JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD

M. Pharmacy (PHARMACEUTICAL MANAGEMENT AND 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	Pharmaceutical Management – I (General and Personnel)	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. Total Quality Management 2. Intellectual Property Rights	25	75	4	--	4
Open Elective I	1. Pharmacoepidemiology and Pharmacoeconomics 2. Herbal Cosmetics Technology 3. Phytochemistry 4. Pharmaceutical Formulation Technology 5. Pharmaceutical Validation	25	75	4	--	4
Laboratory I	Modern Pharmaceutical Analytical Techniques Lab	25	75	--	6	3
Laboratory II	Pharmaceutical Management 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	Pharmaceutical Management –II (Production, Marketing, Finance and Project)	25	75	4	--	4
Core Course V	Analytical Method Validation and Copyrights and Trademarks	25	75	4	--	4
Core Course VI	Pharmaceutical Market Research and Analysis	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. Nano Based Drug Delivery Systems 3. Nutraceuticals 4. Advanced Drug Delivery Systems 5. Clinical Research and Pharmacovigilance	25	75	4	--	4
Laboratory III	Analytical Method Validation Lab	25	75	--	6	3
Laboratory IV	Pharmaceutical Market Research and Analysis 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 (PM & RA)

PHARMACEUTICAL MANAGEMENT - II (Core course - IV)
(PRODUCTION, MARKETING, FINANCE & PROJECT)

Course Objective: To know the pharmaceutical product management, planning, marketing accounts and finance. They also know the Inventory control, concept and techniques to improve production In packaging, marketing, sale and accounting.

Course Outcome: Student will get knowledge about production management, production planning and control, design and development of packaging, marketing of pharmaceuticals.

UNIT I

Production Management: Fundamentals of production, organization, economic policy, manufacturing economics, production capacities, production lines and job balancing, visible and invisible inputs, methodology of activities. Development of efficient work methods, quality control and management of R&D.

Production planning and control, production processes - mass, job and project; plant location and lay out; work study (preliminary idea only), materials management- purchase, inventory control and store keeping. Productivity management: Concepts, problems, tools and techniques for improvement. Operation research techniques by PERT and CPM.

Considerations for design of large scale manufacturing units including intricate design criteria for units to manufacture sterile and non-sterile products with special reference to tablets, capsules, and injections.

Design and development of packaging units including recent advances in packaging techniques for various types of sterile and non-sterile dosage forms.

Warehousing design, construction, maintenance and sanitation; good warehousing practice, materials management.

UNIT II

Pharmaceutical Marketing: Evolution of marketing concept; production oriented, sales oriented, promotion oriented and consumer oriented (modern concept); market segmentation; concept of marketing, mix Role of 7 P's (Product, Price, Promotion, Place, Physical Evidence, Process, People) in Pharmaceutical Marketing Management, corporate planning & strategy, Pharmaceutical industrial marketing management. Pharmaceutical marketing environment. Product management. E-Pharma Marketing.

UNIT III

Product Planning: Selection of product, new product development and product differentiation, pricing, promotion – personal selling; salesmanship, qualities of salesman, management of sales force, advertising, publicity and window display, channels of distribution.

Marketing Research: Definition and importance, Pharmaceutical Marketing Research techniques, marketing information system, pharmaceutical marketing research area.

Market Demands and Sales Forecasting: Major concepts in the demand measurement, estimating current demands, geo-demographic analysis, estimating industry sales, market share and future demand, sales forecasting.

UNIT IV

Introduction to financial management, financial planning and control, working capital management, management of fixed assets.

Concepts and techniques of financial management decision, concepts in evaluation – time value of money, valuation of a firm's stock, capital assets pricing model, investment in assets and required returns, risk analysis, financing and dividend policies, capital structure decision, working capital management, management of cash, management of accounts receivable, inventory management.
Banking and finance: Service and functions of bank, finance planning and sources of finance, short, intermediate and long term financing, tools of financial analysis, financial ratio analysis, funds analysis and financial forecasting, operating and financial leverages. General principles of insurance.
Introduction to financial management, financial planning and control, working capital management, management of fixed assets.
Evaluation of investment decisions by payback period, accounting rate of return, net present value methods, break even analysis.

UNIT V

Accounting & Finance: Financial accounting, GAAP, cost accounting, budgetary control, valuation of inventory and assets, modern trends, role of internal auditing, internal versus external auditing, accounting control and information systems.
Project definition, preparation of feasibility assessment and selection, project reporting, conventional project appraisal; limitations, towards a new framework. Projections, profitability, cost and benefit analysis, appraisal criteria – financial, economic and social. Risk analysis.
Institutional Finance and Project Appraisal: Framework for domestic/ international finance evaluation, project identification, feasibility, appraisal, financial and capital structures, capital market instruments, managing new issues, negotiations with FIs, FIIs, and other market players, issue pricing, SEBI guidelines, syndication of loans including term loans, lease financing.

TEXT AND REFERENCE BOOKS:

1. Financial Management by Johnson, R.W.; The Ronald Press.
2. Fundamental of Financial Management by Van Horne, J.C.; Prentice Hall of India (P) Limited.
3. Stock Exchange and Investment Analysis by Briston, R. J.
4. Indian Financial System by Khan, M. Y.; Tata McGraw Hill.
5. Tax Planning for Industrial Projects by Agarwal R. K.; Hind Law Publishers, New Delhi.
6. Project Management by Chaudhary, S.; Tata McGraw Hill.
7. Project Management: A System Approach to Planning Scheduling and Controlling by Harold Kerzner; CRS Publishers and Distributors, Delhi.
8. Financial Management by Gupta And Sharma I st Edition 1996.
9. Accounting for Management Planning and Control III rd Edition Richard M. Lynch
10. Management by Tripathi P. C. and Reddy P. N.; Tata McGraw Hill.
11. Business Organization and Management by Shukla M. C.; S. Chand and Company.
12. Business Organization and Management by Sherlakar S. A.; Himalaya.
13. Personnel Management by Filippo E. B.; McGraw Hill.
14. Marketing Management by Kotler Philip.; Prentice Hall of India.
15. Organizational Behavior by Rao and Narayan; Konark Publishers.
16. Personnel Management by Tripathi P. C.; S. Chand and Company.
17. Principle and Practice of Marketing in India by Memoria C. B.
18. Principles of Pharmaceutical Marketing By Mickey Smith C.B.S. Publications.
19. Marketing Hand Book Vol. II , Marketing Management by Edwin – E Bobrow, Mark – D. Bobrow.
20. Production and Operations Management by S.N.Chary

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

ANALYTICAL METHOD VALIDATION, COPY RIGHTS, AND TRADE MARKS (Core course - V)

Course Objective: The students will know the validation guidelines, different methods of validation, implementation of validation. They also know about the law related to copyrights, trademarks and their implementation

Course Outcome: Students will get knowledge about ICH guidelines for validation, FDA drafts and techniques which are used for validation and their implementation. They also know the rights and laws related to copyrights and trademarks.

UNIT I
Validation guidelines
1. ICH Q2A: Text on validation of analytical procedures: Definitions and terminology (March 1995)
2. ICH Q2B: Validation of analytical procedures: Methodology (June 1997)
3. FDA: (Draft) Guidance for Industry: Analytical procedures and methods validation
4. Pharmacopoeias: USP and European Pharmacopoeia

UNIT II
What methods to be validated?
Defined for:
- Identification
- Quantitative tests for content of impurities
- limit tests for control of impurities
- Quantitative tests for active moiety in drug substances and drug products

Referred to:
- Dissolution testing
- Particle size determination (drug substance)

UNIT III
Implementation of Guidelines
- Standard protocols
- Set up as procedures
- Mutual agreement on tests
- Mutual agreement on criteria
- Mutual agreement on documentation

==> MUTUAL DEVELOPMENT PROCEDURES (MDP)

UNIT IV
Copyright: Law relating to copyright in India. Copyright Act, 1957and its amendments. Subject matter of copyright protection. Rights of owners of copyrights. Infringement of copyright, remedies against infringement of copyright. Authorities and institutions under the copyright Act.
Trademarks: The trademarks legislation in India. Service marks, certification Marks, Collective marks, Distinctiveness of Trade Marks, Distinct Marks. Subject matter of Trade marks. Acquisition of registered Trade Mark. Register and conditions for Registration. Infringement of Trade marks.

UNIT V
Trade mark laws and governing of trademarks, role of Indian trade mark office.

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 Pharmaceuticals –A compendium of guidelines- WHO publication.
5. Theory and practice of industrial pharmacy by Liberian and Lachman.
6. Pharmaceutical Process validation by Berry and Nash.
7. Intellectual properties rights by GB Reddy.

REFERENCE BOOKS:

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.

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

PHARMACEUTICAL MARKET RESEARCH AND ANALYSIS (Core course - VI)

Course Objective: Students shall know the overview of global pharmaceutical market, growth calculations, innovator new drug evaluation, analysis of finished dosage forms and APIs. They also know about the pharmaceutical companies, R&D strengths, and case study of companies.

Course Outcome: Students will have knowledge about global market, growth calculations depending on regions, market promotion datas, patent extensions, analysis of finished dosage forms and APIs. They also study data base related to strategies of companies.

UNIT I

- Introduction and overview of global pharmaceutical market
- Growth calculations based on Therapeutic category vs regions
- Innovator new drug candidate evaluation and strategic development cycle.
- Calculation of market promotion data
- Patent extension strategies
- Return on investment and R&D pipeline

UNIT II

Analysis of finished dosage forms based on

- Therapy
- Product
- Companies
- Quantity
- Value
- Country wise
- Region wise etc

Analysis of Active Pharmaceutical Ingredients based on

- Product,
- Quantities
- Value

Critical evaluation of databases for the global market research

- IMS
- Newport
- Export data etc

UNIT III

Lead analysis of Innovator vis-à-vis with Therapeutic Category & Generic drug makers vis-à-vis with Therapeutic Category

UNIT IV

Pharmaceutical Companies Portfolio, financials, R&D strengths and pipeline strength analysis

UNIT V

Case studies- Pharma growth stories of companies

Market research using SAS programmes on market trends

Multi Variate Analysis programmes to analyze in relationship between various factors governing the market growth.

TEXT AND REFERENCE BOOKS:

1. Principles of Pharmaceutical Marketing by MICKEY SMITH
2. Principles and Practice of Drug Manufacturing Management by MD BURANDE
3. Pharmaceutical Market research and analysis by Donald R. Lehmann
4. Pharmaceutical Market in 21st Century by Mickey C. Smith
5. Pharmaceutical Marketing: A Practical Guide by Dimitris Dogramatzis
6. Strategic management of health care organizations by Linda E. Swayne, Walter Jack Duncan, Peter M. Ginter
7. Managing Health Care Business Strategy by George B. Moseley, III, George B. Moseley
8. Pharmaceutical Management by Sachin Atkar

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

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 (PM & RA)

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.

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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 (PM & RA)

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 (PM & RA)

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. (PM & RA)

NUTRACEUTICALS (Open Elective – II)

Course Objectives: The students will expose to characteristic features of various phytochemicals as neutraceuticals in various diseased conditions and also know the role of antioxidant in free radical induced disease conditions and will expose to various food laws and regulations

Course Outcome: Helps the student to understand the importance of Neutraceuticals in various common problems with the concept of free radicals.

UNIT I

a. Definitions of Functional foods, Nutraceuticals and Dietary supplements. Classification of Nutraceuticals, Health problems and diseases that can be prevented or cured by Nutraceuticals i.e. weight control, diabetes, cancer etc.
b. Source, Name of marker compounds and their chemical nature, Medicinal uses and health benefits of following used as nutraceuticals/functional foods:
Spirulina, Soyabean, Ginseng, Garlic, Broccoli, Gingko, Flaxseeds

UNIT II

Phytochemicals as neutraceuticals: Occurrence and characteristic features(chemical nature medicinal benefits) of following

a) Carotenoids- α and β-Carotene, Lycopene, Xanthophylls, lutein
b) Sulfides: Diallylsulfides, Allyltrisulfide.
c) Polyphenolics: Reservetrol
d) Flavonoids- Rutin , Naringin, Quercitin, Anthocyanidins, catechins, Flavones
e) Prebiotates / Probiotics.: Fructo oligosaccharides, Lacto bacillum
f) Phytoestrogens : Isoflavones, daidzein, Geebustin, lignans
g) Tocopherols

UNIT III

a) Introduction to free radicals: Free radicals, reactive oxygen species, production of free radicals in cells, damaging reactions of free radicals on lipids, proteins, Carbohydrates, nucleic acids.
b) Measurement of free radicals: Lipid peroxidation products, lipid hydroperoxide, malondialdehyde.

UNIT IV

a. Free radicals in Diabetes mellitus, Inflammation, Ischemic reperfusion injury, Cancer, Atherosclerosis, Free radicals in brain metabolism and pathology, kidney damage, muscle damage. Free radicals involvement in other disorders. Free radicals theory of ageing.
b. Antioxidants: Endogenous antioxidants – enzymatic and nonenzymatic antioxidant defence, Superoxide dismutase, catalase, Glutathione peroxidase, Glutathione Vitamin C, Vitamin E, α- Lipoic acid, melatonin
Synthetic antioxidants: Butylatedhydroxy Toluene, Butylatedhydroxy Anisole.

UNIT V

Food Laws and Regulations; FDA, FPO, MPO, AGMARK. HACCP and GMPs on Food Safety. Adulteration of foods.
Regulations and Claims – Current Products: Label Claims, Nutrient Content Claims, Health Claims, Dietary Supplements Claims

REFERENCES:

1. Dietetics by Sri Lakshmi
2. Role of dietary fibres and neutraceuticals in preventing diseases by K. T Agusti and P. Faizal: BS Publication.
3. Advanced Nutritional Therapies by Cooper. K.A., (1996).
4. The Food Pharmacy by Jean Carper, Simon & Schuster, UK Ltd., (1988).
5. Prescription for Nutritional Healing by James F. Balch and Phyllis A. Balch 2nd Edn. Avery Publishing Group, NY (1997).
6. G. Gibson and C. Williams Editors *2000 Functional foods* Woodhead Publ. Co. London.
7. Goldberg, I. *Functional Foods*. 1994. Chapman and Hall, New York.
8. Labuza, T. P. 2000 Functional Foods and Dietary Supplements: Safety, Good Manufacturing Practice (GMPs) and Shelf Life Testing in *Essentials of Functional Foods* M. K. Sachmidl and T. P. Labuza eds. Aspen Press.
9. Handbook of Nutraceuticals and Functional Foods, Third Edition (Modern Nutrition)
10. Shils, ME, Olson, JA, Shike, M. 1994 *Modern Nutrition in Health and Disease*. Eighth edition. Lea and Febiger

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

ADVANCED DRUG DELIVERY SYSTEMS (Open Elective – II)

Course Objective: The students shall know the pharmacokinetic and pharmacodynamic on the basis of CDDS. They also know the design evaluation and application related to oral, parenteral, transdermal, implants, bioadhesives and targeted drug delivery systems.

Course Outcomes: Students will know the fabrication, design, evaluation and application of above drug delivery systems.

UNIT I

Fundamentals of controlled drug delivery systems, pharmacokinetic and pharmacodynamic basis of controlled drug delivery. Design, fabrication, evaluation and applications of the following controlled releasing systems

a. Controlled release oral drug delivery systems
b. Parenteral controlled release drug delivery systems

UNIT II

Design, fabrication, evaluation, and applications of the following:

a) Implantable Therapeutic systems
b) Transdermal delivery systems
c) Ocular and Intrauterine delivery systems
d) Vaccine delivery : Delivery systems used to promote uptake, absorption enhancers, oral immunization, controlled release microparticles form vaccine development

UNIT III

Biochemical and molecular biology approaches to controlled drug delivery of

a. Bioadhesive drug delivery systems
b. Nasal drug delivery systems
c. Drug delivery to Colon

UNIT IV

Biochemical and molecular biology approaches to control drug delivery of

a. Liposomes
b. Niosomes
c. Microspheres
d. Nanoparticles
e. Resealed erythrocytes

UNIT V

Drug targeting to particular organs

a. Delivery to lungs
b. Delivery to the brain and problems involved
c. Drug targeting in neoplasams

TEXT BOOKS:

1. Novel Drug Delivery System by Yie W. Chien.
2. Controlled Drug Delivery by Joseph R. Robinson and Vincent H. L. Lee.
3. Controlled and Novel Drug Delivery Systems by N. K. Jain.
4. Targeted and Controlled Drug Delivery (Novel carrier systems) by S. P. Vyas and Khar.

5. Modern Pharmaceutics by Gilbert S. Banker and Christopher T. Rhodes..
6. Advances in Drug Delivery, Vol 1, 2, 3 by Y. Madhusudan Rao, A. V. Jithan
7. Oral Drug Delivery Technology, 2nd ed, by Aukunuru Jithan

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

CLINICAL RESEARCH AND PHARMACOVIGILANCE (Open Elective – II)

Course Objective:
This subject will provide a value addition and current requirement for the students in clinical research and pharmacovigilance. It will teach the students on conceptualizing, designing, conducting, managing, and reporting of clinical trials. This subject also focuses on global scenario of pharmacovigilance in different methods that can be used to generate safety data. It will teach the students in developing drug safety data in pre-clinical, clinical phases of drug development and post market surveillance.

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

- Explain the regulatory requirements for conducting clinical trial
- Demonstrate the types of clinical trial designs
- Explain the responsibilities of key players involved in clinical trials
- Execute safety monitoring, reporting and close-out activities
- Explain the principles of Pharmacovigilance
- Detect new adverse drug reactions and their assessment
- Perform the adverse drug reaction reporting systems and communication in pharmacovigilance

UNIT- I
Regulatory Perspectives of Clinical Trials: Origin and Principles of International Conference on Harmonization - Good Clinical Practice (ICH-GCP) guidelines Ethical Committee: Institutional Review Board, Ethical Guidelines for Biomedical Research and Human Participant-Schedule Y, ICMR, Informed Consent Process: Structure and content of an Informed Consent Process Ethical principles governing informed consent process

UNIT- II
Clinical Trials: Types and Design: Experimental Study- RCT and Non RCT, Observation Study: Cohort, Case Control, Cross sectional Clinical Trial Study Team Roles and responsibilities of Clinical Trial Personnel: Investigator, Study Coordinator, Sponsor, Contract Research Organization and its management.

UNIT- III
Clinical Trial Documentation: Guidelines to the preparation of documents, Preparation of protocol, Investigator Brochure, Case Report Forms, Clinical Study Report Clinical Trial Monitoring-Safety Monitoring in CT Adverse Drug Reactions: Definition and types. Detection and reporting methods. Severity and seriousness assessment. predictability and preventability assessment. Management of adverse drug reactions; Terminologies of ADR.

UNIT- IV
Basic aspects, terminologies, and establishment of pharmacovigilance:
History and progress of pharmacovigilance, Significance of safety monitoring, Pharmacovigilance in India and international aspects, WHO international drug monitoring programme, WHO and Regulatory terminologies of ADR, evaluation of medication safety, Establishing pharmacovigilance centres in Hospitals, Industry and National programmes related to pharmacovigilance. Roles and responsibilities in Pharmacovigilance.

UNIT- V

Methods, ADR reporting and tools used in pharmacovigilance:

International classification of diseases, International Nonproprietary names for drugs, Passive and Active surveillance, Comparative observational studies, targeted clinical investigations and Vaccine safety surveillance. Spontaneous reporting system and Reporting to regulatory authorities, Guidelines for ADRs reporting. Argus, Aris G Pharmacovigilance, VigiFlow, Statistical methods for evaluating medication safety
data.

REFERENCES:

1. Central Drugs Standard Control Organization- Good Clinical Practices, Guidelines for Clinical Trials on Pharmaceutical Products in India. New Delhi: Ministry of Health; 2001.
2. International Conference on Harmonization of Technical requirements for registration of Pharmaceuticals for human use. ICH Harmonized Tripartite Guideline. Guideline for Good Clinical Practice. E6; May 1996.230
3. Ethical Guidelines for Biomedical Research on Human Subjects 2000. Indian Council of Medical Research, New Delhi.
4. Textbook of Clinical Trials edited by David Machin, Simon Day and Sylvan Green, March 2005, John Wiley and Sons.
5. Clinical Data Management edited by R K Rondels, S A Varley, C F Webbs. Second Edition, Jan 2000, Wiley Publications.
6. Handbook of clinical Research. Julia Lloyd and Ann Raven Ed. Churchill Livingstone.
7. Principles of Clinical Research edited by Giovanna di Ignazio, Di Giovanna and Haynes.
8. Textbook of PHarmacovigilance: Concept and Practice. G.P. Mohanta and P. K. Manna. 2016, PharmaMed Press.
9. A textbook of Clinical Pharmacy Practice: Essential Concepts and Skills. Second Edition, 2012, University Press

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ANALYTICAL METHOD VALIDATION – LAB

Practical work shall be carried out based on the theory syllabus.

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PHARMACEUTICAL MARKET RESEARCH AND ANALYSIS – LAB

Practical work shall be carried out based on the theory syllabus