SAVITRIBAI PHULE PUNE UNIVERSITY

FACULTY OF SCIENCE AND TECHNOLOGY

RULES AND SYLLABUS

FIRST YEAR MASTER OF PHARMACY (M. Pharm.)
COURSE (EFFECTIVE FROM ACADEMIC YEAR 2019-2020)
PHARMACEUTICAL ANALYSIS (MPA)

Course of study for M. Pharm. (Pharmaceutical Analysis)

Course Code	Course	Credit Hours	Credit Points	Hrs./wk	Marks
SEMESTER I					
MPAT101T	Modern Pharmaceutical Analytical Techniques	4	4	4	100
MPA102T	Advanced Pharmaceutical Analysis	4	4	4	100
MPA103T	Quality Control and Quality Assurance	4	4	4	100
MPA104T	Food Analysis	4	4	4	100
MPA105P	Pharmaceutical Analysis Practical I	12	6	12	150
-	Seminar/Assignment	7	4	7	100
	Total	**35**	**26**	**35**	**650**
SEMESTER II					
MPA201T	Advanced Instrumental Analysis	4	4	4	100
MPA202T	Modern Bio–Analytical Techniques	4	4	4	100
MPA203T	Pharmaceutical Validation	4	4	4	100
MPA204T	Herbal and Cosmetic Analysis	4	4	4	100
MPA205P	Pharmaceutical Analysis Practical II	12	6	12	150
-	Seminar/Assignment	7	4	7	100
	Total	**35**	**26**	**35**	**650**

ADVANCED PHARMACEUTICAL ANALYSIS

(MPA 102T)

SCOPE:

This subject deals with the various aspects of Impurity, Impurities in new drug and products, residual solvents, Elemental impurities, Impurity profiling and characterization of degradents, It also includes stability testing of phytopharmaceuticals and the biological testing of various vaccines.

OBJECTIVE

After completion of the course students shall be able to understand-

- Analysis of impurities in Drugs and Drug Products
- Stability studies of Drugs, Phytopharmaceuticals and Biological products

THEORY **60 Hrs**

1. Impurities and Degradents: Overview of Impurity, Definition, classification of impurities in drug substance or Active Pharmaceutical Ingredients and in new drug products, Quantification of impurities as per ICH guidelines.

   Residual solvents: General principles, classification of residual solvents, Analytical procedures, limits of residual solvents, reporting levels of residual solvents.

   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.

   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. **12 Hrs**

2. Stability testing protocols: Selection of batches, container orientation, test parameters, sampling frequency, specification, storage conditions, recording of results.

   Important mechanistic and stability related information provided by results of study of factors like temperature, pH, buffering species ionic strength and dielectric constant on the reaction rates with practical considerations. **10 Hrs**

3. Stability studies, Impurity profiling and degradent characterization: Basics of impurity profiling and degradent characterization, Method development, Stability studies and concepts of accelerated stability testing & shelf life calculation, Stability zones, WHO and ICH stability testing guidelines, steps in development with practical considerations.
   Photostability testing guidelines, ICH stability guidelines for biological products. **10 Hrs**

4. Stability testing of phytopharmaceuticals: Regulatory requirements, protocols, HPTLC/HPLC finger printing, interactions and complexity. **08 Hrs**

5. Biological tests and assays of the following: a.) Rabies vaccine b.) Tetanus Antitoxoid c.) Oxytocin d.) Heparin sodium IP e.) Antivenom.

   PCR, PCR studies for gene regulation, (Principle and Procedures) **10 Hrs**

6. 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. **10 Hrs**

REFERENCES

1. Indian Pharmacopoeia Vol I, II & III 2007, 2010, 2014.
2. Practical HPLC method development - Snyder, Kirkland, Glajch, 2nd edition, John Wiley & Sons.
3. Analytical Profiles of drug substances - Klaus Florey, Volume 1 - 20, Elsevier, 2005
4. Analytical Profiles of drug substances and Excipients - Harry G Brittan, Volume 21 - 30, Elsevier, 2005.
5. The analysis of drugs in biological fluids – Joseph Chamberlain, 2nd edition, CRC press, London.
6. ICH Guidelines for impurity profiles and stability studies.
7. ICH (www.ich.org) and WHO (www.who.int) guidelines.
8. Pharmaceutical Stress Testing (Predicting Drug Degradation),Steven Baertschi and Karen Alsante, Informa Healthcare.
9. Drug Stability (Principles and Practices),S.James, Jens ThuroCarstensen, Taylor & Francis.
10. Stability-indicating HPLC Methods for Drug Analysis,Quanyun A. Xu, Lawrence A. Trissel, American Pharmacist Association..
11. Stability of Drugs and Dosage Forms, Sumic Yoshioka, Valentino Stella, Springer.
12. Physical Pharmacy and Pharmaceutical Sciences, Patrick Sinko, Alfred Martin, Lippincott Williams and Wilkins.
13. Handbook of Stability Testing in Pharmaceutical Development: Regulations, Methodologies, and Best Practices, Kim Huynh-Ba, Springer.
14. Stability and Characterization of Protein & Peptide of Drugs,Y. John Wang, Inbunden.
15. Peptide and Protein Drug Analysis, Ronald Reid, Taylor and Francis.

QUALITY CONTROL AND QUALITY ASSURANCE
(MPA 103T)

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

THEORY **60 Hrs**

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 non clinical testing, control on animal house, report preparation and documentation, CPCSEA guidelines. **12 Hrs**

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. **12 Hrs**

3 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. **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, 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. **12 Hrs**

REFERENCES

1. Quality Assurance Guide by organization of Pharmaceutical Procedures of India, 3rd revised edition, Volume I & II, Mumbai, 1996.
2. Good Laboratory Practice Regulations, 2nd Edition, Sandy Weinberg Vol. 69, Marcel Dekker Series, 1995.
3. Quality Assurance of Pharmaceuticals– A compedium of Guide lines and related materials Vol I & II, 2nd edition, WHO Publications, 1999.
4. How to Practice GMP's - P P Sharma, Vandana Publications, Agra, 1991.
5. The International Pharmacopoeia - Vol I, II, III, IV & V – General Methods of Analysis and Quality specification for Pharmaceutical Substances, Excepients and Dosage forms, 3rd edition, WHO, Geneva, 2005.

7 Good laboratory Practice Regulations - Allen F. Hirsch, Volume 38, Marcel Dekker Series, 1989.

8 ICH guidelines.

9 ISO 9000 and total quality management.

7 The drugs and cosmetics act 1940 - Deshpande, Nilesh Gandhi, 4th edition, Susmit Publishers, 2006.

8 QA Manual - D.H. Shah, 1st edition, Business Horizons, 2000.

9 Good Manufacturing Practices for Pharmaceuticals a plan for total quality control - Sidney H.Willig, Vol. 52, 3rd edition, Marcel Dekker Series.

10 Steinborn L. GMP/ISO Quality Audit Manual for Healthcare Manufacturers and Their Suppliers, Sixth Edition, (Volume 1 – With Checklists and Software Package). Taylor & Francis 2003.

11 Sarker DK. Quality Systems and Controls for Pharmaceuticals. John Wiley & Sons; 2008.

FOOD ANALYSIS

(MPA 104T)

SCOPE

This course is designed to impart knowledge on analysis of food constituents and finished food products. The course includes application of instrumental analysis in determination of pesticides in variety of food products.

OBJECTIVES

At completion of this course student shall be able to understand -

- Food constituents
- Food additives
- Finished food products
- Pesticides in food
- Knowledge on food regulations and legislations

THEORY 60Hrs

1 Carbohydrates: classification and properties of food carbohydrates ,General method of analysis and metabolism of carbohydrates, Dietary Fibers, Crudes Fibers 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. **12 Hrs**

2 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.

Vitamins: classification of vitamins, methods of analysis of vitamins, Principles of microbial assay of vitamins of B series. **12 Hrs**

3 Food additives: Introduction, analysis of preservative, antioxidant, artificial sweeteners, flavors, flavors enhancers, stabilizers, thickening and jelling agents.

Pigments and synthetic dyes: Natural pigments,their occurrence and characteristic properties, permitted synthetics, Non–permitted synthetic dyes used by industries, Method of detection of natural, permitted and non-permitted dyes. **12 Hrs**

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.**12 Hrs**

5 Pesticide analysis: Effects of pest and insects on various food, use of pesticides in agriculture, pesticide cycle, organophosphorus and organochlorine 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, FDA and US–FDA **12 Hrs**

REFERENCES

1 The chemical analysis of foods - David Pearson, Seventh edition,Churchill Livingstone, Edinburgh London, 1976.

2 Introduction to the Chemical analysis of foods - S. Nielsen, Jones & Bartlett publishers, Boston London, 1994.

3 Official methods of analysis of AOAC International, sixth edition, Volume I & II, 1997.

4 Analysis of Food constituents - Multon, Wiley VCH.

5 William Horwitz, Official methods of analysis of AOAC International, 18th edition, 2005.

PHARMACEUTICAL ANALYSIS PRACTICALS - I

(MPA 105P)

1	Analysis of Pharmacopoeial compounds in bulk and in their formulations (tablet / capsules / semisolids) by UV Vis spectrophotometry
2	Simultaneous estimation of multi component 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 raw materials as per official monographs (one API and one excipient)
8	In process and finished product quality control tests for tablets, capsules, parenterals and creams
9	Quality control tests for Primary and secondary packing materials
10	Preparation of Master Formula Record.
11	Preparation of Batch Manufacturing Record.
12	Testing of related and foreign substances in drugs and raw materials
13	Impurity profiling of drugs (Any 01)
14	Determination of total reducing sugar
15	Determination of proteins
16	Determination of saponification value, Iodine value, Peroxide value, Acid value in food products
17	Determination of fat content and rancidity in food products
18	Analysis of natural and synthetic colors in food
19	Determination of preservatives in food
20	Determination of pesticide residue in food products
21	Analysis of vitamin content in food products

ADVANCED INSTRUMENTAL ANALYSIS

(MPA 201T)

SCOPE

This subject deals with various hyphenated analytical instrumental techniques for identification, characterization and quantification of drugs.

OBJECTIVES

After completion of course student is able to know-

- Interpretation of the UV, IR, NMR and Mass spectra of various organic compounds
- Theoretical and practical skills of the hyphenated techniques
- Identification of organic compounds

THOERY **60 Hrs**

1 HPLC: Principle, System suitability parameters-peak shapes, capacity factor, selectivity, plate number, plate height, resolution. Band broadening. New developments in HPLC-role and principles of ultra, nano liquid 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. **12 Hrs**

2 UV and IR spectroscopy: Woodward - Fieser rule for 1,3- butadienes, cyclic dienes and α, β–carbonyl compounds and interpretation compounds of enones.
ATR–IR and other sample attachments, Interpretation of IR Spectra of Organic Compounds. **12 Hrs**

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. **12Hrs**

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, meta stable 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. **16Hrs**

5 NMR spectroscopy: 1-D and 2-D NMR, NOESY and COSY techniques, Interpretation and Applications of NMR spectroscopy. LC-NMR hyphenations. **08 Hrs**

REFERENCES

1. Spectrometric Identification of Organic compounds,Robert M Silverstein, Sixth edition, John Wiley & Sons, 2004.
2. Principles of Instrumental Analysis, Doglas A Skoog, F. James Holler, Timothy A. Nieman, 5th edition, Eastern press, Bangalore, 1998.
3. Instrumental methods of analysis, Willards, 7th edition, CBS publishers.
4. Organic Spectroscopy,William Kemp, 3rd edition, ELBS, 1991.
5. Quantitative Analysis of Drugs in Pharmaceutical formulation, P D Sethi, 3rd Edition, CBS Publishers, New Delhi, 1997.
6. Pharmacuetical Analysis, Modern Methods - Part B, J W Munson, Volume 11, Marcel Dekker Series
7. Organic Spectroscopy, Donald L. Paviya, 5th Edition.

MODERN BIO-ANALYTICAL TECHNIQUES
(MPA 202T)

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.

THEORY **60 Hrs**

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. **12 Hrs**

2 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. **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 offlow cytometry. **12 Hrs**

5 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. **12 Hrs**

REFERENCES

1. Analysis of drugs in Biological fluids, Joseph Chamberlain, 2nd Edition. CRC Press, Newyork. 1995.
2. Principles of Instrumental Analysis, Doglas A Skoog, F. James Holler,
3. Pharmaceutical Analysi, Higuchi, Brochmman and Hassen, 2ndEdition, Wiley - Interscience Publications, 1961.
4. Pharmaceutical Analysis, Modern methods- Part B – J W Munson, Volume 11, Marcel Dekker Series
5. Practical HPLC method Development, Snyder, Kirkland, Glaich, 2nd Edition, John Wiley & Sons, New Jercy. USA.
6. Chromatographic Analysis of Pharmaceuticals,John A Adamovics, 2nd Edition, Marcel Dekker, Newyork, USA. 1997.
7. Chromatographic methods in clinical chemistry & Toxicology, Roger L Bertholf, Ruth E Winecker, John Wiley & Sons, New Jercy, USA. 2007.
8. Good Laboratory Practice Regulations, 2ndEdition, Sandy Weinberg Vol. 69, Marcel Dekker Series, 1995.
9. Good laboratory Practice Regulations - Allen F. Hirsch, Volume 38, Marcel Dekker Series, 1989.
10. ICH, USFDA & CDSCO Guidelines.

PHARMACEUTICAL VALIDATION

(MPA 203T)

SCOPE

The main purpose of the subject is to understand about validation and how it can be applied to industry and thus to improve the quality of the products. The subject covers the complete information about validation, types, methodology and applications.

OBJECTIVES

Upon completion of the subject student shall be able to-

- Explain the aspects of validation
- Carry out validation of manufacturing processes
- Apply the knowledge of validation to instruments and equipment's
- Validate the manufacturing facilities

THEORY **60 Hrs**

1 Introduction: Definition of Qualification and Validation, Advantage of Validation, Streamlining of Qualification & Validation process and Validation Master Plan.

Qualification: User Requirement Specification, Design Qualification, Factory Acceptance Test (FAT)/ Site Acceptance Test (SAT), Installation Qualification, Operational Qualification, Performance Qualification, Re-Qualification (Maintaining status – Calibration, Preventive Maintenance, Change management), Qualification of Manufacturing Equipment's, Qualification of Analytical Instruments and Laboratory equipment's. **12 Hrs**

2 Quality by design (QbD) and process analytical technology (PAT): Current approach and its limitations. Why QbD is required, Advantages, Elements of QbD, Terminology: QTPP. CMA, CQA, CPP, RLD, Design space, Design of Experiments, Risk Assessment and mitigation / minimization. Quality by Design, Formulations by Design, QbD for drug products, QbD for Drug Substances, QbD for Excipients, Analytical QbD.

FDA initiative on process analytical technology- PAT guidance, standards and regulatory requirements. **10 Hrs**

3 Validation of Utility systems: Pharmaceutical Water System & pure steam, HVAC system, Compressed air and nitrogen.

Cleaning Validation: Cleaning method development and validation of analytical method used in cleaning. Cleaning of Equipment, Cleaning of Facilities, Cleaning in place (CIP), Steam in Place (SIP). **10 Hrs**

4 Process Validation: Concept, Process and documentation of Process Validation. Prospective, Concurrent & Retrospective Validation, Re validation criteria, Process Validation of various formulations (Tablets, Capsules, Ointment/Creams, Liquid Orals), Aseptic filling: Media fill validation, USFDA guidelines on Process Validation- A life cycle approach. **10 Hrs**

5 Qualification of analytical instruments: Electronic balance, pH meter, UV-Visible spectrophotometer, FTIR, GC, HPLC, HPTLC.

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 GAMP 5. **10Hrs**

6 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 ramification 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. **08 Hrs**

REFERENCES

1. B. T. Loftus & R. A. Nash, "Pharmaceutical Process Validation", Drugs and Pharm Sci. Series, Vol. 129, 3rd Ed., Marcel Dekker Inc., N.Y.
2. The Theory & Practice of Industrial Pharmacy, 3rd edition, Leon Lachman, Herbert A. Lieberman, Joseph. L. Karig, Varghese Publishing House, Bombay.
3. Validation Master plan by Terveeks or Deeks, Davis Harwood International publishing.
4. Validation of Aseptic Pharmaceutical Processes, 2nd Edition, by Carleton &Agalloco, (Marcel Dekker).
5. Michael Levin, Pharmaceutical Process Scale–Up", Drugs and Pharm. Sci. Series, Vol. 157,2nd Ed., Marcel Dekker Inc., N.Y.
6. Validation Standard Operating Procedures: A Step by Step Guide for Achieving Compliance in the Pharmaceutical, Medical Device, and Biotech Industries, Syed ImtiazHaider
7. Pharmaceutical Equipment Validation: The Ultimate Qualification Handbook, Phillip A. Cloud, Interpharm Press.
8. Validation of Pharmaceutical Processes: Sterile Products, Frederick J. Carlton (Ed.) and James Agalloco (Ed.), Marcel Dekker, 2nd Ed.
9. Analytical Method validation and Instrument Performance Verification by Churg Chan, Heiman Lam, Y.C. Lee, Yue. Zhang, Wiley Inter Science.

HERBAL AND COSMETIC ANALYSIS
(MPA 204T)

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's used in cosmetic industries for this 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.

THEORY **60 Hrs**

1. 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. **12 Hrs**

2 Adulteration and Deterioration: Introduction, types of adulteration/substitution of herbal drugs, Causes and measure of adulteration, Sampling Procedures, Determination of Foreign Matter, and 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 and its protocol. **12 Hrs**

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.
   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. **12 Hrs**

4 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. **12 Hrs**

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. **12 Hrs**

REFERENCES

1. Pharmacognosy, Trease and Evans, 16th Ed, Saunders Ltd..
2. Pharmacognosy, Kokate, Purohit and Gokhale.
3. Quality Control Methods for Medicinal Plant, WHO, Geneva.
4. Pharmacognosy &Pharmacobiotechnology, Ashutosh Kar, Anshan Ltd.
5. Essential of Pharmacognosy, .S.H.Ansari.
6. Cosmetics - Formulation, Manufacturing and Quality Control, P.P. Sharma, 4th edition,Vandana Publications Pvt. Ltd., Delhi.
7. Indian Standard specification, for raw materials, BIS, New Delhi.
8. Indian Standard specification for 28 finished cosmetics BIS, New Delhi.
9. Harry's Cosmeticology, 8th edition.
10. Suppliers catalogue on specialized cosmetic excipient.
11. Poucher’s Perfumes, Cosmetics and Soaps, Butler, H. (Ed.)
12. Handbook of Cosmetic Science and Technology – 3rd edition, Andre O Barel.

PHARMACEUTICAL ANALYSIS PRACTICALS – II
(MPA 205P)

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. Identification of organic compounds using FT-IR, H^1 NMR, C^{13} NMR and Mass spectra.
6. Protocol preparation and performance of analytical/Bioanalytical method validation.
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 for the conduct of BA/BE studies according to guidelines.
11. Qualification of following Pharma equipment
    a) Powder Mixer (Dry) b) Tablet Compression Machine
12. Validation of an analytical method for a drug.
13. Process validation of any non-sterile or sterile dosage form
14. Qualification of at least two analytical instruments
15. Cleaning validation of one equipment
16. Case study on application of QbD
17. Quantitative analysis of rancidity in lipsticks and hair oil.
18. Determination of aryl amine content and developer in hair dye.
19. Determination of foam height and SLS content of Shampoo.
20. Determination of total fatty matter in creams (Soap, skin and hair creams)
21. Determination of calcium thioglycolate in depilatories.