



ANDHRA KESARI UNIVERSITY:: ONGOLE
(A State University, Recognised by UGC)
M.PHARMACY(PHARMACEUTICAL ANALYSIS)
R23 STRUCTURE AND SYLLABUS



(For the students admitted from the academic year 2025-2026 onwards)

COURSE STRUCTURE & SCHEME OF MARKS

I YEAR I Semester

Components of Study	Course Code	Course Title	L	T	P	Credits	Internal	External	Total
Professional Core-I	R23PA11	Modern Pharmaceutical Analytical Techniques	3	1	0	4	25	75	100
Professional Core-II	R23PA12	Pharmaceutical Food Analysis	3	1	0	4	25	75	100
Professional Elective-I	R23PA13A	1. Advanced Pharmaceutical Analysis	3	1	0	4	25	75	100
	R23PA13B	2. Drug Regulatory Affairs							
	R23PA13C	3. Phyto chemistry							
Professional Elective-II	R23PA14A	1. Pharmaceutical Validation	3	1	0	4	25	75	100
	R23PA14B	2. Cosmetics and Cosmeceuticals							
	R23PA14C	3. Stability of Drugs and Dosage forms							
	R23PA15	Research Methodology & IPR	2	0	0	2	50	-	50
Laboratory-I	R23PA16	Modern Pharmaceutical Analytical Techniques lab	0	0	6	4	25	75	100
Laboratory-II	R23PA17	Pharmaceutical food Analysis Lab	0	0	6	4	25	75	100
Audit-II	R23PA18	Audit course-I (NonCredit)	2	0	0	0			
		Seminar & Assignment	0	0	4	2	50 (25+25)	--	50
		TOTAL	16	4	16	28	250	450	700

I YEAR II Semester

Components of Study	Course Code	Course Title	L	T	P	Credits	Internal	External	Total
Professional Core-III	R23PA21	Advanced Instrumental Analysis-I	3	1	0	4	25	75	100
Professional Core-IV	R23PA22	Pharmaceutical Quality Control & Quality Assurance	3	1	0	4	25	75	100
Professional Elective-III	R23PA23A	1. Modern Bio-analytical Techniques	3	1	0	4	25	75	100
	R23PA23B	2. Herbal Cosmetics							
	R23PA23C	3. Pharmaco epidemiology & Pharmacoeconomics							
Professional Elective-IV	R23PA24A	1. Advanced Instrumental Analysis- II	3	1	0	4	25	75	100
	R23PA24B	2. Nutraceuticals							
	R23PA24C	3. Clinical Research and Pharmacovigilance							
Laboratory-III	R23PA25	Advanced Instrumental Analysis I Lab	0	0	6	4	25	75	100
Laboratory-IV	R23PA26	Pharmaceutical Quality Control & Quality Assurance Lab	0	0	6	4	25	75	100
	R23PA27	Mini project (with presentation) & Assignment	2	0	0	4	100 (50+50)	--	100
Audit-II	R23PA28	Audit Course-II (non-credit)	2	0	0	0			
		Total	16	4	16	28	250	450	700



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COURSE STRUCTURE & SCHEME OF MARKS

II YEAR I Semester

Components of Study	Course Code	CourseTitle	L	T	P	Credits	Internal	External	Total
Professional Elective-V	R23PA31A	1. Biostatistics	3	1	0	4	25	75	100
	R23PA31B	2. Scale up and Technology Transfer							
	R23PA31C	3. Production Area Design and Packaging Development							
Open Elective	R23PA32	1. Screening Methods in Pharmacology 2. Entrepreneurship Management 3. Cosmetic Science 4. Hazards and Safety Management 5. Audits and Regulatory Compliance	3	1	0	4	25	75	100
Dissertation	R23PA33	Comprehensive Viva-Voce	0	0	8	4	--	100	100
	R23PA34	Dissertation Work Review-II	0	0	24	10	50	50	100
		Total	6	2	32	22	100	300	400

Important Note: The students are required to start their project work/Dissertation work from IInd year Ist semester only (i.e from III rd semester onwards) as per resolution of BOS meeting held on 08.01.2026.

II YEAR II SEMESTER

Componentsof Study	Course Code	CourseTitle	L	T	P	Credits	Internal	External	Total
Dissertation	R23PA41	Dissertation Work Review- III	0	0	24	10	50	50	100
Dissertation	R23PA42	Dissertation Viva- Voce	0	0	20	10		100	100
		Total	0	0	44	20	50	150	200
						98	Total Marks		2000

ANDHRA KESARI UNIVERISTY, ONGOLE
M.Pharm I Year I Sem (Pharmaceutical Analysis)

MODERN PHARMACEUTICAL ANALYTICAL TECHNIQUES (Professional Core - I) (R23PA11)

Course Objective: The course is designed to impart the knowledge in the field of Pharmaceutical Analysis. The various modern analytical techniques like UV-Visible, IR, NMR, Mass, GC, HPLC, different chromatographic methods and other important topics are taught to enable the students to understand and apply the principles involved in the determination of different bulk drugs and their formulation. In addition to the theoretical aspects, the basic practical knowledge relevant to the analysis is also imparted.

Course Outcome: The appreciable knowledge will be gained by the students in the Modern Analytical Techniques and can apply the theories in the Analysis of various bulk drugs and their formulations. The students will also be in a position to apply their knowledge in developing the new methods for the determination and validate the procedures.

UNIT I

Introduction to chromatography and classification of chromatographic methods based on the mechanism of separation

- a. **Column Chromatography:** Adsorption and partition, theory, preparation, procedure and methods of detection
- b. **Thin Layer Chromatography:** Theory, preparation, procedures, detection of compounds
- c. **Paper Chromatography:** Theory, different techniques employed, filter papers used, qualitative and quantitative detection

UNIT II

- a. **Gas chromatography:** Introduction, fundamentals, instrumentation, columns: preparation and operation, detection, derivatization.
- b. **HPLC:** Basic parameters, Principles and instrumentation, solvents and columns used, Operational modes, detection and applications of HPLC
- c. **HPTLC:** Theory and principle, instrumentation, elution techniques and pharmaceutical applications

UNIT III

- a. **UV-Visible spectroscopy:** Introduction, electromagnetic spectrum, absorbance laws and limitations, instrumentation-design and working principle, chromophore concept, auxochromes, Wood-Fisher rules for calculating absorption maximum, applications of UV-Visible spectroscopy
- b. **IR spectroscopy:** Basic principles -Molecular vibrations, vibrational frequency, factors influencing vibrational frequencies, sampling techniques, instrumentation, interpretation of spectra, FT-IR, theory and applications

UNIT IV

Mass spectroscopy: Theory, ionization techniques: electron impact ionization, chemical ionization, field ionization, fast atom bombardment, plasma desorption, fragmentation process: types of fission, resolution, GC/MS, **interpretation of spectra** and applications for identification and structure determination.

UNIT V

NMR: Theory, instrumentation, chemical shift, shielding and deshielding effects, splitting of signals, spin-spin coupling, proton exchange reactions, coupling constant(J), nuclear overhauser effect (NOE), ¹³CNMR spectra and its applications, 2D-NMR, COSY and applications in pharmacy.

REFERENCES:

1. Instrumental Methods of Chemical Analysis by B.K Sharma
2. Organic spectroscopy by Y.R Sharma Principles of Instrumental Analysis - Douglas 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. A Text book of Pharmaceutical Analysis by Kerrenth A. Connors
5. Vogel's Text book of Quantitative Chemical Analysis by A.I. Vogel
6. Practical Pharmaceutical Chemistry by A.H. Beckett and J.B. Stenlake
7. Organic Chemistry by I. L. Finar
8. Organic spectroscopy by William Kemp
9. Quantitative Analysis of Drugs by D. C. Garrett
10. Quantitative Analysis of Drugs in Pharmaceutical Formulations by P. D. Sethi
11. Spectrophotometric identification of Organic Compounds by Silverstein
12. HPTLC by P.D. Seth
13. Indian Pharmacopoeia 2007
14. High Performance thin layer chromatography for the analysis of medicinal plants by Eike Reich, Anne Schibli
15. Introduction to instrumental analysis by Robert. D. Braun

ANDHRA KESARI UNIVERISTY, ONGOLE
M.Pharm I Year I Sem (Pharmaceutical Analysis)

PHARMACEUTICAL FOOD ANALYSIS (Professional Core – II) (R23PA12)

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

Course Outcome: At completion of this course student shall be able to understand various analytical techniques in the determination of

- Food constituents
- Food additives
- Finished food products
- Pesticides in food
- Pharmaceuticals (API & Dosage forms)
- And also student shall have the knowledge on food regulations and legislations

UNIT I

- a. **Carbohydrates:** Classification and properties of food carbohydrates, General methods of analysis of food carbohydrates
- b. **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

UNIT II

Probiotics: Definition, history, importance, mode of action, identification advantages and disadvantages of probiotics. Applications of Probiotics

UNIT III

Lipids: Classification, general methods of analysis, refining of fats and oils; hydrogenation of vegetable oils, Determination of adulteration in fats and oils.

UNIT IV

Vitamins: Classification of vitamins, methods of analysis of vitamins, Principles of microbial assay of vitamins of B-series

UNIT V

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

TEXT BOOKS:

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. Dr. William Horwitz, Official methods of analysis of AOAC International
6. 18th edition, 2005. Theory and Practice of Industrial Pharmacy by Lieberman and Lachman

REFERENCES:

1. Remington's Pharmaceutical Sciences by Alfonso and Gennaro
2. Food Chemistry and Nutrition: A Comprehensive Treatise, Sumathi S, Pharmamed Press.
3. David Pearson, The Chemical Analysis of Foods, 7th edn, Churchill Livingstone, Edinburgh.
4. Nielsen S. Introduction to chemical analysis of foods. Jones & Bartlett Publishers, Boston, 1974
5. Indian Pharmacopoeia 2012

ANDHRA KESARI UNIVERISTY, ONGOLE
M.Pharm I Year I Sem (Pharmaceutical Analysis)

ADVANCED PHARMACEUTICAL ANALYSIS (Professional Elective - I) (R23PA13A)

Course Objective: The principles and procedures for the determination of various pharmaceutical bulk drugs and their formulations belonging to different categories are discussed in detail. The applications of the important reagents like MBTH, FC, PDAB etc. in the determination of the pharmaceuticals are also discussed.

Course Outcome: The quantitative determination of various organic compounds is clearly understood. The spectral analysis, dissolution parameters and microbial assays are also learned.

UNIT I

Principles and procedures involved in the determination of the official compounds in IP with the following analytical techniques

- | | |
|------------------------|--------------------------|
| A. Non-aqueous | C. Complexometric |
| B. Oxidation-reduction | D. Diazotization methods |
| E. Neutralization | F. Acid – Base |

UNIT II

A detailed study of the principles and procedures involved in the quantitative determination of the following organic functional groups

- | | |
|----------------|-------------------------|
| A. Amines | C. Carbonyl compounds |
| B. Esters | D. Hydroxy and carboxyl |
| E. Amino Acids | |

UNIT III

- a. **Reference Standards:** Types, preparation methods and uses.
- b. Principles and procedures involved in using the following reagents in the determination of pharmaceutical dosage forms official in IP
 - a. MBTH (3-methyl-2-benzothiazolone hydrazone)
 - b. F.C. Reagent (Folin-Ciocalteu)
 - c. PDAB (*para*-Dimethyl Amino Benzaldehyde)
 - d. 2, 3, 5 - *tri*Phenyltetrazolium salt
 - e. 2,6 *di*-ChloroquinoneChlorimide
 - f. *N* - (1-naphthyl) ethylenediaminedihydrochloride (B.M. Reagent)
 - g. Carr – Price Reagent
 - h. 2,4 - DNP

UNIT IV

- a. **Analysis of Excipients:** Tests related to excipients such as bulk density, tapped density, particle size distribution, pH, moisture content, viscosity (dynamic), loss on drying, ash content, conductivity.
- b. **Excipients of interest:** Disintegrating agents, binders, emulsifiers, viscosity modifiers and preservatives including preservative challenge test.

UNIT V

- a. **Dissolution Tests:** Types of Dissolution apparatus, dissolution test requirements for immediate release, delayed release, extended-release dosage forms, coated, uncoated, enteric coated, gelatin capsules etc.
- b. **Microbiological assays and Biological tests:** Antimicrobial effectiveness testing, microbial limit tests, sterility test. Antibiotics-microbial assays, bacterial endotoxins test.

TEXT BOOKS:

1. Pharmaceutical Chemistry by Becket and Stanlake
2. Pharmaceutical Analysis by Higuchi, Bechmman and Hassan
3. Instrumental Methods of Chemical Analysis By B.K. Sharma
4. A Text Book of Pharmaceutical Analysis by Kennenth A. Conners
5. Organic spectroscopy by Y.R Sharma Principles of Instrumental Analysis - Doglas A Skoog, F. James Holler, Timothy A. Nieman, 5th edition, Eastern press, Bangalore, 1998.
6. Instrumental methods of analysis – Willards, 7th edition, CBS publishers.
7. Fundamentals of Analytical Chemistry, DK Sarkar, Pharmamed Press

REFERENCES:

1. Remington's Pharmaceutical Sciences by Alfonso and Gennaro
2. Quantitative Analysis of Drugs in Pharmaceutical Formulations by P.D. Sethi
3. Indian Pharmacopoeia 2010
4. Journals (Indian Drugs, IJPS etc.)

ANDHRA KESARI UNIVERISTY, ONGOLE
M.Pharm I Year I Sem (Pharmaceutical Analysis)
DRUG REGULATORY AFFAIRS (Professional Elective - I) (R23PA13B)

Course Objective: The topics which are present in the Drug regulatory affairs are very much useful which increases the knowledge regarding the regulatory aspects in the pharmaceutical industries.

Course Outcome:

- Students will come to know the different competent regulatory authorities globally.
- Students be aware of technical aspects pertaining to the marketing authorization application (MAA)
- The regulatory guidelines and directions framed by the regulatory authorities will be helpful to place the drug products in market for marketing approvals.

UNIT I

Drug Regulatory Aspects (India)

1. Indian drug regulatory authorities, Central and State regulatory bodies (FDA)
2. Drugs and Cosmetics Act and Rules with latest Amendments (Selective)
3. Special emphasis – Schedule M and Y
4. New drugs – Importation, Registration, development, Clinical Trials, BE NOC & BE studies
5. Various Licences – Test Lic., Import lic., for testing of drugs and API's, Manufacturing Contract and Loan licence manufacturing.

UNIT II

Good Manufacturing Practices (GMP)

1. Indian GMP certification, WHO GMP certification.
2. ICH guidelines for stability testing and other relevant ones (Q1-Q10)
3. Export permissions and manufacturing for semi-regulated countries
4. Understanding of the plant layouts with special emphasis on the environment & safety (HVAC, Water Systems, Stores Management, Effluent etc.)
5. Quality Assurance and Quality Control – Basic understanding for in-built quality.

UNIT III

A detailed study of regulatory aspects that affect drug product design, manufacture and distribution in a developed country such as USA and in a developing country such as Brazil, Hatch Waxmann Act; Bolar Provisions and other FDA Regulations. Regulatory aspects of pharmaceutical and bulk drug manufacture, regulatory drug analysis.

UNIT IV

Documentation related to manufacturing, cleaning methods, retention samples and records, quality control, batch release documents, distribution records, complaints and recalls.

Quality, safety and legislation for cosmetic products and herbal products.

UNIT V

Governing Regulatory Bodies across the globe.

Country Authority Submission

- a. U.S Food & Drug Administration USDMF
- b. Canada Therapeutic Product Directorate DMF
- c. Europe
 - 1) European Medicines Agency (EMA/ National Authorities) EDMF
 - 2) European Directorate for Quality of Medicines CEP/COS & Health Care Products.
 - 3) MHRA – Medicines and Health Care Products Regulatory Agency

- d. Product Filing
- e. Responding Regulatory Deficiencies
- f. Final Approval Procedure

Preparation, review and submission of Drug Master Files to Regulatory Authorities as per their specific requirements.

TEXT AND REFERENCE BOOKS:

1. Original laws published by Govt. of India.
2. Text Book of Forensic Pharmacy by Mithal B. M.; Vallabh Prakashan, New Delhi.
3. Laws of Drugs in India by Hussain.
4. Text Book of Forensic Pharmacy by Jain N. K.; Vallabh Prakashan, New Delhi.
5. Pharmaceutical Regulatory Affairs - Selected Topics, CVS Subramanyam and J Thimmasetty, Vallabh Prakashan Delhi - 2013

ANDHRA KESARI UNIVERISTY, ONGOLE
M.Pharm I Year I Sem (Pharmaceutical Analysis)
PHYTOCHEMISTRY (Professional Elective - I) (R23PA13C)

Course Objective: Helps the students to get exposed to natural product drug discovery and to perform quantitative and qualitative evaluation of herbal extracts. To understand the chemistry of important phytoconstituents of different categories.

Course Outcome: On the basis of chemistry data of phytoconstituents students will acquire knowledge on various types of phytoconstituents present in the plants.

UNIT I

Biosynthetic pathways and Radio tracing techniques: containing drugs:

- a) Methods of Biogenetic Investigations, detailed study of isotropic tracer techniques.
- b) Study of Biosynthetic pathways of of following phyto-pharmaceuticals: Atropine, Morphine, Cardiac glycosides and Flavonoids.

UNIT II

Drug discovery and development: Approaches to discovery and development of natural products as potential new drugs. Sourcing and archiving Natural products for discovery, evaluating natural products for therapeutic properties, Identifying the biologically active Natural products, the lead structure selection process and Optimization with suitable examples from the following source: artemesin, andrographolides.

UNIT III

- a) Extraction/Isolation methods for specific Phytochemical groups, Choice of solvents and Interfering compounds for general Isolation and purification of desired phytoconstituents.
- b) Recent sophisticated extraction techniques like: Super critical fluid extraction and Ultra-sonic extraction. Separation of phytoconstituents by Vacuum and Flash column chromatography.

UNIT IV

Sources, Chemical structure, Identification tests, mechanism of action SAR, uses of the following phyto-pharmaceuticals:

- a) Atropine, caffeine, Morphine and brief account on its derivatives and analogues
- b) Camptothecin, Digoxin
- c) Taxol, Podophyllotoxin

UNIT V

- a. Natural colorants: Biological Source, colouring principles, chemical nature and usage of the following Annatto, Cochineal, Caramel, Henna, Indigo, Madder, Saffron, Turmeric
- b. Flavours and Perfumes: Sandal wood oil, Orange oil, Lemon oil, Palmarosa oil, Geranium oil.

REFERENCES:

1. Phytochemical methods of chemical analysis by Harbone
2. Modern methods of plant analysis- peach & M. V. Tracey Vol. 1 to VII
3. Pharmacognosy & Phytochemistry of medical plants by Jean Brunton
4. Thin layer chromatography by Stahl
5. Chemistry of natural products by Atur Rahman
6. Comprehensive Medicinal Chemistry, Vol 1-6, Elsevier Publication
7. Medicinal Chemistry Drug Discovery by Donald J, Abrahm,
8. Plant drug analysis by Wagner
9. Clarke's isolation & identification of drugs by AC Mottal

10. Chromatography of Alkaloids by Varpoorte Swendson
11. Jenkins Quantitative pharmaceutical chemistry by AN Kenwell
12. Standardization of botanicals by V. Rajpal Vol 1 & 2
13. Pharmacognosy and Phytochemistry: A Comprehensive Approach, S L Deore, Pharmamed Press
14. Medicinal chemistry and drug discovery by Burger's
15. Foye's Principles of medicinal chemistry.
16. Pharmacognosy and phytochemistry by Biren seth
17. Herbal Perfumes and cosmetics by Panda
18. Herbal Drug Technology by SS Agarwal
19. Pharmacognosy and Phytochemistry by VD Rangari.
20. Textbook of Pharmacognosy by G. E. Trease, W. C. Evans, ELBS

ANDHRA KESARI UNIVERISTY, ONGOLE
M.Pharm I Year I Sem (Pharmaceutical Analysis)
PHARMACEUTICAL VALIDATION (Professional Elective - II) (R23PA14A)

Course Objective: 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 application.

Course Outcome: Upon completion of the subject student shall be able to

- Explain the aspect of validation
- Carryout validation of manufacturing processes
- Apply the knowledge of validation to instruments and equipments

UNIT I

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, Qualification of Analytical Instruments and Laboratory equipments.

UNIT II

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

Qualification of Glassware: Volumetric flask, pipette, Measuring cylinder, beakers and burette.

UNIT III

Qualification of laboratory equipments: Hardness tester, Friability test apparatus, tap density tester, Disintegration tester, Dissolution test apparatus.

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

UNIT IV

Cleaning Validation: Cleaning Validation - Cleaning Method development, Validation and validation of analytical method used in cleaning. Cleaning of Equipment. Cleaning of Facilities. Cleaning in place (CIP).

UNIT V

Analytical method validation: General principles, Validation of analytical method as per ICH guidelines and USP.

- Validate the manufacturing facilities

REFERENCES:

1. 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. Pharmaceutical Facilities: Design, Layouts and Validation, Potdar, Pharmamed Press

6. Michael Levin, Pharmaceutical Process Scale-Up, Drugs and Pharm. Sci. Series, Vol. 157, 2nd Ed., Marcel Dekker Inc., N.Y.
7. Validation Standard Operating Procedures: A Step by Step Guide for Achieving Compliance in the Pharmaceutical, Medical Device, and Biotech Industries, Syed Imtiaz Haider
8. Pharmaceutical Equipment Validation: The Ultimate Qualification Handbook, Phillip A. Cloud, Interpharm Press
9. Validation of Pharmaceutical Processes: Sterile Products, Frederick J. Carlton (Ed.) and James Agalloco (Ed.), Marcel Dekker, 2nd Ed.
10. Analytical Method validation and Instrument Performance Verification by Churg Chan, Heiman Lam

ANDHRA KESARI UNIVERISTY, ONGOLE
M.Pharm I Year I Sem (Pharmaceutical Analysis)

COSMETICS AND COSMECEUTICALS (Professional Elective - II) (R23PA14B)

Course Objectives: Upon completion of the course, the students shall be able to understand

- Key ingredients used in cosmetics and cosmeceuticals.
- Key building blocks for various formulations.
- Current technologies in the market
- Various key ingredients and basic science to develop cosmetics and cosmeceuticals
- Scientific knowledge to develop cosmetics and cosmeceuticals with desired Safety, stability, and efficacy.

Course Outcomes: Upon completion of the subject student shall able to know Regulatory biological aspects of cosmetics, excipients used for various formulations, designing of cosmeceuticals and herbal products

UNIT I

Cosmetics – Regulatory: Definition of cosmetic products as per Indian regulation. Indian regulatory requirements for labeling of cosmetics Regulatory provisions relating to import of cosmetics. Misbranded and spurious cosmetics. Regulatory provisions relating to manufacture of cosmetics – Conditions for obtaining license, prohibition of manufacture and sale of certain cosmetics, loan license, offences and penalties.

UNIT II

Cosmetics - Biological aspects: Structure of skin relating to problems like dry skin, acne, pigmentation, prickly heat, wrinkles and body odor. Structure of hair and hair growth cycle. Common problems associated with oral cavity. Cleansing and care needs for face, eye lids, lips, hands, feet, nail, scalp, neck, body and under-arm.

UNIT III

Formulation Building blocks: Building blocks for different product formulations of cosmetics/cosmeceuticals. Surfactants – Classification and application. Emollients, rheological additives: classification and application. Antimicrobial used as preservatives, their merits and demerits. Factors affecting microbial preservative efficacy. Building blocks for formulation of a moisturizing cream, vanishing cream, cold cream, shampoo and toothpaste. Soaps and syndet bars.
Perfumes; Classification of perfumes. Perfume ingredients listed as allergens in EU regulation.
Controversial ingredients: Parabens, formaldehyde liberators, dioxane.

UNIT IV

Design of cosmeceutical products: Sun protection, sunscreens classification and regulatory aspects. Addressing dry skin, acne, sun-protection, pigmentation, prickly heat, wrinkles, body odor., dandruff, dental cavities, bleeding gums, mouth odor and sensitive teeth through cosmeceutical formulations.

UNIT V

Herbal Cosmetics: Herbal ingredients used in Hair care, skin care and oral care. Review of guidelines for herbal cosmetics by private bodies like cosmos with respect to preservatives, emollients, foaming agents, emulsifiers and rheology modifiers. Challenges in formulating herbal cosmetics.

REFERENCES

1. Harry's Cosmeticology. 8th edition
2. Poucher'sperfumecosmeticsandSoaps, 10th edition.
3. Cosmetics - Formulation, Manufacture and quality control, P. P. Sharma, 4th edition
4. Handbook of cosmetic science and Technology A.O.Barel, M.Paye and H.I. Maibach. 3 rd edition
5. Cosmeceuticals by Y Madhusudan Rao, Pharmamed Press
6. Cosmetic and Toiletries recent suppliers' catalogue.
7. CTFA directory.

ANDHRA KESARI UNIVERISTY, ONGOLE
M.Pharm I Year I Sem (Pharmaceutical Analysis)
STABILITY OF DRUGS AND DOSAGE FORMS (Professional Elective –II) (R23PA14C)

Course Objective: These topics are designed impart a specialized knowledge to preserve the properties of drugs and dosage forms during manufacture storage and shelf life. The understanding of properties and evaluation of stability during storage, by solution and solid state against several factors of degradation.

Course Outcome: The students should describe the evaluation of stability of solutions, solids and formulations against adverse conditions. The students should be able to suggest the measures to retain stability and storage conditions for retaining the efficacy of the products.

UNIT I

Drug decomposition mechanisms:

1. Hydrolysis and acyltransfers: Nature of reaction, structure and utility, stabilization of pharmaceutical examples.
2. Oxidation: Nature of oxidation, kinetics of oxidation, oxidation pathways of pharmaceutical, Interest Inhibition of oxidation
3. Photolysis: Energetics of photolysis, kinetics photolysis, photolytic reactions of pharmaceutical interest, prevention of photolytic reactions.

UNIT II

Solid state chemical decomposition: Kinetic of solids state decomposition, pharmaceutical examples of solid-state decomposition, Pure drugs, drug excipient and drug-drug interaction in solid state, methods of stabilization.

Physical stability testing of dosage forms:

1. Solids – tablets, capsules, powder and granules
2. Disperse systems
3. Microbial decomposition
4. Over-view, physical stability of novel drug carriers, liposomes, niosomes, nano-particles.

UNIT III

Identification and quantitative determination of preservatives, Antioxidants, colouring materials, emulsifiers and stabilizers in pharmaceutical formulation.

Analysis of drugs from biological samples including, selection of biological sample, extraction of drugs by various methods as LLE, SPE and Membrane filtration. Factors affecting extraction of drugs.

UNIT IV

General method of analysis to determine the quality of raw materials used in cosmetic industry. Indian Standard Specifications (ISI) laid down for sampling and testing of various cosmetics in finished form by the Bureau of Indian Standards.

UNIT V

Methods of analysis to determine the quality of cosmetics in the finished forms such as Hair care products, Skin care products, Baby care products, Dental products, Personal hygiene products, Colour cosmetics, Ethnic products, Colour makeup preparation, Lipsticks, Hair setting lotions and Eyeshadows. Toxicity testing in cosmetics and Safety and Legislation of Cosmetic products.

Stability studies: Concept of stability studies.

- a) cGMP & ICH guidelines for Accelerated stability Testing.
- b) Interaction of containers & closure Compatibility Testing.

REFERENCES:

1. Comprehensive Pharmacy Review 5th Edition by Leon Shargel, Alan H. Mutnick, Paul F. Souney, Larry N. Sawson – 2004.
2. A. H. Beckett and J. B. Stenlake Practical Pharmaceutical Chemistry, Part I and Part II, 4th Edition. 3. G. H. Jeffery, J. Basset, J. Mendham, R. C. Denny (Rev. by) Vogels Text Book of Quantitative Chemical Analysis, 5th Edition 1989, ELBS.
3. The Controller of Publications; New Delhi, Govt. of India, Indian Pharmacopoeia, Vol. I and Vol. II - 2010.
4. J. B. Wilkinson and R. J. Moore, Herry's Cosmeticology; Longman Scientific and Technical Publishers, Singapore.
5. P.D. Sethi; Quantitative Analysis of Drugs in Pharmaceutical Formulations, 3rd Edition - 1997,
6. Classification of cosmetics raw materials and adjuncts IS 3958 of Indian Standards Institution (BIS).
7. Cosmetic and toilet goods – methods of sampling IS 3958 of Indian Standards Institution (BIS).
8. Methods of sampling and test for various cosmetics as laid down by Bureau of Indian Standards.
9. Drug stability: Principles and practices by Jens T. Carstensen
10. Stability Testing of Drug Products by W. Grimm. 12. Stability of Drugs and Dosage Forms by Yoshioka and Stella.

ANDHRA KESARI UNIVERISTY, ONGOLE
M.Pharm I Year I Sem (Pharmaceutical Analysis)
RESEARCH METHODOLOGY AND IPR (R23PA15)

Course Objectives:

- To understand the research problem
- To know the literature studies, plagiarism and ethics
- To get the knowledge about technical writing
- To analyze the nature of intellectual property rights and new developments
- To know the patent rights

Course Outcomes: At the end of this course, students will be able to

- Understand research problem formulation.
- Analyze research related information
- Follow research ethics
- Understand that today's world is controlled by Computer, Information Technology, but tomorrow world will be ruled by ideas, concept, and creativity.
- Understanding that when IPR would take such important place in growth of individuals & nation, it is needless to emphasis the need of information about Intellectual Property Right to be promoted among students in general & engineering in particular.
- Understand that IPR protection provides an incentive to inventors for further research work and investment in R & D, which leads to creation of new and better products, and in turn brings about, economic growth and social benefits.

UNIT I

Meaning of research problem, Sources of research problem, Criteria Characteristics of a good research problem, Errors in selecting a research problem, Scope and objectives of research problem. Approaches of investigation of solutions for research problem, data collection, analysis, interpretation, Necessary instrumentations

UNIT II

Effective literature studies approaches, analysis, Plagiarism, Research ethics

UNIT III

Effective technical writing, how to write report, Paper Developing a Research Proposal, Format of research proposal, a presentation and assessment by a review committee

UNIT IV

Nature of Intellectual Property: Patents, Designs, Trade and Copyright. Process of Patenting and Development: technological research, innovation, patenting, development. International Scenario: International cooperation on Intellectual Property. Procedure for grants of patents, Patenting under PCT.

UNIT V

Patent Rights: Scope of Patent Rights. Licensing and transfer of technology. Patent information and databases. Geographical Indications. New Developments in IPR: Administration of Patent System. New developments in IPR; IPR of Biological Systems, Computer Software etc. Traditional knowledge Case Studies, IPR and IITs.

TEXT BOOKS:

1. Stuart Melville and Wayne Goddard, "Research methodology: an introduction for science & engineering students"

2. Wayne Goddard and Stuart Melville, "Research Methodology: An Introduction".
3. Pharmaceutical Research Methodology and Biostatistics, B Subba Rao, Pharmamed Press.
4. Intellectual Property Rights in Pharmaceutical Industry, B Subba Rao, Pharmamed Press.

REFERENCES:

1. Ranjit Kumar, 2nd Edition, "Research Methodology: A Step by Step Guide for beginners"
2. Halbert, "Resisting Intellectual Property", Taylor & Francis Ltd ,2007.
3. Mayall, "Industrial Design", McGraw Hill, 1992.
4. Niebel, "Product Design", McGraw Hill, 1974.
5. Asimov, "Introduction to Design", Prentice Hall, 1962.
6. Robert P. Merges, Peter S. Menell, Mark A. Lemley, "Intellectual Property in New
7. Technological Age", 2016.
8. T. Ramappa, "Intellectual Property Rights Under WTO", S. Chand, 2008

ANDHRA KESARI UNIVERISTY, ONGOLE
M.Pharm I Year I Sem (Pharmaceutical Analysis)
MODERN PHARMACEUTICAL ANALYTICAL TECHNIQUES LAB (Laboratory – I)(R23PA16)

LIST OF EXPERIMENTS:

1. Colorimetry / UV / Visible, Spectroscopy, scanning of few compounds for UV-absorption, calculation of Assay / content uniformity / % of drug release (2-3 experiments.)
2. Simultaneous estimation of multi component containing formulations by UV spectrophotometry
3. Experiment base on HPLC (Isocratic and gradient) Techniques – (2 experiments)
4. Incompatibility studies, identification and functional groups – Determination by FTIR (2 experiments)
5. Separation and calculation of Rf values by using paper chromatography, TLC, HPTLC Technique (2-3 experiments)
6. Calibration of glasswares
7. Calibration of pH meter
8. Calibration of UV-Visible spectrophotometer
9. Calibration of FTIR spectrophotometer
10. Calibration of HPLC instrument

ANDHRA KESARI UNIVERISTY, ONGOLE
M.Pharm I Year I Sem (Pharmaceutical Analysis)
PHARMACEUTICAL FOOD ANALYSIS LAB (Laboratory –II) (R23PA17)

LIST OF EXPERIMENTS:

1. Determination of total reducing sugar
2. Determination of proteins
3. Determination of saponification value, Iodine value, Peroxide value, Acid value in food products
4. Determination of fat content and rancidity in food products
5. Analysis of natural and synthetic colors & food additives in food
6. Determination of preservatives in food
7. Determination of pesticide residue in food products
8. Assay of any two Analgesic & Antipyretic drugs (API & dosage forms) official in IP
9. Assay of any two Antihistamines (API & dosage forms) official in IP
10. Assay of any two Diuretics (API & dosage forms) official in IP
11. Microbiological assay of any two Antibiotics official in IP

ANDHRA KESARI UNIVERISTY, ONGOLE
M.Pharm I Year II Sem (Pharmaceutical Analysis)
ADVANCED INSTRUMENTAL ANALYSIS – I (Professional Core - III) (R23PA21)

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.

Course Outcome: By the completion of topics the students will come out with the thorough knowledge of various spectral aspects of X-Ray, IR, SEM, ORD etc which help them in further projects works and also industrial opportunities.

UNIT I

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

UNIT II

- a. **Biochromatography:** Size exclusion chromatography, ion exchange chromatography, ion pair chromatography, affinity chromatography general principles, stationary phases and mobile phases.
- b. **Super critical fluid chromatography:** Principles, instrumentation, pharmaceutical applications.

UNIT III

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,

UNIT IV

- a. **DSC:** Principle, thermal transitions, instrumentation (Heat flux and power- compensation designs), Modulated DSC, Hyper DSC, experimental parameters (sample preparation, experimental conditions, calibration, heating and cooling rates, resolution, Sources of errors) and their influence, advantages and disadvantages, pharmaceutical applications.
- b. **DTA:** Principle, instrumentation, advantage and disadvantage, pharmaceutical application, derivative differential thermal analysis (DDTA).
- c. **TGA:** Principle, instrumentation, factors affecting results, advantages and disadvantages, pharmaceutical application.

UNIT V

Scanning electron microscope (SEM): Principles, Instrumentation and applications.
Optical Rotatory Dispersion (ORD), Circular Dichroism, Cotton effect, Octane rule and applications.

REFERENCES:

1. Instrumental Methods of Chemical Analysis by B.K Sharma
2. Organic spectroscopy by Y.R Sharma
3. A Text book of Pharmaceutical Analysis by Kerrenth A. Connors
4. Vogel's Text book of Quantitative Chemical Analysis by A.I. Vogel
5. Practical Pharmaceutical Chemistry by A.H. Beckett and J.B. Stenlake
6. Organic Chemistry by I. L. Finar
7. Organic spectroscopy by William Kemp
8. Quantitative Analysis of Drugs by D. C. Garrett
9. Quantitative Analysis of Drugs in Pharmaceutical Formulations by P. D. Sethi
10. Spectrophotometric identification of Organic Compounds by Silverstein
11. HPTLC by P.D. Seth

ANDHRA KESARI UNIVERISTY, ONGOLE
M.Pharm I Year II Sem (Pharmaceutical Analysis)
PHARMACEUTICAL QUALITY CONTROL AND QUALITY ASSURANCE
(Professional Core – IV) (R23PA22)

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.

Course Outcome: The study of this subject builds the confidence in the minds on the students to develop and formulate high quality pharmaceutical products.

UNIT I

- a. **Impurity and stability studies:** Definition, classification of impurities in drug Substance or Active Pharmaceutical Ingredients and quantification of impurities as per ICH guidelines.
- b. **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
- c. **Impurities in residual solvents:** General principles, classification of residual solvents, Analytical procedures, limits of residual solvents, reporting levels of residual solvents.

UNIT II

- a. Concepts of Quality Assurance, Total Quality Management, Philosophy of GMP and cGMP
- b. Guidelines for Quality Assurance of Human Blood Products and large volume parenterals.

UNIT III

- a. Organization and personnel, responsibilities, training hygiene
- b. **Premises:** Location, design, plan Layout, construction, maintenance and sanitations, environmental control, sterile areas, control of contamination.
- c. **Equipments:** Selection, purchase specifications, maintenance, clean in place, sterilize in place – Raw – materials: Purchase specifications, maintenance of stores, selection of vendors, controls and raw materials.

UNIT IV

- a. Packaging and labeling controls, line clearance and other packaging materials.
- b. Quality Control Laboratory: Responsibilities, good laboratory practices, routine controls, instruments, protocols, non-clinical testing, controls on animal house, data generation and storage.

UNIT V

Manufacture and controls on dosage forms

- a. Manufacturing documents, Master Formula, Batch Formula, Records, Standard Operating Procedures,
- b. In process quality control on various dosage forms sterile and biological products, standard operating procedures for various operations like cleaning, filling, drying, compression, coating, disinfection, sterilization, membrane filtration etc.

TEXT BOOKS:

1. The International Pharmacopoeia Vol 1,2,3,4, 3rd edition General Methods of Analysis Quality Specifications for Pharmaceutical Substances, Excipients, Dosage Forms.
2. Quality Assurance of Pharmaceuticals. A Compendium of Guidelines and Related Material Vol. 1 and Vol. 2, WHO 2007)
3. GMP by Mehra

4. Pharmaceutical Process Validation by Berry and Nash
5. How to Practice GMP's – P.P. Sharma

REFERENCES:

1. Basic Tests for Pharmaceutical Substances - WHO (1991)
2. The Drugs and Cosmetic Act 1940 by Vijay Malik
3. Q.A. Manual by D.H. Shah
4. Pharmaceutical Quality Assurance and Management, K. P. Bhusari, Pharmamed Press
5. SOP Guidelines by D.H. Shah
6. Quality Assurance Guide by OPPI
7. Good Manufacturing-Practices for Pharmaceuticals, by Graham Bunn and Joseph 6th Ed. D. Nally (Dec 26, 2006)
8. Analytical Profiles of drug substances and Excipients – Harry G Brittan, Volume 21 – 30, Elsevier, 2005.

ANDHRA KESARI UNIVERISTY, ONGOLE**M.Pharm I Year II Sem (Pharmaceutical Analysis)****MODERN BIO-ANALYTICAL TECHNIQUES (Professional Elective - IV) (R23PA23A)**

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

Course Outcomes: 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

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.

UNIT II

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 III**Bioanalysis and bioanalytical method validation:**

- a. Types of body fluids, requirement of analysis, matrix effects, non-biological analytical samples.
- b. Bioanalytical method validation: USFDA and EMEA guidelines. Acceptance criteria in comparison to non-biological samples.

UNIT IV

Pre-Formulation: A consideration of following characteristics of medicinal agents in their dosage form:

Physical characteristics-Particle size, polymorphism, crystal form, solubility, Interfacial tension, Salt formation, wetting of solids, flow characteristics, compressibility and Partition coefficient.

Chemical Characteristics-Degradation: Hydrolytic, oxidative, reductive and photolytic, Drug – Excipient compatibility studies.

UNIT V

- a. **Automation and computer-aided analysis, LIMS:** The concept of auto samplers and high throughput analysis, computer-controlled instrumentation and networked laboratory. Peculiarities of laboratory information management systems (LIMS).
- b. **Drug Product Performance, In Vivo:** Purpose of Bioavailability Studies, Bioavailability and Bioequivalence Studies.

REFERENCES:

1. Analysis of drugs in Biological fluids - Joseph Chamberlain, 2nd Edition.CRC Press, New York. 1995.
2. Principles of Instrumental Analysis - Doglas A Skoog, F. James Holler, Timothy A. Nieman, 5th edition, Eastern press, Bangalore, 1998.
3. Pharmaceutical Analysis - Higuchi, Brochmman and Hassen, 2nd Edition, 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 Jerco. USA.
6. Chromatographic Analysis of Pharmaceuticals – John A Adamovics, 2nd Edition, Marcel Dekker, New York, USA. 1997.
7. Chromatographic methods in clinical chemistry & Toxicology – Roger L Bertholf, Ruth E Winecker, John Wiley & Sons, New Jersey, USA. 2007.
8. Good Laboratory Practice Regulations, 2nd Edition, 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
11. Palmer

ANDHRA KESARI UNIVERISTY, ONGOLE
M.Pharm I Year II Sem (Pharmaceutical Analysis)
HERBAL COSMETICS (Professional Elective - III) (R23PA23B)

Course Objective: The topics helps the students to get exposed to processes involved in the manufacturing of herbal cosmetics including the skin and hair care herbal products preparation and their evaluation.

Course Outcome: Students will learn about the raw materials used in herbal cosmetics and get exposed tovarious preparations of herbal cosmetics.

UNIT I

Introduction: Herbal/ natural cosmetics, Classification & Economic aspects.

Regulatory Provisions relation to manufacture of cosmetics: -

License, GMP, offences & Penalties, Import & Export of Herbal/natural cosmetics, Industries involved in the production of Herbal/natural cosmetics.

UNIT II

- a) Commonly used herbal cosmetics raw materials –water, preservatives, surfactants, oils /waxes, colors, and some functional herbs
- b) Processes used in the manufacture of cosmetics-Emulsification, Mixing, compaction, Molding, Packing.
- c) General principles of quality control of herbal cosmetics

UNIT III

Skin care Products: Physiology and chemistry of skin, Method of preparation, pharmaceutical and Pharmacological evaluation procedures for various formulations like Creams, Lotions, Lipsticks, Face packs. Elaborative study of five formulations under each category with regard to their composition and claims for various herbs used in them.

UNIT IV

Hair care Products: Hair structure and its chemistry

Method of preparation, pharmaceutical and Pharmacological evaluation procedures for various formulations like Hair dyes, Creams, Oils and Shampoos. Elaborative study of five formulations under each category with regard to their composition and claims for various herbs used in them.

UNIT V

Herbs in cosmetics:

A brief account of following herbals or herb extracts or herbal products of cosmetic importance such as Acacia concinna pods, Aloe Vera, Almond oil, Neem, Citrus aurantium peels, Henna, Turmeric, Liquorices, Olive oil, tea tree oil and wheat germ oil with special emphasis on their source, active principles and cosmetic properties.

REFERENCES:

1. Cosmetics- Formulation, Manufacturing and Quality control –P. P. Sharma
2. Herbal Cosmetics Hand Book- H. Panda
3. Herbal Cosmetics by P.K Chattopadhyay
4. The Complete Technology Book on Herbal Perfumes and Cosmetics by H. Panda

ANDHRA KESARI UNIVERISTY, ONGOLE
M.Pharm. I Year II Sem (Pharmaceutical Analysis)
PHARMACOEPIDEMIOLOGY & PHARMACOECONOMICS (Professional Elective - III) (R23PA23C)

Course Objective: This course enables students to understand various pharmacoepidemiological methods and their clinical applications. Also, it aims to impart knowledge on basic concepts, assumptions, terminology, and methods associated with Pharmacoeconomics and health related outcomes, and when should be appropriate Pharmacoeconomic model should be applied for a health care regimen.

Course Outcome: Upon completion of this course it is expected that students shall be able to:

- Understand the various epidemiological methods and their applications
- Understand the fundamental principles of Pharmacoeconomics.
- Identify and determine relevant cost and consequences associated with pharmacy products and services.
- Perform the key Pharmacoeconomics analysis methods
- Understand the Pharmacoeconomic decision analysis methods and its applications.
- Describe current Pharmacoeconomic methods and issues.
- Understand the applications of Pharmacoeconomics to various pharmacy settings.

UNIT I

Introduction to Pharmacoepidemiology: Definition, Scope, Need, Aims & Applications; Outcome measurement: Outcome measures, Drug use measures: Monetary units, Number of prescriptions, units of drug dispensed, defined daily doses, prescribed daily doses, Diagnosis and Therapy surveys, Prevalence, Incidence rate, Monetary units, number of prescriptions, unit of drugs dispensed, defined daily doses and prescribed daily doses, medications adherence measurements. Concept of risk: Measurement of risk, Attributable risk and relative risk, Time- risk relationship and odds ratio

UNIT II

Pharmacoepidemiological Methods: Qualitative models: Drug Utilization Review; Quantitative models: case reports, case series, Cross sectional studies, Cohort and case control studies, Calculation of Odds' ratio, Meta-analysis models, Drug effects study in populations: Spontaneous reporting, Prescription event monitoring, Post marketing surveillance, Record linkage systems, Applications of Pharmacoepidemiology

UNIT III

Introduction to Pharmacoeconomics: Definition, history of Pharmacoeconomics, Need of Pharmacoeconomic studies in Indian healthcare system. Cost categorization and resources for cost estimation: Direct costs. Indirect costs. Intangible costs. Outcomes and Measurements of Pharmacoeconomics: Types of outcomes: Clinical outcome, Economic outcomes, Humanistic outcomes; Quality Adjusted Life Years, Disability Adjusted Life Years Incremental Cost-Effective Ratio, Average Cost-Effective Ratio. Person Time, Willingness to Pay, Time Trade Off and Discounting.

UNIT IV

Pharmacoeconomic evaluations: Definition, Steps involved, Applications, Advantages and disadvantages of the following Pharmacoeconomic models: Cost Minimization Analysis (CMA), Cost Benefit Analysis (CBA), Cost Effective Analysis (CEA), Cost Utility Analysis (CUA), Cost of Illness (COI), Cost Consequences Analysis (COA).

UNIT V

Definition, Steps involved, Applications, Advantages and disadvantages of the following:

Health related quality of life (HRQOL): Definition, Need for measurement of HRQOL, Common HRQOL measures. Definition, Steps involved, Applications of the following: Decision Analysis and Decision tree, Sensitivity analysis, Markov Modeling, Software used in Pharmacoeconomic analysis, Applications of Pharmacoeconomics.

REFERENCES:

1. Rascati K L. Essentials of Pharmacoeconomics, Woulters Kluwe rLippincott Williams & Wilkins, Philadelphia.
2. Thomas E Getzen. Health economics. Fundamentals and Flow of Funds. John Wiley & Sons, USA.
3. Andrew Briggs, Karl Claxton, Mark Sculpher. Decision Modeling for Health Economic Evaluation, Oxford University Press, London.
4. K G Revikumar, Pharmacoepidemiology and Pharmacoeconomics Concepts and Practices.
5. Michael Drummond, Mark Sculpher, George Torrence, Bernie O'Brien and Greg Stoddart. Methods for the Economic Evaluation of Health Care Programs Oxford University Press, London.
6. George E Mackinnon III. Understanding health outcomes and Pharmacoeconomics.
7. Graker, Dennis. Pharmacoeconomics and outcomes.
8. Walley, Pharmacoeconomics.
9. Pharmacoeconomic – ed. by Nowakowska – University of Medical Sciences, Poznan.
10. Relevant review articles from recent medical and pharmaceutical literature
11. Guru Prasad Mohanta and P K Manna, Textbook of Pharmacovigilance Concepts and Practice

ANDHRA KESARI UNIVERISTY, ONGOLE
M.Pharm Sem – II (PHARMACEUTICAL ANALYSIS)
ADVANCED INSTRUMENTAL ANALYSIS – II (Professional Elective - IV)
(R23PA23A)

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.

Course Outcome: By the completion of topics the students will come out with the thorough knowledge of various electrochemical methods, fluorimetry, AAS, RIA, ELISA etc. which help them in further projects works and also industrial opportunities

UNIT I

Polarography – Principle, Ilkovic equation, construction and working of dropping mercury electrode and rotating platinum electrode, applications.

Amperometry - Principles, instrumentation and applications including amperometric titrations.

UNIT II

- a. **Potentiometry** – Electrochemical cell, construction and working of reference (Standard hydrogen, silver chloride electrode and calomel electrode) and indicator electrodes (metal electrodes and glass electrode), methods to determine end point of potentiometric titration and applications.
- b. **Conductometry**– Introduction, Conductivity cell, Conductometric titrations, applications

UNIT III

Spectrofluorimetry: Theory of Fluorescence, Factors affecting fluorescence (Characteristics of drugs that can be analyzed by fluorimetry), Quenchers, Instrumentation and Applications of fluorescence spectrophotometer.

UNIT IV

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

UNIT V

- a. **Radio chemical methods including RIA:** Radio Active Isotopes, tagging of compounds, Labeled Reagents, Isotope dilution Analysis, Scintillation counter, RIA.
- b. **ELISA:** Principle, types and application of ELISA

REFERENCES:

1. Instrumental Methods of Chemical Analysis by B.K Sharma
2. Organic spectroscopy by Y.R Sharma
3. A Text book of Pharmaceutical Analysis by Kerrenth A. Connors
4. Vogel's Text book of Quantitative Chemical Analysis by A.I. Vogel
5. Practical Pharmaceutical Chemistry by A.H. Beckett and J.B. Stenlake
6. Organic Chemistry by I. L. Finar
7. Organic spectroscopy by William Kemp
8. Quantitative Analysis of Drugs by D. C. Garrett
9. Quantitative Analysis of Drugs in Pharmaceutical Formulations by P. D. Sethi
10. Spectrophotometric identification of Organic Compounds by Silverstein
11. HPTLC by P.D. Seth

ANDHRA KESARI UNIVERISTY, ONGOLE
M.Pharm I Year II Sem (Pharmaceutical Analysis)
NUTRACEUTICALS (Professional Elective - IV) (R23PA24B)

Course Objectives: The students will expose to characteristic features of various phytochemicals as nutraceuticals in various diseased conditions and also know the role of antioxidant in free radical induced disease conditions and will expose to various food laws and regulations

Course Outcome: Helps the student to understand the importance of Nutraceuticals in various common problems with the concept of free radicals

UNIT I

a. Definitions of Functional foods, Nutraceuticals and Dietary supplements. Classification of Nutraceuticals, Health problems and diseases that can be prevented or cured by Nutraceuticals i.e. weight control, diabetes, cancer etc.

b. Source, Name of marker compounds and their chemical nature, Medicinal uses and health benefits of following used as nutraceuticals/functional foods:

Spirulina, Soya bean, Ginseng, Garlic, Broccoli, Gingko, Flaxseeds

UNIT II

Phytochemicals as nutraceuticals: Occurrence and characteristic features (chemical nature medicinal benefits) of following

- a. Carotenoids- α and β -Carotene, Lycopene, Xanthophylls, lutein
- b. Sulfides: Diallylsulfides, Allyltrisulfide.
- c. Polyphenolics: Resveratrol
- d. Flavonoids- Rutin, Naringin, Quercetin, Anthocyanidins, catechins, Flavones
- e. Prebiotates / Probiotics.: Fructo oligosaccharides, Lacto bacillum
- f. Phytoestrogens, Isoflavones, daidzein, Geebustin, lignans
- g. Tocopherols

UNIT III

a. Introduction to free radicals: Free radicals, reactive oxygen species, production of free radicals in cells, damaging reactions of free radicals on lipids, proteins, Carbohydrates, nucleic acids.

b. Measurement of free radicals: Lipid peroxidation products, lipid hydroperoxide, malondialdehyde.

UNIT IV

a. Free radicals in Diabetes mellitus, Inflammation, Ischemic reperfusion injury, Cancer, Atherosclerosis, Free radicals in brain metabolism and pathology, kidney damage, muscle damage. Free radicals involvement in other disorders. Free radicals theory of ageing.

b. Antioxidants: Endogenous antioxidants – enzymatic and nonenzymatic antioxidant defence, Superoxide dismutase, catalase, Glutathione peroxidase, Glutathione Vitamin C, Vitamin E, α -Lipoic acid, melatonin

c. Synthetic antioxidants: Butylatedhydroxy Toluene, Butylatedhydroxy Anisole.

UNIT V

Food Laws and Regulations; FDA, FPO, MPO, AGMARK. HACCP and GMPs on Food Safety. Adulteration of foods.

Regulations and Claims – Current Products: Label Claims, Nutrient Content Claims, Health Claims, Dietary Supplements Claims

REFERENCES:

1. Dietetics by Sri Lakshmi

2. Role of dietary fibres and nutraceuticals in preventing diseases by K. T Agusti and P. Faizal: BS Publication.
3. Advanced Nutritional Therapies by Cooper. K.A., (1996).
4. The Food Pharmacy by Jean Carper, Simon & Schuster, UK Ltd., (1988).
5. Prescription for Nutritional Healing by James F. Balch and Phyllis A. Balch 2nd Edn., Avery Publishing Group, NY (1997).
6. G. Gibson and C. Williams Editors *2000 Functional foods* Woodhead Publ. Co. London.
7. Goldberg, I. *Functional Foods*. 1994. Chapman and Hall, New York.
8. Labuza, T.P. 2000 Functional Foods and Dietary Supplements: Safety, Good Manufacturing Practice (GMPs) and Shelf Life Testing in *Essentials of Functional Foods* M. K. Sachmidl and T.P. Labuza eds. Aspen Press.
9. Handbook of Nutraceuticals and Functional Foods, Third Edition (Modern Nutrition)
10. Shils, ME, Olson, JA, Shike, M. 1994 *Modern Nutrition in Health and Disease*. Eighth edition. Lea and Febiger

ANDHRA KESARI UNIVERISTY, ONGOLE**M.Pharm I Year II Sem (Pharmaceutical Analysis)****CLINICAL RESEARCH AND PHARMACOVIGILANCE (Professional Elective - IV) (R23PA24C)**

Course Objective: This subject will provide a value addition and current requirement for the students in clinical research and pharmacovigilance. It will teach the students on conceptualizing, designing, conducting, managing and reporting of clinical trials. This subject also focuses on global scenario of pharmacovigilance in different methods that can be used to generate safety data. It will teach the students in developing drug safety data in pre-clinical, clinical phases of drug development and post market surveillance.

Course Outcomes: Upon completion of the course, the student shall be able to,

- Explain the regulatory requirements for conducting clinical trial
- Demonstrate the types of clinical trial designs
- Explain the responsibilities of key players involved in clinical trials
- Execute safety monitoring, reporting and close-out activities
- Explain the principles of Pharmacovigilance
- Detect new adverse drug reactions and their assessment
- Perform the adverse drug reaction reporting systems and communication in pharmacovigilance

UNIT I

Regulatory Perspectives of Clinical Trials: Origin and Principles of International Conference on Harmonization - Good Clinical Practice (ICH-GCP) guidelines Ethical Committee: Institutional Review Board, Ethical Guidelines for Biomedical Research and Human Participant-Schedule Y, ICMR, Informed Consent Process: Structure and content of an Informed Consent Process Ethical principles governing informed consent process

UNIT II

Clinical Trials: Types and Design: Experimental Study- RCT and Non RCT, Observation Study: Cohort, Case Control, Cross sectional Clinical Trial Study Team Roles and responsibilities of Clinical Trial Personnel: Investigator, Study Coordinator, Sponsor, Contract Research Organization and its management.

UNIT III

Clinical Trial Documentation: Guidelines to the preparation of documents, Preparation of protocol, Investigator Brochure, Case Report Forms, Clinical Study Report Clinical Trial Monitoring-Safety Monitoring in CT Adverse Drug Reactions: Definition and types. Detection and reporting methods. Severity and seriousness assessment. predictability and preventability assessment. Management of adverse drug reactions; Terminologies of ADR.

UNIT IV

Basic aspects, terminologies and establishment of pharmacovigilance: History and progress of pharmacovigilance, Significance of safety monitoring, Pharmacovigilance in India and international aspects, WHO international drug monitoring programme, WHO and Regulatory terminologies of ADR, evaluation of medication safety, establishing pharmacovigilance centres in Hospitals, Industry and Nationalprogrammesrelatedtopharmacovigilance.RolesandresponsibilitiesinPharmacovigilance.

UNIT V

Methods, ADR reporting and tools used in pharmacovigilance: International classification of diseases, International Nonproprietary names for drugs, Passive and Active surveillance, Comparative observational studies, targeted clinical investigations and Vaccine safety surveillance.

Spontaneous reporting system and Reporting to regulatory authorities, Guidelines for ADRs reporting. Argus, ArisG Pharmacovigilance, VigiFlow, Statistical methods for evaluating medication safety data.

REFERENCES:

1. Central Drugs Standard Control Organization- Good Clinical Practices, Guidelines for Clinical Trials on Pharmaceutical Products in India. New Delhi: Ministry of Health; 2001.
2. International Conference on Harmonization of Technical requirements for registration of Pharmaceuticals for human use. ICH Harmonized Tripartite Guideline. Guideline for Good Clinical Practice. E6; May1996.230
3. Ethical Guidelines for Biomedical Research on Human Subjects 2000. Indian Council of Medical Research, New Delhi.
4. Textbook of Clinical Trials edited by David Machin, Simon Day and Sylvan Green, March 2005, John Wiley and Sons.
5. Clinical Data Management edited by R K Rondels, S A Varley, C F Webbs. Second Edition, Jan 2000, Wiley Publications.
6. A Textbook of Clinical Research and Pharmacovigilance by KPR Chowdary, Pharmamed Press
7. Handbook of clinical Research. Julia Lloyd and Ann Raven Ed. Churchill Livingstone.
8. Principles of Clinical Research edited by Giovanna di Ignazio, Di Giovanna and Haynes.
9. Textbook of Pharmacovigilance: Concept and Practice. G. P. Mohanta and P. K. Manna. 2016, Pharma Med Press.
10. A textbook of Clinical Pharmacy Practice: Essential Concepts and Skills. Second Edition, 2012, University Press

ANDHRA KESARI UNIVERISTY, ONGOLE
M.Pharm I Year II Sem (Pharmaceutical Analysis)
ADVANCED INSTRUMENTAL ANALYSIS-I LAB (Laboratory –III) (R23PA25)

LIST OF EXPERIMENTS:

1. Determination of chlorides and sulphates by Nephelo -Tubmidimetry
2. Determination of compounds of sodium, potassium and calcium by Flame photometry.
3. Estimation of riboflavin/quinine sulphate by flourimetry
4. Assay of official compounds by potentiometric titrations **(Any 2)**
5. Assay of official compounds by conductimetric titrations **(Any 2)**
6. Demonstration on ELISA
7. Quenching of fluorescence
8. Perform phosphate interference on absorption of calcium

(Note: Minimum of two experiments covering each of the above-mentioned topics)

ANDHRA KESARI UNIVERISTY, ONGOLE
M.Pharm I Year II Sem (Pharmaceutical Analysis)
PHARMACEUTICAL QUALITY CONTROL AND QUALITY ASSURANCE LAB (R23PA26)

LIST OF EXPERIMENTS:

1. QC tests for tablets (minimum 2 experiments)
2. QC tests for capsules (minimum 2 experiments)
3. QC tests for oral liquids monophasic (minimum 2 experiments)
4. QC tests for oral liquids biphasic (minimum 2 experiments)
5. Forced degradation studies of some drugs.
6. Interpretation of spectras by IR, NMR and MASS
7. Assay of drug formulations using UV-Spectrophotometer (Any four)
8. Demonstration of functional groups of the given samples by IR Spectrophotometer.
9. Physicochemical tests for water
10. Solubility studies of weakly acidic and weakly basic drugs.

ANDHRA KESARI UNIVERISTY, ONGOLE
M.Pharm II Year I Sem (Pharmaceutical Analysis)
BIostatISTICS (Professional Elective - V) (R23PA31A)

Course Objective: The student shall know the introduction, scope of biostatistics and Research work, calculation and present of the data.

Course Outcome: The student will be known the Biostatistics arrangement, presentation and formation of tables and charts. They also know the correlation and regression & application of different methods, analysis of data

UNIT I

Introduction and scope of biostatistics: Use of statistics in Pharmacy. Population and Sample collection. Stages of research, types of data and methods of data collections. Data arrangement and presentation, formation of table and charts.

UNIT II

Measures of central tendency: computation of means, median and mode from grouped and ungrouped data.

Measure of dispersion: computation of variance, standard deviation, standard error and their coefficients.

UNIT III

Measures of Correlation and Regression

Probability rules: Binomial, Poison and Normal distribution.

UNIT IV

Experimental designing, planning of an experiment, replication and randomization.

Analysis of Variance (ANOVA): 1-way, 2- Way

UNIT V

Hypothesis testing: Student 't' test, Chi square test,

Non- Parametric Tests: Sign Test, Sign Rank Test, Wilcoxon Sign Rank Test

REFERENCES:

1. Statistics for business and economics 3rd edition by Vikas books publications
2. Biostatistics & Computer applications by GN Rao and NK Tiwari
3. Sokal, R.R. and Rohlf, F.J. 1987. An Introduction to Biostatistics. W.H. Freeman and Company.
4. Bailey, N.T.J. 1981. Statistical Methods in Biology. English University Press.
5. Mitchell, K. and Glover, T. 2001. Introduction to Biostatistics. McGraw Hill, Publishing Co.

ANDHRA KESARI UNIVERISTY, ONGOLE
M.Pharm II Year I Sem (Pharmaceutical Analysis)

SCALE UP AND TECHNOLOGY TRANSFER (Professional Elective - V) (R23PA31B)

Course Objective: This course is designed to impart knowledge and skills necessary to train the students to be on scale up, technology transfer process and industrial safety issues.

Course Outcome: On completion of this course it is expected that students will be able to;

- Manage the scale up process in pharmaceutical industry.
- Assist in technology transfer.
- To establish safety guidelines, which prevent industrial hazards.

UNIT I

Pilot plant design: Basic requirements for design, facility, equipment selection, for tablets, capsules, liquid orals, parentral and semisolid preparations.

Scale up: Importance, Technology transfer from R & D to pilot plant to plant scale, process scale up for tablets, capsules, liquid orals, semisolids, parentral, NDDS products – stress on formula, equipments, product uniformity, stability, raw materials, physical layout, input, in-process and finished product specifications, problems encountered during transfer of technology

UNIT II

Validation: General concepts, types, procedures & protocols, documentation, VMF. Analytical method validation, cleaning validation and vender qualification.

UNIT III

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

UNIT IV

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

UNIT V

Industrial safety: Hazards – fire, mechanical, electrical, chemical and pharmaceutical, Monitoring & prevention systems, industrial effluent testing & treatment. Control of environmental pollution.

REFERENCES:

1. Pharmaceutical process validation, JR Berry, Nash, Vol 57, Marcel Dekker, NY.
2. Pharmaceutical Production facilities, design and applications, by GC Cole, Taylor and Francis.
3. Pharmaceutical project management, T. Kennedy, Vol 86, Marcel Dekker, NY.
4. The theory & Practice of Industrial Pharmacy, L. Lachman, H.A. Lieberman, Varghese Publ Bombay.
5. Tablet machine instruments in pharmaceuticals, PR Watt, John Wiloy.
6. Pharmaceutical dosage forms, Tablets, Vol 1, 2, 3 by Lachman, Lieberman, Marcel Dekker, NY.
7. Pharmaceutical dosage forms, Parentral medications, Vol 1, 2 by K.E. Avis, Marcel Dekker, NY.
8. Dispersed system Vol 1, 2, 3 by Lachman, Lieberman, Marcel Dekker, NY.
9. Subrahmanyam, CVS, Pharmaceutical production and Management, 2007, Vallabh Prakashan, Dehli.
10. Pharmaceutical Process Scale-up 2nd Ed. Levin Michael, CRC press

ANDHRA KESARI UNIVERISTY, ONGOLE**M.Pharm II Year I Sem (Pharmaceutical Analysis)****PRODUCTION AREA DESIGN & PACKAGING DEVELOPMENT (Professional Elective - V) (R23PA31C)**

Course Objectives: The student shall learn about Industrial area design, Current good manufacturing practices. They also learn about packaging components, polymers and metals used in packaging. They also understand about the storage conditions of different formulations and their stability evaluations.

Course Outcome: At the end of the semester student will get an idea about Industrial area design and packaging of different formulations and its stability conditions.

UNIT I

Production Area Design: Selection of plant location, Design of plant for bulk drugs and formulations (Solids, Semisolids, Injectables, Nutraceuticals etc.), General utilities such as purified water, portable water, water for injection, Air handling units-Relative humidity and Temperature control, Material and personnel movement. Warehouse handling-API, Excipients, packaging materials and solvents.

UNIT II

Current Good Manufacturing Practices: GMP design for buildings & facilities. GMP layout design. Clean room classifications. Segregation & cross contamination control. HVAC (heating, ventilation & air-conditioning) systems. Clean room environment control. Documentation and record keeping: Specifications and testing procedures, Specifications for finished products, Master Formulae, Packaging instructions. Batch processing records, Standard operating procedures.

UNIT III

Pharmaceutical packaging and Design: Introduction, Packaging system, Components of packaging, Symbols used on packages and labels. Package development and Design research. Packaging materials- Polymers and Plasters, Glass, Metal and Blister and strip packaging.

UNIT IV

Stability of Packaging: Introduction, Legislation, Regulation, Pharmaceutical Stability Testing in Climatic Cabinets, Pharmaceutical Stability Testing Conditions, Photo-Stability Testing, Review of Pharmaceutical Product Stability, Packaging and the ICH Guidelines.

UNIT V

Packaging of Solids, Semisolids, Parenterals, Ophthalmic and Aerosols: Introduction, Packaging of Solid and semisolids, Packaging of Sterile Pharmaceuticals, Packaging Components, Inspection of Filled Injectable Products, Storage and Labelling, Packaging of Ophthalmics, Selection of Packaging Materials, Packaging of Aerosols.

REFERENCES:

1. Lachman; Lieberman Herbert A.; Kanig, The theory and Practice of Industrial Pharmacy.
2. Gilbert Banker and Christopher Rhodes. Modern Pharmaceutics.
3. Aulton's Pharmaceutics: The design and Manufacture of Medicine
4. D. A. Dean, Roy Evans, Ian Hall. Pharmaceutical packaging technology. Tylor and Francis.
5. Edward J. Bauer, Pharmaceutical Packaging Handbook. Bausch and Lomb, Rochester
6. Pharmaceutical Facilities: Design, Layouts and Validation, Potdar, Pharmamed Press
7. Wilmer A. Jenkins, Kenton R. Osborn. Packaging drugs and pharmaceuticals.
8. Remington: The Science and Practice of Pharmacy. 8. Michael E. Aulton, Kevin Tylor
9. Pharmaceutical Packaging Technology, UK jain, Pharmamed Press

Andhra Kesari University, Ongole
M.Pharm II Year I Sem (Pharmaceutical Analysis)

SCREENING METHODS IN PHARMACOLOGY (Open Elective) R23PA32A

Course Objective: The students are going to study about various techniques for screening of drugs for various pharmacological activities and guide lines for handling animals and human and animal ethics for screening of drugs.

Course Outcome: The expected outcomes are students will know how to handle animals and know about various techniques for screening of drugs for different pharmacological activities, guidelines and regulations for screening new drug molecules on animals.

UNIT I

Care Handling and breeding techniques of laboratory animals, Regulations for laboratory animals, CPCSEA guidelines, alternatives to animal studies, Good laboratory Practices.

UNIT II

Bioassays: Basic principles of Biological standardization: Methods used in the bio-assay of Rabbis Vaccine, Oxytocin, Tetanus Antitoxin and Diphtheria Vaccine. Test for pyrogens.

UNIT III

Toxicity tests: OECD guidelines, determination of LD50, acute, sub-acute and chronic toxicity studies.

UNIT IV

Organization of screening for the Pharmacological activity of new substances with emphasis on the evaluation of cardiac and anti-diabetic activities.

UNIT V

Organization of screening for the Pharmacological activity of new substances with emphasis on the evaluation of psychopharmacological, anti-inflammatory and analgesic activities.

TEXT BOOKS:

1. Screening methods in Pharmacology, Vol.-1&2 by Robert.A. Turner and Peter Hebborn.
2. Drug discovery and evaluation by H.G. Vogel and W.H. Vogel, Springerverlag, Berlin Heideleberg.
3. Handbook of experimental pharmacology by S.K. Kulkarni, Vallabh Prakashan, Delhi.

REFERENCE BOOKS:

1. ICH of technical requirements for registration of pharmaceuticals for human use, ICH harmonized tripartite guidelines - Guidelines for good clinical practice, E6, May 1996.
2. Good clinical practice - Guidelines for Clinical trials on pharmaceutical products in India, Central drug standard control organization, New Delhi, Minister of Health- 2001.

Andhra Kesari University, Ongole

M.Pharm II Year I Sem (Pharmaceutical Analysis)

ENTREPRENEURSHIP MANAGEMENT (Open Elective)

R23PA32B

Course Objectives: This course is designed to impart knowledge and skills necessary to train the students on entrepreneurship management.

Course Outcomes: On completion of this course it is expected that students will be able to;

- The Role of enterprise in national and global economy
- Dynamics of motivation and concepts of entrepreneurship
- Demands and challenges of Growth Strategies and Networking

UNIT I

Conceptual Frame Work: Concept need and process in entrepreneurship development. Role of enterprise in national and global economy. Types of enterprise – Merits and Demerits. Government policies and schemes for enterprise development. Institutional support in enterprise development and management.

UNIT II

Entrepreneur: Entrepreneurial motivation - dynamics of motivation. Entrepreneurial competency - Concepts. Developing Entrepreneurial competencies - requirements and understanding the process of entrepreneurship development, self-awareness, interpersonal skills, creativity, assertiveness, achievement, factors affecting entrepreneur role.

UNIT III

Launching and Organizing an Enterprise: Environment scanning – Information, sources, schemes of assistance, problems. Enterprise selection, market assessment, enterprise feasibility study, SWOT Analysis. Resource mobilization -finance, technology, raw material, site and manpower. Costing and marketing management and quality control. Feedback, monitoring and evaluation.

UNIT IV

Growth Strategies and Networking: Performance appraisal and assessment. Profitability and control measures, demands and challenges. Need for diversification. Future Growth – Techniques of expansion and diversification, vision strategies. Concept and dynamics. Methods, Joint venture, co-ordination and feasibility study.

UNIT V

Preparing Project Proposal to Start on New Enterprise Project work – Feasibility report; Planning, resource mobilization and implementation.

RECOMMENDED BOOKS:

1. Akhauri, M. M. P.(1990): Entrepreneurship for Women in India, NIESBUD, New Delhi.
2. Hisrich, R. D & Brush, C.G. (1996) The Women Entrepreneurs, D.C. Health& Co., Toranto.
3. Hisrich, R.D. and Peters, M.P. (1995): Entrepreneurship - Starting Developing and Managing a New Enterprise, Richard D., Inwin, INC, USA.
4. Meredith, G.G. etal (1982): Practice of Entrepreneurship, ILO, Geneva.
5. Patel, V.C. (1987): Women Entrepreneurship - Developing New Entrepreneurs, Ahmedabad EDII
6. Arya kumar.(2012): Entrepreneurship- Creating and Leading an Entrepreneurial Organization, Pearson

Andhra Kesari University, Ongole
M.Pharm II Year I Sem (Pharmaceutical Analysis)

COSMETIC SCIENCE (Open Elective) R23PA32C

Course Objectives: These topics are designed impart a specialized knowledge to know various cosmetics, their preparation, properties, MOA, uses etc. The understanding of properties and evaluation of these cosmetics by analytical methods.

Course Outcomes: The students should describe the properties and uses of various cosmetics on various parts of the body. The students should be able to suggest the proper usage of cosmetics.

UNIT I

Classification of cosmetics and cosmeceutical products.

Definition of cosmetics as per Indian and EU regulations, Evolution of cosmeceuticals from cosmetics, cosmetics as quasi and OTC drugs.

Cosmetic excipients: Surfactants, rheology modifiers, humectants, emollients, preservatives, classification and application.

Skin: Basic structure and function of skin.

Hair: Basic structure of hair, hair growth cycle.

Oral Cavity: Common problem associated with teeth and gums.

UNIT II

Principles of formulation and building blocks of skin care products: Face cream, Moisturizing cream, Cold cream, Vanishing cream and their advantages and disadvantages. Application of these products in formulation of cosmeceuticals.

Anti perspirants and Deodorants: Actives and MOA.

Principles of formulation and building blocks of hair care products: Conditioning shampoo, hair conditioner, anti-dandruff shampoos, hair oils.

Chemistry and formulation of Para-phenylene di amine-based hair dye.

Principles of formulation and building blocks of oral care products: Tooth paste for bleeding gums, sensitive teeth, teeth whitening, mouth wash.

UNIT III

Sun protection, classification of sunscreens and SPF.

Role of herbs in cosmetics:

Skin care - Aloe and turmeric

Hair care - Henna and amla

Oral care - Clove and neem

Analytical Cosmetics: BIS specification and analytical method for shampoo, skin cream and tooth paste.

UNIT IV

Principle of cosmetic evaluation – Principle of sebumeter, corneometer. Measurement of TEWL, skin color, hair tensile strength, hair combing properties. Soaps and Syndet bars, evaluation and skin benefits.

UNIT V

Oily and dry skin, causes leading to dry skin, skin moisturization. Basic understanding of the terms comedogenic, dermatitis.

Cosmetic problems associated with hair and scalp: Dandruff, hair fall causes.

Cosmetic problems associated with skin: Blemishes, wrinkles, acne, prickly heat and body odor.

Anti-perspirants and deodorants – Actives and MOA

RECOMMENDED BOOKS:

1. Harry's cosmeticology, Wilkinson, Moore, 7th edition, George Godwin.
2. Cosmetics – Formulation, Manufacturing and Quality control, P.P. Sharma, 4th edition, Vandana Publications Pvt. Ltd. Delhi.
3. Text book of cosmeticology by Sanju Nanda &Roop K. Khar, Tata Publishers.

Andhra Kesari University, Ongole
M.Pharm II Year I Sem (Pharmaceutical Analysis)

HAZARDS AND SAFETY MANAGEMENT (Open Elective)R23PA32D

Course Objectives: This course is designed to convey the knowledge necessary to understand issues related to different kinds of hazard and their management. Basic theoretical and practical discussions integrate the proficiency to handle the emergency situation in the pharmaceutical product development process and provides the principle-based approach to solve the complex tribulations.

Course Outcomes: At completion of this course it is expected that students will be able to

- Understand about environmental problems among learners.
- Impart basic knowledge about the environment and its allied problems.
- Develop an attitude of concern for the industry environment.
- Ensure safety standards in pharmaceutical industry
- Provide comprehensive knowledge on the safety management
- Empower an ideas to clear mechanism and management in different kinds of hazard management system
- Teach the method of Hazard assessment, procedure, methodology for provide safe industrial atmosphere.

UNIT I

Multidisciplinary nature of environmental studies: Natural Resources, Renewable and non-renewable resources, Natural resources and associated problems, Human and health safety measures.

a) Forest resources b) Water resources c) Mineral resources d) Energy resources e) Land resources

Ecosystems: Concept of an ecosystem and Structure and function of an ecosystem. Environmental hazards: Hazards based on Air, Water, Soil and Radioisotopes.

UNIT II

Air based hazards: Sources, Types of Hazards, Air circulation maintenance industry for sterile area and non-sterile area, Preliminary Hazard Analysis (PHA) Fire protection system: Fire prevention, types of fire extinguishers and critical Hazard management system.

UNIT III

Chemical based hazards: Sources of chemical hazards, Hazards of Organic synthesis, sulphonating hazard, Organic solvent hazard, Control measures for chemical hazards, Management of combustible gases, Toxic gases and Oxygen displacing gases management, Regulations for chemical hazard, Management of over-Exposure to chemicals and TLV concept.

UNIT IV

Fire and Explosion: Introduction, Industrial processes and hazards potential, mechanical electrical, thermal and process hazards. Safety and hazards regulations, Fire protection system: Fire prevention, types of fire extinguishers and critical Hazard management system mechanical and chemical explosion, multiphase reactions, transport effects and global rates. Preventive and protective management from fires and explosion electricity passivation, ventilation, and sprinkling, proofing, relief systems -relief valves, flares, scrubbers.

UNIT V

Hazard and risk management: Self-protective measures against workplace hazards. Critical training for risk management, Process of hazard management, ICH guidelines on risk assessment and Risk management methods and Tools Factory act and rules, fundamentals of accident prevention,

elements of safety Program and safety management, Physicochemical measurements of effluents, BOD, COD, Determination of some contaminants, Effluent treatment procedure, Role of emergency services.

RECOMMENDED BOOKS:

1. Y.K. Sing, Environmental Science, New Age International Pvt, Publishers, Bangalore
2. "Quantitative Risk Assessment in Chemical Process Industries" American Institute of Chemical Industries, Centre for Chemical Process safety.
3. Safety and Health in Industry: A Handbook by AM Sarma, Pharmamed Press
4. Occupational Hazards Safety and Environmental Studies by A M Sarma Pharmamed Press
5. Occupational Health and Hygiene in Industries, Raja Sekhar Mamillapalli, Visweswara Rao
6. Bharucha Erach, The Biodiversity of India, Mapin Publishing Pvt. Ltd., Ahmedabad - 380013, India,
7. Hazardous Chemicals: Safety Management and Global Regulations, T.S.S. Dikshith, CRC press

Andhra Kesari University, Ongole
M.Pharm II Year I Sem (Pharmaceutical Analysis)

AUDITS AND REGULATORY COMPLIANCE (Open Elective) R23PA32E

Course Objectives: This course deals with the understanding and process for auditing in pharmaceutical industries. This subject covers the methodology involved in the auditing process of different in pharmaceutical industries.

Course Outcome: Upon completion of this course the student should be able to

- To understand the importance of auditing
- To understand the methodology of auditing
- To carry out the audit process
- To prepare the auditing report
- To prepare the check list for auditing

UNIT I

Introduction: Objectives, Management of audit, Responsibilities, Planning process, information gathering, administration, Classifications of deficiencies

UNIT II

Role of quality systems and audits in pharmaceutical manufacturing environment: cGMP Regulations, Quality assurance functions, Quality systems approach, Management responsibilities, Resource, Manufacturing operations, Evaluation activities, Transitioning to quality system approach, Audit checklist for drug industries.

UNIT III

Auditing of vendors and production department: Bulk Pharmaceutical Chemicals and packaging material Vendor audit, Warehouse and weighing, Dry Production: Granulation, tableting, coating, capsules, sterile production and packaging.

UNIT IV

Auditing of Microbiological laboratory: Auditing the manufacturing process, Product and process information, General areas of interest in the building raw materials, Water, Packaging materials.

UNIT V

Auditing of Quality Assurance and engineering department: Quality Assurance Maintenance, Critical systems: HVAC, Water, Water for Injection systems, ETP.

RECOMMENDED BOOKS:

1. Compliance auditing for Pharmaceutical Manufacturers. Karen Ginsbury and Gil Bismuth, Interpharm/CRC, Boca Raton, London New York, Washington D.C.
2. Pharmaceutical Manufacturing Handbook, Regulations and Quality by Shayne Cox Gad. Wiley- Interscience, A John Wiley and sons, Inc., Publications.
3. Handbook of microbiological Quality control. Rosamund M. Baird, Norman A. Hodges, Stephen P. Denyar. CRC Press.2000.
4. Laboratory auditing for quality and regulatory compliance. Donald C. Singer, Raluca-Ioana Stefan, Jacobus F. Van Staden. Taylor and Francis (2005).