JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD

M. Pharmacy (QUALITY ASSURANCE AND PHARMA REGULATORY AFFAIRS)

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	Quality Assurance	25	75	4	--	4
Core Course II	Drug Regulatory Affairs	25	75	4	--	4
Core Course III	Modern Pharmaceutical Analytical Techniques	25	75	4	--	4
Core Elective I	1. Quality Management Systems 2. Intellectual Property Rights	25	75	4	--	4
Open Elective I	1. Pharmaceutical Validation 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	Quality Assurance 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	Principles and Practice of Quality Assurance	25	75	4	--	4
Core Course V	Modern Pharmaceutical Technology	25	75	4	--	4
Core Course VI	Regulatory submissions: Drugs, Biologicals and Medical devices	25	75	4	--	4
Core Elective II	1. Biostatistics And Research Methodology 2. Stability of Drugs and Dosage Forms	25	75	4	--	4
Open Elective II	1. Screening Methods in Pharmacology 2. Spectral Analysis 3. Entrepreneurship management 4. Nano Based Drug Delivery Systems 5. Herbal & Cosmetics Analysis	25	75	4	--	4
Laboratory III	Principles and Practice of Quality Assurance Lab	25	75	--	6	3
Laboratory IV	Regulatory submissions: Drugs, Biological and Medical devices Lab	25	75	--	6	3
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 (QA & PRA)

PRINCIPLES AND PRACTICE OF QUALITY ASSURANCE (Core course - IV)

Course Objective: This subject consists of topics regarding Q.C responsibilities sampling plans retention of samples and provides the distribution procedure and maintenance of records. It practically covers aspects of pharmaceutical processing activities.

Course Outcome: From this subject get the knowledge about documentation &release procedure and the authority of person for Q.C laboratory. Students learn the sample retention, release of finished product for sale &distribution and legal regulations &restriction on using animals in the laboratory. Preparation of sop on distributions.

Quality Management:

UNIT I

Quality control laboratory responsibilities, good laboratory practices, routine controls, instruments, sampling plans, standard test procedures, non clinical testing, controls on animal house, data generation and storage, .

UNIT II

\Ware housing, good ware housing practices materials management. Finished product release, quality review, quality audit. Batch release documents. quality control documentation, retention samples, records, audits of quality control facilities

UNIT III

Distribution and distribution records. Handling of returned goods.
Complaints and recalls, evaluation of complaints, recall procedures, related records and documents.
Waste disposal, scrap disposal producers and records.

Validation :

UNIT IV

Qualification, validation, and calibration of equipment. Validation of process like mixing , granulation, drying, compression, filtration filling etc.
Validation of sterilization methods and equipment, dry heat sterilization, autoclaving, membrane filtration.

UNIT V

Validation and audits of analytical procedures, validation and personnel, validation and security measures for electronic data processing.

RECOMMENDED BOOKS:

1. Pharmaceutical Process Validation – Robert A. Nash, Alfred H. Wachter
2. Process Validation in manufacturing of biopharmaceuticals: Guidelines – Anurag Singh Rathore, Gail Sofer, G. K. Sofer
3. Pharmaceutical Quality Assurance – Mr. Manohar A. Potdar
4. Quality Assurance of Pharmaceuticals: A Compendium of Guidelines and Related Materials (v. 1) by WHO

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

MODERN PHARMACEUTICAL TECHNOLOGY (Core course - V)

Course Objective: Which give preformulation studies, Methodology.
Production techniques for tablets & capsules .which give the information of stability testing of solid & liquid dosage forms .Provide the pilot plant scale up techniques and optimization methods &their applications in pharmaceutical industry.

Course Outcome: Student learn about the preformulation parameters. Solid state properties .Student get the knowledge about compression machine, coating machines capsule mfg. They will study the physical & chemical stability testing of pharmaceutical dosage form& packages.

UNIT I
Preformulation studies: Goals of preformulation, preformulation parameters, methodology, solid state properties, solubility and partition coefficient, drug-excipient compatibility.

UNIT II
Tablets and Capsules: Improved production techniques for tablets, new materials, processes, equipment high shear mixers, compression machines, coating machines, coating techniques in tablet technology for product development and computerization for in process quality control of tablets.
Special techniques and advances in capsule manufacture, processing and control including pharmaceutical aspects, physical stability and packaging.

UNIT III
Stability testing & dating of solid and liquid dosage forms: Difference in approaches for stability testing of solid and liquids, kinetic principles, PHYSICAL & chemical stability testing of pharmaceutical dosage forms and packages.

UNIT IV
Pilot plant Scale up techniques:
Evaluation of formula, equipments, raw materials, process, stability , uniformity. Techniques related to tablets including coating, capsules, liquid dosage forms & semi solid dosage forms.

UNIT V
Optimization techniques in pharmaceutical formulation and processing
Introduction, optimization parameters, classical optimization, statistical design, applied optimization methods and their applications in pharmaceutical industry.

TEXT BOOKS:

1. Pharmaceutics - The Science of Dosage form design by ME Aulton.
2. Pharmaceutical Dosage forms - Tablets (Vol I, II and III) by Lieberman, Lachman and Schwartz.
3. Pharmaceutical Dosage forms - Capsules (Vol I, II and III) by Avis, Lieberman and Lachman.
4. Pharmaceutical Dosage forms – Disperse systems (Vol I, II and III) by Avis, Lieberman and Lachman.
5. Modern Pharmaceutics by Gilbert S. Banker and Christopher T. Rhodes.

RECOMMENDED BOOKS:

1. The Theory and Practice of industrial Pharmacy by Leon Lachman, Herbert A. Lieberman.
2. Remington's Science and Practice of Pharmacy by A. Gennaro**.**

3. Ansel’s Pharmaceutical Dosage form and Drug delivery system by Loyd V. Allen, Jr. Nicholas G. Popovich, Howard C. Ansel.
4. Generic Drug Product Development by Leon Shargel and Isadore Kanfer.
5. Dispensing for Pharmaceutical Students by S

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

REGULATORY SUBMISSIONS – DRUGS, BIOLOGICAL AND MEDICAL DEVICES
(Core course - VI)

Course Objective: This subject gives the details about the regulatory aspect for development of new drugs according to global agencies like USA, UK, and India. This subject provides the information about process for global pharmaceutical product approvals .Which give the guidance on preparation & submission of electronic documents CTD.

Course Outcome: Students prefer the collections &organizations regulatory package for development of drugs to global agencies IND .Students get the guidelines for preclinical testing &clinical testing in E.U. Regulatory considerations for manufacturing, packaging & labelling of pharmaceuticals in E.U. They will learn the about the annual reports post approval changes.

UNIT I

Overview of regulations pharmaceutical products

1. Drugs (new and generic)
2. Biologics (new and biosimilars)
3. Medical devices
4. Combination products examples : drug-drug and drug-device

Overview of regulations (FDA, ICH, EMA, WHO) for drugs

1. New drugs
2. Generic drugs
3. Orphan drugs

UNIT II

Overview of regulations for biologics

1. Newly developed biologics
2. Biosimilars

Overview of regulations for medical devices

1. Classifications
2. Exemptions
3. Approval process – premarket approval (PMA) or premarket notification (510k)

UNIT III

Collecting and organizing regulatory package for development of new drugs to global agencies: Investigational New Drug Application (IND), Investigational Medicinal Product Dossier (IMPD), Investigator's Brochure (IB)

Collecting and organizing regulatory package for approval of new drugs to global agencies. New Drug Applications for Global Pharmaceutical Product Approvals (NDA, BLA), Abbreviated and Supplemental New Drug Applications (ANDAs and SNDAs) and Pre-Market Approvals (PMAs) and notifications (510k).

UNIT IV

Common Technical Document (CTD)

Preparation and submission of electronic documents: The CTD and eCTD.

Drug regulatory authorities in European Union (EU) with special reference to EMA and UKMHRA:

Introduction, Organization and General Guidelines.

Regulatory consideration for pre-clinical testing and clinical testing in EU, types of filing process (centralized, de- centralized, RMS countries), SPCs, SPC exclusivities,

Registration application for marketing approval in EU, Common Technical Document and Drug Master Files, in EU, Factory Inspection.
Regulatory considerations for manufacturing, packaging and, labeling of pharmaceuticals in EU.

UNIT V

Post-market regulatory obligations

Responsibilities and reporting of annual reports, post approval changes, post approval clinical studies and managing the outcomes.

TEXT BOOKS:

1. Guidebook for drug Regulatory submissions by Sandy Weinberg, Clayton state university, Copyright © 2009 by John Wiley & Sons, Inc. Published by John Wiley & Sons, Inc., Hoboken, New Jersey
2. Real World Drug Discovery, A Chemist's Guide to Biotech and Pharmaceutical Research by Robert M. Rydzewski Copyright _ 2008 Elsevier Ltd Elsevier The Boulevard, Langford Lane, Kidlington, Oxford OX5 1GB, UK, Radarweg 29, PO Box 211, 1000 AE Amsterdam, The Netherlands
3. Reliable design of medical devices / Richard C. Fries.--2nd edn. Published in 2006 by CRC Press Taylor & Francis Group 6000 Broken Sound Parkway NW, Suite 300 Boca Raton, FL 33487-2742

REFERENCES:

1. New Drug Approval Process, R.A.Guarino,4th Edition , Marcel Dekker, NY
2. New Drug Approval Process Global Challenges and Solutions RICHARD A. GUARINO., Fifth Ed. informa Healthcare
3. DRUGS From Discovery to Approval, Second Edition RICK NG, A-Bio Pharma Pte Ltd, Singapore, Copyright © 2009 Published by John Wiley & Sons, Inc., Hoboken, New Jersey
4. New Drug Development: Regulatory Paradigms for Clinical Pharmacology and Biopharmaceutics, edited by Chandrahas G. Sahajwalla
5. Drug discovery from Bedside to Wall Street Tamas Bartfai & Graham V. Lees, 2006,ElsevierInc Elsevier Academic Press, 30 Corporate Drive, Suite 400, Burlington, MA01803, USA
6. Drug discovery and development / edited by Mukund S. Chorghade Copyright © 2007 by John Wiley & Sons, Published by John Wiley & Sons, Inc., Hoboken, New Jersey.
7. FDA administration enforcement manual/ Florence R. Parker, © 2005 by CRC Press LLC, CRC Press LLC, 2000 N.W. Corporate Blvd., Boca Raton, Florida 33431.(Taylor & Francis Group, the academic division of T&F Informa plc.)
8. Commercial Manual onDrugs and Cosmetics 2004, 2nd edition Published by *Commercial* Law Publishers (India) Pvt. Ltd., Dehli.
9. Good Manufacturing Practices for Pharmaceuticals, S.H. Wiling, Vol. 78, Marcel Decker.
10. Protection of Industrial Property rights by P.Das and Gokul Das
11. Webistes: fda.org, wipo.int, patentlawlinks.com, hc-sc.gc.ca, ich.org
12. Marketing authorization of pharmaceutical Products with special reference to Multisource (generic) products: A manual for drug regulatory authorities WHO Division of Drug Management and Policies in Geneva from 7 to 8 April and 6 to 8 July 1998

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

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, 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

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 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 (QA & PRA)

STABILITY OF DRUGS AND DOSAGE FORMS (Core 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. Sawnson – 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 (QA & PRA)

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 Rabbis Vaccine, Oxytocin, Tetanus Antitoxin and Diphtheria Vaccine. Test for pyrogens.

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

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

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

TEXT BOOKS:

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

REFERENCE BOOKS:

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

JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD
I Year – II Sem M. Pharm (QA & PRA)
SPECTRAL ANALYSIS (Open 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, power 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. **Spectroflourimetry:** Theory of Fluorescence, Factors affecting fluorescence (Characteristics of drugs that can be analyzed by flourimetry), 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
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 (QA & PRA)
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

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

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 sysnthesis 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 Nanosicence 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 Nanomaterilas: 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 (QA & PRA)

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 (QA & PRA)

PRINCIPLES AND PRACTICE OF QUALITY ASSURANCE LAB

1. Qualification of following Pharma equipment
   a. Autoclave
   b. Hot air oven
   c. Powder Mixer (Dry)
   d. Tablet Compression Machine
2. Validation of an analytical method for a drug
3. Validation of a processing area
4. Qualification of at least two analytical instruments
5. Cleaning validation of one equipment
6. Qualification of Pharmaceutical Testing Equipment (Dissolution testing apparatus, Friability Apparatus, Disintegration Tester)
7. Check list for Bulk Pharmaceutical Chemicals vendors
8. Check list for tableting production.
9. Check list for sterile production area
10. Check list for Water for injection.
11. Design of plant layout: Sterile and non-sterile
12. Case study on application of QbD
13. Case study on application of PAT

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

REGULATORY SUBMISSIONS: DRUGS, BIOLOGICS AND MEDICAL DEVICES LAB

1. General formats for Drug Applications
2. Development and drafting of documents
3. Dossair template generation (Formulations)
4. DMF template Generation (API)
5. Electronic data submission templates