JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD

(Established by an Act No.30 of 2008 of A.P. State Legislature)

Kukatpally, Hyderabad – 500 085, Andhra Pradesh (India)

M. PHARM. (PHARMACEUTICAL ANALYSIS AND QUALITY ASSURANCE/ QUALITY ASSURANCE) PAQA/QA

COURSE STRUCTURE AND SYLLABUS

I Year I Semester

Code	Group	Subject	L	P	Credits
		Modern Pharmaceutical Analytical Techniques	3	0	3
		Advanced Biostatistics and Research Methods	3	0	3
		Advanced Pharmaceutical Analysis - I	3	0	3
		Instrumental Methods of Pharmaceutical Analysis	3	0	3
		Quality Control of Bulk Drugs and Formulations	3	0	3
	Lab	Modern Pharmaceutical Analytical Techniques Lab	0	3	2
	Lab	Advanced Pharmaceutical Analysis - I Lab	0	3	2
		Seminar	0	0	2
		Total Credits	15	6	21

I Year II Semester

Code	Group	Subject	L	P	Credits
		Intellectual Property Rights and Drug Regulatory Affairs	3	0	3
		Pharmacological Screening Methods and Clinical Research	3	0	3
		Advanced Pharmaceutical Analysis -II	3	0	3
		Quality Assurance	3	0	3
		Pharmaceutical Product Development and Management	3	0	3
	Lab	Advanced Pharmaceutical Analysis - II Lab	0	3	2
	Lab	Pharmaceutical Product Development and Management Lab	0	3	2
		Seminar	0	0	2
		Total Credits	15	6	21

II Year - I Semester

Code	Group	Subject	L	P	Credits
		Comprehensive Viva	0	0	2
		Project Seminar	0	3	2
		Project work	0	0	18
		Total Credits	0	3	22

II Year - II Semester

Code	Group	Subject	L	P	Credits
		Project work and Seminar	0	0	22
		Total Credits	0	0	22

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I Year – I Sem M.Pharm (PAQA/QA)

MODERN PHARMACEUTICAL ANALYTICAL TECHNIQUES

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

UNIT I

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

a. Column Chromatography: Adsorption and partition, theory, preparation, procedure and methods of detection

b. Thin Layer Chromatography: Theory, preparation, procedures, detection of compounds

c. Paper Chromatography: Theory, different techniques employed, filter papers used, qualitative and quantitative detection

d.Counter – current extraction, solid phase extraction techniques, gel filtration

UNIT II

a. Gas chromatography: Introduction, fundamentals, instrumentation, columns: preparation and operation, detection, dramatization.

b. HPLC: Principles and instrumentation, solvents and columns used, detection and applications

c. HPTLC: Theory and principle, instrumentation, elution techniques and pharmaceutical applications

UNIT III

a. UV-Visible spectroscopy: Introduction, electromagnetic spectrum, absorbance laws and limitations, instrumentation-design and working principle, chromophore concept, auxochromes, Wood-Fisher rules for calculating absorption maximum, applications of UV-Visible spectroscopy

b. IR spectroscopy: Basic principles-Molecular vibrations, vibrational frequency, factors influencing vibrational frequencies, sampling techniques, instrumentation, interpretation of spectra, FT-IR, theory and applications

UNIT IV

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

UNIT V

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

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

Recommended/ Reference books

1) Instrumental Methods of Chemical Analysis by B.K Sharma
2) Organic spectroscopy by Y.R Sharma
3) A Text book of Pharmaceutical Analysis by Kerrenth A. Connors
4) Vogel's Text book of Quantitative Chemical Analysis by A.I. Vogel
5) Practical Pharmaceutical Chemistry by A.H. Beckett and J.B. Stenlake
6) Organic Chemistry by I. L. Finar
7) Organic spectroscopy by William Kemp
8) Quantitative Analysis of Drugs by D. C. Garrett
9) Quantitative Analysis of Drugs in Pharmaceutical Formulations by P. D. Sethi
10) Spectrophotometric identification of Organic Compounds by Silverstein
11) HPTLC by P.D. Seth
12) Indian Pharmacopoeia, 2010.
13) High Performance thin layer chromatography for the analysis of medicinal plants by Eike Reich, Anne Schibli
14) Introduction to instrumental analysis by Robert. D. Braun

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I Year – I Sem M.Pharm (PAQA/QA)

ADVANCED BIOSTATISTICS AND RESEARCH METHODS

Objective: The student shall know the introduction, scope of biostatistics and Research work, calculation and present of all data. It also informs the students, how the present research work writing and correlating.

UNIT I

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

UNIT II

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

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

UNIT III

Measures of Correlation and Regression: Experimental designing, planning of an experiment, replication and randomization. Probit analysis.

Probability rules: Binomial, Poison and Normal distribution.

Hypothesis testing: Student't' test, Chi square test, Analysis of Variance (ANOVA): 1-way, 2-way, 3-ways

UNIT IV

Developing a research question, Resources for research question,
Literature Review: Traditional Qualitative Review,
Meta-Analysis—A Quantitative Review
Preparation of Research Proposal
Variables—Definition of Variable, Types of variables (Dependent and Independent variables, Confounded variables), Measurement of variables, Types of measurement scales and their comparison. Reliability and Validity of Measurements.

UNIT V

The research report paper writing/ thesis writing
Different parts of the research paper

1. Title-Title of project with authors' name
2. Abstract – Statement of the problem, Background list in brief and purpose and scope
3. Key words
4. Methodology- subject, apparatus, instrumentation and procedure
5. Results – tables, graphs figure and statistical presentation
6. Discussion support or non support of hypothesis, practical and theoretical implications
7. Conclusion
8. Acknowledgements
9. References
10. Errata

11. Importance of Spell check for entire projects
12. Uses of footnotes

Outcome: The student will be known the Biostatistics arrangement, presentation and formation of tables and charts. They also know the correlation and regression & application of different methods, analysis of data and also learn how to write dissertation, thesis and Research paper.

Text Books

1.Deepak Chawla Neena Sondhi, Research Methodology Concepts and Cases, Vikas books publishers
2.Donald H. McBurney -Theresa L. White "Research Methods" (Cengage learning India Pvt. Ltd)

Reference Books

1. Remington"s Pharmaceutical Sciences
2. Theory & Practice of Industrial Pharmacy by Lachman
3. Statistics for business and economics 3rd edition by Vikas books publications
4. Biostatistics & Computer applications by GN Rao and NK Tiwari
5. Sokal, R.R. and Rohlf, F.J. 1987. An Introduction to Biostatistics. W.H. Freeman and Company.
6. Bailey, N.T.J. 1981. Statistical Methods in Biology. English University Press.
7. Mitchell, K. and Glover, T. 2001. Introduction to Biostatistics. McGraw Hill, Publishing Co.
8. Biostatistics and Computer Applications by G.N. Rao and N.K. Tiwari
9. Fundamentals of Biostatistics by Khan and Khanum
10. Research Methodology by RK Khanna bis and Suvasis Saha
11. Research methods and Quantity methods by G.N.Rao
12. A practical approach to PG dissertation

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I Year – I Sem M.Pharm (PAQA/QA)

ADVANCED PHARMACEUTICAL ANALYSIS – I

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

UNIT I

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

A. Non-aqueous
B. Oxidation-reduction
C. Complexometric
D. Diazotization methods

UNIT II

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

A. Amines
B. Esters
C. Carbonyl compounds
D. Hydroxy and carboxyl

UNIT III

Principles and procedures involved in using the following reagents in the determination of pharmaceutical dosage forms official in IP

a. MBTH (3-methyl-2-benzothiazolone hydrazone)
b. F.C. Reagent (Folin-Ciocalteu)
c. PDAB (*para*-Dimethyl Amino Benzaldehyde)
d. 2, 3, 5 - *tri* Phenyltetrazolium salt
e. 2,6 *di* - Chloroquinone Chlorimide
f. *N* - (1-naphthyl) ethylenediamine dihydrochloride (B.M. Reagent)

UNIT IV

Principles and procedures involved in the quantitative determination of the various pharmaceutical preparations and dosage forms (IP) of the following

A. Alkaloids
B. Antibiotics
C. Glycosides
D. Vitamins

UNIT V

Principle and procedures involved in the quantitative determination of the various pharmaceutical preparations and dosage forms (IP) of the following

A. Analgesics & Antipyretics
B. Antihypertensives
C. Antihistamines
D. Diuretics

Outcome: The study of these principles shall enlighten the applicability of the same technique / reagent for the determination of the bulk drugs and their formulations belonging to the similar category.

Text Books

1.Pharmaceutical Chemistry by Becket and Stanlake
2.Pharmaceutical Analysis by Higuchi, Bechmman and Hassan
3.Instrumental Methods of Chemical Analysis By B.K. Sharma
4.A Text Book of Pharmaceutical Analysis by Kennenth A. Conners

References

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

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INSTRUMENTAL METHODS OF PHARMACEUTICAL ANALYSIS

Objective: This subject makes clear to learn how to handle and calibrate the highly sophisticated instruments used in the analysis of pharmaceutical substances (bulk drugs and their formulations). This also tells how to carry out the RIA and ELISA.

UNIT I

Study on handling, principle and procedure for the calibration of the following instruments

A. UV-Visible spectrophotometer
B. FT-IR spectrometer
C. Dissolution Test Apparatus
D. GC
E. HPLC
F. Fluorimeter

UNIT II

Principle, instrumentation and applications of the following spectroscopic methods

A. Atomic Absorption Spectroscopy
B. Atomic Emission Spectroscopy

UNIT III

Principle, instrumentation and applications of the following spectroscopic methods

A. NIR (Near Infra Red) Spectroscopy
B. Raman Spectroscopy
C. ESR (Electron Spin Resonance) Spectroscopy
D. Polarimetry

UNIT IV

Advanced Separation Techniques: Principle, instrumentation and applications of the following

A. UPLC (Ultra Performance Liquid Chromatography)
B. SFC (Super Critical Fluid Chromatography)
C. Capillary Electrophoresis

UNIT V

Electrophoresis: Principles, instrumentation and applications of moving boundary electrophoresis, zone electrophoresis (ZE), isotachphoresis, isoelectric focusing (IEF), continuous electrophoresis (preparative) and blotting techniques.

Principle, instrumentation, applications and limitations of Radio Immuno Assay (RIA) and ELISA

Outcome: The learning of this subject shall simplify the aspects of handling and calibrate the instruments. The students will also be in a position to involve in the community pharmacy aspects by gaining the skills of carrying out the Radio Immuno Assay (RIA) and ELISA.

Text books

1. Skoog, DA, Holler, FJ, Crouch, SR. Principles of Instrumental Analysis. 6th ed., Baba Barkha Nath Printers, Haryana, 2007.

2. Silverstein, RM, Webstar, FX. Spectrometric Identification of Organic Compounds. 6th ed., John Wiley & Sons (Asia) Pvt. Ltd., Singapore, 2005.
3. William Kemp. Organic spectroscopy, 3rd ed., Palgrave, New York, 2006.
4. Jag Mohan, Organic spectroscopy: Principles and Applications, 2nd ed., Narosa Publishing House Pvt Ltd., New Delhi, 2005.
5. Sharma BK. Instrumental Methods of Chemical Analysis, 25th Ed., Goel Publishing house, Meerut, 2006.

References books

1. Willard HH, Merritt LL, Dean JA, Settle FA. Instrumental Methods of Analysis, 7th ed., CBS Publishers & Distributors, New Delhi, 1986.
2. Pavia DL, Lampman GM, Kriz GS, Vyvyan JA. Introduction to Spectroscopy. 4th ed., Brookescole Publishers, California, 2008.
3. Ewing, GW. Instrumental Methods of Chemical Analysis, 5th ed., McGraw Hill Book Company, New York, 1985.
4. Schirmer, RE. Modem Methods of Pharmaceutical Analysis, Vol. I & II, 2nd ed., CRC Press, Florida, 2000.
5. Moffat, AC, Osselton, MC, Widdop, B. Clarke's Analysis of Drugs and Poisons, Vol. I & II, 3rd ed., K.M. Varghese Company, Mumbai, 2004.
6. Conners KA. A Text Book of Pharmaceutical Analysis, 3rd ed., John Wiley & Sons, Singapore, 2004.

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I Year – I Sem M.Pharm (PAQA/QA)

QUALITY CONTROL OF BULK DRUGS AND FORMULATIONS

Objective: The quality control aspects like in process quality control tests, impurity profiles, quality control of nutraceuticals and excipients.

UNIT I

Impurity Profiling of Pharmaceuticals: Sources of impurities, their effect on drug stability and therapeutic actions. Determination of impurities in bulk drugs and Formulations: Isolation, characterization and analytical methods.

UNIT II

In process quality control tests carried on the following dosage forms

A. Tablets B. Capsules C. Parenterals D. Liquid Orals

UNIT III

Quality Control of Excipients: Tests related to excipients such as bulk density, tapped density, particle size distribution, pH, moisture content, viscosity (dynamic), gelling temperature, swelling temperature, loss on drying, residue on ignition, conductivity, congealing range, readily carbonizable substances and readily oxidizable substances, melting point and melting range. Excipients of interest: disintegrating agents, binders, emulsifiers, viscosity modifiers and preservatives including preservative challenge test.

UNIT IV

Quality Control of Nutraceuticals: Vitamins (A, B_1, B_2, B_{12}, C, D, E and K), micro nutrients and health supplements including free radical scavengers.

UNIT V

Quality Control of Food Constituents: Carbohydrates, proteins and fats with emphasis in the determination of moisture, ash, nitrogen and physical constituents. Analytical methods for milk

Outcome: The quality aspects bulk drugs, excipients nutraceuticals etc. and their control is clearly understood. The precautions to be taken during the process of manufacturing the formulations are also learned.

Text books

1) Pharmaceutical Chemistry by Beckett and Stanlake
2) Quantitative Analysis of Drugs in Pharmaceutical Formulations by P.D.Sethi
3) Pharmaceutical Analysis by Higuchi, Bechmman and Hassan
4) Theory and Practice of Industrial Pharmacy by Lieberman and Lachman
5) Ahuja S, Alsante KM. Handbook of isolation and characterization of impurities in pharmaceuticals. Academic press, California, 2003

Reference books

1) Remington's Pharmaceutical Sciences by Alfonso and Gennaro
2) David Pearson. The Chemical Analysis of Foods, 7th ed., Churchill Livingstone, Edinburgh, 1976.
3) Nielsen S. Introduction to the chemical analysis of foods. Jones & Bartlett Publishers, Boston, 1974
4) Indian Pharmacopoeia 2012

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MODERN PHARMACEUTICAL ANALYTICAL TECHNIQUES LAB

List of experiments

1. Colorimetry / UV / Visible, Spectroscopy, scanning of few compounds for UV-absorption, calculation of Assay / content uniformity / % of drug release (2-3 experiments.)
2. Estimation of multi components formulation by UV of two different methods
3. Experiment base on HPLC (Isocratic and gradient) Techniques – (2 experiments)
4. Incompatibility studies, identification and functional groups – Determination by FTIR (2 experiments)
5. Separation and calculation of Rf values by using paper chromatography, TLC, HPTLC Technique (2-3 experiments)
6. Interpretation of spectra and structure determination of Mass Spectroscopy
7. Separation of protein drug substances by electrophoresis.
8. Workshop on IR and NMR interpretation
9. Development and evaluation of drugs by derivative spectroscopy.

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I Year – I Sem M.Pharm (PAQA/QA)

ADVANCED PHARMACEUTICAL ANALYSIS - I LAB

List of experiments

1. Determination of official compounds by Non-aqueous titrations
2. Determination of drugs containing di and trivalent metal ions by complexometric titrations
3. Determination of sulfa drugs by diazotization
4. Determination of Vitamin C by redox titration
5. Quantitative determination of hydroxy, carboxyl. amino and carbonyl groups present in drugs
6. Quantitative determination of suitable drugs using the reagents mentioned in Unit III
7. Quantitative determination of pharmaceutical dosage forms belonging to alkaloids, antibiotics, vitamins, glycosides and steroids

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I Year – II Sem M.Pharm (PAQA/QA)

INTELLECTUAL PROPERTY RIGHTS AND REGULATORY AFFAIRS

Objective: Various types of Intellectual Property Rights Patentable Subject History of Indian Patent Protection, Patent filing procedure in India, Opposition- pre-grant opposition and post-grant opposition, Patent filing procedure under PCT, advantages, patent search and literature and Salient features of Indian Patents are discussed in detail.

Intellectual Property Rights

UNIT I

Introduction, Types of Intellectual Property Rights (Patents, Trademarks, Copyrights, Geographical Indications Industrial Designs and Trade secrets), Patentable Subject Matter (Novelty, Non-Obviousness, Utility, enablement and Best mode),

UNIT II

a. History of Indian Patent Protection, Rationale behind Patent System, Objectives and Advantages of Patent System, and future challenges. Indian Patents Act 1970, Definitions and Key Terminology, Types of Patent applications, Inventions not patentable (section 3 and 4).
b. Patent filing procedure in India (Patent Prosecution), Specifications (Provisional and Complete), Claims- types of claims and legal importance of claims, Grant of patent, Rights of Patentee and co-owners
c. Opposition- pre-grant opposition and post-grant opposition, Anticipation, Infringement, Compulsory Licensing, revocation of patents, and power of Controller.
d. Patent filing procedure under PCT, advantages, patent search and literature

UNIT III

a**.** Salient features of Indian Patents (Amendments) Act 1999, 2002 and 2005. US and European Patent System,

b. Background, Salient Features and Impact of International Treaties / Conventions like

i. Paris Convention, Berne convention
ii. World Trade Organization (WTO)
iii. World Intellectual Property Organization (WIPO)
iv. Trade Related Aspects of Intellectual Property Rights (TRIPS)
v. Patent Co-operation Treaty (PCT), Mandrid Protocol

Regulatory Affairs

UNIT IV

a**.** National Drug Regulatory requirements, National Drug Policy, Drugs and Cosmetics Act and its amendments, overview of schedules, detail study of schedule M and Schedule Y.

b. USFDA, FDA guidelines on IND, NDA and ANDA approvals, and SUPAC changes and understanding on 505 (b) (2) applications

UNIT V

a**.** Requirement of GLP Guidance and recommendation on Dissolution and Bio-equivalence requirement. Types of ANDA filing (Para I, II, III, IV filing). Exclusivities (NCE, NS, NP, NDF, PED, ODE, PC)

b. ICH objectives and Guidelines- stability testing, WHO guidelines, ISOs- Production design, certification. ICH 8(QbD), ICH Q9 and ICHQ10.

Outcome: The clear information about the patent laws, intellectual property rights and drug regulation in India and abroad is gained by the students.

Recommended / Reference Books

1.Deepak Chawla Neena Sondhi, Research Methodology Concepts and Cases, Vikas books publishers
2. Draft manual of Patent Practice and Procedure -2008 , The Patent Office, India
3. Manual of Patent Office Practice and Procedure -2010
4. Original Laws Published by Govt. of India
5. Protection of Industrial Property rights by P.Das and Gokul Das
6. Law and Drugs, Law Publications by S.N. Katju
7. Laws of drugs in India, Hussain
8. New drug approval process,5th edition, by Guarino
9. Commercial Manual on Drugs and Cosmetics 2004, 2nd edition
10. Drugs and Cosmetics act by Vijay Malik
11. Good Manufacturing Practices for Pharmaceuticals, S.H. Wiling, Vol. 78, Marcel Decker.
12. fda.org,wipo.int,patentlawlinks.com, hc-sc.gc.ca,ich.org,cder.org
13. Drug regulatory affairs by C.V.S.Subramanyam
14. Current good manufacturing practices for pharmaceuticals by Manohar A.Potdar

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I Year – II Sem M.Pharm (PAQA/QA)

PHARMACOLOGICAL SCREENING METHODS AND CLINICAL RESEARCH

Objective:- The students is 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.

UNIT I

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

UNIT II

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

UNIT III

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

UNIT IV

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

UNIT V

Clinical evaluation of new drugs, Phases of clinical trial, protocol design, Ethics in human research.

Outcome: - The expected outcomes are student will know how to handle animals and know about various techniques for screening drugs for different pharmacological activities and guidelines and regulations for screening new drug molecules on animals and human volunteers.

Text Books:

1. Screening methods in Pharmacology, Vol.-1&2 by Robert .A. Turner and Peter Hebborn.
2. Drug discovery and evaluation by H.G.Vogel and W.H.Vogel, Springerverlag, Berlin Heideleberg.
3. Handbook of experimental pharmacology by S.K. Kulkarni, Vallabh Prakashan, Delhi.
4. Textbook of clinical trials edited by David Machin, Simon Day and Sylvan green.
5. Principles of clinical research edited by Giovanna di ignazio, Di Giovanna and Haynes

Reference Books:

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

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ADVANCED PHARMACEUTICAL ANALYSIS – II

Objective: Analysis of the presence of different elements present in pharmaceutical substances is discussed. The importance of the thermal analysis is also added for the discussion.

UNIT I

Concepts, principles and procedures of various instrumental methods like UV-Visible, HPLC & GC in the Method Development for the determination of bulk drugs and their formulations.

UNIT II

Analysis of the following elements
1.Sodium, Potassium & Calcium
2.Phosphorous & Sulphur
3.Chlorine, Bromine and Iodine

UNIT III

Advanced study of the principles and procedures involved in the instrumental methods of the following
1.Flamephotometry
2.Fluorimetry
3.Nephelo - Turbidimetry and Refractometry

UNIT IV

Thermal Methods of Analysis: Principles, instrumentation and applications of Thermogravimetric Analysis (TGA), Differential Thermal Analysis (DTA), Differential Scanning Calorimetry (DSC), and Thermo Mechanical Analysis (TMA).

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

UNIT V

Hyphenated Techniques: Principle, procedure and applications involved in the following
LC-MS & GC-MS
1. ICP-MS
2. Tandem Mass Spectrometry

Outcome: This enables the students to analyze the presence of the different elements present in the pharmaceutical substances.

Text books:

1) Remington's Pharmaceutical Sciences by Alfonso and Gennaro
2) Quantitative Analysis of Drugs in Pharmaceutical Formulations by P.D. Sethi
3) Pharmaceutical Analysis by Higuchi, Bechmman and Hassan
4) Instrumental Methods of Chemical Analysis By B.K. Sharma
5) A Text Book of Pharmaceutical Analysis by Kennenth A. Conners

6) Skoog, DA, Holler, FJ, Crouch, SR. Principles of instrumental analysis. 6th ed., Baba Barkha Nath Printers, Haryana, 2007

Reference books:

1) Willard HH, Merritt LL, Dean JA, Settle FA. Instrumental methods of analysis, 7th ed., CBS Publishers & Distributors, New Delhi, 1986
2) Quality Assurance of Pharmaceuticals (A Compendium of Guidelines and Selected Materials), Vol. I & II (Pharma. Book Syndicate, Book Street, Hyderabad)
3) Quantitative Chemical Analysis, Daniel C. Harris, 8th Edition, 2011
4) Indian Pharmacopoeia 2010
6) Journals like Indian Drugs, IJPS etc.

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I Year – II Sem M.Pharm (PAQA/QA)

QUALITY ASSURANCE

Objective: The concepts of quality assurance and validation, the aspects of quality in the organization, personnel and the controls in packaging as well as manufacturing are explained.

UNIT I

a. Concepts of Quality Assurance, Total Quality Management, Philosophy of GMP and cGMP
b. Preparation of audit, Conducting audit, Audit Analysis, Audit Report and Audit follow up

UNIT II

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

UNIT III

a. Concepts of Validation: Types of validation, Master plan, protocol for process validation, cleaning validation, validation of air handling, validation of equipment and facilities in sterile and non-sterile areas.
b. Prevalidation activities, Protocol preparation, Protocol execution, Deviations and change controls, summary and certification. Revalidation

UNIT IV

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

UNIT V

Manufacture and controls on dosage forms
a. Manufacturing documents, Master Formula, Batch Formula, Records, Standard Operating Procedures,
b. In process quality control on various dosage forms sterile and biological products, standard operating procedures for various operations like cleaning, filling drying, compression, coating, disinfection, sterilization, membrane filtration etc.
c. Guidelines for Quality Assurance of Human Blood Products and large volume parenterals.

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

Text Books

1. The International Pharmacopoeia Vol 1,2,3,4, 3rd edition General Methods of Analysis Quality Specifications for Pharmaceutical Substances, Excipients, Dosage Forms.
2. Quality Assurance of Pharmaceuticals. A Compendium of Guidelines and Related Material Vol. 1 and Vol. 2, WHO 2007)
3. GMP by Mehra
4. Pharmaceutical Process Validation by Berry and Nash
5. How to Practice GMP's – P.P. Sharma

References Books

1. Basic Tests for Pharmaceutical Substances - WHO (1991)
2. The Drugs and Cosmetic Act 1940 by Vijay Malik
3. Q.A. Manual by D.H. Shah
4. SOP Guidelines by D.H. Shah
5. Quality Assurance Guide by OPPI
6. Good Manufacturing-Practices for Pharmaceuticals, by Graham Bunn and Joseph 6th Ed. D. Nally (Dec 26, 2006)

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PHARMACEUTICAL PRODUCT DEVELOPMENT AND MANAGEMENT

Objective: The students shall know the molecular optimization of APIs, different physical preformulation parameters, drug excipients compatibility studies, degradation kinetics, solid state stability and shelf life. They also know the equipment design and their qualification, USFDA guidelines for GLP, silent features of ISO, NABL and also environment health and safety.

UNIT I

Preformulation Studies: Molecular optimization of APIs (drug substances), crystal morphology and variations, powder flow, structure modification, drug-excipient compatibility studies, methods of determination.

UNIT II

Product Stability: Degradation kinetics, mechanisms, stability testing of drugs and pharmaceuticals, factors influencing-media effects and pH effects, accelerated stability studies, interpretation of kinetic data (API & Formulations). Solid state stability and shelf-life assignment.

UNIT III

Detailed study on Equipment Design, Installation, Operational and Performance Qualification

UNIT IV

a. US FDA Guidelines for GLP in non-clinical testing laboratories (only salient features will be covered)

b. Organization & Functioning of Accreditation bodies- ISO-9000, ISO-14000, NABL and OSHA (ISO 18000)

UNIT V

a. Environment Health and Safety (EHS): Hazards- Fire, mechanical, chemical and pharmaceutical, monitoring and prevention systems, industrial effluents testing and treatment, control of environmental pollution

b. Ware housing –Design, construction, maintenance and sanitation for materials and products – good warehousing practices.

Outcome: students will have knowledge about preformulation studies, product stability, USFDA guidelines, environment health and safety and warehousing procedures.

Text books:

1. Ira R. Berry and R.A. Nash (eds) Pharmaceutical Process Validation, Marcel Dekker Inc, New York
2. Pharmaceutical Process Validation by Loftus and Nash..
3. Remington's Pharmaceutical Sciences, The science and practice of Pharmacy, 20th Edition, Vol. I&II,.
4. Quality Assurance of Pharmaceutical – A compendium of guidelines. – WHO publication..
5. Theory and practice of industrial practice of industrial pharmacy by Liberian and Lachman.

References:

1. GMP by Sidney Herbal, Willing.
2. Quality Assurance Guide Organization of Pharmaceutical products of India.
3. Drugs and Cosmetics Act 1969 and Rules 1945.
4. S.H. Willing M.M.T. Tuckerman, W.S. Hitchings IV, Good Manufacturing Practices for Pharmaceuticals, Marcel Decker Inc, M. New York.
5. P.P. Sharma, How to Practice GMP's Vandhana Publications, Agra
6. Lippincott Williams Wilkins, Philadelphia, 2000
7. Quality assurance guide supplied by Organization of Pharmaceutical procedure of India.
8. Basic tests for Pharmaceutical Substances, WHO, Geneva, All India traveler book seller, India, 1990.
9. Handbook of Environmental Health and Safety: Principles and Practices, Herman Koren, Michel S. Bisesi, National Environmental Health Association.

M. PHARM. (PAQA/ QA)-R13 Regulations

JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD

I Year – II Sem M.Pharm (PAQA/QA)

Advanced Pharmaceutical Analysis - II Lab

List of Experiments

1. Determination of bulk Drugs and formulations by UV-Visible, HPLC, GC etc. methods
2. Determination of total chloride in thiamine HCl
3. Detection and determination of preservatives, antioxidants and colourants in pharmaceutical preparations
4. Determination of chlorides and sulphates by Nephelo -Tubmidimetry
5. Determination of moisture content in sorbitol, sodium citrate, ampicillin etc.
6. Assays of official compounds by Flourimetry
7. Determination of compounds of sodium, potassium and calcium by Flame photometry.

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

M. PHARM. (PAQA/ QA)-R13 Regulations

JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD

I Year – II Sem M.Pharm (PAQA/QA)

Pharmaceutical Product Development and Management Lab

List of Experiments

1. Calibration of instruments like UV-Visible, FT-IR, HPLC, GC and Spectrofluorimeter
2. Identification of impurities and related substances in API
3. Determination of viscosity of the excipients and finished products using Brook Field'd Viscosity
4. Monograph analysis of Excipients, Bulk Drugs and Formulations as per IP 2010.
5. Preparation of protocols for analytical method validation

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