

## Course Scheme and Syllabus for M. PHARM (PHARMACOGNOSY) 2021-2023

### M. Pharm Semester I

Course Number	Subject	Scheme of studies per week			Credits	Int Marks	Ext Marks
		L	T	P			
1COG01	Program Core –I Phytochemistry	3	1	0	4	30	70
1COG02	Program Core –II Advanced Pharmacognosy -I	3	1	0	4	30	70
1COGPE03	Program Elective –I 1.Modern Pharmaceutical Analytical Techniques 2. Drug Regulatory Affairs 3. Pharmaceutical Food Analysis	3	1	0	4	30	70
1COGPE04	Program Elective-II 1.Industrial Pharmacognostical Technology 2. Pharmaceutical Validation 3. Cosmetics and Cosmeceuticals	3	1	0	4	30	70
1A01	Research Methodology& Intellectual Property Rights	2	0	0	2	30	70
1A02	Audit Course- I 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	2	0	0	0	0	0
1COGL05	Phytochemistry Lab	0	0	6	3	30	70
1COGL06	Modern Pharmaceutical Analytical Techniques lab	0	0	6	3	30	70
1COG S01	Seminar/Assignment	0	0	4	2	30	70
<b>Total credits:</b>		<b>16</b>	<b>04</b>	<b>16</b>	<b>26</b>	<b>240</b>	<b>560</b>

### M.Pharm Semester II

Course Number	Subject	Scheme of studies per week			Credits	Int Marks	Ext Marks
		L	T	L			
2COGPC07	Program Core –III Advanced Pharmacognosy – II	3	1	0	4	30	70
2COGPC08	Program Core –IV Indian System of Medicine	3	1	0	4	30	70
2COGPE09	Program Elective –III 1. Herbal Cosmetics 2. Pharmaceutical Quality Control and Quality Assurance 3. Pharmacoepidemiology and Pharmacoeconomics	3	1	0	4	30	70
2COGPE10	Program Elective –IV 1. Medicinal Plant Biotechnology 2. Nutraceuticals 3. Clinical Research and Pharmacovigilance	3	1	0	4	30	70
2A03	Audit Course –II 1. English for Research Paper Writing 2. Disaster Management 3. Sanskrit for Technical Knowledge	2	0	0	0	0	0

	4. Value Education 5. Constitution of India 6. Pedagogy Studies 7. Stress Management by Yoga 8. Personality Development through Life Enlightenment Skills						
2COGL11	Advanced Pharmacognosy – II Lab	0	0	6	3	30	70
2COGL12	Herbal Cosmetics Lab	0	0	6	3	30	70
2COG13	Mini Project	2	0	2	3	30	70
1COG S02	Seminar/Assignment	0	0	4	2	30	70
<b>Total Credits</b>		<b>16</b>	<b>04</b>	<b>16</b>	<b>26</b>	<b>240</b>	<b>560</b>

\* 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	Int Marks	Ext Marks
		L	T	P			
3COGPE14	Program Elective – V 1. Herbal Drug Technology 2. Stability of Drugs and Dosage Forms 3. Production Area Design and Packaging Development	3	0	0	3	30	70
	Open Elective 1. Screening Methods in Pharmacology 2. Biostatistics 3. Entrepreneur Management 4. Cosmetic Science 5. Hazards and Safety Management 6. Audits and Regulatory Complaints	3	0	0	3	30	70
	3COGCV01	Comprehensive Viva voce	0	0	8	4	30
3COG16	Dissertatio - I						
	a. Dissertation work Review - I	0			0	0	0
	b. Dissertation work Review - II	0	0	20	10	100	0
<b>Total Credits</b>		<b>6</b>	<b>0</b>	<b>28</b>	<b>20</b>	<b>190</b>	<b>210</b>

\* 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	Int Marks	Ext Marks
		L	T	P			
4COG17	Dissertation Work Review – II & Viva Voce	0	0	32	16	30	0
<b>Total credits:</b>		<b>0</b>	<b>0</b>	<b>32</b>	<b>16</b>	<b>30</b>	<b>70</b>

**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 constituents 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. The lead structure selection process and optimization with suitable examples. Sourcing and archiving Natural products for discovery, Evaluating natural products for therapeutic properties, Identifying the biologically active Natural products.

**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, Separation of phytoconstituents by Flash column chromatography, Principle and working of LC MS

**UNIT IV**

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

- a) Morphine and brief account on its derivatives and analogues
- b) Camptothecin, c) Taxol

**UNIT V**

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

(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 nutraceuticals and phytp  
Pharmaceuticals

**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 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. Hepatoprotectives
  - a. *Phyllanthus amarus*
  - b. *Silybum marianum*
3. Cardioprotectives
  - a. *Coleus forskolin*
  - b. *Allium sativum*
4. Antiviral
  - a. *Oregano vulgare*
  - b. *Sambucus nigra*

**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 Nutraceuticals, Health problems and diseases that can be prevented or cured by Nutraceuticals i.e. weight control, diabetes, cancer and arthritis

b) Source, Name of marker compounds and their chemical nature, Medicinal uses and health benefits of following used as neutraceuticals like Spirulina, Ginseng, Ginger, Broccoli, Ginkgo and Flaxseeds.

**UNIT-V**

**Phytopharmaceuticals:**

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

a) Carotenoids – i)  $\alpha$  and  $\beta$  - Carotene ii) Xanthophylls

- b) Limonoids – i) d-Limonene ii)  $\alpha$  – Terpineol
- c) Flavonoids – i) Resveratrol ii) Quercetin
- d) Phenolic acids- Ellagic acid
- e) Saponins – Shatavarins

**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 of Botanicals by V. Rajpal, Vol 1, 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 2<sup>nd</sup> 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. 1COGPE03**

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

**(Programme Elective - I)**  
**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

**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, LC/MS, 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), <sup>13</sup>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 - Douglas 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. 1COGPE03**

**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 Cosmetics 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 Management, Effluent etc.)
5. Quality Assurance and Quality 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 authorization 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. 1COGPE03**

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

(Programme Elective - 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, **C**
- 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, 7<sup>th</sup> 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: 1COGPE04**

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

**(Program Elective-II)**

**1. 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.

Recent guidelines of DCGI on herbal formulations.

**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 matters, 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 Mukharjee (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 2<sup>nd</sup> Edition by S.L. Doore, S.S Khadabadi and B.A. Baviskar

**Course No: 1COGPE04**

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

**(Program Elective-II)**  
**2. 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 Imtiaz Haider
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: 1COGPE04**

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

**(Program Elective-II)**  
**3. COSMETICS AND COSMECEUTICALS**

**Objectives:**

Upon completion of the course, the students shall be able to understand key ingredients used in cosmetics and cosmeceutical. Key building blocks for various formulations. Current technologies in the market, 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 cosmetics as per Indian regulation. Indian regulatory requirements for labelling of cosmetics. Regulatory provisions relating to import of cosmetics. Misbranded and spurious cosmetics. Regulatory provisions relating 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.

**UNIT-IV**

Design and evaluation of cosmeceutical products: Creams, Lipsticks, Sun screens, Shampoos, Hair preparations and dental preparations.

**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.

**Outcome:** The students will learn the use of different ingredients in cosmetics products. They will know the manufacturing of cosmetics and its application. They will learn about the regulatory requirements of cosmetic products.

**REFERENCES**

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

**TEXT BOOKS:**

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

**Course No: 1A01**

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

**RESEARCH METHODOLOGY AND INTELLECTUAL PROPERTY RIGHTS**

**Unit I:**

Meaning of research problem, Sources of research problem, Criteria Characteristics of a good research problem, Errors in selecting a research problem, Scope and objectives of research problem. Approaches of investigation of solutions for research problem, data collection, analysis, interpretation, Necessary instrumentations

**Unit II:**

Effective literature studies approaches, analysis Plagiarism, Research ethics, Effective technical writing, how to write report, Paper Developing a Research Proposal, Format of research proposal, a presentation and assessment by a review committee

**Unit III:**

Nature of Intellectual Property: Patents, Designs, Trade and Copyright. Process of Patenting and Development: technological research, innovation, patenting, development. International Scenario: International cooperation on Intellectual Property. Procedure for grants of patents, Patenting under PCT.

**Unit IV:**

Patent Rights: Scope of Patent Rights. Licensing and transfer of technology. Patent information and databases. Geographical Indications.

**Unit V:**

New Developments in IPR: Administration of Patent System. New developments in IPR; IPR of Biological Systems, Computer Software etc. Traditional knowledge Case Studies, IPR and IITs.

**Course Outcomes:**

At the end of this course, students will be able to CO1 Understand research problem formulation. CO2 Analyze research related information and Follow research ethics, CO3 Understand that today's world is controlled by Computer, Information Technology, but tomorrow world will be ruled by ideas, concept, and creativity. CO4 Understanding that when IPR would take such important place in growth of individuals & nation, it is needless to emphasize the need of information about Intellectual Property Right to be promoted among students in general & engineering in particular. CO5 Understand that IPR protection provides an incentive to inventors for further research work and investment in R & D, which leads to creation of new and better products, and in turn brings about, economic growth and social benefits.

**REFERENCES:**

1. Stuart Melville and Wayne Goddard, "Research methodology: an introduction

- for science & engineering students”
2. Wayne Goddard and Stuart Melville, “Research Methodology: An Introduction”
  3. Ranjit Kumar, 2nd Edition, “Research Methodology: A Step by Step Guide for beginners”
  4. Halbert, “Resisting Intellectual Property”, Taylor & Francis Ltd , 2007.
  5. Mayall, “Industrial Design”, McGraw Hill, 1992.
  6. Asimov, “Introduction to Design”, Prentice Hall, 1962.
  7. Robert P. Merges, Peter S. Menell, Mark A. Lemley, “ Intellectual Property in New Technological Age”, 2016.
  8. T. Ramappa, “Intellectual Property Rights Under WTO”, S. Chand, 2008

**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

**Laboratory - 2**  
**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 R<sub>f</sub> 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
10. Isolation of phytoconstituents from plant extract using column chromatography
11. Identification/ Separation of phytoconstituents from plant extract by HPTLC
12. Development of fingerprint of selected medicinal plant extracts commonly used in herbal drug industry viz. Ashwagandha, Tulsi, Bael, Amla, Ginger, Aloe, Vidang, Senna, Lawsonia by TLC/HPTLC method.
13. Demonstration of HPLC- estimation of glycerrhizin

Course No: 2COGPC07

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

**(Program Core –III)**  
**ADVANCED PHARMACOGNOSY-II**

**Objective**

Helps the students to know about common bitters, laxatives and the analytical profiles of some herbal drugs 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*, *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. *invivo* 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 2<sup>nd</sup> 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: 2COGPC08**

**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, Jhatyadi 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 i) Solid Dose forms
  - ii) Topical Preparations and other dose forms
- b) Siddha systems of medicines, their merits and demerits

**UNIT V**

- a) Principles of Unani and Introduction to different dosage forms and preparations of Unani Formulations for the treatment of Arthritis, Diabetes, Cardiac problems, Respiratory disorders, Digestive disorders and Obesity.

b) Aromatherapy – Introduction, aroma oils for common problems and 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: 2COGPE09**

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

**(Program Elective –III)**  
**1. 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. Aromatherapy (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: 2COGPE09

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

**(Program Elective –III)**

**2. PHARMACEUTICAL QUALITY CONTROL AND QUALITY ASSURANCE**

**Objectives**

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

**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 sanitation, 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 6<sup>th</sup> 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, 3<sup>rd</sup> 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

**(Program Elective –III)**

**3. 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 care regimen.

**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: 2COGPE10**

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

**(Program Elective –IV)**  
**1. 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, Nutritional requirements, Media preparation, Explant preparation, Establishment of Aseptic cultures- Initiation and maintenance of callus and suspension culture. Biotechnological applications of Plant Tissue culture in pharmacy and allied fields.

**UNIT II**

Different tissue culture techniques: Types and techniques of plant tissue culture, growth parameters, Organogenesis and embryogenesis, Protoplast isolation and culture.

**UNIT III**

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

**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 .Hairy root 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 2<sup>nd</sup> Edition by S.L. Doore, S.S Khadabadi and B.A. Baviskar

Course No: 2COGPE10

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

**(Program Elective –IV)**

**2. NUTRACEUTICALS**

**Objectives:** The students will expose to characteristic features of various phytochemicals as nutraceuticals 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 nutraceuticals: Occurrence and characteristic features(chemical nature medicinal benefits) of following

- a) Carotenoids-  $\alpha$  and  $\beta$ -Carotene, Lycopene, Xanthophylls, lutein
- b) Sulfides: Diallylsulfides, Allyltrisulfide.
- c) Polyphenolics: Resveratrol
- d) Flavonoids- Rutin, Naringin, Quercetin, Anthocyanidins, catechins, Flavones
- e) Prebiotics / Probiotics.: Fructo oligosaccharides, Lacto bacillum
- f) Phytoestrogens : Isoflavones, daidzein, Genistein, 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,  $\alpha$ - 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 Nutraceuticals in various commom problems with the concept of free radicals

### REFERENCES:

1. Dietetics by Sri Lakshmi
2. Role of dietary fibres and nutraceuticals in preventing diseases by K.T Agusti and P.Faizal: BSPublication.
3. Prescription for Nutritional Healing by James F.Balch and Phyllis A.Balch<sup>2<sup>nd</sup></sup>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: 2COGPE10**

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

**(Program Elective –IV)**

**3. 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 informed consent process

**UNIT-II**

**Clinical Trials: Types and Design:**

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

**UNIT-III**

**Clinical Trial Documentation:**

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

**UNIT-IV**

**Basic aspects, terminologies and establishment of pharmacovigilance:**

History and progress of pharmacovigilance, Significance of safety monitoring, Pharmacovigilance in India and international aspects, WHO international drug monitoring programme, WHO and Regulatory terminologies of ADR, evaluation of medication safety, Establishing pharmacovigilance 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

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**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

**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

**Laboratory-4**  
**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 shampoos



**JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD**  
**M.Pharm Sem - III (PHARMACOGNOSY)**

**(Programme Elective - V)**

**1. HERBAL DRUG TECHNOLOGY**

**Objectives:** Helps the students in getting exposed to methods of extraction, preparation and purification of herbal extracts. To acquire knowledge on the extraction preparation and evaluation of herbal preparation. They will expose to various research institutions of natural products.

**UNIT I**

Herbal Extracts: Types of extracts, Extraction methods

Equipment for preparing herbal extracts: Process and equipments- Name of the equipment and its uses with merits and demerits in each of the following unit operations in the extraction process.

- i) Size reduction
- ii) Extraction
- iii) Filtration
- iv) Distillation
- v) Drying of extracts

**UNIT II**

Definition, classification of natural excipients: Sources, Chemical nature, Description parameters  
Pharmaceutical uses and storage conditions of following Natural excipients:

- a) Binding agents, disintegrating agents, diluents, emulsifying agents:  
Acacia, Tragacanth, Alginates, CMC, Gelatin, Pectin, Lactose, Starches,
- b) Ointment bases, suppository bases and Hardening agents: Beeswax, Cocoa butter, Lanolin, Hard paraffin

**UNIT III**

A brief account on different research institutes of both national and international status like AYUSH, NMPB, CDRL, NBRI, ICMR, CSIR-IICT, CIMAP, NIN.

**UNIT IV**

a) Herbs as raw materials : Definition of herb, herbal medicines, herbal medicinal product and herbal drug preparations- Source, selection, Role of literature in medicinal plant research, identification and authentication of herbal materials, Drying and processing of herbal raw materials, Packing and labeling of finished products,

b) Herbal drug regulatory Affairs:

Introduction, Objectives of Herbal Drug Regulation, Current Status of Herbal Drug Regulatory Affairs

**UNIT V**

a) Methods of preparation and Evaluation of Herbal Tablets, Capsules, Ointments. Study of any three formulations under each category with respect to their formulas and claims for various herbs used in them

b) Novel dosage forms: Liposomes, micro-emulsion, nano-emulsion, mucoadhesive drug delivery

**Out comes:** Helps the students to understand the organization and research of natural products in herbal drugs industries.

**Recommended/ Reference books:**

1. Textbook of Pharmacognosy by G.E.Trease, W.C.Evans, ELBS
2. Textbook of HPTLC by P.D. Seth.
3. Herbal Perfumes and cosmetics by Panda

4. Pharmacognosy by V.E Tyler, LR Brandy and JE Robbers (KM Varghese & co., Mumbai)
5. Natural Excipients by R. S Gaud, Surana.
6. Handbook of Cosmetics by B.M. mittal and R.N Saha.
7. Herbal Drug industry by Chowdary
8. Herbal Drug Technology by SS Agarwal
9. Pharmacognosy and Phytochemistry by VD Rangari.
10. Indian Pharmacopoeia

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

(Programme Elective - V)

**2. 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. Sawnsen – 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. 3COGPE14**

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

**(Programme Elective - V)**

**3. 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

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

**(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 Rabbits Vaccine, Oxytocin, Tetanus Antitoxin and Diphtheria Vaccine. Test for pyrogens.

**UNIT III**

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

**UNIT IV**

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

**UNIT V**

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

**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, Springer-Verlag, Berlin Heidelberg.
3. Handbook of experimental pharmacology by S.K. Kulkarni, VallabhPrakashan, Delhi.



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

(Open Elective)

## 2. 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, Poisson 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 3<sup>rd</sup> 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.

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

**(Open Elective)**

**3. 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 in entrepreneurship development. Role of enterprise in national and global economy. Types of enterprise – Merits and Demerits. Government policies and schemes for enterprise development. Institutional support in enterprise development and management.

**UNIT II**

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

**UNIT III**

Launching And Organising An Enterprise: Environment scanning – Information, sources, schemes of assistance, problems. Enterprise selection, market assessment, enterprise feasibility study, SWOT Analysis. Resource 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

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

(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 gums.

UNIT II

**Principles of formulation and building blocks of skin care products:** Face cream, Moisturizing cream, Cold cream, Vanishing cream and their advantages and disadvantages. Application of these products in formulation of cosmeceuticals.

**Anti persnants 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-phenylene 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 tawl, 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, 7<sup>th</sup> edition, George Godwin.
2. Cosmetics – Formulation, Manufacturing and Quality control, P.P. Sharma, 4<sup>th</sup> edition, Vandana Publications Pvt. Ltd. Delhi.
3. Text book of cosmeticology by Sanju Nanda & Roop K. Khar, Tata Publishers.

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

(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 Publishing Pvt. Ltd., Ahmedabad – 380 013, India,
4. Hazardous Chemicals: Safety Management and Global Regulations, T.S.S. Dikshith, CRC press

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

**(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).

**JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD**  
**M.Pharm Semester – I & II (PHARMACOGNOSY)**

**AUDIT COURSE**

**1. ENGLISH FOR RESEARCH PAPER WRITING**

**UNIT I:**

Planning and Preparation, Word Order, Breaking up long sentences, Structuring Paragraphs and Sentences, Being Concise and Removing Redundancy, Avoiding Ambiguity and Vagueness.

**UNIT II:**

Clarifying Who Did What, Highlighting Your Findings, Hedging and Criticizing, Paraphrasing and Plagiarism, Sections of a Paper, Abstracts, Introduction.

**UNIT III:**

Review of the Literature, Methods, Results, Discussion, Conclusions, The Final Check.

**UNIT IV:**

Key skills are needed when writing a Title, key skills are needed when writing an Abstract, key skills are needed when writing an Introduction, skills needed when writing a Review of the Literature.

**UNIT V:**

Skills are needed when writing the Methods, skills needed when writing the Results, skills are needed when writing the Discussion, skills are needed when writing the Conclusions, useful phrases, how to ensure paper is as good as it could possibly be the first-time submission

**COURSE OUTCOMES:**

Students will be able to:

1. Understand that how to improve your writing skills and level of readability
2. Learn about what to write in each section
3. Understand the skills needed when writing a Title Ensure the good quality of paper at very first-time submission

**REFERENCES:**

1. Goldbort R (2006) Writing for Science, Yale University Press (available on Google Books)
2. Day R (2006) How to Write and Publish a Scientific Paper, Cambridge University Press
3. Highman N (1998), Handbook of Writing for the Mathematical Sciences, SIAM. Highman's book.

**TEXT BOOKS:**

1. Adrian Wallwork, English for Writing Research Papers, Springer New York Dordrecht Heidelberg London, 2011

**JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD**  
**M.Pharm Semester – I & II (PHARMACOGNOSY)**  
**AUDIT COURSE**

**2. DISASTER MANAGEMENT**

**UNIT I:**

Introduction Disaster: Definition, Factors And Significance; Difference Between Hazard And Disaster; Natural And Manmade Disasters: Difference, Nature, Types And Magnitude.

**UNIT II :**

Repercussions Of Disasters And Hazards: Economic Damage, Loss Of Human And Animal Life, Destruction Of Ecosystem. Natural Disasters: Earthquakes, Volcanisms, Cyclones, Tsunamis, Floods, Droughts And Famines, Landslides And Avalanches, Man-made disaster: Nuclear Reactor Meltdown, Industrial Accidents, Oil Slicks And Spills, Outbreaks Of Disease And Epidemics, War And Conflicts.

**UNIT III:**

Disaster Prone Areas In India Study Of Seismic Zones; Areas Prone To Floods And Droughts, Landslides And Avalanches; Areas Prone To Cyclonic And Coastal Hazards With Special Reference To Tsunami; Post-Disaster Diseases And Epidemics.

**UNIT IV:**

Disaster Preparedness And Management Preparedness: Monitoring Of Phenomena Triggering A Disaster Or Hazard; Evaluation Of Risk :Application Of Remote Sensing Data From Meteorological And Other Agencies, Media Reports: Governmental And Community Preparedness.

**UNIT V:**

Risk Assessment

Disaster Risk: Concept And Elements, Disaster Risk Reduction, Global And National Disaster Risk Situation. Techniques Of Risk Assessment, Global Co-Operation In Risk Assessment And Warning, People's Participation In Risk Assessment. Strategies for Survival. Disaster Mitigation Meaning, Concept And Strategies Of Disaster Mitigation, Emerging Trends In Mitigation. Structural Mitigation And Non-Structural Mitigation, Programs Of Disaster Mitigation In India.

**COURSE OUTCOMES:**

Students will be able to:

1. Learn to demonstrate a critical understanding of key concepts in disaster risk reduction and humanitarian response.
2. Critically evaluate disaster risk reduction and humanitarian response policy and practice from multiple perspectives.
3. Develop an understanding of standards of humanitarian response and practical relevance

in specific types of disasters and conflict situations.

4. Critically understand the strengths and weaknesses of disaster management approaches, planning and programming in different countries, particularly their home country or the countries they work in.

**REFERNCES:**

1. R. Nishith, Singh AK, “Disaster Management in India: Perspectives, issues and strategies “New Royal book Company.
2. Sahni, PardeepEt.Al. (Eds.),” Disaster Mitigation Experiences And Reflections”, Prentice Hall Of India, New Delhi.

**TEXT BOOKS:**

1. Goel S. L., Disaster Administration And Management Text And Case Studies”,Deep &Deep Publication Pvt. Ltd., New Delhi.

**JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD**  
**M.Pharm Semester – I & II (PHARMACOGNOSY)**  
**AUDIT COURSE**

**3. SANSKRIT FOR TECHNICAL KNOWLEDGE**

**UNIT I:**

Alphabets in Sanskrit, Past/Present/Future Tense, Simple Sentences

**UNIT II:**

Order Introduction of roots Technical information about Sanskrit Literature

**UNIT III:**

Technical concepts of Engineering-Electrical, Mechanical, Architecture, Mathematics

**COURSE OUTCOMES:**

Students will be able to

3. Understanding basic Sanskrit language
4. Ancient Sanskrit literature about science & technology can be understood
5. Being a logical language will help to develop logic in students

**REFERENCES:**

1. “Abhyaspustakam” – Dr. Vishwas, Samskrita-Bharti Publication, New Delhi
2. “Teach Yourself Sanskrit” Prathama Deeksha-VempatiKutumbshastri, Rashtriya Sanskrit Sansthanam, New Delhi Publication
3. “India’s Glorious Scientific Tradition” Suresh Soni, Ocean books (P) Ltd., New Delhi.

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**AUDIT COURSE**

**4. VALUE EDUCATION**

**Unit I:**

Values and self-development–Social values and individual attitudes. Work ethics, Indian vision of humanism. Moral and non-moral valuation. Standards and principles. Value judgements.

**Unit II:**

Importance of cultivation of values. Sense of duty. Devotion, Self-reliance. Confidence, Concentration. Truthfulness, Cleanliness. Honesty, Humanity. Power of faith, National Unity. Patriotism. Love for nature, Discipline.

**Unit III:**

Personality and Behavior Development-Soul and Scientific attitude. Positive Thinking. Integrity and discipline. Punctuality, Love and Kindness. Avoid fault Thinking. Free from anger, Dignity of labour. Universal brotherhood and religious tolerance.

**Unit IV:**

True friendship. Happiness Vs suffering, love for truth. Aware of self-destructive habits. Association and Cooperation. Doing best for saving nature.

**Unit V:**

Character and Competence –Holy books vs Blind faith. Self-management and Good health. Science of reincarnation. Equality, Nonviolence, Humility, Role of Women. All religions and same message. Mind your Mind, Self-control. Honesty, Studying effectively.

**COURSE OUTCOMES**

Students will be able to

1. Knowledge of self-development
2. Learn the importance of Human values
3. Developing the overall personality

**REFERENCES:**

1. Chakroborty, S.K. “Values and Ethics for organizations Theory and practice”, Oxford University Press, New Delhi.

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**AUDIT COURSE**

**5. CONSTITUTION OF INDIA**

**Unit I:**

**History of Making of the Indian Constitution:** History Drafting Committee, (Composition & Working). Philosophy of the Indian Constitution: Preamble Salient Features.

**Unit II:**

**Contours of Constitutional Rights & Duties:** Fundamental Rights. Right to Equality. Right to Freedom. Right against Exploitation. Right to Freedom of Religion. Cultural and Educational Rights. Right to Constitutional Remedies. Directive Principles of State Policy. Fundamental Duties.

**Unit III:**

**Organs of Governance:** Parliament. Composition. Qualifications and Disqualifications. Powers and Functions. Executive. President. Governor. Council of Ministers. Judiciary, Appointment and Transfer of Judges, Qualifications Powers and Functions.

**Unit IV:**

**Local Administration:** District's Administration head: Role and Importance. Municipalities: Introduction, Mayor and role of Elected Representative CEO of Municipal Corporation. Pachayati raj: Introduction, PRI: ZilaPachayat. Elected officials and their roles, CEO ZilaPachayat: Position and role. Block level: Organizational Hierarchy (Different departments). Village level: Role of Elected and Appointed officials, Importance of grass root democracy.

**Unit V:**

**Election Commission:** Election Commission: Role and Functioning. Chief Election Commissioner and Election Commissioners. State Election Commission: Role and Functioning. Institute and Bodies for the welfare of SC/ST/OBC and women.

**Course Outcomes:**

**Students will be able to:**

1. Discuss the growth of the demand for civil rights in India for the bulk of Indians before the arrival of Gandhi in Indian politics.
2. Discuss the intellectual origins of the framework of argument that informed the conceptualization of social reforms leading to revolution in India.
3. Discuss the circumstances surrounding the foundation of the Congress Socialist Party [CSP] under the leadership of Jawaharlal Nehru and the eventual failure of the proposal of direct elections through adult suffrage in the Indian Constitution.
4. Discuss the passage of the Hindu Code Bill of 1956.

**REFERENCES:**

1. Dr. S. N. Busi, Dr. B. R. Ambedkar framing of Indian Constitution, 1st Edition, 2015.
2. M. P. Jain, Indian Constitution Law, 7th Edn., Lexis Nexis, 2014.
3. D.D. Basu, Introduction to the Constitution of India, Lexis Nexis, 2015.

**TEXT BOOKS:**

1. The Constitution of India, 1950 (Bare Act), Government Publication.



**JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD**  
**M.Pharm Semester – I & II (PHARMACOGNOSY)**  
**AUDIT COURSE**

**6.PEDAGOGY STUDIES**

**Unit I:**

**Introduction and Methodology:** Aims and rationale, Policy background, Conceptual framework and terminology. Theories of learning, Curriculum, Teacher education. Conceptual framework, Research questions. Overview of methodology and Searching.

**Unit II:**

Thematic overview: Pedagogical practices are being used by teachers in formal and informal classrooms in developing countries. Curriculum, Teacher education.

**Unit III:**

Evidence on the effectiveness of pedagogical practices. Methodology for the in depth stage: quality assessment of included studies. How can teacher education (curriculum and practicum) and the school curriculum and guidance materials best support effective pedagogy? Theory of change. Strength and nature of the body of evidence for effective pedagogical practices. Pedagogic theory and pedagogical approaches. Teachers' attitudes and beliefs and Pedagogic strategies.

**Unit IV:**

Professional development: alignment with classroom practices and follow-up support. Peer support. Support from the head teacher and the community. Curriculum and assessment. Barriers to learning: limited resources and large class sizes.

**Unit V:**

**Research gaps and future directions:** Research design Contexts. Pedagogy. Teacher education. Curriculum and assessment. Dissemination and research impact.

**COURSE OUTCOMES**

Students will be able to understand:

1. What pedagogical practices are being used by teachers in formal and informal classrooms in developing countries?
2. What is the evidence on the effectiveness of these pedagogical practices, in what conditions, and with what population of learners?
3. How can teacher education (curriculum and practicum) and the school curriculum and guidance materials best support effective pedagogy?

**REFERENCES:**

1. Ackers J, Hardman F (2001) Classroom interaction in Kenyan primary schools, Compare, 31 (2): 245-261.
2. Agrawal M (2004) Curricular reform in schools: The importance of evaluation, Journal of Curriculum Studies, 36 (3): 361-379.
3. Akyeamong K (2003) Teacher training in Ghana-does it count? Multi-site teacher education research project (MUSTER) country report 1. London: DFID.

4. Akyeampong K, Lussier K, Pryor J, Westbrook J (2013) Improving teaching and learning of basic maths and reading in Africa: Does teacher preparation count? *International Journal Educational Development*, 33 (3): 272–282.
5. Alexander RJ (2001) *Culture and pedagogy: International comparisons in primary education*. Oxford and Boston: Blackwell.
6. Chavan M (2003) Read India: A mass scale, rapid, 'learning to read' campaign. [www.pratham.org/images/resource%20working%20paper%202.pdf](http://www.pratham.org/images/resource%20working%20paper%202.pdf).

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**M.Pharm Semester – I & II (PHARMACOGNOSY)**  
**AUDIT COURSE**

**7.STRESS MANAGEMENT BY YOGA**

**Unit I:**

Definitions of Eight parts of yog (Ashtanga).

**Unit II:**

Yam and Niyam. Do`s and Don`t`s in life.

- i) Ahinsa, satya, astheya, bramhacharya and aparigraha.
- ii) Shaucha, santosh, tapa, swadhyay, ishwarpranidhan.

**Unit III:**

Asan and Pranayam

- i) Various yog poses and their benefits for mind & body.
- ii) Regularization of breathing techniques and its effects-Types of pranayam.

**COURSE OUTCOMES:**

Students will be able to:

1. Develop healthy mind in a healthy body thus improving social health also
2. Improve efficiency.

**REFERENCES:**

1. 'Yogic Asanas for Group Tarining-Part-I":Janardan Swami Yogabhyasi Mandal, Nagpur.

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**AUDIT COURSE**

**8. PERSONALITY DEVELOPMENT THROUGH LIFE ENLIGHTENMENT**  
**SKILLS**

**Unit I:**

Neetisatakam-Holistic development of personality; Verses- 19,20,21,22 (wisdom). Verses- 29,31,32 (pride & heroism). Verses- 26,28,63,65 (virtue). Verses- 52,53,59 (don't's). Verses- 71,73,75,78 (do's).

**Unit II:**

Approach to day to day work and duties. Shrimad BhagwadGeeta: Chapter 2-Verses 41, 47,48. Chapter 3-Verses 13, 21, 27, 35. Chapter 6-Verses 5,13,17, 23, 35. Chapter 18-Verses 45, 46, 48.

**Unit III:**

Statements of basic knowledge. Shrimad BhagwadGeeta: Chapter2-Verses 56, 62, 68. Chapter 12 - Verses 13, 14, 15, 16,17, 18. Personality of Role model. Shrimad Bhagwad Geeta: Chapter2-Verses 17. Chapter 3-Verses 36,37,42. Chapter 4-Verses 18, 38,39. Chapter18 – Verses 37,38,63.

**COURSE OUTCOMES**

Students will be able to

1. Study of Shrimad-Bhagwad-Geeta will help the student in developing his personality and achieve the highest goal in life
2. The person who has studied Geeta will lead the nation and mankind to peace and prosperity
3. Study of Neetishatakam will help in developing versatile personality of students.

**REFERENCES:**

1. "Srimad Bhagavad Gita" by Swami SwarupanandaAdvaita Ashram (Publication Department), Kolkata.
2. Bhartrihari's Three Satakam (Niti-sringar-vairagya) by P.Gopinath

**TEXT BOOKS:**

1. Rashtriya Sanskrit Sansthanam, New Delhi.