., Hyderabad, 2007.
10. Nelson DL, Cox MM. Lehninger Principles of Biochemistry. 4th Ed., Replika Press Pvt. Ltd., India, 2006.
11. Murray RK, Granner DK, Rodwell VW. Harper's Illustrated Biochemistry, 27th Ed., McGraw-Hill, New Delhi, 2006.
12. David Pearson. The Chemical Analysis of Foods, 7th Ed., Churchill Livingstone, Edinburgh, 1976.
13. Nielsen S. Introduction to the Chemical Analysis of Foods. Jones & Bartlett Publishers, Boston, 1974.

INSRUMENTAL METHODS OF ANALYSIS

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.09.885.14.T	Exam Duration	:	3 Hrs.

Course Objectives:

This subject is aimed at giving in-depth knowledge about different instrument/equipment based analytical principles and their application in characterization of formulations, excipients, interaction & compatibility studies.

- *To give more stress on application based knowledge than instrumentation based one.*
- *To give hands on training on use of as many different sophisticated instruments as possible.*

Course Outcomes:

After the students have undergone this course, they shall acquire knowledge on theoretical aspects and interpretative skills ofvarious instrumental methods of analysis. This knowledge and skills will help the students in understanding the application of these methods in formulation development of various dosage forms.

Unit - I :

Microscopy: Principle, Construction, Instrumentation and Applications of Microscopy, Confocal Microscopy, Atomic Force Microscopy, Scanning Electron Microscopy (SEM), Transmission Electron Microscopy (TEM); Optical Rotatory Dispersion (ORD) and Circular Dichroism (CD): Principles and Theoretical Aspects – Instrumentation, Sample Handling and Applications.

Unit - II :

Potentiometry and pH metry: Principles, Measurement and Applications – Potentiometry; Electrodes, Cells, Cell Potential, Measurement of pH, End Point Evaluation Methods, Null Point.

Conductometry and Amperometry: Principles, Instrumentation, Measurement and Applications - Conductivity Conductance, Equivalent and Molar Conductance, Wheatstone Bridge Principle and Amperometry.

Unit - III :

Spectrophotometry: Principles, Instrumentation and Applications of Raman, Laser, Plasma, Atomic Absorption Spectroscopy and Flame Photometry.

Spectro-fluorimetry: Theory, Instrumentation and Applications of Fluorescence, Phosphorescence, Chemi-Luminiscence;

Unit - IV :

Hyphenated Techniques: Theory, Principle, Instrumentation and Applications LC-MS, GC-MS, MS-MS and LC-NMR in Pharmacy;

Particles Size Analysis: Theory, Principle, Instrumentation and Applications of Zetameter, Photon Correlation Spectroscopy, Counter-Counter Apparatus,

Unit - V :

Pharmacopoeial Methods of Analysis: Physical Tests; Limit Tests; Special Tests; Dissolution Tests; Stability Tests; Miscellaneous Tests; Microbial Assays

Sample Preparation for Analysis: Different Techniques of Sample Preparation from Body fluids, Tissue Extracts, Cell culture Extracts and Phyto-chemical Extracts.

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. Willard HR, Merritt LL, Dean JA, Settle FA. Instrumental Methods of Analysis, 7th Ed., CBS Publishers & distributors, New Delhi, 1986.
4. Ewing GW. Instrumental Methods of Chemical Analysis, 5th ed., McGraw Hill Book Company, NY, 1985.
5. Schirmer RE. Modem Methods of Pharmaceutical Analysis, Vol. I & II, 2nd Ed., CRC Press, Florida, 2000.
6. Lee DC, Webb M. Pharmaceutical Analysis, Blackwell publishing, Australia, 2004.
7. Gurdeep R. Chatwal, Instrumental Methods of Chemical Analysis, Himalaya Publishing House, 2006.
8. Ashutoshkar, Pharmaceutical Drug Analysis, New Age International Publishers New Delhi.
9. Whoston C. X-ray Methods, John Wiley & Sons, New York, 1987

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 (c hange 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 :

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 Laboratory: Scope, Organization, Personnel – DesirableQualities 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, T hreshold 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 Pvt. Ltd., Delhi, 2000.
4. Quality Assurance of Pharmaceutical (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. D.A. Berry, Statistical Methodology in Pharmaceutical Science, Marcel Dekker, NY.
10. DH Shah, Quality Assurance Manual: Business Horizons, New Delhi.
11. 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:

PHARMACEUTICAL 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 Practical's:

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 biorelevant 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 pre-formulation 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.

ANALYTICAL METHOD 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	:	Practical	End Semester	:	75
Course Code	:	PY.09.885.22.T	Exam Duration	:	6 Hrs.

Course Objectives:

Develop and validate analytical and bioanalytical methods for pharmaceuticals vis-a-vis regulatory compliance.
Understand the latest internationally recognized standards and developments in analytical assurance.

Course Outcomes:

To equip students with comprehensive knowledge on regulatoryaspects of analytical techniques.

Unit - I :

Analytical Validation: Introduction; History; Definition; Types of Validation; Prospective Validation, Retrospective Validation, Concurrent Validation, Revalidation, Validation Master Plan and Validation Protocol.

Unit - II :

Analytical Procedures Validation: Needs, Types, Accuracy, Precision, Linearity, Robustness, Specificity, Ruggedness, System suitability Parameters, LOQ, and LOD. Sources of Errors, Use of Significant Figures and their Correct Usage as per ICH Guidelines, USP requirement of Analytical Validation Different Category of Assays.

Unit - III :

Development of Analytical Method Validation: Introduction, Calibration, Performance, Maintenance and Validation of various Analytical Instruments such as Analytical Balance, UV-Visible Spectrophotometer, FT-IR Spectrophotometer, GC, HPLC, GC-MS and LC-MS

Unit - IV :

Drug Analysis in Biological Matrices: Selection and Quantification of Biological sample, Extraction of Drugs by Various Methods as LLE, SPE and Membrane Filtration, Factors affecting Extraction of Drugs;

Bio Analytical Method Validation: Full Validation; Partial Validation and Cross-Validation.

Unit - V :

Utilities Validation Methods: Methods of Validation for the Following Utilities – Pharmaceutical Water Systems – DM Water Validation, AHU Validation, HVAC System and Sterilization Validation;

Cleaning Validation (CV): Validation of Cleaning Process; Elements of Validation Protocol; Determination of Acceptable Limits for Cleaning Process; Factors to consider in setting the Limits; Numerical Calculation of Limits.

Books and References:

1. Nash RA, Wachter AH. Pharmaceutical Process Validation, 3rd ed., CBS Publications, New Delhi, 2005.
2. Carleton FJ, Apalloco JP. Validation of Pharmaceutical Processes-Sterile Products. Marcel Dekker, NY, 2006.
3. Haider Si. Pharmaceutical Master Validation Plan. St.Lucie Press, Noida, 2006.
4. Ahuja S, Alasante KM. Handbook of Isolation and Characterization of Impurities in Pharmaceuticals. Elsevier Publications, New Delhi, 2005.

5. Parker M. Quality Assurance and TQM for Analytical Laboratories, The Royal Society of Chemistry Pub.
6. Shah DH. SOP Guidelines. Business Horizons, New Delhi, 2004.
7. Mehra ML. Good Manufacturing Practices (GMP), University Book Agency.
8. Maitra K, Ghosh SK. A Guide to Total Quality Management.
9. Snyder, Kirkland & Glajch, Practical HPLC Method Development, 2nd Ed, 1997, Wiley Interscience, New York.

QUALITY CONTROL METHODS

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.09.885.23.T	Exam Duration	:	6 Hrs.

Course Objectives:

To equip student to be professionally competent to achieve global quality standards in the pharmaceutical industry.

Course Outcomes:

At the end of the course the student is able to apply the knowledge of quality control methods to enhance the market value of the drug products

Unit - I :

Qualitative Analysis Functional Groups of APIs: Analytical principles, procedures and applications involved in the use of the following reagent based function group analysis.

a) MBTH (3-methyl-2-benzothiazoline hydrazone).
b) Folin – Ciocalteu (FC) reagent.
c) 2,6- Dichloroquinone chlorimide.
d) 2,3,5- Triphenyl tetrazolium salt.
e) 1,2- naptho quininone -4- sulfonate.
f) Bratton-Marshall reagent.
g) PDAC (P-Dimethyl amino cinnamaldehyde) .
h) PDAB (P-Dimethyl amino benzaldehyde)

Unit - II :

Quantitative Analysis of Functional Groups: Principles and Procedures involved in Quantitative Determination of the following functional groups:

A) Hydroxy B) Aldehyde C) Ketone D) Amine E) Methoxyl F) Ester G) Carboxyl

Unit - III

Quantitative Analysis of Drugs in DosageForms: Principles and procedures involved in the analysis of drugs in dosage forms:

A) Anti-bacterials (penicillins, erythromycin) and fluoroquinolones
B) Steroids (cholesterol, progesterone, and androsterone);
C) Anti-inflammatory drugs (nimusuline, diclofenac. Ibuprofen and indomethacin);
D) Anti-hypertensive drugs (propranolol, levodopa); and
E) Anti-diarrhoeals (metronidazole, tinidazole).

Unit - IV :

Quality Control of Excipients: Tests related to excipients (disintegrating agents, binders, emulsifiers, viscosity modifiers and preservatives) such as bulk density, tapped density, particle size distribution, pH, moisture content, viscosity (dynamic), gelling temperature, swelling temperature, loss on drying, residue on ignition, conductivity, congealing range, readily carbonizable substances and readily oxidizable substances, melting point and melting range, including preservative challenge test.

Unit - V :

Quality Control of Packaging Materials: Containers – Glass: light transmission, chemical resistance – glass containers, powdered glass test, water attack test. Biological tests – plastics and other polymers: physicochemical tests – plastics, polyethylene containers, single unit containers and unit dose containers for non sterile solids and liquid dosage forms, customized patientmedication packages, containers – permeation, metal containers, and rubber closures.

Books and References:

1. Hiaguchi T, Brochmann E, Hanssen H, Hanseen H. Pharmaceutical Analysis, CBS Publishers & Distributors, New Delhi, 2004.
2. Rowe RC, Sheskey PJ, Owen SC. Handbook of Pharmaceutical Excipients. 5th Ed., Pharmaceutical Press, Britain, 2006.
3. Lachman L, LiebermanHA, Kanig JL. The Theoryand Practiceof Industrial Pharmacy, 3rd Ed., Varghese Publishers, Mumbai 1987.
4. Sethi PD. Quantitative Analysis of Drugs in Pharmaceutical Formulations, 3rd Ed., CBS Publishers & Distributors, New Delhi, 2008.
5. Beckett AH, Stenlake JB. Practical Pharmaceutical Chemistry, Part I & II, 4th Ed., CBS Publishers & Distributors, New Delhi, 2004.
6. Remington: The Science and Practice of Pharmacy. 21st ed., vol. I & II, Lippincatt Williams & Wilkins, New Delhi, 2005.
7. Indian Pharmacopoeia. Controller of Publication, Delhi, 2007.
8. British Pharmacopoeia. British Pharmacopoeia Commission Office, London, 2008.
9. United States Pharmacopoeia. United States Pharmacopeia Convention, Inc. USA

Biological Standardization

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.09.885.24.T	Exam Duration	:	3 Hrs.

Course Objectives:

To train students about various biological evaluation methods & the significance of such tests.

To impart knowledge about official / non-official methods of evaluation for a wide range of drug dosage forms.

To give them training in carrying out some of these techniques in the laboratory.

Course Outcomes:

At the end of the course the student acquire the wide exposure to students in the area of New Chemical Entity pre-clinical evaluations and related areas.

Unit - I : Detailed Study of Principles and Procedures Involved in Bioassay of

1. Heparin, Insulin, Posterior Pituitary; 2. Diphtheria, Typhoid

Unit - II : Principles and Procedures involved in Biological Tests of the following

1. Living contaminants in vaccines, 2. Endotoxins, 3. Histamine like substances, 4. Toxic elements.

Unit - III : Microbiological Assay

1. Vitamins - Cyano-cobalamine; 2. Antibiotics such as Neomycin Sulfate; 3. Vaccine - Diphtheria

Unit - IV : Biological Assay and Pyrogen Assay

Overview, types – direct, indirect and assay based on quantal responses, parallel line bioassays, bench top and primary bioassay screening, statistical principles in bioassay- randomization, replication and elimination of variation; Preservative efficacy or Antimicrobial Effectiveness testing as per USP; Evaluation of Oxytocin, Rabies Vaccine and Tetanus Antitoxin;

Production, Chemistry, Properties and Tests of Bacterial Pyrogens and Endotoxin;

Unit - V : Bioassay of Biologics

Detailed Study of Principles and Procedures involved in Bioassay of Estrogens, Hepatitis Vaccine, Biological Assay of Gas-Gangrene Antitoxin, Blood and Blood related Products (Anti-Blood Grouping Serum, Human Albumin, Human Plasma Protein fraction, Human Blood Coagulation factors), and Biological Assay of Biotechnology Products (erythropoietin, interferons, streptokinase)

Books and References:

1. Indian Pharmacopoeia 2007, Controller of Publications, Govt of India, New Delhi.
2. Bochmman & Hassan, Pharmaceutical Analysis, edited by Higuchi.
3. DC Garrott, Quantitative Analysis of Drugs. CBS Publishers, New Delhi.
4. RV Smith, JT Stewart, Textbook of Biopharmaceutical Analysis.
5. Pulok K Mukherjee: QualityControl of Herbal Drugs, Business Horizons Pharm. Publishers, New Delhi.
6. British Pharmacopoeia, Department of Health, UK.
7. Classification of Cosmetic Raw Materials.

ELECTIVE

PHARMACEUTICAL PACKAGING 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 develop understanding and provide scientific basics of the packaging technology

To understands the types of packaging and improve the standards of packaging technology

Course Outcomes:

To appreciate the importance of Pharmaceutical Packaging Technology

Unit - I :

Pharmaceutical Packaging: Purpose of packaging, prerequisites of an ideal package, various types of inner and outer packages used for different pharmaceutical dosage forms, selection of a suitable package, storage temperature, hazards encountered by the package during storage and distribution.

Product-Package Compatibility: Stability of product, packaging selection and development criteria.

Flexible Packaging: Types of films, co-extruded films, foils, coating and laminates, shrink and stretch films.

Corrugated and Solid fiber Boards and Boxes: Type of corrugation methods.

Caps and Closures: Types; caps, closures, liners, child resistant caps. elastomeric closures for parenterals,

Unit - II :

Glass Containers for Pharmaceuticals: Glass types, their chemical performance, testing and quality control.

Plastics Containers for Pharmaceuticals: Classification of plastics, plastic polymers and their physico-chemical, mechanical and biological properties; Additives and fabrication processes. Plastic container for parenterals and transfusion sterile drip kits. Quality control testing and biological toxicity.

Paper and Paper Board: Types ofpaper, folding cartons, quality control testing of paper and paper board.

Metal containers: Aluminum & Tin Plate Drums, Collapsible Tubes & Aerosol Containers, Lacquering, Coating & Lining.

Unit - III :

Sterile product packaging: General principles of packaging of sterile products. Various types of containers used for sterile products including small volume and large volume parenterals. Types of closures used for the sterile products. Sterile product filling and sealing machinery i.e. ampoule filling and sealing machine. Limitations and merits of various packages. Evaluation of the sterile product packages.

Environmental Considerations: Packaging and recycling of packaging materials along with national and international regulations

Unit - IV :

Packaging Machinery: Introduction, strip packaging machinery, form, fill and seal machines, liquid and solid filling machines, capping machines, machinery employed for liquid formulation packaging.

Advances in Packaging Technology: Blister packaging, tamper evident packaging systems, child resistant packaging, aerosol packaging, etc.

Unit - V :

Labels and Labeling: Objectives and contents of a pharmaceutical label. Types of label (including bilingual label, bar code label, radiofrequency(RF) label, structured program label, in-mouldlabel and decorative labels), legal requirements of labeling, packaginginserts and outserts. Adhesives and machineryemployed for labeling. Concept of paperless labeling and new developments in labeling technologies.

Books and References:

1. Dean D.A., Evans E.R. Hall I.H. Pharmaceutical Packaging Technology. Taylor & Francis.
2. Jain U.K., Goupale D.C., Nayak S. Pharmaceutical Packaging Technology. Pharma Med Press.
3. Kirwan M.J. Paper and Paper Board Packaging Technology. Blackwell Publishing Ltd.
4. Walter Soroka. Fundamentals of Packaging Technology. Institute of Packaging Professionals.
5. Lockhart H., Paine F.A. Packaging of Pharmaceuticals & Healthcare Products. Blackie Academic & Prof.
6. Hendrickson R. Remington The Science and Practice of Pharmacy, Lippincott Williams & Wilkins, 21st Ed.
7. Herrick A.D. Drug Products, Labeling, Packaging, Regulation. General Books, LLC.
8. Yam K.L. The Wiley Encyclopedia of Packaging Technology. John Wiley & Sons.
9. Selke S.E.M. Understanding Plastic Packaging Technology. Karl Hanser Verlag.
10. Hanlon J.F., Kelsey R.J., Forcinio H.E. Handbook of Package Engineering. Technomic Pub. Co.

ELECTIVE

QUALITY ASSURANCE AND MANAGEMENT

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:

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 management and documentation.

Course Outcomes:

To equip student to be professionally knowledgeable to sustain global quality standards and productive management output in the pharmaceutical industry.

Unit - I :

Basic Concepts of Quality Assurance: 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 & Humidity Control Tests, Tests for Air flow Pattern, Microbiological Monitoring) Buildings & Facilities (Design and Construction Features, Construction Materials, Lighting, Air Handling System, Sanitation & Maintenance) Equipment's (Construction, Cleaning and Maintenance, Calibration & Handling)

Unit - II :

Equipment Qualification (EQ): Design Qualification (DQ); Installation Qualification (IQ); Operating Qualification (OQ) and Performance Qualification (PQ)

Standard Operating Procedures (SOP): Operations like Cleaning, Filling, Drying, Compression, Coating, Disinfection, Sterilization, Membrane Filtration etc.

Total Quality Management (TQM): Principles, Elements of TQM, Continuous Improvement and Learning, Management Tools, Tools and Techniques of Quality, New Quality Tools and T echniques

Unit - III :

Inventory Management: Costs, Inventory Categories, Selective Inventory Control, Reorder Quantity Methods and EOQ, Inventory Models, Safety Stock-Stock Out, Lead Time–Reorder Time Methods, Modem Inventory Managements Systems, Inventory Evaluation.

Materials Management: Introduction; Purchasing; Raw Materials; Packaging Materials; Intermediate and Bulk Products; Finished Products; Rejected and Recovered Materials; Recalled Products; Returned goods; Reagents and Culture Media; Waste Materials; Reference standards; Miscellaneous Materials;

Unit - IV :

Human Resources Management: Introduction; Qualification Experience and Training; Responsibilities and Key Personnel; Personal hygiene and clothing; Legal Aspects; Consultants

Facilities Management: Introduction; Principal Area; Plumbing and Drainage system; Lighting; Ventilation; Heating; Air-Conditioning; Sewage, Refuge and Disposal of Water; Washing and Toilet Facilities; Sanitation; Maintenance; Utilities; Water; Power; Steam; Vacuum; Air; Gases; etc.,

Unit - V :

Manufacturing Operationsand Control: Cleaning Validation; Sanitation of Manufacturing Premises, Mix –ups and Cross Contamination, Processing of Intermediates and Bulk product, Packaging Operations, Process Deviations, Drug Product Inspection, Expiration Dating, Examination of Labels, Cartons and Other Printed Materials.

Documentation and Records: Introduction; Specifications; Master Production and Control Record; Batch Production and ControlRecord; Important SOPs and Record; ChangeControl; Site Master File; Changecontract format; Product complaint document; Internal audit document; Product recall document; IPQC document; Material receipt; Sampling; Dispensing & Storage document;

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 Pvt. Ltd., Delhi, 2000.
4. Quality Assurance of Pharmaceutical (A Compendium of Guidelines and Selected M aterials) 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 Productionand Management, 2005, Vallabh Prakashan, NewDelhi.
9. Quality Assurance Manual, DH Shah, Business horizons, New Delhi.
10. Quality Assurance and Quality Management in Pharmaceutical Industry, Y. Anjaneyulu, R. Marayya. Pharma Book Syndicate, Hyderabad
11. 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. (USFDA guidelines)
    c. MHRA, UK Guidelines on GMP
    d. GMP Guidelines byMedicines Control Council of South Africa
    e. Schedule M of D & C Act

12. Sidney H. Willing, GMP for Pharmaceuticals, 5th Edition, Marcel Decker Series

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.

ANALYTICAL METHOD VALIDATION

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.09.885.22.P	Exam Duration	:	6 Hrs.

Course Objectives:

To provide the basic principles involved in the Analytical Method Validation

Course Outcomes:

To understand the significance of Analytical Method Validation

1. Analytical method validation for the parameters accuracy, precision, repeatability, specificity, system suitability, selectivity and robustness for the following drugs/formulations byUV-Visible Spectroscopyand HPLC.(7Expts)
   a. Paracetamol tablets
   b. Diclofenac sodium gel.
   c. Cetrizine syrup.
   d. Metronidazole infusion.
   e. Chloramphenicol capsules.
   f. Ibuprofen and Paracetamol tablets
   g. Paracetamol and Diclofenac sodium tablets.
2. Validation of following equipment
   a. Autoclave
   b. Hot air oven
   c. Powder Mixer (Dry)
   d. Tablet Compression Machine
3. Validation of a processing area
4. Validation of at least two analytical instruments.
5. Cleaning validation ofone equipment.
6. Identification of impurities in drug substances byTLCand LC method - Aspirin, Paracetamoland Ranitidine HCl.(3Expts)
7. Stability indicating assays for Ranitidine HCl and Aspirin by LC method.(2Expts)
8. Limittest for heavy metals of herbal preparations - Arsenic, lead, cadmiumand mercury.(2Expts)
9. Determination of residual solvents by GC. (2Expts)

Books and References:

1. Ira R. Berry & Robert Nash, Pharmaceutical Process Validation, Second Edn, Marcel Dekker Inc.
2. F.J. Carleton and J.P. Agalloco, Validation of Pharmaceutical Process (Sterile Products), Second Edition Revised & Expanded, Marcel Decker Inc.
3. M.A. Potdar, Pharmaceutical Quality Assurance, Nirali Prakashan, Pune.
4. M.A. Potdar, Current Good Manufacturing Practices, Pharma-Med Press, Hyderabad.

QUALITY CONTROL METHODS

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.09.885.23.P	Exam Duration	:	6 Hrs.

Course Objectives:

To learn and understand the conceptual and experimental basics of quality control methods

Course Outcomes:

To ensure the quality of drugs and drug formulations

List of Experiments:

1. Qualitative and Quantitative Analysis of Some Pharmaceutical Dosage Form using the following reagents and reactions.
   a. Oxidative Coupling Reaction using 3-Methyl – 2 – Benzothiazolinone hydrazine (MBTH)
   b. Condensation Reaction using the Reagent
   c. p-Dimethyl Amino Cinnamaldehyde (PDAC)
   d. Folin Ciocatecu (FC) Reagent
   e. Diazotization followed by Coupling Reaction
   f. Oxidation followed by Complexation Reaction
2. Analysis of Active Pharmaceutical Ingredients (API)
3. Quality Control Tests of Packaging Materials
4. Identification of Impurities and related substances in API's (Albendazole, Metronidazole, Diclofenac, Paracetamol, Aspirin, Ibuprofen)
5. Detection and Quantitative Determination of Antioxidants and Preservatives
6. Effectiveness of Anti-Microbial Preservatives (Preservative Challenge Test)
7. Evaluation of Congealing Temperature, Gelling Temperature, and Swelling Temperature of Excipients
8. Determination of Viscosity of Exceipients using Brook-Field Viscometer
9. Simultaneous Estimation of Drugs in fixed dose combinations
10. Experiments based on Gel Doc System for Protein based Drugs

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 Development for 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

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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)