M. Pharm. Pharmaceutical Analysis (1st Year)

Total Contact Hours = 32 Total Marks = 600 Total Credits = 26

SEMESTER 1st		Contact Hrs			Marks			Credits
Subject Code	**Subject Name**	**L**	**T**	**P**	**Int.**	**Ext.**	**Total**	
MPHA5 - 101	Pharmaceutical Analytical Techniques	3	1	-	40	60	100	4
MPHA5 - 102	Spectral Analysis	3	1	-	40	60	100	4
MPHA5 - 103	Advanced Spectroscopic Techniques	3	1	-	40	60	100	4
MPHA5 - 104	Basics of Pharmaceutical Research - I	3	1	-	40	60	100	4
MPHA5 - 105	Pharmaceutical Analysis Practical - I	-	-	12	60	40	100	6
MPHA5 - 106	Seminar/ Assignment	-	4	-	100	-	100	4
Total	**Theory = 4 Lab = 1**	**12**	**8**	**12**	**320**	**280**	**600**	**26**

Total Contact Hours = 32 Total Marks = 600 Total Credits = 26

SEMESTER 2nd		Contact Hrs			Marks			Credits
Subject Code	**Subject Name**	**L**	**T**	**P**	**Int.**	**Ext.**	**Total**	
MPHA5 - 207	Advanced Pharmaceutical Analysis	4	-	-	40	60	100	4
MPHA5 - 208	Modern Bioanalytical Techniques	4	-	-	40	60	100	4
MPHA5 - 209	Quality Control and Quality Assurance	4	-	-	40	60	100	4
MPHA5 - 210	Herbal and Cosmetic Analysis	4	-	-	40	60	100	4
MPHA5 - 211	Pharmaceutical Analysis Practical - II	-	-	12	60	40	100	6
MPHA5 - 212	Seminar/Assignment	-	4	-	100	-	100	4
Total	**Theory = 4 Labs = 1**	**16**	**4**	**12**	**320**	**280**	**600**	**26**

Overall

Semester	Marks	Credits
1st	600	26
2nd	600	26
Total	**1200**	**52**

PHARMACEUTICAL ANALYSIS TECHNIQUES

Subject Code – MPHA5-101 **L T P C** **Duration – 45 Hrs**
3 1 0 4

UNIT-I (8 Hrs)

Separation Techniques: Chromatography General Principles, Classification, Chromatographic Techniques, Normal and Reversed Phase, Column Chromatography, TLC, Counter Current Chromatography, Droplet Chromatography, Ion Exchange Chromatography.

UNIT-II (7 Hrs)

Gas Chromatography: Theory & Principles, Column Operation, Instrumentation and Applications

High Performance Liquid Chromatography: Theory and Principle, Column Operation Instrumentation and Applications

UNIT-III (15 Hrs)

Electrometric Methods of Analysis: Principle, Procedure of Pharmaceutical Applications of Conductometric Titrations, Amperometric Titrations and Controlled Potential Electrolysis

Light Scattering Methods in Quantitative Analysis: Nephelometry and Turbidometry

Quantitative Analysis Based on Molecular Luminescence: Flourimetry and Phosphorimetry

UNIT-IV (15 Hrs)

Statistical Analysis Methods - Probability: Introduction, Definition, Importance of The Concept of Probability, Experiments & Events, Mutually Exclusive Events, Independent & Dependent Events, Exhaustive Events, Complementary Events, Theorems on Probability, Conditional Probability, Binomial Distribution and Poison Distribution.

Recommended Books

1. K.A. Connors, 'Pharmaceutical Analysis', 3rd Edn., John Wiley & Sons, New York.
2. Beckett & Stanlake, 'Practical Pharmaceutical Chemistry', Part-I & II, 4th Edn.
3. Gerhard Schomburg, 'Gas Chromatography', VCH, Weinheim, New York.
4. R.V. Smith, J.T. Stewart, 'Bio Pharmaceutical Analysis'.
5. S.P. Gupta, 'Statistical Methods', Sultan Chand & Sons, Education Publishers, New Delhi.

SPECTRAL ANALYSIS

Subject Code – MPHA5-102 **L T P C** **Duration – 45 Hrs**
3 1 0 4

UNIT-I (10 Hrs)

Ultraviolet and Visible Spectroscopy: Introduction, Energy Levels, Selection Rules; Woodward Fieser, Fieser Kuhn and Nelson Rule, Influence of Substituents, Ring Size and Strain on Spectra Characteristics, Solvent Effect, Methodology, Spectral Correlation with Structure.

UNIT-II (7 Hrs)

Infrared Spectroscopy: Introduction, Types of Vibrations, Characteristics Regions of the Spectrum, Influence of Substituents, Ring Size, Hydrogen Bonding, Vibrational Coupling, Field Effects on Frequency, Methodology, Spectral Interpretation with example.

UNIT-III (15 Hrs)

Nuclear Magnetic Resonance spectroscopy: Introduction, Magnetic Nuclear, Chemical Shift, Shielding, Relaxation Process, Chemical & Magnetic Non Equivalence, Local Dia Magnetic Shielding and Magnetic Anisotropy, Spin Splitting, Pascal Triangle, Coupling Constant, Mechanism of Coupling, Quadrupole Broadening and Decoupling. Effect of Stereochemistry on the Spectrum, Shift Reagent, Application of HNMR with some Examples. Introduction to the following Techniques would be covered DEPT, APT, COSY, NOESY and INADEQUATE.

UNIT-IV (15 Hrs)

^{13}C Nuclear Magnetic Resonance (^{13}C – NMR): Natural Abundance of ^{13}C, Resolution and Multiplicity FT Mode, RF Mode, Uses of Proton Coupled, Decoupled and Off Resonance Decoupling Techniques, Deuterium Substitution, Chemical Equivalence in Peak Assignment, Chemical Shift, Effect of Substitution on Chemical Shifts, Position of Alkanes, Alkenes, Alkynes and Benzene Spin Coupling and C^{13}- H^1 Coupling

Recommended Books

1. R.M. Silverstein and F.X. Webster, 'Spectrometric Identification of Organic Compounds', John Wiley & Sons, New York.
2. William Kemp, Organic Spectroscopy, ELBS Mac Millan, Hampshire, (U.K.).
3. D.L. Pavia, G.M. Lampman and G.S. Kriz, 'Introduction to Spectroscopy- A Guide for Students of Organic Chemistry', Harcourt College Publishers.
4. D.H. Williams and I. Fleming, 'Spectroscopic Methods in Organic Chemistry', Tata Mc Graw Hill Publishing Company Ltd, New Delhi, India.

ADVANCED SPECTROSCOPIC TECHNIQUES

Subject Code – MPHA5-103 **L T P C** **3 1 0 4** **Duration – 45 Hrs**

UNIT-I (10 Hrs)

Atomic Absorption Spectroscopy: Introduction, Principle, Instrumentation, Differences between Atomic Absorption & Flame Emission Spectroscopy, Advantages & Disadvantages and Applications of Atomic Absorption Spectroscopy.

UNIT-II (15 Hrs)

Mass Spectrometry: Introduction, Essential Components of a Mass Spectrometer, Types of Ions, Molecular Ion, Fragment Ion, Rearrangement Ion, Meta stable Ion, Isotopic Ions and Their Corresponding Peaks, Rules of Fragmentation McLafferty Rearrangement, Retro Diels Alder and Other Fragmentation Patterns**.** Introduction to FAB, LC-MS and GC-MS

UNIT-III (10 Hrs)

ESR: Principle and Correlation with Proton Magnetic Resonance, Derivative Curves, G-Values, Hyperfine Splitting, Applications.

Raman Spectroscopy: Introduction, Principle and Application of Raman Spectroscopy.

UNIT-IV (10 Hrs)

Flame Photometry: Introduction, Instrumentation, Effect of Solvent in Flame Photometry, Applications of Flame Photometry, Interferences in Flame Photometry and Limitations of Flame Photometry

Recommended Books

1. R.M. Silverstein and F.X. Webster, 'Spectrometric Identification of Organic Compounds', John Wiley & Sons, New York.
2. William Kemp, 'Organic Spectroscopy', ELBS MacMillan, Hampshire, (U.K.).

3. D.L. Pavia, G.M. Lampman and G.S. Kriz, 'Introduction to Spectroscopy- A Guide for Students of Organic Chemistry', Harcourt College Publishers.
4. J. March, 'Advanced Organic Chemistry - Reaction Mechanism and Structure', John Wiley and Sons, New York.
5. M.E. Wolff, 'Burger's Medicinal Chemistry', John Willey and Sons, New York.
6. K.A. Connors, 'Pharmaceutical Analysis', 3rd Edn., John Wiley & Sons, New York.
7. Beckett & Stanlake, 'Practical Pharmaceutical Chemistry,' Part-I & II, 4th Edn.
8. Kealey and Haines, 'Analytical Chemistry', Viva Books Pvt. Ltd., New Delhi.

BASICS OF PHARMACEUTICAL RESEARCH - I

Subject Code – MPHA5-103 **L T P C** **Duration – 45 Hrs**
3 1 0 4

UNIT-I (8 Hrs)

Drug Design and Discovery: Stages of Drug Discovery, Discovery of Lead Compounds, Pharmacophore Identification and Structure Modification, Physicochemical Alterations, Quantitative Structure Activity Relationship, High Throuput Screening, Acute, Sub-Acute and Chronic Studies, In-Vivo and In –Vitro Studies, Introduction To Preclinical and Clinical Trials, Toxicological Studies, FDA Review Process and Approval.

UNIT-II (9 Hrs)

Good Laboratory Practice: Scope of GLP, Definitions, Current GLP in manufacturing, responsibilities. General provision, organization and Personnel, Building and Facilities, Equipment, Control of Components and Drug product, Laboratory and Control of Records and Reports, Non-clinical Testing, Controls on Animal House, Report Preparation and Documentation. Application of Computers in Quality Control Laboratory.

Good Clinical Practices: Introduction, Regulatory perspectives, Provisions, Documentation.

UNIT-III (16 Hrs)

Principles of Experimental Pharmacology: Common Laboratory Animals in Pharmacological Research, Limitations of Animal Tests, Alternatives to Animal Use, Anaesthetics used in Laboratory Animals, Some Standard Techniques Used in Laboratory Animals, Euthanasia of Experimental Animals. Regulations for the care and use of Laboratory Animals, CPCSEA, OECD Guidelines.

Analytical Method Validation: General Principles, Validation of Analytical And Bio-analytical Method As Per ICH Guidelines.

Calibration and Qualification of Analytical Instruments: Electronic Balance, Ph Meter, UV-Visible Spectrophotometer, FTIR, GC, HPLC, HPTLC, Disintegration and Dissolution Test Apparatus. **Qualification of Glassware:** Volumetric Flask, Pipette, Beakers and Burette

UNIT-IV (12 Hrs)

Methods in Material Characterization - Particle dimensions: Particle Size and Powder Surface Area, Particle Shape and Surface Morphology.

Characterization of Solid State Structure: Spectroscopy in Pharmaceutical Analysis, X-Ray Diffraction, Solid-State Nuclear Magnetic Resonance, Vibrational Spectroscopy, Calorimetry in Pharmaceutical Analysis, Water Vapour Sorption, Electron and Confocal Microscopy, Density Measurements.

Thermal Methods of Analysis: Theory, Instrumentation and Applications of Thermo Gravimetric Analysis (TGA), Differential Thermal Analysis (DTA), Differential Scanning Calorimetry (DSC) and Thermo Mechanical Analysis (TMA)

X-Ray Diffraction Methods: Introduction, Generation of X-Rays, X-Ray Diffraction, Bragg's

Law, X-Ray Powder Diffraction, Interpretation of Diffraction Patterns and Applications.

Recommended Books

1. M.E. Wolff, 'Burger's Medicinal Chemistry and Drug Discovery, Principle and Practice', John Wiley and Sons, New York.
2. R. Franke, 'Theoretical Drug Design Methods', Vol. VII, Elsevier, New York.
3. R.B. Silverman, 'The Organic Chemistry of Drug Design and Action', Academic Press Inc., San Diego, USA.
4. P.I. Good, 'A Managers Guide to Design and Conduct of Clinical Trials', Wiley-Liss, Hobokem, U.S.A., **2002.**
5. A.C. Cartwright and B.R. Matthews (eds.), 'International Pharmaceutical Product Registration', Elis Horwood, New York, U.S.A., **1994.**
6. H.G. Vogel (ed), 'Drug Discovery and Evaluation-Pharmacological Assays', 2nd Edn., Springer Verlag, Berlin, Germany, **2002**.
7. M.N. Ghosh, 'Fundamentals of Experimental Pharmacology', 2nd Edn., Scientific Book Agency, Calcutta, India, **1984.**
8. Sandy Weinberg, 'Good Laboratory Practices', Vol. 129, 3rd Edn., Drugs and Pharm. Sci. Series, Marcel Dekker Inc.
9. Robert M. Silverstein, 'Spectrometric Identification of Organic Compounds', 6th Edn., Wiley & Sons Publication.
10. Doglass A. Skoog, Holler, Nieman, 'Principles of Instrumental Analysis', 5th Edn., Thomson & Brooks Cole Publication.
11. Hobert H. Willard, 'Instrumental Methods of Analysis', 7th Edn., CBS Publication.
12. Gary D. Christian, 'Analytical Chemistry', 6th Edn., Wiley & Sons Publication.
13. A.H. Beckett, J.B. Stenlake, 'Practical Pharmaceutical Chemistry', Volume I & II, 4th Edn., CBS Publications.
14. Skoog, West, Holler and Crouch, 'Fundamentals of Analytical Chemistry', 8th Edn., Thomson & Brooks Cole Publication.

PHARMACETICAL ANALYSIS LAB

Subject Code – MPHA5 – 105 **L T P C**
0 0 14 7

1. Interpretation of spectra of organic compounds- Workshop involving interpretation of IR, NMR and Mass spectra of Organic compounds to elucidate their chemical structure.
2. Basic chromatographic techniques
3. Experiments Based on HPLC and GC
4. Simultaneous estimation of combination formulations.
5. Use of spectrophotometer for analysis for pharmaceutical compounds & their formulations.

PHARMACEUTICAL ANALYSIS LAB

Subject Code – MPHA5 – 106 **L T P C**
0 0 4 2

1. Introduction, information and retrieval systems.
2. Writing assignments and term papers
3. Reading research papers
4. Organization and presentation of scientific material, research work, dissertations, patents etc.
5. Skills in oral and technical presentations

Each student has to present at least three seminars during the semester.

ADVANCED PHARMACEUTICAL ANALYSIS

Subject Code – MPHA5-207 **L T P C** **Duration – 50 Hrs**
4 0 0 4

Scope

This subject deals with the various aspects of Impurity, Impurities in new drug products, in residual solvents, Elemental impurities, Impurity profiling and characterization of degradants, Stability testing of phytopharmaceuticals and their protocol preparation. It also covers the biological testing of various vaccines and their principle and procedure.

Objective

After completion of the course students shall able to know,

- Appropriate analytical skills required for the analytical method development.
- Principles of various reagents used in functional group analysis that renders necessary support in research methodology and demonstrates its application in the practical related problems.
- Analysis of impurities in drugs, residual solvents and stability studies of drugs and biological products

UNIT-I (12 Hrs)

Impurity and stability studies: Definition, classification of impurities in drug Substance or Active Pharmaceutical Ingredients and quantification of impurities as per ICH guidelines.

Impurities in new drug products: Rationale for the reporting and control of degradation products, reporting degradation products content of batches, listing of degradation products in specifications, qualification of degradation products.

Impurities in Residual Solvents: General principles, classification of residual solvents, Analytical procedures, limits of residual solvents, reporting levels of residual solvents

UNIT-II (13 Hrs)

Elemental Impurities: Element classification, control of elemental impurities, Potential Sources of elemental Impurities, Identification of Potential Elemental Impurities, analytical procedures, instrumentation & C, H, N and S analysis

Impurity Profiling and Degradants Characterization: Method development, Stability studies and concepts of validation accelerated stability testing & shelf life calculation, WHO and ICH stability testing guidelines, Stability zones, steps in development, practical considerations. Basics of impurity profiling and degradant characterization with special emphasis. Photostability testing guidelines, ICH stability guidelines for biological products

UNIT-III (12 Hrs)

Stability Testing Protocols: Selection of batches, container orientation, test parameters, sampling frequency, specification, storage conditions, recording of results, concept of stability, commitment etc. Important mechanistic and stability related information provided by results of study of factors like temperature, pH, buffering species ionic strength and dielectric constant etc. on the reaction rates. With practical considerations.

Stability Testing of Phytopharmaceuticals: Regulatory requirements, protocols, HPTLC/HPLC finger printing, interactions and complexity.

UNIT-IV (13 Hrs)

Biological Tests and Assays of the following:

a) Adsorbed Tetanus vaccine
b) Adsorbed Diphtheria vaccine
c) Human anti haemophilic vaccine
d) Rabies vaccine
e) Tetanus Anti toxin
f) Tetanus Anti serum
g) Oxytocin
h) Heparin sodium IP
i) Antivenom.

PCR, PCR studies for gene regulation, instrumentation (Principle and Procedures)

Immunoassays (IA)

Basic principles, Production of antibodies, Separation of bound and unbound drug, Radioimmunoassay, Optical IA, Enzyme IA, Fluoro IA, Luminiscence IA, Quantification and applications of IA.

Recommended Books

1. Jeffery J. Bassett, J. Mendham, R.C. Denney, 'Vogel's Textbook of Quantitative Chemical Analysis', 5th Edn., ELBS, **1991**.
2. Beckett and Stenlake, 'Practical Pharmaceutical Chemistry', Vol II, 4th Edn., CBS Publishers, New Delhi, **1997**.
3. K.A. Connors, 'Textbook of Pharmaceutical Analysis', 3rd Edn., John Wiley & Sons, **1982**.
4. Higuchi, Brochmman and Hassen, 'Pharmaceutical Analysis', 2nd Edn., Wiley – Inter Science Publication, **1961**.
5. P.D. Sethi, 'Quantitative Analysis of Drugs in Pharmaceutical Formulation', 3rd Edn., CBS Publishers, New Delhi, **1997**.
6. J.W. Munson, 'Pharmaceutical Analysis- Modern Methods', Part B, Volume 11, Marcel Dekker Series.
7. D.C. Carratt, 'The Quantitative Analysis of Drugs,' 3rd Edn., CBS Publishers, New Delhi, **1964**.
8. 'Indian Pharmacopoeia', Vol I, II & III, **2007, 2010, 2014**.
9. 'Methods of Sampling and Microbiological Examination of Water', First Revision, BIS.
10. Snyder, Kirkland, Glajch, 'Practical HPLC Method Development', 2nd Edn., John Wiley & Sons.
11. Klaus Florey, 'Analytical Profiles of Drug Substances', Volume 1 – 20, Elsevier, **2005.**
12. Harry G. Brittan, 'Analytical Profiles of Drug Substances and Excipients', Volume 21 – 30, Elsevier, **2005**.
13. Joseph Chamberlain, 'The Analysis of Drugs in Biological Fluids', 2nd Edn., CRC Press, London.
14. ICH Guidelines for Impurity Profiles and Stability Studies.

MODERN BIO-ANALYTICAL TECHNIQUES

Subject Code – MPHA5-208 **L T P C** **Duration – 50 Hrs**
4 0 0 4

Scope

This subject is designed to provide detailed knowledge about the importance of analysis of drugs in biological matrices.

Objectives

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

- Extraction of drugs from biological samples
- Separation of drugs from biological samples using different techniques
- Guidelines for BA/BE studies.

UNIT-I (14 Hrs)

Extraction of Drugs and Metabolites from Biological Matrices: General need, principle and procedure involved in the Bioanalytical methods such as Protein precipitation, Liquid - Liquid extraction and Solid phase extraction and other novel
sample preparation approach.

Bioanalytical Method Validation: USFDA and EMEA guidelines.

Biopharmaceutical Consideration: Introduction, Biopharmaceutical Factors Affecting Drug Bioavailability, In Vitro: Dissolution and Drug Release Testing, Alternative Methods of Dissolution Testing Transport models, Biopharmaceutics Classification System. Solubility: Experimental methods. Permeability: In-vitro, in-situ and In-vivo methods.

UNIT-II (11 Hrs)

Pharmacokinetics and Toxicokinetics: Basic consideration, Drug interaction (PK-PD interactions), The effect of protein-binding interactions, the effect of tissue-binding interactions, Cytochrome P450-based drug interactions, Drug interactions linked to transporters. Microsomal assays Toxicokinetics Toxicokinetic evaluation in preclinical studies, Importance and applications of toxicokinetic studies. LC-MS in bioactivity screening and proteomics.

UNIT-III (11 Hrs)

Cell Culture Techniques: Basic equipment used in cell culture lab. Cell culture media, various types of cell culture, general procedure for cell cultures; isolation of cells, subculture, cryopreservation, characterization of cells and their applications. Principles and applications of cell viability assays (MTT assays), Principles and applications of flow cytometry.

UNIT-IV (14 Hrs)

Metabolite Identification: In-vitro / in-vivo approaches, protocols and sample preparation. Microsomal approaches (Rat liver microsomes (RLM) and Human liver microsomes (HLM) in Met –ID. Regulatory perspectives. In-vitro assay of drug metabolites & drug metabolizing enzymes.

Drug Product Performance, In Vivo: Bioavailability and Bioequivalence - Drug Product Performance, Purpose of Bioavailability Studies, Relative and Absolute Availability. Methods

for Assessing Bioavailability, Bioequivalence Studies, Design and Evaluation of Bioequivalence Studies, Study Designs, Crossover Study Designs, Generic Biologics (Biosimilar Drug Products), Clinical Significance of Bioequivalence Studies

Recommended Books

1. Joseph Chamberlain, 'Analysis of Drugs in Biological Fluids', 2nd Edn., CRC Press, New York, **1995.**
2. Doglas A. Skoog, F. James Holler, Timothy A. Nieman, 'Principles of Instrumental Analysis', 5th Edn., Eastern Press, Bangalore, **1998**.
3. Higuchi, Brochmman and Hassen, 'Pharmaceutical Analysis', 2nd Edn., Wiley – Interscience Publications, **1961.**
4. J.W. Munson, 'Pharmaceutical Analysis: Modern Methods', Part B, Volume 11, Marcel Dekker Series.
5. Snyder, Kirkland, Glaich, 'Practical HPLC Method Development', 2nd Edn., John Wiley & Sons, New Jercy, USA.
6. C. John, A. Adamovics, 'Chromatographic Analysis of Pharmaceuticals', 2nd Edn., Marcel Dekker, New York, USA, **1997.**
7. Roger L. Bertholf, Ruth E. Winecker, 'Chromatographic Methods in Clinical Chemistry & Toxicology', John Wiley & Sons, New Jercy, USA, **2007**.
8. Sandy Weinberg, 'Good Laboratory Practice Regulations', 2nd Edn., Vol. 69, Marcel Dekker Series, **1995.**
9. Allen F. Hirsch, 'Good Laboratory Practice Regulations', Volume 38, Marcel Dekker Series, **1989.**
10. ICH, USFDA & CDSCO Guidelines.

QUALITY CONTROL AND QUALITY ASSURANCE

Subject Code – MPHA5-209 **L T P C** **Duration – 50 Hrs**
4 0 0 4

Scope

This course deals with the various aspects of quality control and quality assurance aspects of pharmaceutical industries. It covers the important aspects like cGMP, QC tests, documentation, quality certifications, GLP and regulatory affairs.

Objectives

At the completion of this subject it is expected that the student shall be able to know

- the cGMP aspects in a pharmaceutical industry
- to appreciate the importance of documentation
- to understand the scope of quality certifications applicable to Pharmaceutical industries
- to understand the responsibilities of QA & QC departments

UNIT-I (10 Hrs)

Concept and Evolution of Quality Control and Quality Assurance: Good Laboratory Practice, GMP, Overview of ICH Guidelines -QSEM, with special emphasis on Q-series guidelines.

Good Laboratory Practices: Scope of GLP, Definitions, Quality assurance unit, protocol for conduct of non-clinical testing, control on animal house, report preparation and documentation.

UNIT-II (12 Hrs)

cGMP guidelines according to schedule M, USFDA (inclusive of CDER and CBER) Pharmaceutical Inspection Convention (PIC), WHO and EMEA covering: Organization and personnel responsibilities, training, hygiene and personal records, drug industry location, design, construction and plant lay out, maintenance, sanitation, environmental control, utilities and maintenance of sterile areas, control of contamination and Good Warehousing Practice. CPCSEA guidelines.

UNIT-III (12 Hrs)

Analysis of raw materials, finished products, packaging materials, in process quality control (IPQC), Developing specification (ICH Q6 and Q3): Purchase specifications and maintenance of stores for raw materials. In process quality control and finished products quality control for following formulation in Pharma industry according to Indian, US and British pharmacopoeias: tablets, capsules, ointments, suppositories, creams, parenteral, ophthalmic and surgical products (How to refer pharmacopoeias), Quality control test for containers, closures and secondary packing materials.

UNIT-IV (16 Hrs)

Documentation in Pharmaceutical Industry: Three tier documentation, Policy, Procedures and Work instructions, and records (Formats), Basic principles- How to maintain, retention and retrieval etc. Standard operating procedures (How to write), Master Formula Record, Batch Formula Record, Quality audit plan and reports. Specification and test procedures, Protocols and reports.

Distribution records. Electronic data.

Manufacturing Operations and Controls: Sanitation of manufacturing premises, mix-ups and cross contamination, processing of intermediates and bulk products, packaging operations, IPQC, release of finished product, process deviations, charge-in of components, time limitations on production, drug product inspection, expiry date calculation, calculation of yields, production record review, change control, sterile products, aseptic process control, packaging.

Recommended Books

1. 'Quality Assurance Guide by Organization of Pharmaceutical Procedures of India', Volume I & II, 3rd Revised Edn., Mumbai, **1996.**
2. Sandy Weinberg, 'Good Laboratory Practice Regulations', Vol. 69, 2nd Edn., Marcel Dekker Series, **1995.**
3. 'Quality Assurance of Pharmaceuticals - A Compendium of Guidelines and Related Materials', Vol I & II, 2nd Edn., WHO Publications, **1999.**
4. P.P. Sharma, 'How to Practice GMP's', Vandana Publications, Agra, **1991.**

5. 'The International Pharmacopoeia', – Vol I, II, III, IV & V – 'General Methods of Analysis and Quality specification for Pharmaceutical Substances, Excipients and Dosage Forms', 3rd Edn., WHO, Geneva, **2005**.
6. Allen F. Hirsch, 'Good Laboratory Practice Regulations', Volume 38, Marcel Dekker Series, **1989.**
7. ICH guidelines.
8. ISO 9000 and Total Quality Management 115.
9. Deshpande, Nilesh Gandhi, 'The Drugs and Cosmetics Act 1940', 4th Edn., Susmit Publishers, **2006**.
10. D.H. Shah, 'QA Manual', 1st Edn., Business Horizons, **2000.**
11. Sidney H. Willig, 'Good Manufacturing Practices for Pharmaceuticals a Plan for Total Quality Control', Vol. 52, 3rd Edn., Marcel Dekker Series.
12. L. Steinborn, 'GMP/ISO Quality Audit Manual for Healthcare Manufacturers and Their Suppliers', 6th Edn., (Volume 1 - With Checklists and Software Package) Taylor & Francis, **2003.**
13. D.K. Sarker, 'Quality Systems and Controls for Pharmaceuticals'. John Wiley & Sons, **2008**.

HERBAL AND COSMETIC ANALYSIS

Subject Code – MPHA5-210 **L T P C** **Duration – 50 Hrs**
4 0 0 4

Scope

This course is designed to impart knowledge on analysis of herbal products. Regulatory requirements, herbal drug interaction with monographs. Performance evaluation of cosmetic products is included for the better understanding of the equipment used in cosmetic industries for the purpose.

Objectives

At completion of this course student shall be able to understand

- Determination of herbal remedies and regulations
- Analysis of natural products and monographs
- Determination of Herbal drug-drug interaction
- Principles of performance evaluation of cosmetic products.

UNIT-I (12 Hrs)

Herbal Remedies- Toxicity and Regulations: Herbals vs Conventional drugs, Efficacy of herbal medicine products, Validation of Herbal Therapies, Pharmacodynamic and Pharmacokinetic issues. Herbal drug standardization: WHO and AYUSH guidelines.

Adulteration and Deterioration: Introduction, types of adulteration/substitution of herbal drugs, Causes and Measure of adulteration, Sampling Procedures, Determination of Foreign Matter, DNA Finger printing techniques in identification of drugs of natural origin, heavy metals, pesticide residues, phototoxin and microbial contamination in herbal formulations.

UNIT-II (12 Hrs)

Regulatory Requirements for Setting Herbal Drug Industry: Global marketing management, Indian and international patent law as applicable herbal drugs and natural products and its protocol.

Testing of Natural Products and Drugs: Effect of herbal medicine on clinical laboratory testing, Adulterant Screening using modern analytical instruments, Regulation and dispensing of herbal drugs, Stability testing of natural products, protocol.

UNIT-III (12 Hrs)

Monographs of Herbal Drugs

Study of monographs of herbal drugs and comparative study in IP, USP, Ayurvedic Pharmacopoeia, American herbal Pharmacopoeia, British herbal Pharmacopoeia, Siddha and Unani Pharmacopoeia, WHO guidelines in quality assessment of herbal drugs

Herbal Drug-Drug Interaction

WHO and AYUSH guidelines for safety monitoring of natural medicine, Spontaneous reporting schemes for bio drug adverse reactions, bio drug-drug and bio drug-food interactions with suitable examples, Challenges in monitoring the safety of herbal medicines

UNIT-IV (14 Hrs)

Evaluation of Cosmetic Products : Determination of acid value, ester value, saponification value, iodine value, peroxide value, rancidity, moisture, ash, volatile matter, heavy metals, fineness of powder, density, viscosity of cosmetic raw materials and finished products. Study of quality of raw materials and general methods of analysis of raw material used in cosmetic manufacture as per BIS

Indian Standard specification laid down for sampling and testing of various cosmetics in finished forms such as baby care products, skin care products, dental products, personal hygiene preparations, lips sticks. Hair products and skin creams by the Bureau Indian Standards.

Recommended Books

1. Trease and Evans, 'Pharmacognosy'.
2. Kokate, Purohit and Gokhale, 'Pharmacognosy'.
3. 'Quality Control Methods for Medicinal Plant', WHO, Geneva.
4. Ashutosh Kar, 'Pharmacognosy & Pharmacobiotechnology'.
5. S.H. Ansari, 'Essentials of Pharmacognosy'.
6. P.P. Sharma, 'Cosmetics – Formulation, Manufacturing and Quality Control', 4th Edn.,
7. Vandana Publications Pvt. Ltd., Delhi.
8. 'Indian Standard Specification, for Raw Materials', BIS, New Delhi.
9. 'Indian Standard Specification for 28 Finished Cosmetics', BIS, New Delhi.
10. 'Harry's Cosmeticology', 8th Edn.
11. Suppliers Catalogue on specialized Cosmetic Excipients
12. Wilkinson, Moore, George Godwin. 'Poucher's Perfumes, Cosmetics and Soaps', 7th Edn.

13. Hilda Butler, 10th Edn., Kluwer Academic Publishers. 'Handbook of Cosmetic Science and Technology', 3rd Edn.

PHARMACEUTICAL ANALYSIS PRACTICALS -II

Subject Code – MPHA5 – 211 **L T P C**
0 0 12 6

1. Comparison of absorption spectra by UV and Wood ward – Fieser Rule
2. Interpretation of organic compounds by FT-IR
3. Interpretation of organic compounds by NMR
4. Interpretation of organic compounds by MS
5. Determination of purity by DSC in pharmaceuticals
6. Identification of organic compounds using FT-IR, NMR, CNMR and Mass spectra
7. Bio molecules separation utilizing various sample preparation techniques and quantitative analysis of components by gel electrophoresis.
8. Bio molecules separation utilizing various sample preparation techniques and Quantitative analysis of components by HPLC techniques.
9. Isolation of analgesics from biological fluids (Blood serum and urine).
10. Protocol preparation and performance of analytical/Bioanalytical method validation.
11. Protocol preparation for the conduct of BA/BE studies according to guidelines.
12. In process and finished product quality control tests for tablets, capsules, parenteral and creams
13. Quality control tests for Primary and secondary packing materials
14. Assay of raw materials as per official monographs
15. Testing of related and foreign substances in drugs and raw materials
16. Preparation of Master Formula Record.
17. Preparation of Batch Manufacturing Record.
18. Quantitative analysis of rancidity in lipsticks and hair oil
19. Determination of aryl amine content and Developer in hair dye
20. Determination of foam height and SLS content of Shampoo.
21. Determination of total fatty matter in creams (Soap, skin and hair creams)
22. Determination of acid value and saponification value.
23. Determination of calcium thioglycolate in depilatories

SEMINARS/ASSIGNMENTS

Subject Code – MPHA5 – 212 **L T P C**
0 4 0 4

- Introduction, information and retrieval systems.
- Writing assignments and term papers
- Reading research papers
- Organization & Presentation of Scientific Material, Research Work, Dissertations, Patents etc.
- Skills in oral and technical presentations

- Tutorials related to subject taught

Each student has to present at least three seminars during the semester.