

JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD

M. Pharmacy (PHARMACEUTICAL ANALYSIS & QUALITY ASSURANCE) / (QUALITY ASSURANCE)

**COURSE STRUCTURE AND SYLLABUS
Effective from Academic Year 2017-18 Admitted Batch**

I Year – I Semester

Category	Course Title	Int. marks	Ext. marks	L	P	C
Core Course I	Advanced Pharmaceutical Analysis	25	75	4	--	4
Core Course II	Food Analysis	25	75	4	--	4
Core Course III	Modern Pharmaceutical Analytical Techniques	25	75	4	--	4
Core Elective I	1. Pharmaceutical Validation 2. Intellectual Property Rights	25	75	4	--	4
Open Elective I	1. Drug Regulatory Affairs 2. Pharmacoepidemiology and Pharmacoeconomics 3. Pharmaceutical Management 4. Herbal Cosmetics Technology 5. Pharmaceutical Formulation Technology	25	75	4	--	4
Laboratory I	Modern Pharmaceutical Analytical Techniques Lab	25	75	-	-6	3
Laboratory II	Advanced Pharmaceutical Analysis Lab	25	75	--	6	3
Seminar I	Seminar	50	--	--	4	2
Total Credits				20	16	28

I Year – II Semester

Category	Course Title	Int. marks	Ext. marks	L	P	C
Core Course IV	Advanced Instrumental Analysis	25	75	4	--	4
Core Course V	Quality Control and Quality Assurance	25	75	4	--	4
Core Course VI	Modern Bio analytical Techniques	25	75	4	--	4
Core Elective II	1. Biostatistics And Research Methodology 2. Spectral Analysis	25	75	4	--	4
Open Elective II	1. Screening Methods in Pharmacology 2. Stability of Drugs and Dosage Forms 3. Entrepreneurship management 4. Nano Based Drug Delivery Systems 5. Herbal & Cosmetics Analysis	25	75	4	--	4
Laboratory III	Advanced Instrumental Analysis Lab	25	75	-	6	4
Laboratory IV	Quality Control and Quality Assurance Lab	25	75	--	6	2
Seminar II	Seminar	50	--	--	4	2
Total Credits				20	16	28

II Year - I Semester

Course Title	Int. marks	Ext. marks	L	P	C
Comprehensive Viva-Voce	--	100	--	--	4
Project work Review I	50	--	--	24	12
Total Credits			--	24	16

II Year - II Semester

Course Title	Int. marks	Ext. marks	L	P	C
Project work Review II	50	--	--	8	4
Project Evaluation (Viva-Voce)	--	150	--	16	12
Total Credits			--	24	16

JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD
I Year – II Sem M. Pharm (PAQA/QA)

ADVANCED INSTRUMENTAL ANALYSIS (Core Course - IV)

Course Objectives: This subject deals with various hyphenated analytical instrumental techniques for identification, characterization, and quantification of drugs. Instruments dealt are LC-MS, GC-MS, and hyphenated techniques.

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

UNIT - I

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

UNIT - II

- a. **Biochromatography:** Size exclusion chromatography, ion exchange chromatography, ion pair chromatography, affinity chromatography general principles, stationary phases and mobile phases.
- b. **Super critical fluid chromatography:** Principles, instrumentation, pharmaceutical applications.
- c. **Raman:** Principle (absorption, diffraction, scattering and emission of wave, molecular interaction), instrumentation (Dispersive Raman, FT-Raman), advantage and disadvantage, pharmaceutical applications including detection of counterfeit

UNIT - III

Capillary electrophoresis: Overview of CE in pharmaceutical analysis, basic configuration, CE characteristics, principles of CE, methods and modes of CE. General considerations and method Development in CE,

UNIT - IV

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

UNIT - V

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

REFERENCES:

1. Instrumental Methods of Chemical Analysis by B.K Sharma
2. Organic spectroscopy by Y.R Sharma
3. A Text book of Pharmaceutical Analysis by Kerrenth A. Connors

4. Vogel's Text book of Quantitative Chemical Analysis by A.I. Vogel
5. Practical Pharmaceutical Chemistry by A.H. Beckett and J.B. Stenlake
6. Organic Chemistry by I. L. Finar
7. Organic spectroscopy by William Kemp
8. Quantitative Analysis of Drugs by D. C. Garrett
9. Quantitative Analysis of Drugs in Pharmaceutical Formulations by P. D. Sethi
10. Spectrophotometric identification of Organic Compounds by Silverstein
11. HPTLC by P.D. Seth
12. Spectroscopy by Donald L Pavia, Gary M Lampman, George S Kriz, James A Vyvyan

JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD
I Year – II Sem M. Pharm (PAQA/QA)

QUALITY CONTROL AND QUALITY ASSURANCE (Core Course - V)

Course Objectives: This course deals with the various aspects of quality control and quality assurance aspects of pharmaceutical industries. It covers the important aspects like cGMP, QC tests, documentation, quality certifications, GLP and regulatory affairs.

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

UNIT I

- a. **Impurity and stability studies:** Definition, classification of impurities in drug Substance or Active Pharmaceutical Ingredients and quantification of impurities as per ICH guidelines.
- b. **Impurities in new drug products:** Rationale for the reporting and control of degradation products, reporting degradation products content of batches, listing of degradation products in specifications, qualification of degradation products
- c. **Impurities in residual solvents:** General principles, classification of residual solvents, Analytical Procedures, limits of residual solvents, reporting levels of residual solvents

UNIT II

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

UNIT III

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

UNIT IV

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

UNIT V

Manufacture and controls on dosage forms

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

TEXT BOOKS:

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

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

REFERENCES 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)

JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD
I Year – II Sem M. Pharm (PAQA/QA)

MODERN BIO-ANALYTICAL TECHNIQUES (Core course - VI)

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

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

- Extraction of drugs from biological samples
- Separation of drugs from biological samples using different techniques
- Guidelines for BA/BE studies

UNIT I

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

UNIT II

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

UNIT III

Bioanalysis and bioanalytical method validation:

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

UNIT IV

Pre-Formulation:

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

Physical characteristics-

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

Chemical Characteristics-

Degradation: Hydrolytic, oxidative, reductive and photolytic, Drug - Excipient Compatibility studies.

UNIT V

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

REFERENCES:

1. Analysis of drugs in Biological fluids - Joseph Chamberlain, 2nd Edition. CRC Press, New York. 1995.

2. Principles of Instrumental Analysis - Douglas A. Skoog, F. James Holler, Timothy A. Nieman, 5th edition, Eastern press, Bangalore, 1998.
3. Pharmaceutical Analysis - Higuchi, Brochman 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 Jersey. USA.
6. Chromatographic Analysis of Pharmaceuticals – John A Adamovics, 2nd Edition, Marcel Dekker, Newyork, USA. 1997.
7. Chromatographic methods in clinical chemistry & Toxicology – Roger L Bertholf, Ruth E Winecker, John Wiley & Sons, New Jercy, USA. 2007.
8. Good Laboratory Practice Regulations, 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, Palmer**

JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD
I Year – II Sem M. Pharm (PAQA/QA)

BIostatistics AND RESEARCH METHODOLOGY (Core Elective – II)

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

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

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, Poisson 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

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 G N Rao and N K 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 R K Khanna bis and Suvasis Saha
11. Research methods and Quantity methods by G. N. Rao
12. A practical approach to PG dissertation.

JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD
I Year – II Sem M. Pharm (PAQA/QA)
SPECTRAL ANALYSIS (Core Elective - II)

Course Objective: The students will acquire the knowledge about the various aspects of X-Ray diffraction methods, all types of IR methods, particle sizing methods, also DSC, DTA, TGA etc

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

UNIT - I

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

UNIT - II

- a. **FT-NIR:** Principle (overtones, combinations, fermi resonance, interferences etc.), instrumentation (dispersion spectrometer and FT-NIR), advantage, and disadvantage, qualitative and quantitative applications, including PAT and non-destructive analysis.
- b. **ATR:** Principle (total internal reflection, evanescent wave, etc.), instrumentation (ATR crystal, IR beam), advantages, and disadvantages, pharmaceutical applications.

UNIT - III

Electrometric Techniques: Principle, instrumentation and applications of Potentiometer, Amperometer, Conductometer and Polarography.

UNIT - IV

- a. **Spectrofluorimetry:** Theory of Fluorescence, Factors affecting fluorescence (Characteristics of drugs that can be analyzed by fluorimetry), Quenchers, Instrumentation, and Applications of fluorescence spectrophotometer.
- b. **Flame emission spectroscopy and Atomic absorption spectroscopy:** Principle, Instrumentation, Interferences, and applications.

UNIT - V

FT-Raman: Principle (absorption, diffraction, scattering and emission of wave, molecular interaction), instrumentation (Dispersive Raman, FT-Raman), advantage and disadvantage, pharmaceutical applications including detection of counterfeit

REFERENCES:

1. Instrumental Methods of Chemical Analysis by B.K Sharma
2. Organic spectroscopy by Y.R Sharma
3. A Text book of Pharmaceutical Analysis by Kerrenth A. Connors
4. Vogel's Text book of Quantitative Chemical Analysis by A.I. Vogel
5. Practical Pharmaceutical Chemistry by A.H. Beckett and J.B. Stenlake
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I Year – II Sem M. Pharm (PAQA/QA)

SCREENING METHODS IN PHARMACOLOGY (Open Elective - II)

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

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

UNIT I

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

UNIT II

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

UNIT III

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

UNIT IV

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

UNIT V

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

TEXT BOOKS:

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

REFERENCE BOOKS:

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

JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD
I Year – II Sem M. Pharm (PAQA/QA)

STABILITY OF DRUGS AND DOSAGE FORMS (Open Elective - II)

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

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

UNIT - I

Drug decomposition mechanisms:

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

UNIT - II

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

Physical stability testing of dosage forms:

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

UNIT - III

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

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

UNIT - IV

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

UNIT - V

Methods of analysis to determine the quality of cosmetics in the finished forms such as Hair care products, Skin care products, Baby care products, Dental products, Personal hygiene products, Colour cosmetics, Ethnic products, Colour makeup preparation, Lipsticks, Hair setting lotions and 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.
- 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. Sawnsen – 2004.
2. H. Beckett and J. B. Stenlake Practical Pharmaceutical Chemistry, Part I and Part II, 4th Edition. 3. G. H. Jeffery, J. Basset, J. Mendham, R. C. Denny (Rev. by) Vogels Text Book of Quantitative Chemical Analysis, 5th Edition 1989, ELBS.
3. The Controller of Publications; New Delhi, Govt. of India, Indian Pharmacopoeia, Vol. I and Vol. II - 2010.
4. J. B. Wilkinson and R. J. Moore: Herry's Cosmeticology; Longman Scientific and Technical Publishers, Singapore.
5. P. D. Sethi; Quantitative Analysis of Drugs in Pharmaceutical Formulations, 3rd Edition - 1997,
6. Classification of cosmetics raw materials and adjuncts IS 3958 of Indian Standards Institution (BIS).
7. Cosmetic and toilet goods – methods of sampling IS 3958 of Indian Standards Institution (BIS).
8. Methods of sampling and test for various cosmetics as laid down by Bureau of Indian Standards.
9. Drug stability: Principles and practices by Jens T. Carstensen
10. Stability Testing of Drug Products by W. Grimm. 12. Stability of Drugs and Dosage Forms by Yoshioka and Stella.

JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD
I Year – II Sem M. Pharm (PAQA/QA)

ENTREPRENEURSHIP MANAGEMENT (Open Elective - II)

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

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

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

UNIT I

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

UNIT II

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

UNIT III

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

UNIT IV

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

UNIT V

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

TEXT AND REFERENCE BOOKS:

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

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I Year – II Sem M. Pharm (PAQA/QA)

NANO BASED DRUG DELIVERY SYSTEMS (Open Elective – II)

Course Objective - To develop expertise regarding suitability and evaluation of nanomaterials, able to apply the properties to the fabrication of nanopharmaceutical, evaluate the intensity of dosage forms and availability for targeting and controlled delivery.

Course Outcomes – The students should be able to select the right kind of materials, able to develop nano formulations with appropriate technologies, evaluate the product related test and for identified diseases

UNIT I – Introduction to Nanotechnology

- Definition of nanotechnology
- History of nanotechnology
- Unique properties of nanomaterials
- Role of size and size distribution of nanoparticles properties, classification.

UNIT II – Synthesis of Nanomaterials

- a) Physical, chemical and biological Methods
- b) Methods for synthesis of
 - Gold nanoparticles
 - Magnetic nanoparticles
 - Polymeric nanoparticles
 - Self – assembly structures such as liposomes, micelles, aquasomes and nanoemulsions

UNIT III – Biomedical applications of Nanotechnology

- a) Nanotechnology products used for in vitro diagnostics
- b) Improvements to medical or molecular imaging using nanotechnology
- c) Targeted nanomaterials for diagnostic and therapeutic purpose

UNIT IV

Design of nanomaterials for drug delivery, pulmonary and nasal drug delivery, nanomaterials for cancer therapy and cardiovascular diseases. Localized drug delivery systems.

UNIT V

Characterization including the principles, size reduction, analysis of nanoparticles, size, PDI, size separation, stability, methods of analysis regarding integrity and release of drugs

RECOMMENDED BOOKS:

1. Nanomedicine and Nanoproducts: Applications, Disposition and Toxicology in the Human body, Eiki Igarashi, CRC press. 2015
2. Nanotechnology and Drug Delivery Volume one and two: Nanoplatforms in Drug Delivery, Jose L. Arias, CRC press
3. Nano: The Essentials: Understanding Nanoscience and Nanotechnology, T.Pradeep, Tata McGraw-Hill Publishing Company Limited, New Delhi, 2008.
4. Nanocrystals: Synthesis, Properties and Applications, C. N. R. Rao, P. J. Thomas and G.U. Kulakarni, Springer (2007)
5. Nanostructures and Nanomaterials: Synthesis, Properties and Application, Guozhong Gao, Imperial College Press(2004)

6. Nanochemistry: A Classical Approach to Nanomaterials – Royal Society for Chemistry, Cambridge, UK (2005)
7. Nanocomposite science and technology, pulickel M. Ajayan, Linda S. Schadler, paul V. Braun, Wiley-VCH Verlag, Weiheim (2003)
8. Nanoscale materials in chemistry, Edited by Kenneth J. Klabunde, John Wiley & Sons, 2009
9. Nanoparticles as Drug carriers, Vladimir P Torchiling, Imperial College Press, USA, 2006

JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD
I Year – II Sem M. Pharm (PAQA/QA)

HERBAL AND COSMETICS ANALYSIS (Open Elective - 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: 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.

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: WHO and AYUSH guidelines for safety monitoring of natural medicine, Spontaneous reporting schemes for bio drug adverse reactions, bio drug-drug and biodrug-food interactions with suitable examples. Challenges in monitoring the safety of herbal medicines.

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.

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 Ashutosh Kar
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's Perfumes, Cosmetics, and Soaps
12. Hilda Butler, 10th Edition, Kluwer Academic Publishers. Handbook of Cosmetic Science and Technology, 3rd Edition

JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD
I Year – II Sem M. Pharm (PAQA/QA)

ADVANCED INSTRUMENTAL ANALYSIS 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 -Turbidimetry
5. Determination of moisture content in sorbitol, sodium citrate, ampicillin etc.
6. Assays of official compounds by Fluorimetry
7. Determination of compounds of sodium, potassium and calcium by Flame photometry.

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

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I Year – II Sem M. Pharm (PAQA/QA)

QUALITY CONTROL AND QUALITY ASSURANCE LAB

List of Experiments

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