Course Objectives:
- This subject deals with various advanced analytical instrumental techniques for identification, characterization and quantification of drugs.
- The students will be dealing with instruments like NMR, Mass spectrometer, IR, HPLC, GC etc.
- Acquire skills in selecting the suitable techniques for analysis of drugs
- Validate the instruments used in Pharma industry
- Expand the theoretical knowledge on various instrumental techniques available for analysis of organic substances
- Expertise in various spectroscopic studies

Course Outcome:
After completion of course student will
1. Persuade the theoretical and practical skills of the instruments
2. Analyze various drugs in single and combination dosage forms
3. Acquire skills in selecting the suitable techniques for analysis of drugs
4. Validate the instruments used in Pharma industry
5. Expand the theoretical knowledge on various instrumental techniques available for analysis of organic substances
6. Expertise in various spectroscopic studies

THEORY 60Hrs

1. a. UV-Visible spectroscopy: 10Hrs

b. IR spectroscopy:
   Theory, Modes of Molecular vibrations, Sample handling, Instrumentation of Dispersive and Fourier - Transform IR Spectrometer, Factors affecting vibration frequencies and Applications of IR spectroscopy, Data Interpretation.
c. **Spectro fluorimetry:**
Theory of Fluorescence, Factors affecting fluorescence (Characteristics of drugs that can be analysed by fluorimetry), Quenchers, Instrumentation and Applications of fluorescence spectrophotometer.

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

2. **NMR spectroscopy:** 10Hrs
Quantum numbers and their role in NMR, Principle, Instrumentation, Solvent requirement in NMR, Relaxation process, NMR signals in various compounds, Chemical shift, Factors influencing chemical shift, Spin-Spin coupling, Coupling constant, Nuclear magnetic double resonance, Brief outline of principles of FT-NMR and 13C NMR. Applications of NMR spectroscopy.

3. **Mass Spectroscopy:** 10Hrs

4. **Chromatography:** 10Hrs

5. **a.Electrophoresis:** 10Hrs
Principle, Instrumentation, Working conditions, factors affecting separation and applications of the following: a) Paper electrophoresis b) Gel electrophoresis c) Capillary electrophoresis d) Zone electrophoresis e) Moving boundary electrophoresis f) Iso electric focusing

**b. X ray Crystallography:**
Production of X rays, Different X ray methods, Bragg’s law, Rotating crystal technique, X ray powder technique, Types of crystals and applications of X-ray diffraction.

6. **Potentiometry:** 10Hrs
Principle, working, Ion selective Electrodes and Application of potentiometry. Thermal Techniques:
Modulated DSC, Hyper DSC, experimental parameters (sample preparation, experimental conditions, calibration, heating and cooling rates, resolution, source of errors) and their influence, advantage and disadvantages, pharmaceutical applications.


**Reference Books (Latest Editions):**

Course Objectives:
- This subject deals with the various aspects of Impurity, Impurities in new drug products, in residual solvents, Elemental impurities.
- The student will expertise in Impurity profiling and characterization of degradants,
- This subject deals with Stability testing of phytopharmaceuticals and their protocol preparation.
- It also covers the biological testing of various vaccines and their principle and procedure.
- The subject emphasize on assay and different tests for drug products.
- The subject also provides knowledge regarding immunoassay and techniques involved in immunoassay

Course Outcome:
After completion of the course students will,
1. Develop appropriate analytical skills required for the analytical method development
2. Discover principles of various reagents used in functional group analysis that renders necessary support in research methodology
3. Demonstrates the applications of analytical principles in the practical related problems
4. Design the analysis of impurities in drugs and residual solvents
5. Expertise in stability testing and biological methods of purity determination
6. Acquire skills in identifying the impurities in combinational drugs

THEORY

1. Impurity and stability studies: 10Hrs
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 Patches, 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

2. Elemental impurities: 10Hrs
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

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.

3. Impurity profiling and degradants characterization: 10 Hrs
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. Photo stability testing guidelines, ICH stability guidelines for biological products

4. Stability testing of Phytopharmaceuticals: 10Hrs
Regulatory requirements, protocols, HPTLC/HPLC finger printing, interactions and complexity.

5. Biological tests and assays of the following: 10Hrs
A. Adsorbed Tetanus vaccine
B. Adsorbed Diphtheria vaccine
C. Human anti haemophilic vaccine
D. Rabies vaccine
E. Tetanus Antitoxin
F. Tetanus ntiserum
G. Oxytocin
H. Heparin sodiumIP
I. Antivenom. PCR, PCR studies for generegulation, instrumentation (Principle and Procedures)
6. Immunoassays (IA)  
10Hrs

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.

Reference Books (Latest Editions):

9. Methods of sampling and microbiological examination of water, first revision, BIS
14. ICH Guidelines for impurity profiles and stability studies.
Course Objectives:

- The main purpose of the subject is to understand about validation and how it can be applied to industry.
- The subject aims to improve the quality of the products.
- The subject covers the complete information about validation, types, methodology and application.
- The student will receive a deep knowledge on intellectual property rights.
- The subject provides an advanced knowledge on patents and its specifications.
- Different techniques like TOT, IPP and social responsibilities to be followed will be discussed.

Course Outcome:

Upon completion of the subject student will

1. Explain the aspect of validation
2. Carry out validation of manufacturing processes
3. Apply the knowledge of validation to instruments and equipment’s
4. Validate the manufacturing facilities
5. Revise the importance of patent and intellectual property rights.
6. Construct method validation as per ICH guidelines.

THEORY


12Hrs

4. Analytical method validation: General principles, Validation of analytical method as per ICH guidelines and USP. Computerized system validation: Electronic records and digital significance-21 CFR part 11 and GAMP5.

12Hrs

5. General Principles of Intellectual Property: Concepts of Intellectual Property (IP), Intellectual Property Protection (IPP), Intellectual Property Rights (IPR); Economic importance, mechanism for protection of Intellectual Property – patents, Copyright, Trademark; Factors affecting choice of IP protection; Penalties for violation; Role of IP in pharmaceutical industry; Global ramifications and financial implications. Filing a patent applications; patent application forms and guidelines. Types patent applications-provisional and non-provisional, PCT and convention patent applications; International patenting requirement procedures and costs; Rights and responsibilities of a patentee; Practical aspects regarding maintaining of a Patent file; Patent infringement meaning and scope. Significance of transfer technology (TOT), IP and ethics-positive and negative aspects of IPP; Societal responsibility, avoiding unethical practices

Reference Books (Latest Editions):


3. Validation Master plan by Terveeks or Deeks, Davis Harwood International publishing.


8. Validation of Pharmaceutical Processes: Sterile Products, Frederick J. Carlton (Ed.) and James Agalloco
Course Objectives:

- This course is designed to impart knowledge on analysis of food constituents.
- This course is designed to impart knowledge on analysis of finished food products.
- The course includes application of instrumental analysis in the determination of pesticides in variety of food products.
- The subject deals with legislation regulations associated with food products.
- The subject covers a wide knowledge on analytical techniques to be followed in the determination of food regulations.
- The subject also emphasize on analysis of fermented products like wine, spirits etc.

Course Outcome:

At completion of this course student will

1. Understand various analytical techniques in the determination of food constituents
2. Devise various analytical techniques in the determination of food additives
3. Create various analytical techniques in the determination of finished food products
4. Demonstrate various analytical techniques in the determination of pesticides in food
5. Review various analytical techniques in the determination of food regulations
6. Recognize various analytical techniques in the determination of food legislations

THEORY

1. Carbohydrates – Chemistry & classification and properties of food carbohydrates, General methods of analysis of food carbohydrates, Changes in food carbohydrates during processing, Digestion, absorption and metabolism of carbohydrates, Dietary fibre, crude fibre and application of food carbohydrates.

Proteins - Chemistry and classification of amino acids and proteins, Physico-Chemical properties of protein and their structure, general methods of analysis of proteins and amino acids, Digestion, absorption and metabolism of proteins.

2.a. Lipids – Classification, general methods of analysis, refining of fats and oils; hydrogenation of vegetable oils, Determination of adulteration in fats and oils, Various methods used for measurement of spoilage of fats and fatty foods.

12Hrs

3. Food additives – Introduction, analysis of Preservatives, antioxidants, artificial sweeteners, flavors, flavor enhancers, stabilizers, thickening and jelling agents.
   Pigments and synthetic dyes- Natural pigments their occurrence and characteristic properties, permitted synthetic Dyes, Non-Permitted synthetic dyes used by industries, Method of detection of natural, permitted and non-permitted dyes

12Hrs

4. General Analytical methods for milk, milk constituents and milk products like ice cream, milk powder, butter, margarine, cheese including adulterants and contaminants of milk.
   Analysis of fermentation products like wine, spirits, beer and vinegar.

12Hrs

5. Pesticide analysis-Effects of pesticides insects on various food, use of pesticides in agriculture, pesticide cycle, organophosphorus and organo chlorine pesticides analysis, determination of pesticide residues in grain, fruits, vegetables, milk and milk products.
   Legislation regulations of food products with special emphasis on BIS, Agmark and US-FDA

Reference Books (Latest Editions):

4. Analysis of Food constituents–Multon, Wiley VCH.
Course Objectives:

- To estimate the samples using analytical instruments.
- To perform assay of official drug samples using analytical instruments.
- To determine the impurity profile of drugs.
- To separate the mixtures of sample using chromatographic techniques.
- To demonstrate HPLC.
- To demonstrate gas chromatography.

Course Outcome:

At completion of this course student will

1. Demonstrate the analysis of pharmacopoeial compounds and simultaneous estimation by UV-VIS
2. Acquire skills in selecting the suitable techniques for analysis of drugs
3. Expertise in stability testing and biological methods of purity determination
4. Validate impurity profiling of drugs
5. Compare and contrast various methods of analysis and their outcomes
6. Demonstrate calibration of various glassware and instruments used in pharma industry

CONTENTS:

1. Analysis of pharmacopoeial compounds and their formulations by UV Vis spectrophotometer
2. Simultaneous estimation of multicomponent containing formulations by UV spectrophotometry
3. Experiments based on HPLC
4. Experiments based on Gas Chromatography
5. Estimation of riboflavin/quinine sulphate by fluorimetry
6. Estimation of sodium/potassium by flame photometry
7. Assay of official compounds by different titrations
8. Assay of official compounds by instrumental techniques.
9. Quantitative determination of hydroxyl group.
10. Quantitative determination of amino group
11. Colorimetric determination of drugs by using different reagents
12. Impurity profiling of drugs
13. Calibration of glassware’s
14. Calibration of pH meter
15. Calibration of UV-Visible spectrophotometer
16. Calibration of FTIR spectrophotometer
17. Calibration of GC any instrument
18. Calibration of HPLC instrument
19. Cleaning validation of anyone equipment
20. Determination of total reducing sugar
21. Determination of proteins
22. Determination of saponification value, Iodine value, Peroxide value, Acid value in food products
23. Determination of fat content and rancidity in food products
24. Analysis of natural and synthetic colors in food
25. Determination of preservatives in food
26. Determination of pesticide residue in food products
27. Analysis of vitamin content in food product
28. Determination of density and specific gravity of foods
29. Determination of food additive

Reference Books (Latest Editions):
Course Objectives:

- This subject deals with various hyphenated analytical instrumental techniques for identification, characterization and quantification of drugs.
- Instruments dealt are LC-MS, GC-MS, and hyphenated techniques.
- The course provides an elaborate knowledge on HPLC in the field of nanotechnology and approaches for advancement in enantiomeric separations.
- The course offers advanced biochromatographical techniques, its approaches and derivatization.
- The subject includes hyphenation techniques in LC-MS and DART MS analysis.
- 13C NMR, 1-D and 2-D NMR, NOESY and COSY techniques were also included in the study.

Course Outcome:

After completion of course student will,

1. Interpret NMR, Mass and IR spectra of various organic compounds
2. Demonstrate theoretical and practical skills of the hyphenated instruments
3. Undergo Identification of organic compounds
4. Acquire Practical aspects and troubleshooting techniques for HPLC techniques
5. Expertise in controlling the parameters that affect drug manufacturing
6. Acquire Practical aspects and troubleshooting techniques for GC techniques

THEORY

1. HPLC: Principle, instrumentation, pharmaceutical applications, peak shapes, capacity factor, selectivity, plate number, plate height, resolution, band broadening, pumps, injector, detectors, columns, column problems, gradient HPLC, HPLC solvents, trouble shooting, sample preparation, method development, New developments in HPLC-role and principles of ultra, nanoliquid chromatography in pharmaceutical analysis.

Immobilized polysaccharide CSP’s: Advancement in enantiomeric separations, revised phase Chiral method...
development and HILIC approaches. HPLC in Chiral analysis of pharmaceuticals. Preparative HPLC, practical aspects of preparative HPLC.  

2. **Biochromatography:** Size exclusion chromatography, ion exchange chromatography, ion pair chromatography, affinity chromatography general principles, stationary phases and mobile phases. Gas chromatography: Principles, instrumentation, derivatization, head space sampling, columns for GC, detectors, quantification. High performance Thin Layer chromatography: Principles, instrumentation, pharmaceutical applications.  

3. **Super critical fluid chromatography:** Principles, instrumentation, pharmaceutical applications.  

**Capillary electrophoresis:** Overview of CE in pharmaceutical analysis, basic configuration, CE characteristics, principles of CE, methods and modes of CE. General considerations and method development in CE, Crown ethers as buffer additives in capillary electrophoresis. CE-MS hyphenation.  

4. **Mass spectrometry:** Principle, theory, instrumentation of mass spectrometry, different types of ionization like electron impact, chemical, field, FAB and MALD, APCI, ESI, APPI mass fragmentation and its rules, metastable ions, isotopic peaks and applications of mass spectrometry. LC-MS hyphenation and DART MS analysis. Mass analysers (Quadrpole, Time of flight, FT-ICR, ion trap and Orbitrap) instruments. MS/MS systems (Tandem: QqQ, TOF-TOF; Q-IT, Q-TOF, LTQ-FT, LTQ-Orbitrap).  

5. **NMR spectroscopy:** Quantum numbers and their role in NMR, Principle, Instrumentation, Solvent requirement in NMR, Relaxation process, NMR signals in various compounds, Chemical shift, Factors influencing chemical shift, Spin-Spin coupling, Coupling constant, Nuclear magnetic double resonance, Brief outline of principles of FT-NMR with reference to 13CNMR: Spin spin and spin lattice relaxation phenomenon. 13C NMR, 1-D and 2-D NMR, NOESY and COSY techniques, Interpretation and Applications of NMR spectroscopy. LC-NMR hyphenations.
**Reference Books (Latest Editions):**

Course Objectives:
- This subject is designed to provide detailed knowledge about the importance of analysis of drugs in biological matrices.
- The subject deals with different pharmacokinetic and pharmacodynamic parameters
- The subject emphasize on bioavailability and bioequivalence studies
- The course provides a detailed advancement on toxicokinetic studies and its importance in preclinical studies.
- The course outlines on cell culture techniques and its applications including MTT.
- The course provides knowledge on LC-MS in bioactivity screening and proteomics

Course Outcome:
Upon completion of the course, the student will
1. Undergo Extraction of drugs from biological samples
2. Demonstrate separation of drugs from biological samples using different techniques
3. Interpret the guidelines for BA/BE studies
4. Persuade a deep knowledge on BCS classification system and its applications in new drug discovery process
5. Understand various pharmacokinetics and Pharmacodynamic parameters affecting drug efficacy
6. Acquire knowledge on LC-MS in bioactivity screening and proteomics.

THEORY

1. 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.

Testing Transport models, Biopharmaceutics Classification System. Solubility: Experimental methods.
Permeability: *In-vitro, in-situ* and *In-vivo* methods.

12 hrs

3. 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.

12 hrs

4. Cell culture techniques Basic equipments 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.

12 hrs


Reference Books (Latest Editions):


10. ICH, USFDA & CDSCO Guidelines.

11. Palmer
QUALITY CONTROL AND QUALITY ASSURANCE

Course Objectives:
- 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.
- Procedures to ensure confidentiality of inventory and source category information, when required are explained.
- Frequency of QA/QC checks on different parts of the inventory was dealt in the subject.
- The subject covers about GLP responsibilities and regulatory affairs.
- The subject deals with SOPs or standard operating procedures.

Course Outcome:
At the completion of this subject it is expected that the student will,

1. Understand the cGMP aspects in a pharmaceutical industry
2. Appreciate the importance of documentation
3. Understand the scope of quality certifications applicable to Pharmaceutical industries
4. Recognize the responsibilities of QA & QC departments
5. Acquire knowledge on GLP and regulatory Affairs
6. Interpret CPCSEA guidelines

THEORY

1. 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 nonclinical testing, control on animal house, report preparation and documentation.

2. 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.  

12 Hrs

3. Analysis of raw materials, finished products, packaging materials, in process quality control (IPQQC), 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, parenterals, ophthalmic and surgical products (How to refer pharmacopoeias Quality control test for containers, closures and secondary packing materials.  

12 Hrs

4. 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.  

12 Hrs

5. Manufacturing operations and controls: Sanitation of manufacturing premises, mix-ups and cross contamination, processing of intermediates and bulk products, packaging operations, IPQQC, 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.  

12 Hrs

Reference Books (Latest Editions):


7. ISO 9000 and total quality management


Course Objectives:

- This course is designed to impart knowledge on analysis of herbal products.
- Regulatory requirements, herbal drug interaction with monographs were explained.
- Performance evaluation of cosmetic products is included for the better understanding of the equipments used in cosmetic industries for the purpose.
- Describe guidelines for cGMP, GAP, GMP and GLP for quality assurance of herbal drugs in industry
- Describe guidelines for quality control of herbal drugs and evaluation of safety and efficacy of herbal medicines.
- The subject deals with herbal drug interactions

Course Outcome:

At completion of this course student will

1. Determine the herbal remedies and regulations
2. Demonstrate the analysis of natural products and monographs
3. Interpret Herbal drug-drug interaction
4. Exploit the principles of performance evaluation of cosmetic products.
5. Understand the pre requisites to be followed in the preparation of the herbal monographs
6. Express the Indian Standard specification laid down for sampling and testing of various cosmetics

THEORY


2. 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. Regulatory requirements for setting herbal drug industry: Global marketing management, Indian and international patent law as applicable herbal drugs and natural products andits protocol.  

3. 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.


5. 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.

**Reference Books (Latest Editions):**

1. Pharmacognosy by Trease and Evans
2. Pharmacognosy by Kokate, Purohit and Gokhale
4. Pharmacognosy & Pharmacobiotechnology by Ashutosh Kar
5. Essential of Pharmacognosy by Dr. S. H. Ansari
8. Indian Standard specification for 28 finished cosmetics BIS, New Delhi

9. Harry’s Cosmeticology 8th edition

10. Suppliers catalogue on specialized cosmetic excipients


Course Objectives:

- To estimate the samples using analytical instruments.
- To perform the interpretation of organic compound by ftir, nmr, ms etc
- To determine the impurity profile of drugs.
- To separate the mixtures of sample using chromatographic techniques.
- To demonstrate the protocol preparation and performance of bioanalytical method validation
- To demonstrate cosmetic analysis.

Course Outcome:

At completion of this course student will

1. Demonstrate the interpretation of various organic compounds by FT-IR
2. Demonstrate the interpretation of various organic compounds by NMR
3. Demonstrate the interpretation of various organic compounds by mass spectroscopy
4. Interpret Protocol preparation and performance of analytical/ Bioanalytical method validation
5. Formulate cosmetics and carry out its evaluation
6. Appreciate the importance of documentation by preparing master formula record, batch manufacturing records etc.

CONTENTS:

1. Comparison of absorption spectra by UV and Wood ward – Fiesure 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).
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, parenterals 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

**Reference Books (Latest Editions):**