JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD
PHARMACEUTICAL ANALYSIS AND QUALITY ASSURANCE / QA
COURSE STRUCTURE AND SYLLABUS

I Year – II Semester

Category	Course Title	marks	Ext. marks	L	P	C
Core Course IV	Advanced Pharmaceutical Analysis – II	25	75	4	--	4
Core Course V	Spectral Analysis	25	75	4	--	4
Core Course VI	Quality Assurance	25	75	4	--	4
Core Elective II	1. Biostatistics And Research Methodology 2. Screening Methods & Clinical Research	25	75	4	--	4
Open Elective II	1. Stability of Drugs and Dosage Forms 2. Nano Based Drug Delivery Systems 3. Nutraceuticals 4. Pharmaceutical Product development and Management 5. Pharmaceutical Management-II	25	75	4	--	4
Laboratory III	Advanced Pharmaceutical Analysis – II Lab	25	75	4	--	4
Laboratory IV	Spectral Analysis Lab	25	75	--	4	2
Seminar II	Seminar	50	--	--	4	2
Total Credits				**24**	**8**	**28**

JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD

I Year – II Sem M.Pharm (PAQA/QA)

ADVANCED PHARMACEUTICAL ANALYSIS-II

Objective: The principles and procedures for the calibration and validation belonging to different categories are discussed in detail. Bio analytical and Analytical method validation in the determination of the pharmaceuticals is also discussed.

UNIT-I

Calibration and qualification of equipment: Difference of definitions, calibration standards, calibration frequency, examples of calibration of pH meter, FTIR and a UV Spectrophotometer. Definition of qualification process involving DQ, IQ, OQ, CQ and PQ. Brief discussion on protocol of each.

UNIT-II

Validation methods of

i. Equipment and Processing Techniques for mixing, granulation, drying, compression, filtration and filling.
ii. Methods and equipment for sterilization, autoclaving and membrane filtration.
iii. Air handling equipment and facilities in zones
iv. Water purification systems, deionised and distilled water and water for injection

UNIT-III

Bioanalysis and bioanalytical method validation: Types of body fluids, requirement of analysis, matrix effects, sample preparation, non-biological analytical samples. Acceptance criteria in comparison to non-biological samples.

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).

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.

Regulatory Requirements - Impurities in New Drug Substances Q3A&New Drug Products.Q3B (R2).

UNIT-V

Analytical Method Validation

General principles of analytical method validation, Validation of following analytical Instruments - U.V/Visible spectrophotometers, FTIR,HPLC and GC. Dissolution test apparatus

Outcome: The students will get an idea on the process of calibration of instruments, their validation and method development process which are very essential for them to carry out their research works.

Text books:

1) Remington's Pharmaceutical Sciences by Alfonso and Gennaro
2) Quantitative Analysis of Drugs in Pharmaceutical Formulations by P.D.Sethi
3) Pharmaceutical Analysis by Higuchi, Bechmman and Hassan
4) Instrumental Methods of Chemical Analysis By B.K. Sharma
5) A Text Book of Pharmaceutical Analysis by Kennenth A. Conners
6) Skoog, DA, Holler, FJ, Crouch, SR. Principles of instrumental analysis. 6th ed., Baba BarkhaNath Printers, Haryana, 2007

Reference books:

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

JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD

I Year – II Sem M.Pharm (PAQA/QA)

SPECTRAL ANALYSIS

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

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.

c. **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

UNIT-III

Particle sizing: Light interaction methods: Rayleigh or static laser light scattering, photon correlation spectroscopy or dynamic laser light scattering, single particle light scattering, multi-angle light scattering.

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.

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.

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 ASSURANCE

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

UNIT I

a. Concepts of Quality Assurance, Total Quality Management, Philosophy of GMP and cGMP

b. Preparation of audit, Conducting audit, Audit Analysis, Audit Report and Audit follow up

UNIT II

a. Organization and personnel, responsibilities, training hygiene

b. Premises: Location, design, plan Layout, construction, maintenance and sanitations, environmental control, sterile areas, control of contamination.

c. Equipments: Selection, purchase specifications, maintenance, clean in place, sterilize in place – Raw – materials: Purchase specifications, maintenance of stores, selection of vendors, controls and raw materials.

UNIT III

a. Concepts of Validation: Types of validation, Master plan, protocol for process validation, cleaning validation, validation of air handling, validation of equipment and facilities in sterile and non-sterile areas.

b. Prevalidation activities, Protocol preparation, Protocol execution, Deviations and change controls, summary and certification. Revalidation

UNIT IV

a. Packaging and labeling controls, line clearance and other packaging materials.

b. Quality Control Laboratory: Responsibilities, good laboratory practices, routine controls, instruments, protocols, non-clinical testing, controls on animal house, data generation and storage.

UNIT V

Manufacture and controls on dosage forms

a. Manufacturing documents, Master Formula, Batch Formula, Records, Standard Operating Procedures,

b. In process quality control on various dosage forms sterile and biological products, standard operating procedures for various operations like cleaning, filling drying, compression, coating, disinfection, sterilization, membrane filtration etc.

c. Guidelines for Quality Assurance of Human Blood Products and large volume parenterals.

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

Text Books

1. The International Pharmacopoeia Vol 1,2,3,4, 3rd edition General Methods of Analysis Quality Specifications for Pharmaceutical Substances, Excipients, Dosage Forms.
2. Quality Assurance of Pharmaceuticals. A Compendium of Guidelines and Related Material
3. Vol. 1 and Vol. 2, WHO 2007)
4. GMP by Mehra
5. Pharmaceutical Process Validation by Berry and Nash
6. 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)

BIOSTATISTICS AND RESEARCH METHODOLOGY
(Core Elective- II)

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.

UNIT I

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

UNIT II

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

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

UNIT III

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

Probability rules: Binomial, Poison and Normal distribution.

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

UNIT IV

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

UNIT V

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

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

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

Text Books

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

Reference Books

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

SCREENING METHODS AND CLINICAL RESEARCH
(Core Elective- II)

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

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

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

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

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

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

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

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

Reference Books:
1. ICH of technical requirements for registration of pharmaceuticals for human use, ICH harmonized tripartite guidelines - Guidelines for good clinical practice, E6, May 1996.
2. Good clinical practice - Guidelines for Clinical 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 (PA&QA/QA)

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

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

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.

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

REFERENCE BOOKS :

1. Comprehensive Pharmacy Review 5th Edition by Leon Shargel, Alan H. Mutnick, Paul F. Souney, Larry N. Sawnson – 2004.
2. A. 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'sCosmeticology; 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(PA & QA/QA)

NANO BASED DRUG DELIVERY SYSTEMS
(Open Elective- II)

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.

UNIT I – Introduction to Nanotechnology

a) Definition of nanotechnology
b) History of nanotechnology
c) Unique properties of nanomaterials
d) 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

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

Recommended Books:

1. Nanomedicine and Nanoproducts: Applications, Disposition and Toxicologyin 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, GuozhongGao, Imperial College Press(2004)
6. Nanochemistry:A Classical Approach to Nanomaterials – Royal Society for Chemistry, Cambridege, UK (2005)
7. Nanocomposite science and technology, pulickelM.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

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I Year – II Sem M.Pharm(PA & QA/QA)

NUTRACEUTICALS
(Open Elective- II)

Objectives: the students will get exposed to characteristic features of various phytochemicals as Nutraceuticals in various diseased conditions and also know the role of antioxidants in free radical induced diseased conditions and will expose to various food laws and regulations.

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, Allyl trisulfide.
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 : Butylated hydroxy Toluene, Butylated hydroxy Anisole.

UNIT V

Food Laws and Regulations; FDA, FPO, MPO, AGMARK. HACCP and GMPs on Food Safety. Adultration of foods.

Regulations and Claims – Current Products: Label Claims, Nutrient Content Claims, Health Claims, Dietary Supplements Claims

Outcome: Helps the students to understand the importance of Nutraceuticals in various common health problems with the concepts of free radicals.

REFERENCES:

1. Dietetics by Sri Lakshmi
2. Role of dietary fibres and neutraceuticals in preventing diseases by K.T Agusti and P.Faizal: BSPunblication.
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* WoodheadPubl.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

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I Year – II Sem M.Pharm (PAQA/QA)

PHARMACEUTICAL PRODUCT DEVELOPMENT AND MANAGEMENT
(Open Elective- II)

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

UNIT I

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

UNIT II

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

UNIT III

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

UNIT IV

a. US FDA Guidelines for GLP in non-clinical testing laboratories (only salient features will be covered)
b. Organization & Functioning of Accreditation bodies- ISO-9000, ISO-14000, NABL and OSHA (ISO 18000)

UNIT V

a. Environment Health and Safety (EHS): Hazards- Fire, mechanical, chemical and pharmaceutical, monitoring and prevention systems, industrial effluents testing and treatment, control of environmental pollution
b. Ware housing –Design, construction, maintenance and sanitation for materials and products – good warehousing practice

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

Text books:

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

References:

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

JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD

I Year – II Sem M.Pharm (PAQA/QA)

PHARMACEUTICAL MANAGEMENT-II
(Open Elective- II)

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.

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.

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

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
11. Management by Tripathi P. C. and Reddy P. N.; Tata Mc Graw Hill.
12. Business Organization and Management by Shukla M. C.; S. Chand and Company.
13. Business Organization and Management by Sherlakar S. A.; Himalaya.
14. Personnel Management by Filippo E. B.; McGraw Hill.
15. Marketing Management by Kotler Philip.; Prentice Hall of India.
16. Organizational Behavior by Rao and Narayan; Konark Publishers.
17. Personnel Management by Tripathi P. C.; S. Chand and Company.
18. Principle and Practice of Marketing in India by Memoria C. B.
19. Principles of Pharmaceutical Marketing By Mickey Smith C.B.S. Publications.
20. Marketing Hand Book Vol. II , Marketing Management by Edwin – E Bobrow, Mark – D. Bobrow.
21. Production and Operations Management by S.N.Chary

JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD

I Year – II Sem M.Pharm (PAQA/QA)

ADVANCED PHARMACEUTICAL ANALYSIS - II LAB

List of Experiments

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

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

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I Year – II Sem M.Pharm (PAQA/QA)

SPECTRAL ANALYSIS 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.