**JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY ANANTAPUR**

**Course Structure and Syllabi for M.Pharm-Pharmaceutical Analysis & Quality Control**

**(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 | 17S07103 | Food Analysis | 4 | - | - | 4 |
| 4 | 17S04103 | Audit and Regulatory Compliance | 4 | - | - | 4 |
| **5** | **17S07104** | **Modern Pharmaceutical Analytical Techniques Practical** | **-** | **-** | **6** | **3** |
| **6** | **17S04206** | **Food Analysis Practical** | **-** | **-** | **6** | **3** |
| 7 | 17S12101 | 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** | **17S12201** | **Herbal And Cosmetic Analysis Practical** | **-** | **-** | **6** | **3** |
| **6** | **17S12202** | **Advanced Instrumental Analysis Practical** | **-** | **-** | **6** | **3** |
| 7 | 17S12203 | 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. | 17S12301 | Journal Club | 1 | - | - | 1 |
| 3. | 17S12302 | Teaching Assignment | 10 | - | - | 2 |
| 4. | 17S12303 | Comprehensive viva voce | - | - | - | 2 |
| 5. | 17S12304 | Discussion / Presentation (Proposal presentation) | - | - | 2 | 2 |
| 6. | 17S12305 | Research Work | - | - | 28 | 14 |
| Total | | | 15 | - | 30 | 25 |

**IV SEMESTER**

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| S.No | Subject Code | Subject | L | T | P | C |
| 1. | 17S12401 | Journal Club | 1 | - | - | 1 |
| 2. | 17S12402 | Research work | 31 | - | - | 16 |
| 3. | 17S12403 | Discussion/ Final Presentation | 3 | - | - | 3 |
| Total | | | 35 | - | - | 20 |

**JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY ANANTAPUR**

**M. Pharm – I year I Sem. (PA & QC) L T P C**

**4 0 0 4**

**(17S01101) MODERN PHARMACEUTICAL ANALYTICAL TECHNIQUES**

Scope

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

Objectives

After completion of course student is able to know,

* 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.

1. 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.

1. 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

1. 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. (PA & QC) 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 phytopharmaceuticals andtheir 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 perICH guidelinesImpurities 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

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

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.

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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, 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 – I year I Sem. (PA & QC) L T P C**

**4 0 0 4**

**(17S07103) FOOD ANALYSIS**

Scope

This course is designed to impart knowledge on analysis of food constituentsand finished food products. The course includes application of instrumentalanalysis in the determination of pesticides in variety of food products.

Objectives

At completion of this course student shall be able to understand variousanalytical 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. (PA & QC) L T P C**

**4 0 0 4**

**(17S04103) AUDITS AND REGULATORY COMPLIANCE**

Scope

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

Objectives

Upon completion of this course the student should be able to

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

THEORY 60 Hrs

1. 12Hrs

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

2 12Hrs

Role of quality systems and audits in pharmaceuticalmanufacturing environment: cGMP Regulations, Qualityassurance functions, Quality systems approach, Managementresponsibilities, Resource, Manufacturing operations, Evaluationactivities, Transitioning to quality system approach, Audit checklistfor drug industries.

3 12Hrs

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

4 12Hrs

Auditing of Microbiological laboratory: Auditing themanufacturing process, Product and process information, Generalareas of interest in the building raw materials, Water, Packagingmaterials.

5 12Hrs

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

**REFERENCES**

1. Compliance auditing for Pharmaceutical Manufacturers. Karen Ginsburyand Gil Bismuth, Interpharm/CRC, Boca Raton, London New York,Washington D.C.

2. Pharmaceutical Manufacturing Handbook, Regulations and Quality byShayne Cox Gad. Wiley-Interscience, A John Wiley and sons, Inc.,Publications.

3. Handbook of microbiological Quality control. Rosamund M. Baird, NormanA. Hodges, Stephen P. Denyar. CRC Press. 2000.

4. Laboratory auditing for quality and regulatory compliance. Donald C.Singer, Raluca-loana Stefan, Jacobus F. Van Staden. Taylor and Francis(2005).

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**M. Pharm – I year I Sem. (PA & QC) 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. (PA & QC) 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. (PA & QC) 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 DSethi, 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. (PA & QC) 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,Relative and 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, 2ndEdition, John Wiley & Sons, New Jercy. USA.

6. Chromatographic Analysis of Pharmaceuticals – John A Adamovics, 2ndEdition, 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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**M. Pharm – I year II Sem. (PA & QC) 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 regulatoryaffairs.

Objectives

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

* The cGMPaspects in a pharmaceutical industry
* To appreciate the importance of documentation
* To understand the scope of quality certifications applicable toPharmaceutical 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.

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**M. Pharm – I year II Sem. (PA & QC) 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 better understanding 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 vs Conventional drugs, Efficacy of herbal medicine products, Validation of Herbal Therapies, Pharmacodynamic and Pharmacokinetic issues. Herbal drug standardization: WHO and AYUSH guidelines.

2 12Hrs

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, 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 its protocol.

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. (PA & QC) L T P C**

**0 0 6 3**

**(17S12201) HERBAL AND COSMETIC ANALYSIS PRACTICAL**

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

**JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY ANANTAPUR**

**M. Pharm – I year II Sem. (PA & QC) L T P C**

**0 0 6 3**

**(17S12202) ADVANCED INSTRUMENTAL ANALYSIS PRACTICAL**

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/Bioanalytical methodvalidation.

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.

**JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY ANANTAPUR**

**M. Pharm – III Sem. (PA & QC) 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, Correlationcoefficient, regression), non-parametric tests (wilcoxan rank tests, analysis ofvariance, 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.

References

1. *C.R.Kothari* “*Research Methodology Methods & Techniques”, Second Edition, New Delhi: New Age International publisher*
2. *Pharmaceutical Statistics 5th edition by Sanford Bolton and Charles Bon.*
3. *Biostatistics by R.S. Shukla and P.S.Chandel-S.Chand.*
4. *Guidelines On The Regulation Of Scientific Experiments On Animals; Government of India June 2007*, <https://www.aaalac.org/resources/SOP_CPCSEA.pdf>.
5. *WMA Declaration of Helsinki - Ethical Principles for Medical Research Involving Human Subjects:* [*http://anesthesia.gr/wp-content/uploads/2012/01/Decleration-of-Helsinki.pdf*](http://anesthesia.gr/wp-content/uploads/2012/01/Decleration-of-Helsinki.pdf)*.*
6. *Garrett et. al., Health Care Ethics. Prentice Hall, 2nd Edition, 1993,*