JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY ANANTAPUR
Course Structure and Syllabi for M.Pharm-Pharmaceutical Analysis
(JNTUA-Affiliated Pharmacy Colleges 2017-18)

I YEAR - I Semester

S. No	Course Code	Subjects	L	T	P	C
1	17S01101	Modern Pharmaceutical Analytical Techniques	4	-	-	4
2	17S07101	Advanced Pharmaceutical Analysis	4	-	-	4
3	17S07102	Pharmaceutical Validation	4	-	-	4
4	17S07103	Food Analysis	4	-	-	4
5	**17S07104**	**Modern Pharmaceutical Analytical Techniques Practical**	**-**	**-**	**6**	**3**
6	**17S04206**	**Food Analysis Practical**	**-**	**-**	**6**	**3**
7	**17S07105**	**Seminar/Assignment**	**-**	**-**	**7**	**4**
		Total	16	-	19	26

I YEAR II Semester

S. No	Course Code	Subject	L	T	P	C
1	17S07201	Advanced Instrumental Analysis	4	-	-	4
2	17S07202	Modern Bio-Analytical Techniques	4	-	-	4
3	17S07203	Quality Control And Quality Assurance	4	-	-	4
4	17S07204	Herbal and Cosmetic Analysis	4	-	-	4
5	**17S07205**	**Pharmaceutical Analysis Practical I**	**-**	**-**	**6**	**3**
6	**17S07206**	**Pharmaceutical Analysis Practical II**	**-**	**-**	**6**	**3**
7	17S07207	Seminar/Assignment	-	-	7	4
		Total	16	-	19	26

III SEMESTER

S.No	Subject Code	Subject	L	T	P	C
1.	17S01301	Research Methodology and Biostatistics	4	-	-	4
2.	17S07301	Journal Club	1	-	-	1
3.	17S07302	Teaching Assignment	10	-	-	2
4.	17S07303	Comprehensive viva voce	-	-	-	2
5.	17S07304	Discussion / Presentation (Proposal presentation)	-	-	2	2
6.	17S07305	Research Work	-	-	28	14
Total			15	-	30	25

IV SEMESTER

S.No	Subject Code	Subject	L	T	P	C
1.	17S07401	Journal Club	1	-	-	1
2.	17S07402	Research work	31	-	-	16
3.	17S07403	Discussion/ Final Presentation	3	-	-	3
Total			35	-	-	20

JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY ANANTAPUR

M. Pharm – I year I Sem. (Pharmaceutical Analysis)

L	T	P	C
4	0	0	4

(17S01101) MODERN PHARMACEUTICAL ANALYTICAL TECHNIQUES

Scope

This subject deals with various advanced analytical instrumental techniques foridentification, characterization and quantification of drugs. Instruments dealt areNMR, Mass spectrometer, IR, HPLC, GC etc.

Objectives

After completion of course student is able to know about chemicals andexcipients

- The analysis of various drugs in single and combination dosage forms
- Theoretical and practical skills of the instruments

THEORY **60 HOURS**

1. 11 hrs

a. UV-Visible spectroscopy: Introduction, Theory, Laws, Instrumentation associated with UV Visible spectroscopy, Choice of solvents and solvent effect and Applications of UV Visible spectroscopy.

b. IR spectroscopy: Theory, Modes of Molecular vibrations, Sample handling,

Instrumentation of Dispersive and Fourier -Transform IR Spectrometer, Factors

affecting vibrationalfrequencies and Applications of IR spectroscopy

c. Spectroflourimetry: Theory of Fluorescence, Factorsaffecting fluorescence, Quenchers,

Instrumentation andApplications of fluorescence spectrophotometer.

d. Flame emission spectroscopy and Atomic absorptionspectroscopy: Principle,

Instrumentation, Interferences andApplications.

2. 11hrs

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

3. 11hrs

Mass Spectroscopy: Principle, Theory, Instrumentation of MassSpectroscopy, Different types of ionization like electron impact,chemical, field, FAB and MALDI, APCI, ESI, APPI Analyzers

ofQuadrupole and Time of Flight, Mass fragmentation and its rules,Meta stable ions, Isotopic peaks and Applications of Mass spectroscopy

4. 11hrs

Chromatography: Principle, apparatus, instrumentation, chromatographic parameters, factors affecting resolution and applications of the following: a)Paper chromatography b) Thin Layer chromatographyc) Ion exchange chromatography d) Column chromatographye) Gas chromatography f) High Performance Liquidchromatographyg) Affinity chromatography

5 11hrs

a. Electrophoresis: Principle, Instrumentation, Working conditions, factors affecting separation and applications of the following:

a) Paper electrophoresis b) Gel electrophoresis c) Capillary electrophoresis

d) Zone electrophoresis e) Moving boundary electrophoresis f) Iso electric focusing

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

c. Immunological assays: RIA (Radio immuno assay), ELISA, Bioluminescence assays.5hrs

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. Practical Pharmaceutical Chemistry – Beckett and Stenlake, Vol II, 4thedition, CBS Publishers, New Delhi, 1997.
5. Organic Spectroscopy - William Kemp, 3rd edition, ELBS, 1991.
6. Quantitative Analysis of Drugs in Pharmaceutical formulation - P D Sethi, 3rdEdition, CBS Publishers, New Delhi, 1997.
7. Pharmaceutical Analysis- Modern methods – Part B - J W Munson, Volume11, Marcel Dekker Series

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M. Pharm – I year I Sem. (Pharmaceutical Analysis)

L	T	P	C
4	0	0	4

(17S07101) ADVANCED PHARMACEUTICAL ANALYSIS

Scope

This subject deals with the various aspects of Impurity, Impurities in new drugproducts, in residual solvents, Elemental impurities, Impurity profiling andcharacterization of degradents, Stability testing of phytopharmaceuticalsandtheir protocol preparation. It also covers the biological testing of variousvaccines and their principle and procedure.

Objective

After completion of the course students shall able to know,

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

THEORY 60 Hrs

1. 10Hrs

Impurity and stability studies:

Definition, classification of impurities in drug Substance or ActivePharmaceutical Ingredients and quantification of impurities as perICHguidelinesImpurities in new drug products:Rationale for the reporting and control of degradation products,reporting degradation products content of batches, listing ofdegradation products in specifications, qualification of degradationproducts

Impurities in residual solvents:General principles, classification of residual solvents, Analyticalprocedures, limits of residual solvents, reporting levels of residualsolvents

2 10Hrs

Elemental impurities:

Element classification, control of elemental impurities, PotentialSources of elemental Impurities, Identification of PotentialElemental Impurities, analytical procedures, instrumentation & C,H, N and S analysis

Stability testing protocols:

Selection of batches, container orientation, test parameters,sampling frequency, specification, storage conditions, recording ofresults, concept of stability, commitment etc. Importantmechanistic and stability related information provided by results ofstudy of factors like temperature, pH, buffering species ionicstrength and dielectric constant etc. on the reaction rates. Withpractical considerations.

3 10Hrs

Impurity profiling and degradent characterization: Methoddevelopment, Stability studies and concepts of validationaccelerated stability testing & shelf life calculation, WHO and ICHstability testing guidelines, Stability zones, steps in development,practical considerations. Basics of impurity profiling anddegradent characterization with special emphasis. Photostabilitytesting guidelines, ICH stability guidelines for biological products

4 16Hrs

a) Stability testing of phytopharmaceuticals:Regulatory requirements, protocols, HPTLC/HPLC finger printing,interactions and complexity.

b) Biological tests and assays of the following:

a. Adsorbed Tetanus vaccine b. Adsorbed Diphtheria vaccinec. Human anti haemophilic vaccine d. Rabies vaccine e.Tetanus Anti toxin f. Tetanus Anti serum g. Oxytocin h.Heparin sodium IP i. Antivenom. PCR, PCR studies for generegulation, instrumentation (Principle and Procedures)

5 14Hrs

Immunoassays (IA)

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

REFERENCES

1. Vogel‘s textbook of quantitative chemical analysis - Jeffery J Bassett, J.Mendham, R. C. Denney, 5th edition, ELBS, 1991.

2. Practical Pharmaceutical Chemistry - Beckett and Stenlake, Vol II, 4thEdition, CBS publishers, New Delhi, 1997.

3. Textbook of Pharmaceutical Analysis - K A Connors, 3rd Edition, JohnWiley& Sons, 1982.

4. Pharmaceutical Analysis - Higuchi, Brochmman and Hassen, 2nd Edition,Wiley – Inter science Publication, 1961.

5. Quantitative Analysis of Drugs in Pharmaceutical formulation – P D Sethi,3rd Edition, CBS Publishers New Delhi, 1997.

6. Pharmaceutical Analysis- Modern methods - J W Munson – Part B,Volume 11, Marcel Dekker Series.

7. The Quantitative analysis of Drugs - D C Carratt, 3rd edition, CBSPublishers, NewDelhi, 1964.

8. Indian Pharmacopoeia VolI , II & III 2007, 2010, 2014.

9. Methods of sampling and microbiological examination of water, firstrevision, BIS

10. Practical HPLC method development – Snyder, Kirkland, Glajch, 2nd edition, John Wiley & Sons.

11. Analytical Profiles of drug substances – Klaus Florey, Volume 1 – 20,Elsevier, 2005

12. Analytical Profiles of drug substances and Excipients – Harry G Brittan,Volume 21 – 30, Elsevier, 2005.

13. The analysis of drugs in biological fluids - Joseph Chamberlain, 2nd edition, CRC press, London.

14. ICH Guidelines for impurity profiles and stability studies.

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M. Pharm – I year I Sem. (Pharmaceutical Analysis)

L	T	P	C
4	0	0	4

(17S07102) PHARMACEUTICAL VALIDATION

SCOPE

The main purpose of the subject is to understand about validation and how itcan be applied to industry and thus to improve the quality of the products. Thesubject covers the complete information about validation, types, methodologyand application.

Objectives

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
- Validate the manufacturing facilities

THEORY 60 Hrs

1. 12Hrs

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

Qualification: User Requirement Specification, DesignQualification, Factory Acceptance Test (FAT)/ Site AcceptanceTest (SAT), Installation Qualification, Operational Qualification,Performance Qualification, Re- Qualification (Maintaining status-Calibration Preventive Maintenance, Change management),Qualification of Manufacturing Equipments, Qualification ofAnalytical Instruments and Laboratory equipments.

2 12Hrs

Qualification of analytical instruments: Electronic balance, pHmeter, UV-Visible spectrophotometer, FTIR, GC, HPLC, HPTLCQualification of Glassware: Volumetric flask, pipette, Measuringcylinder, beakers and burette.

3 12Hrs

Validation of Utility systems: Pharmaceutical Water System &pure steam, HVAC system, Compressed air and nitrogen.Cleaning Validation: Cleaning Validation - Cleaning Methoddevelopment, Validation and validation of analytical method usedin cleaning. Cleaning of Equipment, Cleaning of Facilities.Cleaning in place (CIP).

4 12Hrs

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

Computerized system validation: Electronic records and digitalsignificance-21 CFR part 11 and GAMP.

5 12Hrs

General Principles of Intellectual Property: Concepts ofIntellectual 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 patentapplications; patent application forms and guidelines. Typespatent applications-provisional and non-provisional, PCT andconvention patent applications; International patenting requirementprocedures and costs; Rights and responsibilities of a patentee;Practical aspects regarding maintaining of a Patent file; Patentinfringement meaning and scope. Significance of transfertechnology (TOT),IP and ethics-positive and negative aspectsof IPP; Societal responsibility, avoiding unethical practices.

REFERENCES

1. B. T. Loftus & R. A. Nash, "Pharmaceutical Process Validation", Drugs andPharm 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 Internationalpublishing.

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 forAchieving Compliance in the Pharmaceutical, Medical Device, and BiotechIndustries, Syed ImtiazHaider

7. Pharmaceutical Equipment Validation: The Ultimate QualificationHandbook, 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 byChurg Chan, Heiman Lam, Y.C. Lee, Yue. Zhang, Wiley Inter Science.

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M. Pharm – I year I Sem. (Pharmaceutical Analysis)

L	T	P	C
4	0	0	4

(17S07103) FOOD ANALYSIS

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 the determination of pesticides in variety of food products.

Objectives

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
- And also student shall have the knowledge on food regulations and legislations

THEORY 60 Hrs

1. 12Hrs

Carbohydrates: classification and properties of foodcarbohydrates, General methods of analysis of foodcarbohydrates, Changes in food carbohydrates during processing,Digestion, absorption and metabolism of carbohydrates, Dietaryfibre, Crude fibre and application of food carbohydratesProteins: Chemistry and classification of amino acids andproteins, Physico-Chemical properties of protein and theirstructure, general methods of analysis of proteins and aminoacids, Digestion, absorption and metabolism of proteins.

2 12Hrs

Lipids: Classification, general methods of analysis, refining of fatsand oils; hydrogenation of vegetable oils, Determination ofadulteration in fats and oils, various methods used formeasurement of spoilage of fats and fatty foods.

Vitamins: classification of vitamins, methods of analysis ofvitamins, Principles of microbial assay of vitamins of B-series.

3 12Hrs

Food additives: Introduction, analysis of Preservatives,antioxidants, artificial sweeteners, flavors, flavor enhancers,stabilizers, thickening and jelling agents.

Pigments and synthetic dyes: Natural pigments, theiroccurrence and characteristic properties, permitted syntheticdyes, Non-permitted synthetic dyes used by industries, Method ofdetection of natural, permitted and non-permitted dyes.

4 12Hrs

General Analytical methods for milk, milk constituents and milkproducts like ice cream, milk powder, butter, margarine, cheeseincluding adulterants and contaminants of milk.Analysis of fermentation products like wine, spirits, beer andvinegar.

5 12Hrs

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 emphasison BIS, Agmark, FDA and US-FDA.

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

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M. Pharm – I year I Sem. (Pharmaceutical Analysis)

L	T	P	C
0	0	6	3

(17S07104) MODERN PHARMACEUTICAL ANALYTICAL TECHNIQUES PRACTICAL

1. Analysis of Pharmacopoeial compounds and their formulations by UV Vis Spectrophotometer.
2. Simultaneous estimation of multi component containing formulations by UV Spectrophotometry
3. Effect of pH and solvent on UV –Spectrum
4. Determination of Molar absorption coefficient
5. Estimation of riboflavin/ quinine sulphate by fluorimetry
6. Study of quenching effect by fluorimetry
7. Estimation of sodium or potassium by flame photometry
8. Colorimetric determination of drugs by using different reagents
9. Qunatitative determination of functional groups
10. Experiments based on Column chromatography
11. Experiments based on HPLC
12. Experiments based on Gas Chromatography
13. Calibration of UV – Visible Spectrophtometer/ HPLC/ GC/ FTIR
14. Cleaning validation of any one analytical equipment

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M. Pharm – I year I Sem. (Pharmaceutical Analysis)	**L**	**T**	**P**	**C**
	0	**0**	**6**	**3**

(17S04206) FOOD ANALYSIS PRACTICAL

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 in food
6. Determination of preservatives in food
7. Determination of pesticide residue in food products
8. Analysis of vitamin content in food products
9. Determination of density and specific gravity of foods
10. Determination of food additives
11. Determination of Aspartame in soft drinks
12. Determination of 4- imidazole in caramel
13. Determination of benzoic acid by titrimetric analysis in beverages/ sauces/ ketchup/ jam
14. UV Spectrophotometric methods for determination of sorbic acid in dairy products
15. Determination of nitrite and nitrate in food products

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M. Pharm – I year II Sem. (Pharmaceutical Analysis)

L	T	P	C
4	0	0	4

(17S07201) ADVANCED INSTRUMENTAL ANALYSIS

Scope

This subject deals with various hyphenated analytical instrumental techniquesfor identification, characterization and quantification of drugs. Instruments dealtare LC-MS, GC-MS, and hyphenated techniques.

Objectives

After completion of course student is able to know,

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

THEORY 60 Hrs

1. 12Hrs

HPLC: Principle, instrumentation, pharmaceutical applications,peak shapes, capacity factor, selectivity, plate number, plateheight, resolution, band broadening, pumps, injector, detectors,columns, column problems, gradient HPLC, HPLC solvents,trouble shooting, sample preparation, method development, Newdevelopments in HPLC-role and principles of ultra, nanoliquidchromatography in pharmaceutical analysis. Immobilizedpolysaccharide CSP's: Advancement in enantiomericseparations,revised phase Chiral method development and HILICapproaches. HPLC in Chiral analysis of pharmaceuticals.Preparative HPLC, practical aspects of preparative HPLC.

2 12Hrs

Biochromatography: Size exclusion chromatography, ionexchange chromatography, ion pair chromatography, affinitychromatography general principles, stationary phases and mobilephases.

Gas chromatography: Principles, instrumentation, derivatization,head space sampling, columns for GC, detectors, quantification.

High performance Thin Layer chromatography: Principles,instrumentation, pharmaceutical applications.

3 12Hrs

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

Capillary electrophoresis: Overview of CE in pharmaceuticalanalysis, basic configuration, CE characteristics, principles of CE,methods and modes of CE. General considerations and

methoddevelopment in CE, Crown ethers as buffer additives in capillaryelectrophoresis. CE-MS hyphenation.

4 12Hrs

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

5 12Hrs

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

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 Pharmaceutical formulations by HPTLC - P D

Sethi, CBS Publishers, New Delhi.

6. Quantitative Analysis of Drugs in Pharmaceutical formulation - P D Sethi,

3rd Edition, CBS Publishers, New Delhi, 1997.

7. Pharmaceutical Analysis- Modern methods – Part B - J W Munson,

Volume 11, Marcel Dekker Series.

8. Organic Spectroscopy by Donald L. Paviya, 5th Edition.

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M. Pharm – I year II Sem. (Pharmaceutical Analysis)

L	T	P	C
4	0	0	4

(17S07202) MODERN BIO-ANALYTICAL TECHNIQUES

Scope

This subject is designed to provide detailed knowledge about the importance ofanalysis 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. 12Hrs

Extraction of drugs and metabolites from biological matrices:General need, principle and procedure involved in theBioanalytical methods such as Protein precipitation, Liquid -Liquid extraction and Solid phase extraction and other novelsample preparation approach.

Bioanalytical method validation: USFDA and EMEA guidelines.

2 12Hrs

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

3 12Hrs

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

4 12Hrs

Cell culture techniquesBasic 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 ofcells and their applications. Principles and applications of cellviability assays (MTT assays), Principles and applications of flowcytometry.

5 12Hrs

Metabolite identification:In-vitro / in-vivo approaches, protocols and sample preparation.Microsomal approaches (Rat liver microsomes (RLM) and Humanlivermicrosomes (HLM) in Met –ID. Regulatory perspectives.In-vitro assay of drug metabolites & drug metabolizing enzymes.Drug Product Performance, In Vivo: Bioavailability andBioequivalence:Drug Product Performance, Purpose of Bioavailability Studies,Relativeand Absolute Availability. Methods for AssessingBioavailability, Bioequivalence Studies, Design and Evaluation ofBioequivalence Studies, Study Designs, Crossover StudyDesigns, Generic Biologics (Biosimilar Drug Products), ClinicalSignificance of Bioequivalence Studies.

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,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 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 LBertholf, Ruth E Winecker, John Wiley & Sons, New Jercy, 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

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L	T	P	C
4	0	0	4

(17S07203) QUALITY CONTROL AND QUALITY ASSURANCE

Scope

This course deals with the various aspects of quality control and qualityassurance aspects of pharmaceutical industries. It covers the important aspectslike 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 cGMPaspects 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. 12Hrs

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

Good Laboratory Practices: Scope of GLP, Definitions, Qualityassurance unit, protocol for conduct of non clinical testing, controlon animal house, report preparation and documentation.

2. 12Hrs

cGMP guidelines according to schedule M, USFDA (inclusiveof CDER and CBER) Pharmaceutical Inspection Convention(PIC), WHO and EMEA covering: Organization and personnelresponsibilities, training, hygiene and personal records, drugindustry location, design, construction and plant lay out,maintenance, sanitation, environmental control, utilities andmaintenance of sterile areas, control of contamination and GoodWarehousing Practice. CPCSEA guidelines.

3. 12Hrs

Analysis of raw materials, finished products, packagingmaterials, in process quality control (IPQC), Developingspecification (ICH Q6 and Q3)Purchase specifications and maintenance of stores for rawmaterials. In process quality control and finished products qualitycontrol for following formulation in Pharma industry according toIndian, US and British pharmacopoeias: tablets, capsules,ointments, suppositories, creams, parenterals, ophthalmic andsurgical products (How to refer pharmacopoeias), Quality controltest for containers, closures and secondary packing materials.

4. 12Hrs

Documentation in pharmaceutical industry: Three tierdocumentation, Policy, Procedures and Work instructions, andrecords (Formats), Basic principles- How to maintain, retention andretrieval etc. Standard operating procedures (How to write), MasterFormula Record, Batch Formula Record, Quality audit plan andreports. Specification and test procedures, Protocols and reports.Distribution records. Electronic data.

5. 12Hrs

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

REFERENCES

1. Quality Assurance Guide by organization of Pharmaceutical Procedures ofIndia, 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 andRelated 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 Methodsof Analysis and Quality specification for Pharmaceutical Substances,

Excepients and Dosage forms, 3rd edition, WHO, Geneva, 2005.

6. Good laboratory Practice Regulations – Allen F. Hirsch, Volume 38, MarcelDekker Series, 1989.

7. ICH guidelines

8. ISO 9000 and total quality management

9. The drugs and cosmetics act 1940 – Deshpande, Nilesh Gandhi, 4thedition, Susmit Publishers, 2006.

10. QA Manual – D.H. Shah, 1st edition, Business Horizons, 2000.

11. Good Manufacturing Practices for Pharmaceuticals a plan for total qualitycontrol – Sidney H. Willig, Vol. 52, 3rd edition, Marcel Dekker Series.

12. Steinborn L. GMP/ISO Quality Audit Manual for Healthcare Manufacturersand Their Suppliers, Sixth Edition, (Volume 1 - With Checklists andSoftware Package). Taylor & Francis; 2003.

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

JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY ANANTAPUR

M. Pharm – I year II Sem. (Pharmaceutical Analysis)	**L**	**T**	**P**	**C**
	4	**0**	**0**	**4**

(17S07204) HERBAL AND COSMETIC ANALYSIS

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 betterunderstanding of the equipments used in cosmetic industries for the purpose.

Objectives

At completion of this course student shall be able to understand

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

THEORY 60 Hrs

1. 12Hrs

Herbal remedies- Toxicity and Regulations: Herbals vsConventional drugs, Efficacy of herbal medicine products,Validation of Herbal Therapies, Pharmacodynamic andPharmacokinetic issues. Herbal drug standardization: WHO andAYUSH guidelines.

2 12Hrs

Adulteration and Deterioration: Introduction, types ofadulteration/substitution of herbal drugs, Causes and Measure ofadulteration, Sampling Procedures, Determination of ForeignMatter, DNA Finger printing techniques in identification of drugs ofnatural origin, heavy metals, pesticide residues, phototoxinandmicrobial contamination in herbal formulations.Regulatory requirements for setting herbal drug industry:Global marketing management, Indian and international patentlaw as applicable herbal drugs and natural products and itsprotocol.

3 12Hrs

Testing of natural products and drugs: Effect of herbalmedicine on clinical laboratory testing, Adulterant Screening usingmodern analytical instruments, Regulation and dispensing ofherbal drugs, Stability testing of natural products, protocol.Monographs of Herbal drugs: Study of monographs of herbaldrugs and comparative study in IP, USP, AyurvedicPharmacopoeia, American herbal Pharmacopoeia, British herbalPharmacopoeia, Siddha and Unani Pharmacopoeia, WHOguidelines in quality assessment of herbal drugs.

4 12Hrs

Herbal drug-drug interaction: WHO and AYUSH guidelines forsafety monitoring of natural medicine, Spontaneous reportingschemes for bio drug adverse reactions, bio drug-drug and biodrug-food interactions with suitable examples. Challenges inmonitoring the safety of herbal medicines.

5 12Hrs

Evaluation of cosmetic products: Determination of acid value,ester value, saponification value, iodine value, peroxide value,rancidity, moisture, ash, volatile matter, heavy metals, fineness ofpowder, density, viscosity of cosmetic raw materials and finishedproducts. Study of quality of raw materials and general methodsof analysis of raw material used in cosmetic manufacture as perBIS.

Indian Standard specification laid down for sampling and testingof various cosmetics in finished forms such as baby careproducts, skin care products, dental products, personal hygienepreparations, lips sticks. Hair products and skin creams by theBureau Indian Standards.

REFERENCES

1. Pharmacognosy by Trease and Evans

2. Pharmacognosy by Kokate, Purohit and Gokhale

3. Quality Control Methods for Medicinal Plant, WHO, Geneva

4. Pharmacognosy &Pharmacobiotechnology by AshutoshKar

5. Essential of Pharmacognosy by Dr.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 excipients

11. Wilkinson, Moore, seventh edition, George Godwin. Poucher'sPerfumes,Cosmetics and Soaps

12. Hilda Butler, 10th Edition, Kluwer Academic Publishers. Handbook ofCosmetic Science and Technology, 3rd Edition,

JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY ANANTAPUR

M. Pharm – I year II Sem. (Pharmaceutical Analysis)	**L**	**T**	**P**	**C**
	0	**0**	**6**	**3**

(17S07205) PHARMACEUTICAL ANALYSIS PRACTICAL - I

1. Comparison of absorption spectra by UV and Wood ward – Fiesure rule

2. Interpretation of organic compounds by FT-IR

3. Interpretation of organic compounds by NMR

4. Interpretation of organic compounds by MS

5. Determination of purity by DSC in pharmaceuticals

6. Identification of organic compounds using FT-IR, NMR, CNMR and Massspectra

7. Bio molecules separation utilizing various sample preparation techniquesand Quantitative analysis of components by gel electrophoresis.

8. Bio molecules separation utilizing various sample preparation techniquesand Quantitative analysis of components by HPLC techniques.

9. Isolation of analgesics from biological fluids (Blood serum and urine).

10. Protocol preparation and performance of analytical/Bioanalyticalmethodvalidation.

11. Protocol preparation for the conduct of BA/BE studies according toguidelines.

12. In process and finished product quality control tests for tablets, capsules,parenterals and creams

13. Quality control tests for Primary and secondary packing materials

14. Assay of raw materials as per official monographs

15. Testing of related and foreign substances in drugs and raw materials

16. Preparation of Master Formula Record.

17. Preparation of Batch Manufacturing Record.

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M. Pharm – I year II Sem. (Pharmaceutical Analysis)	L	T	P	C
	0	0	6	3

(17S07206) PHARMACEUTICAL ANALYSIS PRACTICAL - II

1. Quantitative analysis of rancidity in lipsticks and hair oil
2. Determination of aryl amine content and Developer in hair dye
3. Determination of foam height and SLS content of Shampoo.
4. Determination of total fatty matter in creams (Soap, skin and hair creams)
5. Determination of acid value and saponification value.
6. Determination of calcium thioglycolate in depilatories
7. Determination of tannins
8. Determination of microorganisms in herbal products
9. Specifications for adsorbents used in TLC
10. Determination of total phenol content
11. Determination of aflatoxins
12. Determination of swelling index and foaming index
13. Quality control methods for herbal materials/ Medicinal plant materials

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M. Pharm – III Sem. (Pharmaceutical Analysis)

L	T	P	C
4	0	0	4

(17S01301) RESEARCH METHODOLOGY & BIOSTATISTICS

UNIT – I

General Research Methodology: Research, objective, requirements, practical difficulties, review of literature, study design, types of studies, strategies to eliminate errors/bias, controls, randomization, crossover design, placebo, blinding techniques.

UNIT – II

Biostatistics: Definition, application, sample size, importance of sample size, factors influencing sample size, dropouts, statistical tests of significance, type of significance tests, parametric tests(students "t" test, ANOVA, Correlation coefficient, regression), non-parametric tests (wilcoxan rank tests, analysis of variance, correlation, chi square test), null hypothesis, P values, degree of freedom, interpretation of P values.

UNIT – III

Medical Research: History, values in medical ethics, autonomy, beneficence, non-maleficence, double effect, conflicts between autonomy and beneficence/non-maleficence, euthanasia, informed consent, confidentiality, criticisms of orthodox medical ethics, importance of communication, control resolution, guidelines, ethics committees, cultural concerns, truth telling, online business practices, conflicts of interest, referral, vendor relationships, treatment of family members, sexual relationships, fatality.

UNIT – IV

CPCSEA guidelines for laboratory animal facility: Goals, veterinary care, quarantine, surveillance, diagnosis, treatment and control of disease, personal hygiene, location of animal facilities to laboratories, anesthesia, euthanasia, physical facilities, environment, animal husbandry, record keeping, SOPs, personnel and training, transport of lab animals.

UNIT – V

Declaration of Helsinki: History, introduction, basic principles for all medical research, and additional principles for medical research combined with medical care.

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M.PHARM. PHARMACEUTICAL ANALYSIS

COURSE STRUCTURE & SYLLABI

SEMESTER – I

S. No.	Course codes	Course Name	Hours per week			Credits
			L	T	P	
1.	21S01101	Modern Pharmaceutical Analytical Techniques	4	-	-	4
2.	21S07101	Advanced Pharmaceutical Analysis	4	-	-	4
3.	21S07102	Pharmaceutical and Food Analysis	4	-	-	4
4.	21S07103	Quality Control And Quality Assurance	4	-	-	4
5.	21S01105	Modern Pharmaceutical Analytical Techniques Lab	-	-	6	3
6.	21S07104	Pharmaceutical and Food Analysis Lab	-	-	6	3
7.	21DAC101a 21DAC101b 21DAC101c	**Audit Course – I** English for Research paper writing Disaster Management Sanskrit for Technical Knowledge	2	-	-	0
8.		Seminar/Assignment	-	1	6	4
		Total	18	1	18	26

SEMESTER – II

S.No.	Course codes	Course Name	Hours per week			Credits
			L	T	P	
1.	21S07201	Advanced Instrumental Analysis	4	-	-	4
2.	21S07202	Modern Bio-Analytical Techniques	4	-	-	4
3.	21SOE301a	Pharmaceutical Validation	4	-	-	4
4.	21S07203	Herbal and Cosmetic Analysis	4	-	-	4
5.	21S07204	Advanced Instrumental Analysis Lab	-	-	6	3
6.	21S07205	Modern Bio-Analytical Techniques Lab	-	-	6	3
7.	21DAC201a 21DAC201b 21DAC201c	**Audit Course – II** Pedagogy Studies Stress Management for Yoga Personality Development through Life Enlightenment Skills	2	-	-	0
8.	21S07206	Seminar/Assignment	-	1	6	4
		Total	18	1	18	26

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COURSE STRUCTURE & SYLLABI
SEMSTER - III

S.No.	Course codes	Course Name	Hours per week			Credits
			L	T	P	
1.	21DRM101	Research Methodology and Intellectual Property Right	4	-	-	4
2.	 21SOE301d 21SOE301f 21SOE301e	**Open Electives** Biological Screening methods Stability of Drugs and Dosage forms Pharmacoepidemiology and Pharmacoeconomics	3	-	-	3
3.	21S07301	Teaching Practice/Assignment	-	-	4	2
4.	21S07302	Comprehensive viva voce	-	-	4	2
5.	21S07303	Research Work - I	-		24	12
		Total	7	-	32	23

SEMESTER - IV

S.No.	Course codes	Course Name	Hours per week			Credits
			L	T	P	
1.	21S07401	Co-Curricular Activities	2			2
2.	21S07402	Research Work - II	3		30	18
		Total	5		30	20

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COURSE STRUCTURE & SYLLABI

Course Code	MODERN PHARMACEUTICAL ANALYTICAL TECHNIQUES	L	T	P	C
21S01101		4	0	0	4
	Semester	**I**			

Course Objectives:

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 Outcomes (CO): Student will be able to

- Modern Analytical Techniques and can apply the theories in analysis of various drugs in single and combination dosage forms
- Theoretical and practical skills of the instruments
- Apply their knowledge in developing the new methods for the determination and validate the procedures.

UNIT - I

UV-Visible spectroscopy

Introduction, Theory, Laws, and Instrumentation associated with UV-Visible spectroscopy, Choice of solvents and solvent effect and Applications of UV-Visible spectroscopy, Difference/ Derivative spectroscopy.

UNIT - II

IR spectroscopy

Theory, Modes of Molecular vibrations, Sample handling, Instrumentation of Dispersive and Fourier -Transform IR Spectrometer, Factors affecting vibrational frequencies and Applications of IR spectroscopy, Data Interpretation.

UNIT - III

NMR spectroscopy

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

UNIT – IV

Mass Spectroscopy

Principle, Theory, Instrumentation of Mass Spectroscopy, Different types of ionization like electron impact, chemical, field, FAB and MALDI, APCI, ESI, APPI Analyzers of Quadrupole and Time of Flight, Mass fragmentation and its rules, Meta stable ions, Isotopic peaks and Applications of Mass spectroscopy.

UNIT – V

Chromatography

Introduction to chromatography and classification of chromatographic methods based on the mechanism of separation, Principle, instrumentation, selection of solvents; chromatographic parameters, factors affecting resolution, applications of the following:

a) Thin Layer chromatography; b) High Performance Thin Layer Chromatography
c) Paper Chromatography; d) Column chromatography
e) Gas chromatography; f) High Performance Liquid chromatography

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COURSE STRUCTURE & SYLLABI

g) Affinity chromatography; h) Gel Chromatography
i)Hyphenated techniques :

- Ultra High Performance Liquid chromatography- Mass spectroscopy
- Gas Chromatography-Mass Spectroscopy

Textbooks:

1. Instrumental Methods of Chemical Analysis by B.K Sharma
2. Vogel's Text book of Quantitative Chemical Analysis by A.I. Vogel
3. Textbook of Pharmaceutical Analysis, KA.Connors, 3rd Edition, John Wiley& Sons, 1982.

Reference Books:

4. Spectrometric Identification of Organic compounds - Robert M Silverstein, Sixth edition, John Wiley & Sons, 2004.
5. Principles of Instrumental Analysis - Doglas A Skoog, F. James Holler,T imothy A. Nieman, 5th edition, Eastern press, Bangalore, 1998.
6. Instrumental methods of analysis – Willards, 7th edition, CBS publishers.
7. Practical Pharmaceutical Chemistry – Beckett and Stenlake, Vol II, 4thedition, CBS Publishers, New Delhi, 1997.
8. Organic Spectroscopy - William Kemp, 3rd edition, ELBS, 1991.
9. Quantitative Analysis of Drugs in Pharmaceutical formulation - P D Sethi,3rd Edition, CBS Publishers, New Delhi, 1997.
10. Pharmaceutical Analysis - Modern Methods – Part B - J W Munson, Vol11, Marcel. Dekker Series
11. Spectroscopy of Organic Compounds, 2nd edn., P.S/Kalsi, Wiley esternLtd., Delhi.
12. Organic Chemistry by I. L. Finar
13. Quantitative Analysis of Drugs by D. C. Garrett
14. HPTLC by P.D. Seth
15. Indian Pharmacopoeia 2007
16. High Performance thin layer chromatography for the analysis of medicinal plants by Eike
17. Reich, Anne Schibli
18. Introduction to instrumental analysis by Robert. D. Braun

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COURSE STRUCTURE & SYLLABI

Course Code	ADVANCED PHARMACEUTICAL ANALYSIS	L	T	P	C
21S07101		4	0	0	4
	Semester	**I**			

Course Objectives:

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

Course Outcomes (CO): Student will be able to

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

UNIT - I

Impurity and stability studies

Definition, classification of impurities in drug Substance or Active Pharmaceutical Ingredients and quantification of impurities as per ICH guidelines Impurities in new drug products: Rationale for the reporting and control of degradation products, reporting degradation products content of batches, listing of degradation products in specifications, qualification of degradation products

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

UNIT - II

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

Stability testing protocols

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

UNIT – III

Impurity profiling and degradent characterization

Method development, Stability studies and concepts of validation accelerated stability testing & shelf life calculation, WHO and ICH stability testing guidelines, Stability zones, steps in development, practical considerations. Basics of impurity profiling and degradent characterization with special emphasis. Photo stability testing guidelines, ICH stability guidelines for biological products

UNIT – IV

Stability testing of phytopharmaceuticals

Regulatory requirements, protocols, HPTLC/HPLC finger printing, interactions and complexity.

Biological tests and assays of the following

Adsorbed Tetanus vaccine b. Adsorbed Diphtheria vaccine c. Human anti haemophilic vaccine d. Rabies vaccine e. Tetanus Anti toxin f. Tetanus Anti serum g. Oxytocin h. Heparin sodium IP i. Antivenom. PCR, PCR studies for gene regulation, instrumentation (Principle and Procedures)

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COURSE STRUCTURE & SYLLABI

UNIT – V		

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.

Reference Books:

1. Vogel's textbook of quantitative chemical analysis - Jeffery J Bassett, J.Mendham, R. C. Denney, 5th edition, ELBS, 1991.
2. Practical Pharmaceutical Chemistry - Beckett and Stenlake, Vol II, 4thEdition, CBS publishers, New Delhi, 1997.
3. Textbook of Pharmaceutical Analysis - K A Connors, 3rd Edition, John Wiley& Sons, 1982.102.
4. Pharmaceutical Analysis - Higuchi, Brochmman and Hassen, 2nd Edition, Wiley – Inter science Publication, 1961.
5. Quantitative Analysis of Drugs in Pharmaceutical formulation – P D Sethi,3rd Edition, CBS Publishers New Delhi, 1997.
6. Pharmaceutical Analysis- Modern methods - J W Munson – Part B, Volume 11, Marcel Dekker Series.
7. The Quantitative analysis of Drugs - D C Carratt, 3rd edition, CBS Publishers, New Delhi, 1964.
8. Indian Pharmacopoeia VolI , II & III 2007, 2010, 2014.
9. Methods of sampling and microbiological examination of water, first revision, BIS
10. Practical HPLC method development – Snyder, Kirkland, Glajch, 2ndedition, John Wiley & Sons.
11. Analytical Profiles of drug substances – Klaus Florey, Volume 1 – 20,Elsevier, 2005
12. Analytical Profiles of drug substances and Excipients – Harry G Brittan, Volume 21 – 30, Elsevier, 2005.
13. The analysis of drugs in biological fluids - Joseph Chamberlain, 2ndedition, CRC press, London.
14. ICH Guidelines for impurity profiles and stability studies.

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M.PHARM. PHARMACEUTICAL ANALYSIS

COURSE STRUCTURE & SYLLABI

Course Code	PHARMACEUTICAL AND FOOD ANALYSIS	L	T	P	C
21S07102		4	0	0	4
	Semester	**I**			

Course Objectives:

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 Outcomes (CO): Student will be able to

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

Carbohydrates
Classification and properties of food carbohydrates, General methods of analysis 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

UNIT - II

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

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

UNIT – III

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

UNIT – IV

Food additives
Introduction, analysis of Preservatives, antioxidants, artificial sweeteners, flavors, flavor enhancers, stabilizers, thickening and jelling agents.

Pigments and synthetic dyes
Natural pigments, their occurrence and characteristic properties, permitted synthetic dyes, Non-permitted synthetic dyes used by industries, Method of detection of natural, permitted and non-permitted dyes.

UNIT – V

Milk (constituents and milk products)
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.

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COURSE STRUCTURE & SYLLABI

- Pesticides Analysis in food like organophosphorus and organochlorine
- And also student shall have knowledge in food regulations and legislations

Textbooks:

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

Reference Books:

1. Indian Pharmacopoeia 2012
2. Remington's Pharmaceutical Sciences by Alfonso and Gennaro

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M.PHARM. PHARMACEUTICAL ANALYSIS

COURSE STRUCTURE & SYLLABI

Course Code	QUALITY CONTROL AND QUALITY ASSURANCE	L	T	P	C
21S07103		4	0	0	4
	Semester	**I**			

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 Outcomes (CO): Student will be able to

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

UNIT - I

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

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

UNIT - II

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

UNIT – III

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, parenterals, ophthalmic and surgical products (How to refer pharmacopoeias), Quality control test for containers, closures and secondary packing materials.

UNIT – IV

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.

UNIT – V

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.

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Reference Books:

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.
6. Good laboratory Practice Regulations – Allen F. Hirsch, Volume 38, Marcel Dekker Series, 1989.
7. ICH guidelines
8. ISO 9000 and total quality management
9. The drugs and cosmetics act 1940 – Deshpande, Nilesh Gandhi, 4thedition, Susmit Publishers, 2006.
10. QA Manual – D.H. Shah, 1st edition, Business Horizons, 2000.
11. Good Manufacturing Practices for Pharmaceuticals a plan for total quality control – Sidney H. Willig, Vol. 52, 3rd edition, Marcel Dekker Series.
12. 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.
13. Sarker DK. Quality Systems and Controls for Pharmaceuticals. John Wiley& Sons; 2008.

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COURSE STRUCTURE & SYLLABI

Course Code	MODERN PHARMACEUTICAL ANALYTICAL TECHNIQUES LAB	L	T	P	C
21S01105		0	0	6	3
	Semester	I			

List of Experiments

1. Analysis of Pharmacopoeial compounds and their formulations by UV Vis Spectrophotometer.
2. Simultaneous estimation of multi component containing formulations by UV Spectrophotometry
3. Effect of pH and solvent on UV –Spectrum
4. Determination of Molar absorption coefficient
5. Estimation of riboflavin/ quinine sulphate by fluorimetry
6. Study of quenching effect by fluorimetry
7. Estimation of sodium or potassium by flame photometry
8. Colorimetric determination of drugs by using different reagents
9. Qunatitative determination of functional groups
10. Experiments based on Column chromatography
11. Experiments based on HPLC
12. Experiments based on Gas Chromatography
13. Preparation of Master Formula Record.
14. Preparation of Batch Manufacturing Record.

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M.PHARM. IN PHARMACEUTICAL ANALYSIS

COURSE STRUCTURE & SYLLABI

Course Code	PHARMACEUTICAL AND FOOD ANALYSIS LAB	L	T	P	C
21S07104		0	0	6	3
	Semester	**I**			

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 in food
6. Determination of preservatives in food
7. Determination of pesticide residue in food products
8. Analysis of vitamin content in food products
9. Determination of density and specific gravity of foods
10. Determination of benzoic acid by titrimetric analysis in beverages/ sauces/ ketchup/ jam
11. Assay of any two Analgesic & Antipyretic drugs (API & dosage forms) official in IP
12. Assay of any two Antihistamines (API & dosage forms) official in IP
13. Assay of any two Diuretics (API & dosage forms) official in IP

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M.PHARM. PHARMACEUTICAL ANALYSIS

COURSE STRUCTURE & SYLLABI

Course Code	ADVANCED INSTRUMENTAL ANALYSIS		L	T	P	C
21S07201			4	0	0	4
Pre-requisite		Semester	II			

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 Outcomes (CO): Student will be able to

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

UNIT - I

HPLC

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

UNIT - II

Biochromatography

Size exclusion chromatography, ion exchange chromatography, ion pair chromatography, affinity chromatography general principles, stationary phases and mobile phases.

Gas chromatography: Principles, instrumentation, derivatization, head space sampling, columns for GC, detectors, quantification.

High performance Thin Layer chromatography

Principles, instrumentation, pharmaceutical applications.

UNIT – III

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.

UNIT – IV

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.

UNIT – V

NMR spectroscopy

Quantum numbers and their role in NMR, Principle, Instrumentation, Solvent requirement in NMR, Relaxation process, NMR signals in various compounds, Chemical shift, Factors influencing chemical shift, Spin-Spin coupling, Coupling constant, Nuclear magnetic double resonance, Brief

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COURSE STRUCTURE & SYLLABI

outline of principles of FT-NMR with reference to 13CNMR:Spin spin and spin lattice relaxation phenomenon. 13C NMR, 1-Dand 2-D NMR, NOESY and COSY techniques, Interpretation and Applications of NMR spectroscopy. LC-NMR hyphenations.

Reference Books:

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 Pharmaceutical formulations by HPTLC - P D Sethi, CBS Publishers, New Delhi.
6. Quantitative Analysis of Drugs in Pharmaceutical formulation - P D Sethi, 3rd Edition, CBS Publishers, New Delhi, 1997.
7. Pharmaceutical Analysis- Modern methods – Part B - J W Munson, Volume 11, Marcel Dekker Series.
8. Organic Spectroscopy by Donald L. Paviya, 5th Edition.

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COURSE STRUCTURE & SYLLABI

Course Code	MODERN BIO-ANALYTICAL TECHNIQUES	L	T	P	C
21S07202		4	0	0	4
	Semester	II			

Course Objectives:

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

Course Outcomes (CO): Student will be able to

- 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.

Bioanalytical method validation: USFDA and EMEA guidelines

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

Pharmacokinetics and Toxicokinetics:

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

UNIT – IV

Cell culture techniques

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

UNIT – V

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.

Reference Books:

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COURSE STRUCTURE & SYLLABI

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,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 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 LBertholf, Ruth E Winecker, John Wiley & Sons, New Jercy, 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

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COURSE STRUCTURE & SYLLABI

Course Code	PHARMACEUTICAL VALIDATION	L	T	P	C
21SOE301a		4	0	0	4
	Semester	II			

Course Objectives:

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 Outcomes (CO): Student will be able to

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

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 Equipments, 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

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

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

UNIT – V

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.

Reference Books:

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 Imtiaz Haider
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 byChurg Chan, Heiman Lam, Y.C. Lee, Yue. Zhang, Wiley Inter Science.

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M.PHARM. PHARMACEUTICAL ANALYSIS

COURSE STRUCTURE & SYLLABI

Course Code	HERBAL AND COSMETIC ANALYSIS	L	T	P	C
21S07203		4	0	0	4
	Semester	II			

Course Objectives:

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 equipments used in cosmetic industries for the purpose.

Course Outcomes (CO): Student will be able to

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

UNIT – I

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

UNIT – II

Adulteration and Deterioration:

Introduction, types of adulteration/substitution of herbal drugs, Causes and Measure of adulteration, Sampling Procedures, Determination of Foreign Matter, DNA Finger printing techniques in identification of drugs of natural origin, heavy metals, pesticide residues, phototoxin and microbial contamination in herbal formulations. Regulatory requirements for setting herbal drug industry: Global marketing management, Indian and international patent law as applicable herbal drugs and natural products and its protocol.

UNIT – III

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.

UNIT – IV

Herbal drug-drug interaction

General principles, Validation of analytical method as per ICH guidelines and USP.
Computerized system validation: Electronic records and digitalsignificance-21 CFR part 11 and GAMP.

UNIT – V

Evaluation of cosmetic products:

Determination of acid value, ester value, saponification value, iodine value, peroxide value, rancidity, moisture, ash, volatile matter, heavy metals, fineness of powder, density, viscosity of cosmetic raw materials and finished products. Study of quality of raw materials and general methods of analysis of raw material used in cosmetic manufacture as per BIS.
Indian Standard specification laid down for sampling and testing of various cosmetics in finished

forms such as baby care products, skin care products, dental products, personal hygiene preparations, lips sticks. Hair products and skin creams by the Bureau Indian Standards

Reference Books:

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 Imtiaz Haider
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.

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M.PHARM. PHARMACEUTICAL ANALYSIS

COURSE STRUCTURE & SYLLABI

Course Code	ADVANCED INSTRUMENTAL ANALYSIS LAB	L	T	P	C
21S07204		0	0	6	3
	Semester	II			

List of Experiments

1. Comparison of absorption spectra by UV and Wood ward – Fiesure rule
2. Interpretation of organic compounds by FT-IR
3. Interpretation of organic compounds by NMR
4. Interpretation of organic compounds by MS
5. Determination of purity by DSC in pharmaceuticals
6. Identification of organic compounds using FT-IR, NMR, CNMR and Mass spectra
7. Testing of related and foreign substances in drugs and raw materials
8. Assay of raw materials as per official monographs
9. Calibration of UV – Visible Spectrophtometer/ HPLC/ GC/ FTIR
10. Cleaning validation of any one analytical equipment

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COURSE STRUCTURE & SYLLABI

Course Code	MODERN BIO-ANALYTICAL TECHNIQUES LAB	L	T	P	C
21S07205		0	0	6	3
	Semester	II			

List of Experiments

1. Protocol preparation and performance of bioanalytical method validation
2. Protocol preparation for the conduct of BA/BE studies according to guidelines
3. Bio molecules separation utilizing various sample preparation techniques and Quantitative analysis of components by HPLC techniques
4. Isolation of analgesics from biological fluids (blood serum and urine)
5. Identification of anti-histaminics drug in urine by TLC
6. Extraction of drugs and metabolites from biological matrices by SPE/LLE
7. HPLC separation of modern drug from plasma and its formulations (Diclofenac)
8. Stability indicating method development by HPLC of any API
9. Bio molecules separation utilizing various sample preparation techniques and Quantitative analysis of components by gel electrophoresis
10. Quality control methods for herbal materials/ Medicinal plant materials

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M.PHARM. PHARMACEUTICAL ANALYSIS

COURSE STRUCTURE & SYLLABI

Course Code	RESEARCH METHODOLOGY AND	L	T	P	C
21DRM101	INTELLECTUAL PROPERTY RIGHTS	4	0	0	4
	Semester	**III**			

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 (CO): Student 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

Research Problem
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

Literature review
Effective literature studies approaches, analysis, Plagiarism, Research ethics.

UNIT – III

Report writing
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.

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COURSE STRUCTURE & SYLLABI

Textbooks:

1. Stuart Melville and Wayne Goddard, "Research methodology: an introduction for science & engineering students'"
2. Wayne Goddard and Stuart Melville, "Research Methodology: An Introduction"

Reference Books:

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 Technological Age", 2016.
7. T. Ramappa, "Intellectual Property Rights Under WTO", S. Chand, 2008

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M.PHARM. PHARMACEUTICAL ANALYSIS

COURSE STRUCTURE & SYLLABI

AUDIT COURSE-I

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COURSE STRUCTURE & SYLLABI

Course Code	ENGLISH FOR RESEARCH PAPER WRITING	L	T	P	C
21DAC101a		2	0	0	0
	Semester	I			

Course Objectives: This course will enable students:

- Understand the essentials of writing skills and their level of readability
- Learn about what to write in each section
- Ensure qualitative presentation with linguistic accuracy

Course Outcomes (CO): Student will be able to

- Understand the significance of writing skills and the level of readability
- Analyze and write title, abstract, different sections in research paper
- Develop the skills needed while writing a research paper

UNIT - I		Lecture Hrs:10

1Overview of a Research Paper- Planning and Preparation- Word Order- Useful Phrases - Breaking up Long Sentences-Structuring Paragraphs and Sentences-Being Concise and Removing Redundancy -Avoiding Ambiguity

UNIT - II		Lecture Hrs:10

Essential Components of a Research Paper- Abstracts- Building Hypothesis-Research Problem - Highlight Findings- Hedging and Criticizing, Paraphrasing and Plagiarism, Cauterization

UNIT - III		Lecture Hrs:10

Introducing Review of the Literature – Methodology - Analysis of the Data-Findings - Discussion-Conclusions-Recommendations.

UNIT - IV		Lecture Hrs:9

Key skills needed for writing a Title, Abstract, and Introduction

UNIT - V		Lecture Hrs:9

Appropriate language to formulate Methodology, incorporate Results, put forth Arguments and draw Conclusions

Suggested Reading

1. Goldbort R (2006) Writing for Science, Yale University Press (available on Google Books) Model Curriculum of Engineering & Technology PG Courses [Volume-I]
2. Day R (2006) How to Write and Publish a Scientific Paper, Cambridge University Press
3. Highman N (1998), Handbook of Writing for the Mathematical Sciences, SIAM. Highman'sbook
4. Adrian Wallwork , English for Writing Research Papers, Springer New York Dordrecht Heidelberg London, 2011

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COURSE STRUCTURE & SYLLABI

Course Code	DISASTER MANAGEMENT	L	T	P	C
21DAC101b		2	0	0	0
	Semester	**I**			

Course Objectives: This course will enable students:

- Learn to demonstrate critical understanding of key concepts in disaster risk reduction and humanitarian response.
- Critically evaluatedisasterriskreduction and humanitarian response policy and practice from Multiple perspectives.
- Developanunderstandingofstandardsofhumanitarianresponseandpracticalrelevanceinspecific types of disasters and conflict situations
- Criticallyunderstandthestrengthsandweaknessesofdisastermanagementapproaches,planningand programming in different countries, particularly their home country or the countries they work in

UNIT - I

Introduction:
Disaster:Definition,FactorsandSignificance;DifferenceBetweenHazardandDisaster;Naturaland Manmade Disasters: Difference, Nature, Types and Magnitude.

Disaster Prone Areas in India:
Study of Seismic Zones; Areas Prone to Floods and Droughts, Landslides and Avalanches; Areas Prone to Cyclonic and Coastal Hazards with Special Reference to Tsunami; Post- Disaster Diseases and Epidemics

UNIT - II

Repercussions of Disasters and Hazards:
Economic Damage, Loss of Human and Animal Life, Destruction of Ecosystem. Natural Disasters: Earthquakes,Volcanisms,Cyclones,Tsunamis,Floods,DroughtsandFamines,Landslides and Avalanches, Man-made disaster: Nuclear Reactor Meltdown, Industrial Accidents, Oil Slicks and Spills, Outbreaks of Disease and Epidemics, War and Conflicts.

UNIT - III

Disaster Preparedness and Management:
Preparedness: Monitoring of Phenomena Triggering ADisasteror Hazard; Evaluation of Risk: Application of Remote Sensing, Data from Meteorological and Other Agencies, Media Reports: Governmental and Community Preparedness.

UNIT - IV

Risk Assessment Disaster Risk:
Concept and Elements, Disaster Risk Reduction, Global and National Disaster Risk Situation. TechniquesofRiskAssessment,GlobalCo-OperationinRiskAssessmentand Warning, People's Participation in Risk Assessment. Strategies for Survival.

UNIT - V

Disaster Mitigation:
Meaning,ConceptandStrategiesofDisasterMitigation,EmergingTrendsInMitigation.Structural Mitigationand Non-Structural Mitigation, Programs of Disaster Mitigation in India.

Suggested Reading

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COURSE STRUCTURE & SYLLABI

1. R.Nishith,SinghAK,"DisasterManagementinIndia:Perspectives,issuesandstrategies
2. "'New Royal book Company..Sahni,PardeepEt.Al.(Eds.),"DisasterMitigationExperiencesAndReflections",PrenticeHall OfIndia, New Delhi.
3. GoelS.L.,DisasterAdministrationAndManagementTextAndCaseStudies",Deep&Deep Publication Pvt. Ltd., New Delhi

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M.PHARM. PHARMACEUTICAL ANALYSIS

COURSE STRUCTURE & SYLLABI

Course Code	SANSKRITFOR TECHNICAL KNOWLEDGE	L	T	P	C
21DAC101c		2	0	0	0
	Semester	**I**			

Course Objectives: This course will enable students:

- To get a working knowledge in illustrious Sanskrit, the scientific language in the world
- Learning of Sanskrit to improve brain functioning
- LearningofSanskrittodevelopthelogicinmathematics,science&othersubjects enhancing the memory power
- The engineering scholars equipped with Sanskrit will be able to explore the huge
- Knowledge from ancientliterature

Course Outcomes (CO): Student will be able to

- Understanding basic Sanskrit language
- Ancient Sanskrit literature about science &technology can be understood
- Being a logical language will help to develop logic in students

UNIT - I		
Alphabets in Sanskrit,		
UNIT - II		
Past/Present/Future Tense, Simple Sentences		
UNIT - III		
Order, Introduction of roots		
UNIT - IV		
Technical information about Sanskrit Literature		
UNIT - V		
Technical concepts of Engineering-Electrical, Mechanical, Architecture, Mathematics		

Suggested Reading

1.“Abhyaspustakam” –Dr.Vishwas, Sanskrit-Bharti Publication, New Delhi
2.“Teach Yourself Sanskrit” Prathama Deeksha- VempatiKutumbshastri, RashtriyaSanskrit Sansthanam, New Delhi Publication
3.“India’s Glorious ScientificTradition” Suresh Soni, Ocean books (P) Ltd.,New Delhi

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M.PHARM. IN PHARMACEUTICAL ANALYSIS

COURSE STRUCTURE & SYLLABI

AUDIT COURSE-II

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COURSE STRUCTURE & SYLLABI

Course Code	PEDAGOGY STUDIES	L	T	P	C
21DAC201a		2	0	0	0
	Semester	**II**			

Course Objectives: This course will enable students:

- Reviewexistingevidenceonthereviewtopictoinformprogrammedesignandpolicy making undertaken by the DfID, other agencies and researchers.
- Identify critical evidence gaps to guide the development.

Course Outcomes (CO): Student will be able to

Students will be able to understand:

- Whatpedagogicalpracticesarebeingusedbyteachersinformalandinformalclassrooms in developing countries?
- What is the evidence on the effectiveness of these pedagogical practices, in what conditions, and with what population of learners?
- Howcanteachereducation(curriculumandpracticum)andtheschoolcurriculumand guidance materials best support effective pedagogy?

UNIT - I

Introduction and Methodology: Aims and rationale, Policy back ground, Conceptual frame work and terminology Theories oflearning,Curriculum,Teachereducation.Conceptualframework,Research questions**.** Overview of methodology and Searching.

UNIT - II

Thematic overview: Pedagogical practices are being used by teachers in formal and informal classrooms in developing countries. Curriculum, Teacher education.

UNIT - III

Evidence on theeffectivenessofpedagogicalpractices,Methodologyfortheindepthstage:quality assessmen t of included studies. How can teacher education (curriculumandpracticum) andthescho curriculum and guidance materials best support effective pedagogy? Theory of change. Strength and nature of th body of evidence for effective pedagogical practices. Pedagogic theory and pedagogical approaches. Teachers' attitudes and beliefs and Pedagogic strategies.

UNIT - IV

Professional development: alignment with classroom practices and follow-up support, Peer support, Support from the head teacherandthecommunity.Curriculumandassessment,Barrierstolearning:limitedresourcesand large class sizes

UNIT - V

Researchgapsandfuturedirections: Researchdesign**,**Contexts**,**Pedagogy**,**Teachereducation**,** Curriculum and assessment**,** Dissemination and research impact.

Suggested Reading

1. AckersJ,HardmanF(2001)ClassroominteractioninKenyanprimaryschools,Compare, 31 (2): 245-261.
2. AgrawalM(2004)Curricularreforminschools:Theimportanceofevaluation,Journalof

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3. Curriculum Studies, 36 (3): 361-379.
4. AkyeampongK(2003) Teacher training in Ghana - does it count? Multi-site teachereducation research project (MUSTER) country report 1. London: DFID.
5. Akyeampong K, LussierK, PryorJ, Westbrook J (2013)Improving teaching and learning of basic maths and reading in Africa: Does teacherpreparation count?International Journal Educational Development, 33 (3): 272–282.
6. Alexander RJ(2001) Culture and pedagogy: International comparisons in primary education. Oxford and Boston: Blackwell.
   Chavan M (2003)ReadIndia: A mass scale, rapid, ‘learning to read’campaign.
7. www.pratham.org/images/resource%20working%20paper%202.pdf.

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COURSE STRUCTURE & SYLLABI

Course Code	**STRESSMANAGEMENT BY YOGA**	**L**	**T**	**P**	**C**
21DAC201b		**2**	**0**	**0**	**0**
	Semester	**II**			

Course Objectives: This course will enable students:

- To achieve overall health of body and mind
- To overcome stres

Course Outcomes (CO): Student will be able to

- Develop healthy mind in a healthy body thus improving social health also
- Improve efficiency

UNIT - I		
Definitions of Eight parts of yog.(Ashtanga)		
UNIT - II		
Yam and Niyam.		
UNIT - III		
Do`sand Don't'sin life. i) Ahinsa,satya,astheya,bramhacharyaand aparigrahaii) Shaucha,santosh,tapa,swadhyay,ishwarpranidhan		
UNIT - IV		
Asan and Pranayam		
UNIT - V		
i)Variousyogposesand theirbenefitsformind &body ii)Regularizationofbreathingtechniques and its effects-Types ofpranayam		

Suggested Reading

1.'Yogic Asanas forGroupTarining-Part-I": Janardan SwamiYogabhyasiMandal, Nagpur
2."Rajayogaor conquering the Internal Nature" by Swami Vivekananda, Advaita Ashrama (Publication Department), Kolkata

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COURSE STRUCTURE & SYLLABI

Course Code	PERSONALITY DEVELOPMENT THROUGHLIFE ENLIGHTENMENTSKILLS	L	T	P	C
21DAC201c		2	0	0	0
	Semester	**II**			

Course Objectives: This course will enable students:

- To learn to achieve the highest goal happily
- To become a person with stable mind, pleasing personality and determination
- To awaken wisdom in students

Course Outcomes (CO): Student will be able to

- StudyofShrimad-Bhagwad-Geetawillhelpthestudentindevelopinghispersonalityand achieve the highest goal in life
- The person who has studied Geetawilllead the nation and mankind to peace and prosperity
- Study of Neetishatakam will help in developing versatile personality of students

UNIT - I

Neetisatakam- Holistic development of personality
Verses-19,20,21,22(wisdom)
Verses-29,31,32(pride &heroism)
Verses-26,28,63,65(virtue)

UNIT - II

Neetisatakam- Holistic development of personality
Verses-52,53,59(dont's)
Verses-71,73,75,78(do's)

UNIT - III

Approach to day to day work and duties.
ShrimadBhagwadGeeta:Chapter2-Verses41,47,48,
Chapter3-Verses13,21,27,35,Chapter6-Verses5,13,17,23,35,
Chapter18-Verses45,46,48.

UNIT - IV

Statements of basic knowledge.
ShrimadBhagwadGeeta:Chapter2-Verses 56,62,68
Chapter12 -Verses13,14,15,16,17,18
Personality of Rolemodel. Shrimad Bhagwad Geeta:

UNIT - V

Chapter2-Verses 17,Chapter3-Verses36,37,42,
Chapter4-Verses18,38,39
Chapter18– Verses37,38,63

Suggested Reading

1."SrimadBhagavadGita"bySwamiSwarupanandaAdvaitaAshram(PublicationDepartment), Kolkata
2.Bhartrihari'sThree Satakam (Niti-sringar-vairagya) by P.Gopinath, RashtriyaSanskrit Sansthanam, New Delhi.

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OPEN ELECTIVE

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COURSE STRUCTURE & SYLLABI

Course Code	BIOLOGICAL SCREENING METHODS	L	T	P	C
21SOE301d	(Elective)	3	0	0	3
	Semester	III			

Course Objectives:

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 Outcomes (CO): Student will be able to know

- How to handle animals
- About various techniques for screening of drugs for different pharmacological activities
- Guidelines and regulations for screening new drug molecules on animals.

UNIT – I

Drug discovery process:
Principles, techniques and strategies used in new drug discovery. High throughput screening, human genomics, robotics and economics of drug discovery, Regulations. Alternatives to animal screening procedures, cell-line, patch –clamp technique, In-vitro models, molecular biology techniques.

UNIT – II

Bioassays:
Basic principles of bioassays, official bioassays, experimental models and statistical designs employed in biological standardization.

UNIT – III

Toxicity Evaluations
Principles of toxicity evaluations, ED50, LD50 and TD values, International guidelines (ICH recommendations).
Preclinical studies: General principles and procedures involved in acute, sub-acute, chronic, teratogenicity, mutagenicity and carcinogenicity.

UNIT – IV

Screening of drugs
Screening of different classes of drugs using micro-organisms. Vitamin and antibiotic assays.
Screening methods involved in toxins and pathogens.

UNIT – V

Enzymatic screening methods
α-glucosidase, α- amylase, DNA polymerase, nucleases, L-asparginase, lipases and peptidases.

Reference Books:

1. Basic and clinical pharmacology by Bertram G. Katzung (International edition) lange medical book / Mc Graw Hill, USA 2001 8th edition
2. Pharmacology by Rang H.P, Dale MM and Ritter JM., Churchill Livingston, London, 4/e
3. Goodman and Gilman's The pharmacological basis of therapeutics (International edition) Mc Graw Hill, USA 2001 10th edition.
4. General and applid toxicology by B.Ballantyne, T.Marrs, P.Turner (Eds) The Mc Millan press Ltd, London.
5. Drug Discovery by Vogel's
6. Drug Discovery and evaluation – Pharmacological assays by H.Gerhard.Vogel, 2nd edition, Springer verlag, Berlin, Heidelberg.
7. Tutorial Pharmacy (Vol I and II) by Cooper and Gunns.

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COURSE STRUCTURE & SYLLABI

Course Code	STABILITY OF DRUGS AND DOSAGE FORMS	L	T	P	C
21SOE301f	(Elective)	3	0	0	3
	Semester	III			

Course Objectives:

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 Outcomes (CO): Student will be able to

- Evaluation of stability of solutions, solids and formulations against adverse conditions.
- Suggest the measures to retain stability and storage conditions for retaining the efficacy of the products.

UNIT – I

Drug decomposition mechanisms

1. Hydrolysis and acyl transfers: 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 Eye shadows. 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.

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b) Interaction of containers & closure Compatibility Testing.

Reference Books:

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

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COURSE STRUCTURE & SYLLABI

Course Code	PHARMACOEPIDEMIOLOGY &	L	T	P	C
21SOE301e	PHARMACOECONOMICS (Elective-I)	3	0	0	3
	Semester	III			

Course Objectives:

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 Outcomes (CO): Student will 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).

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UNIT – V		

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

Reference Books:

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