;JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD
Course Scheme and Syllabus for M. PHARM (PHARMACOGNOSY) 2019-2020

M. Pharm Semester I

Course Number	Subject	Scheme of studies per week			Credits
		L	T	P	
1MPG01	Program Core –I Phytochemistry	3	0	0	3
1MPG02	Program Core –II Advanced Pharmacognosy -I	3	0	0	3
1MPGPE-I	Program Elective –I 1. Modern Pharmaceutical Analytical Techniques 2. Drug Regulatory Affairs 3. Pharmaceutical Food Analysis	3	0	0	3
1MPGPE-II	Program Elective-II 4. Industrial Pharmacognostical Technology 5. Pharmaceutical Validation 6. Cosmetics and Cosmeceuticals	3	0	0	3
1MPGA01	Research Methodology& Intellectual Property Rights	2	0	0	2
1MPGA02	Audit Course- I	2	0	0	0
1MPGL03	Laboratory 1- Phytochemistry Lab	0	0	4	2
1MPGL04	Laboratory 2- Program Elective -I-1/3, Program Elective -II-5/6	0	0	4	2
	Total Credits				**18**

M.Pharm Semester II

Course Number	Subject	Scheme of studies per week			Credits
		L	T	L	
2MPG05	Program Core –III Advanced Pharmacognosy – II	3	0	0	3
2MPG06	Program Core –IV Indian System of Medicine	3	0	0	3
2MPGPE-III	Program Elective –III 7. Herbal Cosmetics 8. Pharmaceutical Quality Control and Quality Assurance 9. Pharmacoepidemology and Pharmacoeconomics	3	0	0	3
2MPGPE-IV	Program Elective –IV 10. Medicinal Plant Biotechnology 11. Nutraceuticals 12. Clinical Research and Pharmacovigilance	3	0	0	3
2MPGA03	Audit Course -II	2	0	0	0
2MPGL07	Laboratory 3- Advanced Pharmacognosy – II Lab	0	0	4	2
2MPGL08	Laboratory 4- Program Elective-III-7/8, Program Elective-IV-10/11	0	0	4	2
2MPG09	Mini Project with Seminar	2	0	0	2
	Total Credits				**18**

*** Students are encouraged to go to Industrial Training/Internship for atleast 2-3 months during semester break.**

M. Pharm Semester-III

Course Number	Subject	Scheme of studies per week			Credits
		L	T	P	
3MPGPE-V	Program Elective – V 13. Biostatistics 14. Scale up and Technology Transfer 15. Production Area Design and Packaging Development	3	0	0	3
3MPGOE	Open Elective 1. Screening Methods in Pharmacology 2. Entrepreneur Management 3. Stability of Drugs and Dosage Forms 4. Cosmetic Science 5. Hazards and Safety Management 6. Audits and Regulatory Complaints	3	0	0	3
3MPG10	Dissertation-I/ Industrial Project	0	0	20	10
	Total Credits				**16**

*** Students going for Industrial Project/Thesis will complete these courses through MOOC's**

M. Pharm Semester-IV

Course Number	Subject	Scheme of studies per week			Credits
		L	T	P	
	Dissertation – II	0	0	32	16
	Total credits				**16**

Audit course 1 & 2

1. English for Research Paper Writing
2. Disaster Management
3. Sanskrit for Technical Knowledge
4. Value Education
5. Constitution of India
6. Pedagogy Studies
7. Stress Management by Yoga
8. Personality Development through Life Enlightenment Skills

Course No: 1MPG01

JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD
M.Pharm Semester-I (PHARMACOGNOSY)

(Program Core –I)
PHYTOCHEMISTRY

Objective: Helps the students to get exposed to natural product drug discovery and to perform quantitative and qualitative evaluation of herbal extracts. To understand the chemistry of important phyto consitituents of different categories.

UNIT I

Biosynthetic pathways and Radio tracing techniques: containing drugs:

a) Methods of Biogenetic Investigations, detailed study of isotropic tracer techniques.

b) Study of Biosynthetic pathways of following phyto-pharmaceuticals:
Atropine, Morphine, Cardiac glycosides and Flavonoids.

UNIT II

Drug discovery and development: Approaches to discovery and development of natural products as potential new drugs. Sourcing and archiving Natural products for discovery, Evaluating natural products for therapeutic properties, Identifying the biologically active Natural products, the lead structure selection process and optimization with suitable examples from the following sources: artemesin, andrographolides.

UNIT III

a) Extraction/Isolation methods for specific Phytochemical groups, Choice of solvents and interfering compounds for general Isolation and purification of desired phytoconstituents.

b) Recent sophisticated extraction techniques like: Super critical fluid extraction and Ultra-sonic extraction. Separation of phytoconstituents by Vacuum and Flash column chromatography.

UNIT IV

Sources, Chemical structure, Identification tests, mechanism of action SAR, uses of the following phyto-pharmaceuticals:

a) Caffeine, Morphine and brief account on its derivatives and analogues

b) Camptothecin, Digoxin

c) Taxol, Podophyllotoxin

UNIT V

a. Natural colorants : Biological Source, colouring principles, chemical nature and usage of the following Annatto, Cochineal, Caramel, Henna, Indigo, Madder, Saffron , Turmeric

b. Flavours and Perfumes : Sandal wood oil, Orange oil, Lemon oil, Palmarosa oil, Geranium oil.

Outcome: On the basis of chemistry data of phytoconsitituents students will acquire knowledge on various types of phytoconstituents present in the plants.

REFERENCE BOOKS:

1) Phytochemical methods of chemical analysis by Harbone
2) Modern methods of plant analysis- peach & M.V.Tracey Vol.1 to VII
3) Pharmacognosy & Phytochemistry of medical plants by Jean Brunton
4) Thin layer chromatography by Stahl
5) Chemistry of natural products by Atur Rahman
6) Comprehensive Medicinal Chemistry, Vol 1-6, Elsevier Publication
7) Medicinal Chemistry Drug Discovery by Donald J, Abrahm,
8) Plant drug analysis by Wagner
9) Clarke's isolation & identification of drugs by AC Mottal
10) Chromatography of Alkaloids by Varpoorte Swendson
11) Jenkins Quantitative pharmaceutical chemistry by AN Kenwell
12) Standardisation of botanicals by V. Rajpal Vol 1 & 2
13) Medicinal chemistry and drug discovery by Burger's
14) Foye's Principles of medicinal chemistry .
15) Herbal Perfumes and cosmetics by Panda
16) Herbal Drug Technology by SS Agarwal

TEXT BOOKS:

1) Pharmacognosy and phytochemistry by Biren seth
2) Pharmacognosy and Phytochemistry by VD Rangari.
3) Textbook of Pharmacognosy by G.E.Trease, W.C.Evans,ELBS
4) Biosynthetic pathways in Higher Plants by J.B. Pridham and T. Swain, Elsevier Publications
5) A Text Book of Pharmacognosy by NPS Senegar, Ritesh Agarwal and Ashwini Singh

Course No: 1MPG02

JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD
M.Pharm Semester-I (PHARMACOGNOSY)

(Program Core –II)
ADVANCED PHARMACOGNOSY- I

Objective: To provide an opportunity for the students to understand the cultivation and utilization aspects of drugs falling under this chapter. Helps the students to get exposed to various techniques of plant tissue culture and explore marine origin natural products

UNIT-I

Plant drug cultivation: a) General introduction to the importance of Pharmacognosy in herbal drug industry, Indian Council of Agricultural Research, Current Good Agricultural Practices, Current Good Cultivation Practices.
b) Post harvesting techniques and utilization of the following Medicinal and Aromatic plants: Ashwagandha, Saffron, Safed musli, Davana, Pachouli and Lemon grass

UNIT- II

A brief account on Chemical and Pharmacological aspects and uses of the following medicinal plants-

1. Immunomodulators
   a. *Asparagus racemosus*
   b. *Withania somnifera*
2. Antidiabetics
   a. *Gymnema sylvestera*
   b. *Momordica charantia*
3. Hepatoprotectives
   a. *Phyllanthus amarus*
   b. *Silybum marianum*
4. Cardioprotectives
   a. *Coleus forskolin*
   b. *Cinerarifolium*

UNIT- III

Marine Pharmacognosy:

A brief account of natural products derived from Marine sources with special reference to Cardiovascular, anti-cancer, anti-viral, anti-microbial, anti-parasitic, anticoagulant and anti-inflammatory agents

UNIT- IV

a) Definitions of Functional foods, Nutraceuticals and Dietary supplements. Classification of Neutraceuticals, 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 neutraceuticals like Spirulina, Soyabean, Ginseng, Ginger, Broccoli, Ginkgo, Flaxseeds, Black cohosh.

UNIT-V

Phytopharmaceuticals:

Occurrence, isolation and characteristic features (Chemical nature, uses in pharmacy, medicinal and health benefits) of following.

a) Carotenoids – i) α and β - Carotene ii) Xanthophylls

b) Limonoids – i) d-Limonene ii) α – Terpineol

c) Flavonoids – i) Reservetrol l ii) Rutin iii) Hesperidin iv) Naringin v) Quercetin

d) Phenolic acids- Ellagic acid

e) Saponins – Shatavarins

f) Vitamins- Tocotrienols and Tocopherols

Outcome: The students will gain applicable knowledge about the traditional plants and marine source which helps them to work upon them for proving their use scientifically.

REFERENCES:

1. Ayurvedic formulary of India, Govt. of India
2. Homeopathic Pharmacopoeia
3. Unani Medical Systems
4. Pharmacopoeial standards for Ayurvedic formulations CCRAS,Delhi
5. Ayurvedic pharmacopoeia
6. Indian herbal pharmacopoeia vol.1 & 2 RRL,IDMA
7. Healing plants of peninsular India by Parrota CABI Publications.
8. Principles of integrated medicines by Mathur PR
9. Handbook of Nutraceuticals and Functional Foods, Third Edition (Modern Nutrition)

TEXT BOOKS:

1) Standardization by Botanicals by V.Rajpal , Vol1 , Eastern Publishers New Delhi
2) Cultivation of Medicinal and Aromatic Crops by A A Farooki
3) Advances in Horticulture by Dr. K.L. Chadha
4) Pharmacognosy and Phytochemistry, A Comprehensive Approach 2nd Edition by S.L. Doore, S.S Khadabadi and B.A. Baviskar
5) A Text Book of Pharmacognosy by NPS Senegar, Ritesh Agarwal and Ashwini Singh

Course No. 1MPGPE-I

JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD
M.Pharm Semester-I (PHARMACOGNOSY)

(Programme Elective - I)
1. MODERN PHARMACEUTICAL ANALYTICAL TECHNIQUES

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

UNIT I

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

a. Column Chromatography: Adsorption and partition, theory, preparation, procedure and methods of detection
b. Thin Layer Chromatography: Theory, preparation, procedures, detection of compounds
c. Paper Chromatography: Theory, different techniques employed, filter papers used, qualitative and quantitative detection
d. Counter – current extraction, solid phase extraction techniques, gel filtration

UNIT II

a. Gas chromatography: Introduction, fundamentals, instrumentation, columns: preparation and operation, detection, derivatization.
b. HPLC: Basic parameters, Principles and instrumentation, solvents and columns used, operational modes, detection and applications of HPLC
c. HPTLC: Theory and principle, instrumentation, elution techniques and pharmaceutical applications

UNIT III

a. UV-Visible spectroscopy: Introduction, electromagnetic spectrum, absorbance laws and limitations, instrumentation-design and working principle, chromophore concept, auxochromes, Wood-Fisher rules for calculating absorption maximum, applications of UV-Visible spectroscopy
b. IR spectroscopy: Basic principles-Molecular vibrations, vibrational frequency, factors influencing vibrational frequencies, sampling techniques, instrumentation, interpretation of spectra, FT-IR, theory and applications

UNIT IV

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

UNIT V

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

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

REFERENCES :

1) Organic spectroscopy by Y.R Sharma Principles of Instrumental Analysis - Doglas A Skoog, F. James Holler, Timothy A. Nieman, 5th edition, Eastern press, Bangalore, 1998.
2) Practical Pharmaceutical Chemistry by A.H. Beckett and J.B. Stenlake
3) Organic Chemistry by I. L. Finar
4) Organic spectroscopy by William Kemp
5) Quantitative Analysis of Drugs by D. C. Garrett
6) Quantitative Analysis of Drugs in Pharmaceutical Formulations by P. D. Sethi
7) Spectrophotometric identification of Organic Compounds by Silverstein
8) HPTLC by P.D. Seth
9) Indian Pharmacopoeia 2007
10) High Performance thin layer chromatography for the analysis of medicinal plants by Eike Reich, Anne Schibli

TEXT BOOKS:

11) A Text book of Pharmaceutical Analysis by Kerrenth A. Connors
12) Vogel's Text book of Quantitative Chemical Analysis by A.I. Vogel
13) Instrumental Methods of Chemical Analysis by B.K Sharma
14) Instrumental methods of analysis – Willards, 7th edition, CBS publishers.
15) Introduction to instrumental analysis by Robert. D. Braun

Course No. 1MPGPE-I

JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD
M.Pharm Semester-I (PHARMACOGNOSY)

(Programme Elective - I)
2. DRUG REGULATORY AFFAIRS

Objective: The topics which are present in the Drug regulatory affairs are very much useful which increases the knowledge regarding the regulatory aspects in the pharmaceutical industries.

UNIT I
Drug Regulatory Aspects (India)
1. Indian drug regulatory authorities, Central and State regulatory bodies (FDA)
2. Drugs and Cosmmetics Act and Rules with latest Amendments (Selective)
3. Special emphasis – Schedule M and Y
4. New drugs – Importation, Registration, development, Clinical Trials, BE NOC & BE studies
5. Various Licences – Test Lic., Import lic., for testing of drugs and API's, Manufacturing Contract and Loan licence manufacturing.

UNIT II
Good Manufacturing Practices(GMP)
1. Indian GMP certification, WHO GMP certification.
2. ICH guidelines for stability testing and other relevant ones (Q1-Q10)
3. Export permissions and manufacturing for semi-regulated countries
4. Understanding of the plant layouts with special emphasis on the environment & safety.(HVAC, Water Systems, Stores Managemant, Effluent etc.)
5. Quality Assurance and Qulaity Control – Basic understanding for in-built quality.

UNIT III
A detailed study of regulatory aspects that affect drug product design, manufacture and distribution in a developed country such as USA and in a developing country such as Brazil, Hatch Waxmann Act;
Bolar Provisions and other FDA Regulations. Regulatory aspects of pharmaceutical and bulk drug manufacture, regulatory drug analysis.

UNIT IV
Documentation related to manufacturing, cleaning methods, retention samples and records, quality control, batch release documents, distribution records, complaints and recalls.
Quality, safety and legislation for cosmetic products and herbal products.

UNIT V
Governing Regulatory Bodies across the globe.

Country Authority Submission

a. U.S Food & Drug Administration USDMF
b. Canada Therapeutic Product Directorate DMF

c. Europe
    1) European Medicines Agency (EMEA/ National Authorities) EDMF
    2) European Directorate for Quality of Medicines CEP/COS & Health Care Products.
    3) MHRA – Medicines and Health Care Products Regulatory Agency
d. Product Filing
e. Responding Regulatory Deficiencies
f. Final Approval Procedure

Preparation, review and submission of Drug Master Files to Regulatory Authorities as per their specific requirements.

Outcome:

- Students will come to know the different competent regulatory authorities globally.
- Students be aware of technical aspects pertaining to the marketing authoritization application(MAA)
- The regulatory guidelines and directions framed by the regulatory authorities will be helpful to place the drug products in market for marketing approvals.

REFERENCE BOOKS

1. Original laws published by Govt. of India.
2. Laws of Drugs in India by Hussain.
3. Pharmaceutical Regulatory Affairs - Selected Topics , CVS Subramanyam and J Thimmasetty, VallabhaPrakashan Delhi - 2013

TEXT BOOKS:

1. Text Book of Forensic Pharmacy by Mithal B. M.; VallabhPrakashan, New Delhi.
2. Text Book of Forensic Pharmacy by Jain N. K.; VallabhPrakashan, New Delhi.

Course No. 1MPGPE-I

JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD
M.Pharm Semester-I (PHARMACOGNOSY)

(Programme Core - I)

3. PHARMACEUTICAL FOOD ANALYSIS

Objective

This course is designed to impart knowledge on analysis of food constituents and finished food products. The course includes application of instrumental analysis in the determination of pesticides in variety of food products.

UNIT I

a. **Carbohydrates:** Classification and properties of food carbohydrates, General methods of analysis of food carbohydrates,
b. **Proteins**: Chemistry and classification of amino acids and proteins, Physico-Chemical properties of protein and their structure, general methods of analysis of proteins and amino acids

UNIT II

Probiotics: Definition, history, importance, mode of action, identification advantages and disadvantages of probiotics. Applications of Probiotics

UNIT III

Lipids: Classification, general methods of analysis, refining of fats and oils; hydrogenation of vegetable oils, Determination of adulteration in fats and oils.

UNIT IV

Vitamins: Classification of vitamins, methods of analysis of vitamins, Principles of microbial assay of vitamins of B-series

UNIT V

a. **General Analytical methods** for milk, milk constituents and milk products like ice cream, milk powder, butter, margarine, cheese including adulterants and contaminants of milk.

b. **Analysis of fermentation products** like wine, spirits, beer and vinegar.

Outcome:

At completion of this course student shall be able to understand various analytical techniques in the determination of

- Food constituents
- Food additives
- Finished food products
- Pesticides in food
- And also student shall have the knowledge on food regulations and legislations

REFERENCE BOOKS

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

Indian Pharmacopoeia 2012

TEXT BOOKS

1) The chemical analysis of foods – David Pearson, Seventh edition, Churchill Livingstone, Edinburgh London, 1976
2) Introduction to the Chemical analysis of foods – S. Nielsen, Jones & Bartlett publishers, Boston London, 1994.
3) Official methods of analysis of AOAC International, sixth edition, Volume I & II, 1997.
4) Analysis of Food constituents – Multon, Wiley VCH.
5) Dr. William Horwitz, Official methods of analysis of AOAC International
6) 18th edition, 2005.Theory and Practice of Industrial Pharmacy by Lieberman and Lachman

Course No: 1MPGPE-II

JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD
M.Pharm Semester-I (PHARMACOGNOSY)

(Program Elective-II)
4. INDUSTRIAL PHARMACOGNOSTICAL TECHNOLOGY

Objectives:
To understand the Industrial and commercial potential of drugs of natural origin, integrate traditional Indian systems of medicine with modern medicine and also to know regulatory and quality policy for the trade of herbals and drugs of natural origin.

UNIT I:
Herbal drug industry:
a) Study of infrastructure, staff requirements, project profile, plant and equipment applicable to herbal drug industry. Plant design, layout and construction. Pilot plant scale –up techniques.
b) GMP and GLP

UNIT II:
Regulatory requirements for setting herbal drug industry:
Global marketing management. Regulatory requirements
Export - Import (EXIM) policy. TRIPS
Quality assurance in herbal/ natural drug products. Concepts of TQM, ISO-9000.

UNIT III:
a) A brief account of companies making herbal drug formulations: List of formulations containing single herbal powder/extract, poly herbal powder/ extracts and their composition and uses.
b) Monographs of herbal drugs: General parameters of monographs of herbal drugs in Ayurvedic Pharmacopoeia, Herbal Pharmacopoeia.

UNIT IV:
a) Testing of natural products and drugs: Herbal medicines - clinical laboratory testing.
b) Stability testing of natural products: Indicative substances for quality assurance, GMP and HACCP in traditional system of medicine, methods of stabilization validation of analytical procedures.

UNIT V:
Patents: Patenting of herbal drugs: Benefits of patent protection, Patent application, drafting and filing an application. Indian and international patent laws, proposed amendments as applicable to herbal/natural products and process. Geographical indication, Copyright, Patentable subject maters, novelty, non obviousness, utility, patent processing and grant of patents.

Outcome:

By the end of the course the student shall be able to know: The requirements for setting up the herbal/natural drug industry. The guidelines for quality of herbal/natural medicines and regulatory issues.The patenting/IPR of herbals/natural drugs and trade of raw and finished materials.

REFERENCES (Latest Editions of)

1. GMP for Botanicals - Regulatory and Quality issues on Phytomedicine by Pulok K Mukharjee
   (2003) 1st Edition, Business horizons Robert Verpoorte, New Delhi.
3. Quality control of herbal drugs by Pulok K Mukarjee (2002), Business Horizons Pharmaceutical Publisher, New Delhi.
4. PDR for Herbal Medicines (2000), Medicinal Economic Company, New Jersey.
5. Herbal Drugs Quality and Chemistry by D. D. Joshi

TEXT BOOKS:

1. Herbal drug industry by R.D. Choudhary (1996), Eastern Publisher, New Delhi.
2. Text book of Pharmacognosy and Phytochemistry by Vinod D. RangarI (2002), Part I & II, Career Publication, Nasik, India.
3. Quality control of herbal drugs by P.K. Mukherjee
4. Herbal Drug Technology by SS Agarwal and paridhavi
5. Pharmacognosy and Phytochemistry, A Comprehensive Approach 2nd Edition by S.L. Doore, S.S Khadabadi and B.A. Baviskar

Course No: 1MPGPE-II

JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD
M.Pharm Semester-I (PHARMACOGNOSY)

(Program Elective-II)
5. PHARMACEUTICAL VALIDATION

Objective

The main purpose of the subject is to understand about validation and how it can be applied to industry and thus to improve the quality of the products. The subject covers the complete information about validation, types, methodology and application.

UNIT I

Introduction: Definition of Qualification and Validation, Advantage of Validation, Streamlining of Qualification & Validation process and Validation Master Plan.

Qualification: User Requirement Specification, Design Qualification, Factory Acceptance Test (FAT)/ Site Acceptance Test (SAT), Installation Qualification, Operational Qualification, Performance Qualification, Re- Qualification (Maintaining status-Calibration Preventive Maintenance, Change management),Qualification of Manufacturing Equipments, Qualification of Analytical Instruments and Laboratory equipments.

UNIT II

Qualification of analytical instruments: Electronic balance, pH meter, UV-Visible spectrophotometer, FTIR, GC, HPLC, HPTLC

Qualification of Glassware: Volumetric flask, pipette, Measuring cylinder, beakers and burette.

UNIT III

Qualification of laboratory equipments: Hardness tester, Friability test apparatus, tap density tester, Disintegration tester, Dissolution test apparatus.

Validation of Utility systems: Pharmaceutical water system & pure steam, HVAC system, Compressed air and nitrogen.

UNIT IV

Cleaning Validation: Cleaning Validation - Cleaning Method development, Validation and validation of analytical method used in cleaning. Cleaning of Equipment. Cleaning of Facilities. Cleaning in place (CIP).

UNIT V

Analytical method validation: General principles, Validation of analytical method as per ICH guidelines and USP.

Outcome:

Upon completion of the subject student shall be able to

- Explain the aspect of validation
- Carryout validation of manufacturing processes
- Apply the knowledge of validation to instruments and equipments
- Validate the manufacturing facilities

REFERENCES:

1. B. T. Loftus & R. A. Nash, "Pharmaceutical Process Validation", Drugs and Pharm Sci. Series, Vol.129, 3rd Ed., Marcel Dekker Inc., N.Y.
2. Validation Master plan by Terveeks or Deeks, Davis Harwood International publishing.
3. Validation of Aseptic Pharmaceutical Processes, 2nd Edition, by Carleton &Agalloco, (Marcel Dekker).
4. Michael Levin, Pharmaceutical Process Scale-Up‖, Drugs and Pharm. Sci.Series, Vol. 157,2nd Ed. Marcel Dekker Inc., N.Y.
5. Validation Standard Operating Procedures: A Step by Step Guide for Achieving Compliance in the Pharmaceutical, Medical Device, and Biotech Industries, Syed ImtiazHaider
6. Validation of Pharmaceutical Processes: Sterile Products, Frederick J.Carlton (Ed.) and James Agalloco (Ed.), Marcel Dekker, 2nd Ed.

TEXT BOOKS:

1) The Theory & Practice of Industrial Pharmacy, 3rd edition, Leon Lachman, Herbert A. Lieberman, Joseph. L. Karig, Varghese Publishing House, Bombay.
2) Pharmaceutical Equipment Validation: The Ultimate Qualification Handbook, Phillip A. Cloud, Interpharm Press
3) Analytical Method validation and Instrument Performance Verification by Churg Chan, Heiman Lam,

Course No: 1MPGPE-II

JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD
M.Pharm Semester-I (PHARMACOGNOSY)

(Program Elective-II)
6. COSMETICS AND COSMECEUTICALS

Objectives: Upon completion of the course, the students shall be able to understand.
Key ingredients used in cosmetics and cosmeceuticals. Key building blocks for various formulations. Current technologies in the market. Various key ingredients and basic science to develop cosmetics and cosmeceuticals. Scientific knowledge to develop cosmetics and cosmeceuticals with desired Safety, stability, and efficacy.

UNIT I
Cosmetics – Regulatory: Definition of cosmetic products as per Indian regulation. Indian regulatory requirements for labeling of cosmetics Regulatory provisions relating to import of cosmetics. Misbranded and spurious cosmetics. Regulatory provisions relating to manufacture of cosmetics − Conditions for obtaining license, prohibition of manufacture and sale of certain cosmetics, loan license, offences and penalties.

UNIT II
Cosmetics - Biological aspects: Structure of skin relating to problems like dry skin, acne, pigmentation, prickly heat, wrinkles and body odor. Structure of hair and hair growth cycle. Common problems associated with oral cavity. Cleansing and care needs for face, eye lids, lips, hands, feet, nail, scalp, neck, body and under-arm.

UNIT III
Formulation Building blocks: Building blocks for different product formulations of cosmetics/cosmeceuticals. Surfactants − Classification and application. Emollients, rheological additives: classification and application. Antimicrobial used as preservatives, their merits and demerits. Factors affecting microbial preservative efficacy. Building blocks for formulation of a moisturizing cream, vanishing cream, cold cream, shampoo and toothpaste. Soaps and syndetbars.
Perfumes; Classification of perfumes. Perfume ingredients listed as allergens in EU regulation.
Controversial ingredients: Parabens, formaldehyde liberators, dioxane.

UNIT IV
Design of cosmeceutical products: Sun protection, sunscreens classification and regulatory aspects. Addressing dry skin, acne, sun-protection, pigmentation, prickly heat, wrinkles, body odor., dandruff, dental cavities, bleeding gums, mouth odor and sensitive teeth through cosmeceutical formulations.

UNIT V

Herbal Cosmetics : Herbal ingredients used in Hair care, skin care and oral care. Review of guidelines for herbal cosmetics by private bodies like cosmos with respect to preservatives, emollients, foaming agents, emulsifiers and rheology modifiers. Challenges in formulating herbal cosmetics.

REFERENCES

1. Harry's Cosmeticology. 8th edition.
2. Poucher' sperfumecosmeticsandSoaps,10th edition.
3. Cosmetic and Toiletries recent suppliers catalogue.
4. CTFA directory.

TEXT BOOKS:

1. Cosmetics - Formulation, Manufacture and quality control, P. P. Sharma, 4th edition
2. Handbook of cosmetic science and Technology A.O.Barel, M.Paye and H.I. Maibach. 3 rd edition

Course No: 1MPGL03

JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD
M.Pharm Semester-I (PHARMACOGNOSY)

Laboratory - 1
PHYTOCHEMISTRY LAB

List of experiments:

1. Methods of extraction: Preparation of extracts of organized crude drugs / Herbs by successive solvent extraction method to record the percentage yield and physical status of the respective extracts and for subjecting them to phytochemical screening.
2. Detection of Phytoconstituents by test tubes and TLC methods, such as
   a. Alkaloids, b. Steroids, Triterpenoids and their glycosides and saponins,
   c. Anthracene glycosides d. Flavanoids and their glycosides
   e. Coumarins f. Tannins
3. a. Identification of alkaloids in a mixture by TLC
   e.g. Atropine, Caffeine, Ergot, Piperine, Quinine, Reserpine, Strychnine and Brucine
   b. Color reactions of different groups of alkaloids.
4. Isolation of the following Phytoconstituents
   a. Caffeine from Tea
   b. Caffeine from marketed product
   c. Strychnine and Brucine from Nux-Vomica by Column chromatography.
   d. Piperine from black pepper
   e. Citric acid from Lemon
   f. Nicotine from Tobacco
   g. Pectin from Orange peels
5. Detection, extraction, and estimation of volatile oils by Clevenger's method (Hydrodistillation method), TLC of volatile oils and their pure constituents.
6. Isolation of starches from potatoes and rice
7. Isolation of Bixin from *Bixa orellana*
8. Isolation of Lawsone from Henna
9. Preparation of Curcuminoids
10. Identification of bioactive constituents from plant extracts

Course No: 1MPGL04

JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD
M.Pharm Semester-I (PHARMACOGNOSY)

Laboratory - 2

1. MODERN PHARMACEUTICAL ANALYTICAL TECHNIQUES LAB

List of experiments

1. Colorimetry / UV / Visible, Spectroscopy, scanning of few compounds for UV-absorption, calculation of Assay / content uniformity / % of drug release (2-3 experiments.)
1. Simultaneous estimation of multi component containing formulations by UV spectrophotometry
2. Experiment base on HPLC (Isocratic and gradient) Techniques – (2 experiments)
3. Incompatibility studies, identification and functional groups – Determination by FTIR (2 experiments)
4. Separation and calculation of Rf values by using paper chromatography, TLC, HPTLC Technique (2-3 experiments)
5. Calibration of glasswares
6. Calibration of pH meter
7. Calibration of UV-Visible spectrophotometer
8. Calibration of FTIR spectrophotometer
9. Calibration of HPLC instrument

Course No. 1MPGL04

JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD
M.Pharm Sem – I (PHARMACOGNOSY)

Laboratory – 2

3. PHARMACEUTICAL FOOD ANALYSIS LAB

List of Experiments:

1. Determination of total reducing sugar
2. Determination of proteins
3. Determination of saponification value, Iodine value, Peroxide value, Acid value in food products
4. Determination of fat content and rancidity in food products
5. Analysis of natural and synthetic colors in food
6. Determination of preservatives in food
7. Determination of pesticide residue in food products
8. Analysis of vitamin content in food products
9. Determination of density and specific gravity of foods
10. Determination of food additives

Course No. 1MPGL04

JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD
M.Pharm Sem – I (PHARMACOGNOSY)

Laboratory – 2
5. PHARMACEUTICAL VALIDATION LAB

List of Experiments

1. Calibration of Electronic Balance.
2. Calibration of pH meter.
3. Calibration of Friability test apparatus.
4. Calibration of Tap density tester.
5. Calibration of Disintegration tester.
6. Calibration of Dissolution test apparatus
7. Cleaning validation of any 2 analytical instruments.
8. Analytical method development and validation of any 2 drugs of interest.
9. Preparation of Master Formula Record.
10. Preparation of Batch Manufacturing Record.

Course No. 1MPGL04

JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD
M.Pharm Sem – I (PHARMACOGNOSY)

Laboratory – 2

6. COSMETICS AND COSMECEUTICALS LAB

List of Experiments

1. Preparation and evaluation of Gels like Shaving gels, Anti dandruff Shampoo and Hair styling gels
2. Preparation of Mouth washes
3. Preparation and evaluation of Cold Creams, Vanishing Creams.
4. Preparation and evaluation of Calamine lotion
5. Preparation and evaluation of Face powder and Dusting Powder
6. Preparation and evaluation of Eye liners and Lip sticks
7. Preparation of Anti-Perspirants
8. Preparation of Hand and Body Lotions
9. Preparation and evaluation of Foundation Creams and Cleansing Creams
10. Preparation and Evaluation of Face Masks
11. Preparation of Hair oils to prevent hair fall
12. Preparation and evaluation of Aloe vera Gel
13. Preparation of Antiseptic cream (Turmeric)
14. Preparation and evaluation of Perfumes
15. Preparation and evaluation of Herbal Henna

Course No: 2MPG05

JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD
M.Pharm Semester-II (PHARMACOGNOSY)

(Program Core –III)
ADVANCED PHRMACOGNOSY-II

Objective
Helps the students to know about common bitters, laxatives and the analytical profiles of some herbal drugs and herbal cosmetics used in everyday life.

UNIT I:
Adulteration and Deterioration: Introduction, Types of Adulteration/ Substitution of Herbal drugs, Causes and Measures of Adulteration, Sampling Procedures, Determination of Foreign Matter, DNA Finger printing techniques in identification of drugs of natural origin, detection of heavy metals, pesticide residues, microbial contamination in herbs and their formulations.

UNIT II:
a) A brief account on standardization parameters of herbal drugs.
b) Analytical Profiles of herbal drugs: *Andrographis paniculata, Boswellia serata, Coleus forskholii, Curcuma longa, Embelica officinalis, Psoralea corylifolia.*

UNIT III:

a) **Vegetable bitters:** Biological source, Chemical Nature and description of bitter principles, and of the following – Chirata, Quassia, Calumba, Calamus, Cusparia, Serpentaria
b**) Vegetable Laxatives:** Biological source, Chemical Nature and description of purgation actions and therapeutics of the following: Senna, Cascara, Rubarb, Aloes, Isapgul, agar, castor oil

UNIT IV:
Ethnobotany and Ethnopharmacology: Ethnobotany in herbal drug evaluation, Impact of Ethnobotany in traditional medicine, New development in herbals, Bio-prospecting tools for drug discovery, Role of Ethnopharmacology in drug evaluation, Reverse Pharmacology.

UNIT V
Biological screening of herbal drugs: Introduction and need for Phyto Pharmacological screening, new strategies for evaluating Natural products, *invitro* evaluation techniques for antioxidants, antimicrobial. i*nvivo* evaluation of antiulcer, anticancer, wound healing, Hepatoprotectives

Outcome:

Upon completion of the course, the student shall be able to know the, standardization and evaluation techniques for the herbal drugs.

REFERENCE BOOKS

1. Phytochemical methods of chemical analysis by Harbone
2. Indian herbal Pharmacopoeia
3. Dietetics by Sri Lakshmi
4. Herbal Drug industry by Chowdary

TEXT BOOKS

1. Quality control of herbal drugs by P.K. Mukherjee
2. Standardization of botanicals by V. Rajpal, Vol I &II
3. Herbal Drug industry by Paridhavi
4. Pharmacognosy and Phytochemistry, A Comprehensive Approach 2nd Edition by S.L. Doore, S.S Khadabadi and B.A. Baviskar
5. A Text Book of Pharmacognosy by NPS Senegar, Ritesh Agarwal and Ashwini Singh

Course No: 2MPG06

JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD
M.Pharm Semester-II (PHARMACOGNOSY)

(Program Core –IV)
INDIAN SYSTEM OF MEDICINE

Objectives: Exposure to principles and concepts of alternative systems of medicine like ayurveda, siddha, homeopathy and unani medicine. To acquire knowledge on the methods of preparation and use of formulations of various systems of medicines.

UNIT I

Introduction to various systems of Indigenous Medicine. Principles and Concepts of Ayurveda, History and Development of Ayurvedic medicine. Introduction to different dosage forms and Preparation Methods of Ayurvedic medicines.

UNIT II

Definition and Method of preparation of following Ayurvedic formulations with their uses.

a. Vati : Eladi vati, Lavangadi vati
c. Taila: Bhringaraj taila, Shatabindu taila.
d. Bhasma: Swarna bhasma, Loha bhasma
e. Ghrita : Brahmi ghrita, Jhatyadhi ghrita
f. Asavas/Arishtas: Chandan asava, Dashamoola arishta
g. Lehya : Vasavalehya, Kusumandavalehya

UNIT III

Naturopathy and Yoga practices:

a) Naturopathy - Introduction, basic principles and treatment modalities.
b) Yoga - Introduction and Streams of Yoga. Asanas, Pranayama, Meditations and Relaxation techniques.

UNIT IV

a) A brief History, Origin and development of Homeopathy. Fundamentals, concepts and Principles of Homeopathy. Introduction to different dosage forms and method of preparation of Homeopathic medicines.
b) Siddha systems of medicines, their merits and demerits

UNIT V

a) Principles of Unani and. Introduction to different dosage forms and method of preparations of Unani medicines.
b) Aromatherapy – Introduction, aroma oils for common problems, carrier oils.

Outcome: Helps the students in understanding the influence of various alternative systems of medicine in the development of herbal drugs.

REFERENCE BOOKS:

1) Ayurvedic formulary of India, Govt. of India
2) Homeopathic Pharmacopoeia
3) Unani Medical Systems
4) Pharmacopoeial standards for Ayurvedic formulations CCRAS,Delhi
5) Ayurvedic pharmacopoeia
6) Indian herbal pharmacopoeia vol.1 & 2 RRL,IDMA
7) Vaidya Yoga Ratnavali (Formulary of Ayurvedic Medicines)
8) Ayurvedic drugs and their plant sources by VV. Sivarajan
9) Augmented textbook of Homeopathic Pharmacy by Dr. D. D. Benerjee
10) Yoga - The Science of Holistic Living by V.K.Yoga, Vivekananda Yoga Prakashna Publishing, Bangalore.
11) Homeopathic Pharmacopoeia. Formulary of Homeopathic Medicines, IMCOPS, Chennai.

TEXT BOOKS:

1. Standardization by Botanicals by V.Rajpal , Vol1 , Eastern Publishers New Delhi
2. Healing plants of peninsular India by Parrota CABI Publications.
3. Principles of integrated medicines by Mathur PR
4. Principles and Practice of Homeopathy by Dr. M. L. Dhawale
5. The Complete Book of Essential Oils and Aromatherapy by Valerie Ann Worwood
6. Handbook on Unani Medicines with Formulae, Processes, Uses and Analysis

Course No: 2MPGPE-III

JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD
M.Pharm Semester-II (PHARMACOGNOSY)

(Program Elective –III)
7. HERBAL COSMETICS

Objective: The topics helps the students to get exposed to processes involved in the manufacturing of herbal cosmetics including the skin and hair care herbal products preparation and their evaluation.

UNIT I

Introduction: Herbal/ natural cosmetics, Classification & Economic aspects.

Regulatory Provisions relation to manufacture of cosmetics: -

License, GMP, offences & Penalties, Import & Export of Herbal/natural cosmetics, Industries involved in the production of Herbal/natural cosmetics.

UNIT II

a) Commonly used herbal cosmetics raw materials –water, preservatives, surfactants, oils /waxes, colors, and some functional herbs
b) Processes used in the manufacture of cosmetics-Emulsification, Mixing, compaction, Molding, Packing.
c) General principles of quality control of herbal cosmetics

UNIT III

Skin care Products: Physiology and chemistry of skin, Method of preparation, pharmaceutical and Pharmacological evaluation procedures for various formulations like Creams, Lotions, Lipsticks, Face packs. Elaborative study of five formulations under each category with regard to their composition and claims for various herbs used in them.

UNIT IV

Hair care Products: Hair structure and its chemistry

Method of preparation, pharmaceutical and Pharmacological evaluation procedures for various formulations like Hair dyes, Creams, Oils and Shampoos. Elaborative study of five formulations under each category with regard to their composition and claims for various herbs used in them.

UNIT V

Herbs in cosmetics:

A brief account of following herbals or herb extracts or herbal products of cosmetic importance such as *Acacia concinna* pods, *Aloe Vera*, Almond oil, Neem, *Citrus aurantium* peels, Henna, Turmeric, Liquorices, Olive oil, tea tree oil and wheat germ oil with special emphasis on their source, active principles and cosmetic properties.

Outcome:

Students will learn about the raw materials used in herbal cosmetics and get exposed to various preparations of herbal cosmetics.

REFERENCES:

1. Cosmetics- Formulation, Manufacturing and Quality control –P.P.Sharma
2. Skaria P. Aromatic Plants (Horticulture Science Series), New India Publishing Agency, New Delhi.
3. Kathi Keville and Mindy Green. Aromatheraphy (A Complete Guide to the Healing Art), Sri Satguru Publications, New Delhi.
4. Chattopadhyay PK. Herbal Cosmetics & Ayurvedic Medicines (EOU), National Institute of Industrial Research, Delhi.
5. Balsam MS & Edward Sagarin. Cosmetics Science and Technology, Wiley Interscience, New York.

TEXT BOOKS:

1. Herbal Cosmetics Hand Book- H. Panda
2. Herbal Cosmetics by P.K Chattopadhyay
3. The Complete Technology Book on Herbal Perfumes and Cosmetics by H. Panda
4. Supriya K B. Handbook of Aromatic Plants, Pointer Publishers, Jaipur.

Course No: 2MPGPE-III

JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD
M.Pharm Semester-II (PHARMACOGNOSY)

(Program Elective –III)

8. PHARMACEUTICAL QUALITY CONTROL AND QUALITY ASSURANCE

Objectives

This course deals with the various aspects of quality control and qualityassurance aspects of pharmaceutical industries. It covers the important aspectslike cGMP, QC tests, documentation, quality certifications, GLP and regulatoryaffairs.

UNIT I

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

UNIT II

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

UNIT III

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

UNIT IV

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

UNIT V

Manufacture and controls on dosage forms

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

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

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

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)
7. Analytical Profiles of drug substances and Excipients – Harry G Brittan, Volume 21-30, Elsevier, 2005.

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

Course No: 2MPGPE-III

JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD
M.Pharm Semester-II (PHARMACOGNOSY)

(Program Elective –III)

9. PHARMACOEPIDEMIOLOGY & PHARMACOECONOMICS

Objective:
This course enables students to understand various pharmacoepidemiological methods and their clinical applications. Also, it aims to impart knowledge on basic concepts, assumptions, terminology, and methods associated with Pharmacoeconomics and health related outcomes, and when should be
appropriate Pharmacoeconomic model should be applied for a health careregimen.

UNIT-I
Introduction to Pharmacoepidemiology:
Definition, Scope, Need, Aims & Applications; Outcome measurement: Outcome measures, Drug use measures: Monetary units, Number of prescriptions, units of drug dispensed, defined daily doses, prescribed daily doses, Diagnosis and Therapy surveys, Prevalence, Incidence rate, Monetary units, number of prescriptions, unit of drugs dispensed, defined daily doses and prescribed daily doses, medications adherence measurements. Concept of risk: Measurement of risk, Attributable risk and relative risk, Time- risk relationship and odds ratio

UNIT-II
Pharmacoepidemiological Methods:
Qualitative models: Drug Utilization Review; Quantitative models: case reports, case series, Cross sectional studies, Cohort and case control studies, Calculation of Odds' ratio, Meta analysis models, Drug effects study in populations: Spontaneous reporting, Prescription event monitoring, Post marketing surveillance, Record linkage systems, Applications of Pharmacoepidemiology

UNIT-III
Introduction to Pharmacoeconomics:
Definition, history of Pharmacoeconomics, Need of Pharmacoeconomic studies in Indian healthcare system. Cost categorization and resources for cost estimation: Direct costs. Indirect costs. Intangible costs. Outcomes and Measurements of Pharmacoeconomics: Types of outcomes: Clinical outcome, Economic outcomes, Humanistic outcomes; Quality Adjusted Life Years, Disability Adjusted Life Years Incremental Cost Effective Ratio, Average Cost Effective Ratio. Person Time, Willingness To Pay, Time Trade Off and Discounting.

UNIT-IV
Pharmacoeconomic evaluations:
Definition, Steps involved, Applications, Advantages and disadvantages of the following Pharmacoeconomic models: Cost Minimization Analysis (CMA),Cost Benefit Analysis (CBA), Cost Effective Analysis (CEA), Cost Utility Analysis (CUA), Cost of Illness (COI), Cost Consequences Analysis (COA).

UNIT-V

Definition, Steps involved, Applications, Advantages and disadvantages of the following:

Health related quality of life (HRQOL): Definition, Need for measurement of HRQOL, Common HRQOL measures. Definition, Steps involved, Applications of the following: Decision Analysis and Decision tree, Sensitivity analysis, Markov Modeling, Software used in Pharmacoeconomic analysis, Applications of Pharmacoeconomics.

Outcome:

Upon completion of this course it is expected that students shall be able to:

- Understand the various epidemiological methods and their applications
- Understand the fundamental principles of Pharmacoeconomics.
- Identify and determine relevant cost and consequences associated with pharmacy products and services.
- Perform the key Pharmacoeconomics analysis methods
- Understand the Pharmacoeconomic decision analysis methods and its applications.
- Describe current Pharmacoeconomic methods and issues.
- Understand the applications of Pharmacoeconomics to various pharmacy settings.

REFERENCES

1. Rascati K L. Essentials of Pharmacoeconomics, Woulters Kluwe Lippincott Williams & Wilkins, Philadelphia.
2. Thomas E Getzen. Health economics. Fundamentals and Flow of Funds John Wiley & Sons, USA.
3. Andrew Briggs, Karl Claxton, Mark Sculpher. Decision Modelling for Health Economic Evaluation, Oxford University Press, London.
4. K G Revikumar, Pharmacoepidemiology and Pharmacoeconomics Concepts and Practices.
5. Michael Drummond, Mark Sculpher, George Torrence, Bernie O'Brien and Greg Stoddart. Methods for the Economic Evaluation of Health Care Programmes Oxford University Press, London.
6. Relevant review articles from recent medical and pharmaceutical literature
7. Guru Prasad Mohanta and P K Manna, Textbook of Pharmacovigilance Concepts and Practice

TEXT BOOKS:

1. George E Mackinnon III. Understanding health outcomes and pharmacoeconomics.
2. Graker, Dennis. Pharmacoeconomics and outcomes.
3. Walley, Pharmacoeconomics.
4. Pharmacoeconomic – ed. by Nowakowska – University of Medical Sciences, Poznan.

Course No: 2MPGPE-IV

JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD
M.Pharm Semester-II (PHARMACOGNOSY)

(Program Elective –IV)
10. MEDICINAL PLANT BIOTECHNOLOGY

Objective: The topics are designed to help the students to get exposed to various techniques of plant tissue culture. Use the biotechnological techniques for obtaining and improving the quality of natural products/medicinal plants

UNIT I

Introduction to Plant biotechnology: Historical perspectives, Laboratory Organization, Maintenance of asepsis in tissue culture, Totipotency, Nutritional requirements, Media preparation, Explant preparation, Establishment of Aseptic cultures. Biotechnological applications of Plant Tissue culture in pharmacy and allied fields.

UNIT II

Different tissue culture techniques: Types and techniques of plant tissue culture, Initiation and maintenance of callus and suspension culture, growth parameters, Organogenesis and embryogenesis, Protoplast fusion, synthetic seed

UNIT III

Micro propagation of medicinal and aromatic plants, Immobilization techniques & Secondary Metabolite Production: Immobilization techniques of plant cell and its application, Precursors and elicitors on production of secondary metabolites, Cryopreservation of germ plasm.

UNIT IV

Biotransformation and Trangenesis: Biotransformation of Plant Cell Culture and its importance in secondary metabolite production. Bioreactors for pilot and large scale cultures of plant cells and retention of biosynthetic potential in cell culture**,** Production of ergot alkaloids, single cell proteins, enzymes of pharmaceutical interest. Transgenic technology- Hairy root multiple shoot cultures and their applications.

UNIT V

Secondary metabolism in tissue cultures with emphasis on production of medicinal agents-
Production of Secondary metabolites from callus culture and suspension culture with emphasis on production of biomedicinals like- Ajmalicine, Shikonin, Carotenoids and Rosemarinic acid.

Outcome: Students will gain the knowledge about various strategies of plant tissue culture and students will gain knowledge about various secondary metabolites produced by plant tissue culture.

REFERENCES:

1. Plant Tissue Culture by Bhojwani
2. Molecular Biology and Biotechnology by J.M.Walker and E.D.Gingo
3. Advanced methods in Plant breeding and Biotechnology by David R Mirray
4. Biotechnology by Purohit and Mathur, Agro-Bio, 3rd revised edition.
5. Biotechnological applications to tissue culture by Shargool, Peter D, Shargoal, CKC Press.
6. Pharmacognosy by Varo E. Tyler, Lynn R. Brady and James E. Robberrt, That Tjen, NG

TEXT BOOKS:

1. Medicinal plant biotechnology by Ciddi Veeresham
2. Pharmaceuticals biotechnology by S.P. Vyas & V.K.Dixit
3. Pharmacognosy and Pharmacobiotechnology by Ashutoshkar
4. Introduction to plant tissue culture by M.K.Razadam
5. Plant tissue culture by Street
6. Pharmacognosy and Phytochemistry, A Comprehensive Approach 2nd Edition by S.L. Doore, S.S Khadabadi and B.A. Baviskar

Course No: 2MPGPE-IV

JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD
M.Pharm Semester-II (PHARMACOGNOSY)

(Program Elective –IV)
11. NUTRACEUTICALS

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

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. Adultration of foods.

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

Outcome: Helps the student to understand the importance of Neutraceuticals in various commom problems with the concept 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. Prescription for Nutritional Healing by James F.Balch and Phyllis A.Balch2nd Edn., Avery Publishing Group, NY (1997).
4. G. Gibson and C.williams Editors *2000 Functional foods* WoodheadPubl.Co.London.
5. Goldberg, I. *Functional Foods*. 1994. Chapman and Hall, New York.
6. 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.
7. Shils, ME, Olson, JA, Shike, M. 1994 *Modern Nutrition in Health and Disease*. Eighth edition. Lea and Febiger

TEXT BOOKS:

1) Advanced Nutritional Therapies by Cooper. K.A., (1996).
2) The Food Pharmacy by Jean Carper, Simon & Schuster, UK Ltd., (1988).
3) Handbook of Nutraceuticals and Functional Foods, Third Edition (Modern Nutrition)

Course No: 2MPGPE-IV

JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD
M.Pharm Semester-II (PHARMACOGNOSY)

(Program Elective –IV)
12. CLINICAL RESEARCH AND PHARMACOVIGILANCE

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.

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 inform edconsent 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 centre's 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.

Outcome:

- 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
-

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. Clinical Data Management edited by R K Rondels, S A Varley, C F Webbs. Second Edition, Jan 2000, Wiley Publications.

TEXT BOOKS:

1) Textbook of Clinical Trials edited by David Machin, Simon Day and Sylvan Green, March 2005, John Wiley and Sons.
2) Handbook of clinical Research. Julia Lloyd and Ann Raven Ed. Churchill Livingstone.
3) Principles of Clinical Research edited by Giovanna di Ignazio, Di Giovannaand Haynes.
4) Textbook of Pharmacovigilance: Concept and Practice. G.P. Mohanta and P. K. Manna. 2016, Pharma Med Press.
5) A textbook of Clinical Pharmacy Practice: Essential Concepts and Skills. Second Edition, 2012, University Press

Course No: 2MPGL07

JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD
M.Pharm Semester-II (PHARMACOGNOSY)

Laboratory-3
ADVANCED PHARMACOGNOSY – II LAB

List of Experiments:

1) Preparation and standardization of any two herbal tablets
2) Estimation of total alkaloid content in herbal raw materials
3) Estimation of total flavonoid content in herbal raw materials
4) Formulation of different dosage forms and their standardization.
5) Estimation of aldehyde and ketone in volatile oils by titrimetric methods
6) Estimation of phenolic substances
7) Determination of Sennoside content in Senna leaves by colorimetric analysis
8) Determination of Withania alkaloids/steroids by colorimetric analysis
9) Determination of moisture content, heavy metals and ash values of crude drugs
10) Microscopical evaluation of organized powder crude drugs
11) Screening of herbal extracts/ products for anti microbial and antifungal
12) Screening of herbal extracts/ products for antioxidant activity by free radical scavenging methods
13) Study of analytical profile of any two plants mentioned in theory with special emphasis on marker compounds

Course No: 2MPGL08

JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD
M.Pharm Semester-II (PHARMACOGNOSY)

Laboratory-4
7. HERBAL COSMETICS LAB

List of Experiments:

1. Preparation and standardization of various simple dosage forms from Ayurvedic system.
2. Preparation of certain Aromatherapy formulations
3. Preparation of herbal cosmetic formulation such as lipstick, herbal hair and nail care products
4. Evaluation of herbal tablets and capsules
5. Preparation of sunscreen, skin care formulations.
6. Preparation and evaluation of any two of each hair care and skin care products
7. Preparation and evaluation of poly herbal formulation face cream.
8. Preparation and evaluation of single herbal formulation face cream.
9. Preparation and evaluation of herbal ointments
10. Preparation and evaluation of herbal acid balanced shampoo

Course No: 2MPGL08

JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD
M.Pharm Semester-II (PHARMACOGNOSY)

Laboratory-4

8. PHARMACEUTICAL QUALITY CONTROL AND QUALITY ASSURANCE LAB

List of Experiments

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

Course No: 2MPGL08

JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD
M.Pharm Semester-II (PHARMACOGNOSY)

Laboratory-4
10. MEDICINAL PLANT BIOTECHNOLOGY LAB

List of Experiments

1. Preparation of Plant Tissue Culture media
2. Fermentation technology in lab scale
3. Isolation of nucleic acid from cauliflower heads
4. Isolation of RNA from yeast
5. Quantitative estimation of DNA
6. Immobilization techniques
7. Establishment of callus culture
8. Establishment of suspension culture
9. Gene transfer by rDNA technology
10. Screening methods for rDNA technology
11. Establishment of callus culture for isolation of various secondary metabolities.

Course No: 2MPGL08

JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD
M.Pharm Semester-II (PHARMACOGNOSY)

Laboratory-4
11. Neutraceuticals

List of Experiments

1. Preparation of Herbarium
2. Preparation of Oral rehydration Solution (ORS)
3. Preparation of Protein Powder
4. Preparation of Herbal Neutraceuticals using Ginseng, Spirulina etc.
5. Formulation of Sports food
6. Preparation of Multivitamin formulations
7. Preparation of Pediatric protein and Carbohydrate
8. Preparation of Lactobacillus
9. Preparation of Green Tea and estimation of its antioxidant activity
10. Preparation and Evaluation of Ascorbic acid tablets
11. Preparation of Iron suppliments
12. Preparation and evaluation of Calcium carbonate tablets

Course No. 3MPGPE-V

JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD
M.Pharm Sem - III (PHARMACEUTICAL ANALYSIS)

(Programme Elective - V)

13. BIOSTATISTICS

Objective: The student shall know the introduction, scope of biostatistics and Research work, calculation and present of the data

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
Probability rules: Binomial, Poison and Normal distribution.

UNIT IV
Experimental designing, planning of an experiment, replication and randomization.
Analysis of Variance (ANOVA): 1-way, 2- Way

UNIT V
Hypothesis testing: Student 't' test, Chi square test,
Non- Parametric Tests: Sign Test, Sign Rank Test, Wilcoxon Sign Rank Test

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

REFERENCE BOOKS

1. Statistics for business and economics 3rd edition by Vikas books publications
2. Biostatistics & Computer applications by GN Rao and NK Tiwari
3. Sokal, R.R. and Rohlf, F.J. 1987. An Introduction to Biostatistics. W.H. Freeman and Company.
4. Bailey, N.T.J. 1981. Statistical Methods in Biology. English University Press.
5. Mitchell, K. and Glover, T. 2001. Introduction to Biostatistics. McGraw Hill, Publishing Co.

Course No. 3MPGPE-V

JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD
M.Pharm Sem - III (PHARMACEUTICAL ANALYSIS)

(Programme Elective - V)
14. SCALE UP AND TECHNOLOGY TRANSFER

Objective

This course is designed to impart knowledge and skills necessary to train the students to be on scale up, technology transfer process and industrial safety issues.

UNIT I

Pilot plant design: Basic requirements for design, facility, equipment selection, for tablets, capsules, liquid orals, parentral and semisolid preparations.

Scale up: Importance, Technology transfer from R & D to pilot plant to plant scale, process scale up for tablets, capsules, liquid orals, semisolids, parentral, NDDS products − stress on formula, equipments, product uniformity, stability, raw materials, physical layout, input, in-process and finished product specifications, problems encountered during transfer of technology

UNIT II

Validation: General concepts, types, procedures & protocols, documentation, VMF. Analytical method validation, cleaning validation and vender qualification.

UNIT III

Equipment Qualification: Importance, IQ, OQ, PQ for equipments − autoclave, DHS, membrane filter, rapid mixer granulator, cone blender, FBD, tablet compression machine, liquid filling and sealing machine. Aseptic room validation.

UNIT IV

Process validation: Importance, validation of mixing, granulation, drying, compression, tablet coating, liquid filling and sealing, sterilization, water process systems, environmental control.

UNIT V

Industrial safety: Hazards − fire, mechanical, electrical, chemical and pharmaceutical, Monitoring & prevention systems, industrial effluent testing & treatment. Control of environmental pollution.

Outcome:

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

- Manage the scale up process in pharmaceutical industry.
- Assist in technology transfer.
- To establish safety guidelines, which prevent industrial hazards

REFERENCES

1. Pharmaceutical process validation, JR Berry, Nash, Vol 57, Marcel Dekker, NY.
2. Pharmaceutical Production facilities, design and applications, by GC Cole, Taylor and Francis.
3. Pharmaceutical project management, T.Kennedy, Vol 86, Marcel Dekker, NY.
4. The theory & Practice of Industrial Pharmacy, L.Lachman, H.A.Lieberman, Varghese Publ. Bombay.
5. Tablet machine instruments in pharmaceuticals, PR Watt, John Wiloy. 6. Pharmaceutical dosage forms, Tablets, Vol 1, 2, 3 by Lachman, Lieberman, Marcel Dekker, NY.
7. Pharmaceutical dosage forms, Parentral medications, Vol 1, 2 by K.E. Avis, Marcel Dekker, NY.
8. Dispersed system Vol 1, 2, 3 by Lachman, Lieberman, Marcel Dekker, NY.
9. Subrahmanyam, CVS, Pharmaceutical production and Management, 2007, Vallabh Prakashan,Dehli.

Course No. 3MPGPE-V

JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD

M.Pharm Semester - III (PHARMACEUTICAL ANALYSIS)

(Programme Elective - V)

15. PRODUCTION AREA DESIGN & PACKAGING DEVELOPMENT

Objectives: The student shall learn about Industrial area design, Current good manufacturing practices. They also learn about packaging components, polymers and metals used in packaging. They also understand about the storage conditions of different formulations and their stability evaluations.

UNIT I

Production Area Design: Selection of plant location, Design of plant for bulk drugs and formulations(Solids, Semisolids, Injectables, Neutraceuticals etc.), General utilities such as purified water, portable water, water for injection, Air handling units-Relative humidity and Temperature control, Material and personnel movement. Warehouse handling-API, Excipients, packaging materials and solvents.

UNIT II

Current Good Manufacturing Practices: GMP design for buildings & facilities. GMP layout design. Clean room classifications. Segregation & cross contamination control. HVAC (heating, ventilation & air-conditioning) systems. Clean room environment control. Documentation and record keeping: Specifications and testing procedures, Specifications for finished products, Master Formulae, Packaging instructions. Batch processing records, Standard operating procedures.

UNIT III

Pharmaceutical packaging and Design: Introduction, Packaging system, Components of packaging, Symbols used on packages and labels. Package development and Design research. Packaging materials- Polymers and Plasters, Glass, Metal and Blister and strip packaging.

UNIT IV

Stability of Packaging: Introduction, Legislation, Regulation, Pharmaceutical Stability Testing in Climatic Cabinets, Pharmaceutical Stability Testing Conditions, Photo-Stability Testing, Review of Pharmaceutical Product Stability, Packaging and the ICH Guidelines.

UNIT V

Packaging of Solids, Semisolids, Parenterals, Ophthalmic and Aerosols: Introduction, Packaging of Solid and semisolids, Packaging of Sterile Pharmaceuticals, Packaging Components, Inspection of Filled Injectable Products, Storage and Labelling, Packaging of Ophthalmics, Selection of Packaging Materials, Packaging of Aerosols.

Outcome: At the end of the semester student will get an idea about Industrial area design and packaging of different formulations and its stability conditions.

REFERENCES:

1. Leon Lachman; Lieberman Herbert A.; Kanig, Joseph L. The theory and Practice of Industrial Pharmacy.
2. Gilbert Banker and Christopher Rhodes. Modern Pharmaceutics.
3. Aulton's Pharmaceutics: The design and Manufacture of Medicine
4. D. A. Dean, Roy Evans, Ian Hall. Pharmaceutical packaging technology. Tylor and Francis.
5. Edward J. Bauer, Pharmaceutical Packaging Handbook. Bausch and Lomb, Rochester, New York, USA.
6. Wilmer A. Jenkins, Kenton R. Osborn. Packaging drugs and pharmaceuticals.
7. Remington: The Science and Practice of Pharmacy. 8. Michael E. Aulton, Kevin Tylor

Course No. 3MPGOE

JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD

M.Pharm Semester - III (PHARMACEUTICAL ANALYSIS)

(Open Elective)

1. SCREENING METHODS IN PHARMACOLOGY

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.

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.

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.

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.

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, VallabhPrakashan, Delhi.

Course No. 3MPGOE

JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD
M.Pharm Semester - III (PHARMACEUTICAL ANALYSIS)

(Open Elective)

2. ENTREPRENEURSHIP MANAGEMENT

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

UNIT I

Conceptual Frame Work: Concept need and process inentrepreneurship 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 mobilization -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.

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

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., Toranto.
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

Course No. 3MPGOE

JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD

M.Pharm Semester - III (PHARMACEUTICAL ANALYSIS)

(Open Elective)

3. STABILITY OF DRUGS AND DOSAGE FORMS

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'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.

Course No. 3MPGOE

JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD

M.Pharm Semester - III (PHARMACEUTICAL ANALYSIS)

(Open Elective)

4. COSMETIC SCIENCE

Objective: These topics are designed impart a specialized knowledge to know various cosmetics, their preparation, properties, MOA, uses etc. The understanding of properties and evaluation of these cosmetics by analytical methods.

UNIT I

Classification of cosmetics and cosmeceutical products.
Definition of cosmetics as per Indian and EU regulations, Evolution of cosmeceuticals from cosmetics, cosmetics as quasi and OTC drugs.
Cosmetic excipients: Surfactants, rheology modifiers, humectants, emollients, preservatives, classification and application.
Skin: Basic structure and function of skin.
Hair: Basic structure of hair, hair growth cycle.
Oral Cavity: Common problem associated with teeth and gems.

UNIT II

Principles of formulation and building blocks of skin care products: Face cream, Moisturizing cream, Cold cream, Vanishing cream and their advantages and dis advantages. Application of these products in formulation of cosmeceuticals.
Anti perspants and Deodrants: Actives and MOA.
Principles of formulation and building blocks of hair care products: Conditioning shampoo, hair conditioner, anti – dandruff shampoos, hair oils.
Chemistry and formulation of Para-phylene di amine based hair dye.
Principles of formulation and building blocks of oral care products: Tooth paste for bleeding gums, sensitive teeth, teeth whitening, mouth wash.

UNIT III

Sun protection, classification of sunscreens and SPF.
Role of herbs in cosmetics:
Skin care – Aloe and turmeric
Hair care – Henna and amla
Oral care – Clove and neem
Analytical Cosmetics: BIS specification and analytical method for shampoo, skin cream and tooth paste.

UNIT IV

Principle of cosmetic evaluation – Principle of sebumeter, corneometer. Measurement of tewl, skin color, hair tensile strength, hair combing properties. Soaps and Syndet bars, evaluation and skin benefits.

UNIT V

Oily and dry skin, causes leading to dry skin, skin moisturization. Basic understanding of the terms comedogenic, dermatitis.

Cosmetic problems associated with hair and scalp: Dandruff, hair fall causes.

Cosmetic problems associated with skin: Blemishes, wrinkles, acne, prickly heat and body odor.

Anti persprants and deodorants – Actives and MOA

Outcome:

The students should describe the properties and uses of various cosmetics on various parts of the body. The students should be able to suggest the proper usage of cosmetics.

REFERENCES:

1. Harry's cosmeticology, Wilkinson, Moore, 7th edition, George Godwin.
2. Cosmetics – Formulation, Manufacturing and Quality control, P.P. Sharma, 4th edition, Vandana Publications Pvt. Ltd. Delhi.
3. Text book of cosmeticology by Sanju Nanda & Roop K. Khar, Tata Publishers.

Course No. 3MPGOE

JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD
M.Pharm Semester - III (PHARMACEUTICAL ANALYSIS)

(Open Elective)
5. HAZARDS AND SAFETY MANAGEMENT

Scope

This course is designed to convey the knowledge necessary to understand issues related to different kinds of hazard and their management. Basic theoretical and practical discussions integrate the proficiency to handle the emergency situation in the pharmaceutical product development process and provides the principle based approach to solve the complex tribulations.

Objectives

At completion of this course it is expected that students will be able to

- Understand about environmental problems among learners.
- Impart basic knowledge about the environment and its allied problems.
- Develop an attitude of concern for the industry environment.
- Ensure safety standards in pharmaceutical industry
- Provide comprehensive knowledge on the safety management
- Empower an ideas to clear mechanism and management in different kinds of hazard management system
- Teach the method of Hazard assessment, procedure, methodology for provide safe industrial atmosphere.

UNIT I

Multidisciplinary nature of environmental studies: Natural Resources, Renewable and non-renewable resources, Natural resources and associated problems, Human and health safety measures.

a) Forest resources b) Water resources c) Mineral resources d) Energy resources e) Land resources

Ecosystems: Concept of an ecosystem and Structure and function of an ecosystem. Environmental hazards: Hazards based on Air, Water, Soil and Radioisotopes.

UNIT II

Air based hazards: Sources, Types of Hazards, Air circulation maintenance industry for sterile area and non sterile area, Preliminary Hazard Analysis (PHA) Fire protection system: Fire prevention, types of fire extinguishers and critical Hazard management system.

UNIT III

Chemical based hazards: Sources of chemical hazards, Hazards of Organic synthesis, sulphonating hazard, Organic solvent hazard, Control measures for chemical hazards,
Management of combustible gases, Toxic gases and Oxygen displacing gases management, Regulations for chemical hazard, Management of over-Exposure to chemicals and TLV concept.

UNIT IV

Fire and Explosion: Introduction, Industrial processes and hazards potential, mechanical electrical, thermal and process hazards. Safety and hazards regulations, Fire protection system:
Fire prevention, types of fire extinguishers and critical Hazard management system mechanical and chemical explosion, multiphase reactions, transport effects and global rates. Preventive and protective management from fires and explosion electricity passivation, ventilation, and sprinkling, proofing, relief systems -relief valves, flares, scrubbers.

UNIT V

Hazard and risk management: Self-protective measures against workplace hazards. Critical training for risk management, Process of hazard management, ICH guidelines on risk assessment and Risk management methods and Tools Factory act and rules, fundamentals of accident prevention, elements of safety programme and safety management, Physicochemical measurements of effluents, BOD, COD, Determination of some contaminants, Effluent treatment
procedure, Role of emergency services.

REFERENCES

1. Y.K. Sing, Environmental Science, New Age International Pvt, Publishers, Bangalore
2. "Quantitative Risk Assessment in Chemical Process Industries" American Institute of Chemical Industries, Centre for Chemical Process safety.
3. Bharucha Erach, The Biodiversity of India, Mapin Pu blishing Pvt. Ltd., Ahmedabad – 380 013, India,
4. Hazardous Chemicals: Safety Management and Global Regulations, T.S.S. Dikshith, CRC press

Course No. 3MPGOE

JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD
M.Pharm Semester - III (PHARMACEUTICAL ANALYSIS)

(Open Elective)
6. AUDITS AND REGULATORY COMPLIANCE

Scope

This course deals with the understanding and process for auditing in pharmaceutical industries. This subject covers the methodology involved in the auditing process of different in pharmaceutical industries.

Objectives

Upon completion of this course the student should be able to

- To understand the importance of auditing
- To understand the methodology of auditing
- To carry out the audit process
- To prepare the auditing report
- To prepare the check list for auditing

UNIT I

Introduction: Objectives, Management of audit, Responsibilities, Planning process, information gathering, administration, Classifications of deficiencies

UNIT II

Role of quality systems and audits in pharmaceutical manufacturing environment: cGMP Regulations, Quality assurance functions, Quality systems approach, Management responsibilities, Resource, Manufacturing operations, Evaluation activities, Transitioning to quality system approach, Audit checklist for drug industries.

UNIT III

Auditing of vendors and production department: Bulk Pharmaceutical Chemicals and packaging material Vendor audit, Warehouse and weighing, Dry Production: Granulation, tableting, coating, capsules, sterile production and packaging.

UNIT IV

Auditing of Microbiological laboratory: Auditing the manufacturing process, Product and process information, General areas of interest in the building raw materials, Water, Packaging materials.

UNIT V

Auditing of Quality Assurance and engineering department: Quality Assurance Maintenance, Critical systems: HVAC, Water, Water for Injection systems, ETP.

REFERENCES

1. Compliance auditing for Pharmaceutical Manufacturers. Karen Ginsbury and Gil Bismuth, Interpharm/CRC, Boca Raton, London New York, Washington D.C.
2. Pharmaceutical Manufacturing Handbook, Regulations and Quality by Shayne Cox Gad. Wiley-Interscience, A John Wiley and sons, Inc., Publications.
3. Handbook of microbiological Quality control. Rosamund M. Baird, Norman A. Hodges, Stephen P. Denyar. CRC Press. 2000.
4. Laboratory auditing for quality and regulatory compliance. Donald C. Singer, Raluca-loana Stefan, Jacobus F. Van Staden. Taylor and Francis (2005).