

**JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD**

**M. Pharmacy (PHARMACEUTICAL MANAGEMENT AND REGULATORY AFFAIRS)**

**COURSE STRUCTURE AND SYLLABUS**  
Effective from Academic Year 2017-18 Admitted Batch

**I Year – I Semester**

Category	Course Title	Int. marks	Ext. marks	L	P	C
Core Course I	Pharmaceutical Management – I (General and Personnel)	25	75	4	--	4
Core Course II	Drug Regulatory Affairs	25	75	4	--	4
Core Course III	Modern Pharmaceutical Analytical Techniques	25	75	4	--	4
Core Elective I	1. Total Quality Management 2. Intellectual Property Rights	25	75	4	--	4
Open Elective I	1. Pharmacoepidemiology and Pharmacoeconomics 2. Herbal Cosmetics Technology 3. Phytochemistry 4. Pharmaceutical Formulation Technology 5. Pharmaceutical Validation	25	75	4	--	4
Laboratory I	Modern Pharmaceutical Analytical Techniques Lab	25	75	--	6	3
Laboratory II	Pharmaceutical Management Lab	25	75	--	6	3
Seminar I	Seminar	100	--	--	4	2
<b>Total Credits</b>		<b>275</b>	<b>525</b>	<b>20</b>	<b>16</b>	<b>28</b>

**I Year – II Semester**

Category	Course Title	Int. marks	Ext. marks	L	P	C
Core Course IV	Pharmaceutical Management –II (Production, Marketing, Finance and Project)	25	75	4	--	4
Core Course V	Analytical Method Validation and Copyrights and Trademarks	25	75	4	--	4
Core Course VI	Pharmaceutical Market Research and Analysis	25	75	4	--	4
Core Elective II	1. Biostatistics And Research Methodology 2. Stability of Drugs and Dosage Forms	25	75	4	--	4
Open Elective II	1. Screening Methods in Pharmacology 2. Nano Based Drug Delivery Systems 3. Nutraceuticals 4. Advanced Drug Delivery Systems 5. Clinical Research and Pharmacovigilance	25	75	4	--	4
Laboratory III	Analytical Method Validation Lab	25	75	--	6	3
Laboratory IV	Pharmaceutical Market Research and Analysis Lab	25	75	--	6	3
Seminar II	Seminar	100	--	--	4	2
<b>Total Credits</b>		<b>275</b>	<b>525</b>	<b>20</b>	<b>16</b>	<b>28</b>

**II Year - I Semester**

<b>Course Title</b>	<b>Int. marks</b>	<b>Ext. marks</b>	<b>L</b>	<b>P</b>	<b>C</b>
Comprehensive Viva-Voce	--	100	--	--	4
Project work Review II	100	--	--	24	12
<b>Total Credits</b>	<b>100</b>	<b>100</b>	--	<b>24</b>	<b>16</b>

**II Year - II Semester**

<b>Course Title</b>	<b>Int. marks</b>	<b>Ext. marks</b>	<b>L</b>	<b>P</b>	<b>C</b>
Project work Review III	100	--	--	8	4
Project Evaluation (Viva-Voce)	--	100	--	16	12
<b>Total Credits</b>	<b>100</b>	<b>100</b>	--	<b>24</b>	<b>16</b>

**\$ For Project review I, please refer 7.9 in R17 Academic Regulations**

# JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD

## I Year – I Sem M. Pharm. (PM & RA)

### PHARMACEUTICAL MANAGEMENT-I (GENERAL & PERSONNEL) (Core course-I)

**Course Objective:** The topics which are present in the pharmaceutical management are very much useful to the students in personality development become a perfect pharma professional.

**Course Outcome:**

- These topics are useful for the students to know how to manage a pharma industry and its various departments viz QA, QC, RA, Production etc.
- Along with this it aids the students to develop leadership qualities, communication & interpersonal skills, decisions making, motivation, organization & various managerial functions & professional skills required for a dynamic professional.
- Management helps to understand the concept of managerial control, its levels & role, importance in pharma industry

#### UNIT - I

Pharmaceutical Management: Meaning, Evolution-scientific, administrative and human relation approach. Process of management: Planning, organizing, staffing, directing, coordinating and controlling—a preliminary idea of concepts, processes and techniques.

#### UNIT - II

Fundamental concepts of production, financial, personal, legal and marketing functions with special reference to Pharmaceutical Management. Introduction to budgeting, costing, accounting, auditing and budgetary control. Entrepreneurship development.

#### UNIT - III

Understanding organizations: Meaning, process, types of organization structures and departmentation, line/staff authority, promoting organizational culture. Organizations, pharmaceutical services and functioning of hospital pharmacy, bulk drug unit, formulation unit, Ayurvedic and Unani manufacturing units and testing labs etc.

#### UNIT - IV

Professional Managers; Tasks, responsibilities and skills needed. Leadership; Styles and managing change. Decision Making; Types, procedures, evaluation and selection of alternatives, decision making under various situations. Management information and decision support systems and time management.

Personnel Management: Job Analysis, recruitment, selection, orientation and training, performance appraisal and compensation. Retrenchment, lay off and discharge.

#### UNIT - V

Management of Industrial Relations: Industrial disputes, settlement of disputes through various routes such as bargaining, etc.

Motivational aspects, theories of motivation, group dynamics, rewards and incentives, interpersonal skills, significance of communication, its processes, measures for effective communication, conflict management. Stress management.

#### TEXT AND REFERENCE BOOKS:

1. Marketing Management by Philip Kotlar; Prentice-Hall of India Ltd., New Delhi.0
2. Management and Organization by Louis A. Allen; McGraw Hill, Tokyo..

3. Corporate Strategy by Ansoff, H.T.; McGraw Hill, New York.
4. Modern Management by Hempran David R.; McGraw Hill, New York.
5. Management by Stoner and Freeman; Prentice Hall, New Delhi.
6. Motivation and Personality by Maslow, Abraham, Harper & Row, New York.
7. Management of Organizational Behavior, Utilizing the Human Resources by Harcey, Paul and Blanchard Kenneth; Prentice Hall of India, New Delhi
8. Organization Structure, Process and out comes V<sup>th</sup> Edition Richard. H. Hall
9. Principles and Methods of Pharmacy Management III<sup>rd</sup> Edition Harry A. Smith.
10. Management "Global Perspective Heinz Wehrich, Harold Koontz by Tata Mcgraw Hill".
11. Personnel Management and Industrial Relations by P. C. Tripathi.

# JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD

## I Year – I Sem M. Pharm (PM & RA)

### DRUG REGULATORY AFFAIRS (Core course - II)

**Course 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.

**Course Outcomes:**

- 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.

#### UNIT - I

A study of regulatory aspects that affect drug product design, manufacture and distribution in India with special emphasis on the detailed study of the following Acts (with latest amendments)

#### UNIT - II

The Drugs and Cosmetics Act, 1940 and Rules there under. Recent amendments to Drugs and Cosmetic Act and other relevant rules.

Drugs (Price Control) Order in force. Loan license (contract manufacture). Certification and licensing procedures.

#### 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 (EMA/ National Authorities) EDMF
  - 2) European Directorate for Quality of Medicines CEP/COS & Health Care Products
- 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.

**TEXT AND REFERENCE BOOKS:**

1. Original laws published by Govt. of India.
2. Text Book of Forensic Pharmacy by Mithal B. M.; Vallabh Prakashan, New Delhi.
3. Laws of Drugs in India by Hussain.
4. Text Book of Forensic Pharmacy by Jain N. K.; Vallabh Prakashan, New Delhi.
5. Pharmaceutical Regulatory Affairs - Selected Topics, CVS Subramanyam and J Thimmasetty, Vallabha Prakashan Delhi - 2013

# JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD

## I Year – I Sem M. Pharm. (PM & RA)

### MODERN PHARMACEUTICAL ANALYTICAL TECHNIQUES (Core course - III)

**Course 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.

**Course Outcome:** 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.

#### UNIT - I

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

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

#### UNIT - II

- a. **Gas chromatography:** Introduction, fundamentals, instrumentation, columns: preparation and operation, detection, dramatization.
- b. **HPLC:** Principles and instrumentation, solvents and columns used, detection and applications
- c. **HPTLC:** Theory and principle, instrumentation, elution techniques and pharmaceutical applications

#### UNIT - III

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

#### UNIT - IV

**Mass spectroscopy:** Theory, ionization techniques: electron impact ionization, chemical ionization, field ionization, fast atom bombardment, plasma desorption, fragmentation process: types of fission, resolution, GC/MS, interpretation of spectra 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.

### **REFERENCES:**

1. Instrumental Methods of Chemical Analysis by B.K Sharma
2. Organic spectroscopy by Y.R Sharma
3. A Text book of Pharmaceutical Analysis by Kerrenth A. Connors
4. Vogel's Text book of Quantitative Chemical Analysis by A.I. Vogel
5. Practical Pharmaceutical Chemistry by A.H. Beckett and J.B. Stenlake
6. Organic Chemistry by I. L. Finar
7. Organic spectroscopy by William Kemp
8. Quantitative Analysis of Drugs by D. C. Garrett
9. Quantitative Analysis of Drugs in Pharmaceutical Formulations by P. D. Sethi
10. Spectrophotometric identification of Organic Compounds by Silverstein
11. HPTLC by P.D. Seth
12. Indian Pharmacopoeia 2007
13. High Performance thin layer chromatography for the analysis of medicinal plants by Eike Reich, Anne Schibli
14. Introduction to instrumental analysis by Robert. D. Braun

# JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD

## I Year – I Sem M. Pharm. (PM & RA)

### TOTAL QUALITY MANAGEMENT (Core Elective I)

**Course Objective:** Total quality management constitutes very useful chapter like –good manufacturing practices, GLP, GCP, ICH etc. Which increases the knowledge of students in various quality control & regulatory aspects.

**Outcome:** Total quality management helps the students to learn the established regulatory guidelines in GMP, GCP, GLP, USFDA, WHO, ISO etc to become a perfect budding pharmacist.

It is very useful to students to acquire vast knowledge regarding the quality control aspects of different regulatory bodies as per their requirements throughout the world.

#### UNIT - I

Concepts and Philosophy of TQM, GLP, GMP (orange guide).

#### UNIT - II

Drug regulatory and accrediting agencies of the world (USFDA, TGA, ICH, WHO, ISO etc.)

#### UNIT - III

Good manufacturing practices: Organization and personnel, responsibilities, training, hygiene.

Premises: Location, design, plant layout, construction, maintenance and sanitation, environmental control, utilities and services like gas, water, maintenance of sterile areas, control of contamination.

Equipments: Selection, purchase specifications, maintenance, clean-in-place, sterilize-in-place, methods (TP and STP).

Raw materials: Purchase specifications, maintenance of stores, selection of vendors, controls on raw materials and finished dosage forms.

Manufacture of and controls on dosage forms: Manufacturing documents, master formula, batch formula records, standard operating procedures, quality audits of manufacturing processes and facilities.

In process quality controls on various dosage forms; sterile and non–sterile, standard operating procedures for various operations like cleaning, filling, drying, compression, coating, disinfections, sterilization, membrane filtration etc.,

Packaging and labelling control, line clearance, reconciliation of labels, cartons and other packaging materials.

Quality Control Laboratory: Responsibilities, good laboratory practices, routine controls instruments, reagents, sampling plans, standard test procedures, protocols, non-clinical testing, controls on animal house.

Data generation and storage, quality control documents, retention samples, records and audits of quality control facilities.

Finished products release, quality review, quality audits, batch release document.

#### UNIT - IV

Regulatory Considerations for Pre-clinical and Clinical Evaluation: Pre-clinical requirements currently in use. Regulatory requirements of single dose and repeat dose toxicity studies. Study of specific toxicities such as mutagenicity, carcinogenicity and teratogenicity. Animal pharmacokinetics and toxicokinetics. Regulatory requirements of clinical evaluation, pharmacokinetics in man genetic polymorphism. Design and interpretation of clinical trials.

Quality assurance standards as per ISO.

## **UNIT - V**

Globalization of drug industry, present status and scope of pharmaceutical industry in India.  
WHO and NABL certification, ICH guidelines for manufacturing and quality assurance of drug formulation.

### **TEXT AND REFERENCE BOOKS:**

1. Guidelines for Developing National Drug Policies; WHO Publications, 1998.
2. Quality Assurance of Pharmaceuticals—A Compendium of Guidelines and Related Materials, Vol.-1; WHO Publications.
3. A Guide to Total Quality Management by Kaushik Maitra and Sedhan K. Ghosh.
4. GMP by Mehra.
5. How to Practice GMP by P.P. Sharma.
6. ISO 9000 and Total Quality Management by Sadhan K.Ghosh.
7. Good Manufacturing Practices for Pharmaceuticals-A Plan for Total Quality Control by Sidney H. Willing & James R Stoker. (Drugs & Pharm. Sciences) Vol. 78; Marcel Dekker Inc.
8. OPPI-Quality Assurance.
9. USP.
10. Current good manufacturing practices for pharmaceuticals by Manohar A. Potdar
11. Quality assurance and quality management in pharmaceutical industry by Y. Anjaneyulu and marayya
12. Total Quality Management, An integrated Approach by D. R. Kiran , BS Publications
13. Total Quality Management, 3<sup>rd</sup> edition by Joel E. Ross. CRC press

# JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD

## I Year – I Sem M. Pharm. (PM & RA)

### INTELLECTUAL PROPERTY RIGHTS (Core Elective - I)

**Course Objective:** Various types of Intellectual Property Rights Patentable Subject History of Indian Patent Protection, Patent filing procedure in India, Opposition- pre-grant opposition and post-grant opposition, Patent filing procedure under PCT, advantages, patent search and literature and Salient features of Indian Patents are discussed in detail.

**Course Outcome:** The clear information about the patent laws, intellectual property rights and drug regulation in India and abroad is gained by the students.

#### UNIT - I

Introduction, Types of Intellectual Property Rights (Patents, Trademarks, Copyrights, Geographical Indications Industrial Designs and Trade secrets), Patentable Subject Matter (Novelty, Non-Obviousness, Utility, enablement and Best mode),

#### UNIT - II

- a. History of Indian Patent Protection, Rationale behind Patent System, Objectives and Advantages of Patent System, and future challenges. Indian Patents Act 1970, Definitions and Key Terminology, Types of Patent applications, Inventions not patentable (section 3 and 4).
- b. Patent filing procedure in India (Patent Prosecution), Specifications (Provisional and Complete), Claims- types of claims and legal importance of claims, Grant of patent, Rights of Patentee and co-owners
- c. Opposition- pre-grant opposition and post-grant opposition, Anticipation, Infringement, Compulsory Licensing, revocation of patents, and power of Controller.
- d. Patent filing procedure under PCT, advantages, patent search and literature

#### UNIT - III

- a. Salient features of Indian Patents (Amendments) Act 1999, 2002 and 2005. US and European Patent System,
- b. Background, Salient Features and Impact of International Treaties / Conventions like
  1. Paris Convention, Berne convention
  2. World Trade Organization (WTO)
  3. World Intellectual Property Organization (WIPO)
  4. Trade Related Aspects of Intellectual Property Rights (TRIPS)
  5. Patent Co-operation Treaty (PCT), Madrid Protocol

#### UNIT - IV

- a. PCT Application procedure and review procedure
- b. National phase application procedure for US& EU
- c. Patent prosecution procedure in US and EU
- d. WIPO and its role in IPR
- e. Hatch- Waxman provision for IPR

#### UNIT - V

- a. Patent in validation process in India, US and Europe
- b. IPR related to copyright, trade mark, trade secret and geographical indication.
- c. Patent application writing
- d. Claim construction and claims.

**RECOMMENDED BOOKS:**

1. Research Methodology concepts and cases by Depak Chawla, Neena Sondhi
2. Draft manual of Patent Practice and Procedure -2008 , The Patent Office, India
3. Manual of Patent Office Practice and Procedure -2010
4. Original Laws Published by Govt. of India
5. Protection of Industrial Property rights by P.Das and Gokul Das
6. Law and Drugs, Law Publications by S.N. Katju
7. Laws of drugs in India, Hussain
8. New drug approval process, 5<sup>th</sup> edition, by Guarino
9. Commercial Manual on Drugs and Cosmetics 2004, 2<sup>nd</sup> edition
10. Drugs and Cosmetics act by Vijay Malik
11. Good Manufacturing Practices for Pharmaceuticals, S.H. Wiling, Vol. 78, Marcel Decker.
12. [fda.org](http://fda.org), [wipo.int](http://wipo.int), [patentlawlinks.com](http://patentlawlinks.com), [hc-sc.gc.ca](http://hc-sc.gc.ca), [ich.org](http://ich.org), [cder.org](http://cder.org)
13. Current good manufacturing practices for pharmaceuticals by Manohar A. Potdar
14. Pharmaceutical Regulatory affairs –selected topics. CVS subhramanyam and J Thimma settee. Delhi, Vallabha Prakasham, 2012

# JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD

## I Year – I Sem M. Pharm. (PM & RA)

### PHARMACOEPIDEMIOLOGY & PHARMACOECONOMICS (Open Elective – I)

#### **Course 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.

**Course 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.

#### **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.

#### **REFERENCES:**

1. Rascati K L. Essentials of Pharmacoeconomics, Woulters Kluwer 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. George E Mackinnon III. Understanding health outcomes and pharmacoeconomics.
7. Graker, Dennis. Pharmacoeconomics and outcomes.
8. Walley, Pharmacoeconomics.
9. Pharmacoeconomic – ed. by Nowakowska – University of Medical Sciences, Poznan.
10. Relevant review articles from recent medical and pharmaceutical literature
11. Guru Prasad Mohanta and P K Manna, Textbook of Pharmacovigilance Concepts and Practice

# JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD

## I Year – I Sem M. Pharm. (PM & RA)

### HERBAL COSMETICS TECHNOLOGY (Open elective - I)

**Course 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

**Course Outcome:** Students will learn about the raw materials used in herbal cosmetics and get exposed to various preparations herbal cosmetics.

#### UNIT - I

- a) Introduction, historical background and present status of Herbal cosmetics
- b) Processes used in the manufacture of cosmetics-Emulsification, Mixing, compaction, Moulding, Packing. Raw materials used in preparation of herbal cosmetics
- c) Machinery and Equipment for Cosmetics: Cream, Liquid, Powder and emulsion making machinery
- d) Quality, safety and efficacy of Herbal cosmetics

#### UNIT - II

**Skin care Products:** 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 - III

**Hair care Products:** Method of preparation, pharmaceutical and Pharmacological evaluation procedures for various formulations like hair dyes, creams, Lotions, Jels, 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 - IV

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, Liquorice, Olive oil, tea tree oil and wheat germ oil with special emphasis on their source, active principles and cosmetic properties.

#### UNIT - V

- a) General Principles of Quality control and standardization of cosmetics-Raw material control, Packaging material control, finished product control, Shelf testing.
- b) Natural colorants : Biological Source, coloring principles, chemical nature and usage of the following Annato, Cochineal, Caramel, Henna, Indigo, Madder, Saffron , Turmeric
- c) Flavors and Perfumes : Sandal wood oil, Orange oil, Lemon oil, Vanilla, Palmarosa, geranium oil

#### REFERENCES:

1. Cosmetics- Formulation, Manufacturing and Quality control –P.P. Sharma
2. Herbal Cosmetics Hand Book- H. Panda
3. Herbal Cosmetics by P. K Chattopadhyay
4. The Complete Technology Book on Herbal Perfumes and Cosmetics by H. Panda

# JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD

## I Year – I Sem M. Pharm. (PM & RA)

### PHYTOCHEMISTRY (Open Elective – I)

**Course 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 phytoconstituents of different categories.

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

#### UNIT - I

Extraction and Phytochemical studies: Recent advances in extractions with emphasis on selection of method and choice of solvent for extraction, successive and exhaustive extraction and Methods of fractionation. Separation of phytoconstituents by latest CCCET, SCFE techniques including prep and Flash column chromatography.

#### UNIT - II

Sources, Chemical structure, Identification tests, mechanism of action, SAR and uses of following Alkaloids

- a) Caffeine
- b) Quinine, Reserpine, Atropine, Vinca alkaloids
- c) Morphine and brief account on its derivatives and analogues

#### UNIT - III

Sources, Chemical structure, Identification tests, mechanism of action SAR, uses and semi-synthetic derivatives of the following phytopharmaceuticals:

Camptothecin, Podophyllotoxin, Taxol, Digoxin and Artemisinin

#### UNIT - IV

Structure elucidation of the following compounds by spectroscopic Techniques like UV, IR, NMR (1H, 13C)

- a. Carvone, Citral, Menthol
- b. Luteolin, Kaempferol
- c. Nicotine, Caffeine

#### UNIT - V

Drug discovery and development: History of herbs as source of drugs and drug discovery. Sourcing and archiving Natural products for discovery. Evaluating natural products for therapeutic properties, identifying the biologically active Natural products, the lead structure selection process and structure development with suitable examples from the following source: artemesin, andrographolides.

#### RECOMMENDED/ 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, Abraham,

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. Standardization of botanicals by V. Rajpal Vol 1 & 2
13. Medicinal chemistry and drug discovery by Burger's
14. Chemistry of Natural Products by S. V. Bhat, B. A. Nagasampagi, M. Sivakumar
15. Herbal Drugs: Quality and Chemistry by D. D. Joshi

# JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD

## I Year – I Sem M. Pharm. (PM & RA)

### PHARMACEUTICAL FORMULATION TECHNOLOGY (Open Elective – I)

**Course Objectives:** Students will know the preformulation studies, methodology, different excipients used in solid dosage forms and their evaluation with references to production technologies. The students also know the optimization techniques and their applications in pharmaceutical industries.

**Course Outcome:** Students shall explain the preformulation parameters, apply ICH guidelines and evaluate drug, drug excipients compatibility. Students also explain about formulation and development, use of excipients in tablets, powders, capsules, micro-encapsules and coating techniques. They also learn and apply the statistical design in different formulations.

#### Unit - I:

**Preformulation:** Goals of preformulation, solid state manipulation and characterization. pH dependent solubility of drug, equilibrium solubility, intrinsic dissolution of drug, particle size distribution.

Flow of Powders: Physical properties and importance. Angle of repose, Carr's index, compressibility, bulk density, tapped density.

#### Unit - II:

Excipients used in various dosage forms like tablets, capsules, emulsions, suspensions, semisolids and sterile products. Knowledge of packing materials. Drug- excipient compatibility- Drug stability, factors affecting stability, stabilization methods.

#### Unit - III:

**Tablets:** Types of tablets, granulation methods, highlighting operations such as mixing, drying, milling, blending, lubrication and compression.

Tablet coating: Types of coating, steps involved in coating process- pan coating and fluid bed coating and problems associated with coating.

Hard Gelatin Capsules: General principles and steps involved in the production of drug loaded hard gelatin capsules, filling operation, filling of powders, granules and pellets.

#### Unit - IV:

**Dissolution:** Principles of dissolution, factors influencing dissolution, official methods and apparatus. Dissolution of immediate release, controlled release and delayed release products.

#### Unit - V:

**Stability testing:** Chemical degradation and preventive measures. Various stability testing conditions and use of stabilizers in packing

#### TEXT BOOKS:

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

7. Industrial Pharmacy - Selected Topics , CVS Subramanyam and J Thimmasetty, Vallabha Prakashan Delhi - 2013

**REFERENCE BOOKS:**

1. The Theory and Practice of industrial Pharmacy by Leon Lachman, Herbert A. Lieberman.
2. Remington's Science and Practice of Pharmacy by A. Gennaro.
3. Ansel's Pharmaceutical Dosage form and Drug delivery system by Loyd V. Allen, Jr. Nicholas G. Popovich, Howard C. Ansel.
4. Generic Drug Product Development by Leon Shargel and Isadore Kanfer.
5. Dispensing for Pharmaceutical Students by SJ Carter.

# JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD

## I Year – I Sem M. Pharm. (PM & RA)

### PHARMACEUTICAL VALIDATION (Open Elective – I)

#### **Course 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.

**Course 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

#### **UNIT - I**

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

#### **UNIT - II**

**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 - III**

**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 - IV**

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

**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.

#### **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. The Theory & Practice of Industrial Pharmacy, 3rd edition, Leon Lachman, Herbert A. Lieberman, Joseph. L. Karig, Varghese Publishing House, Bombay.
3. Validation Master plan by Terveeks or Deeks, Davis Harwood International publishing.
4. Validation of Aseptic Pharmaceutical Processes, 2nd Edition, by Carleton & Agalloco, (Marcel Dekker).

5. Michael Levin, Pharmaceutical Process Scale-Up, Drugs and Pharm. Sci. Series, Vol. 157, 2nd Ed., Marcel Dekker Inc., N.Y.
6. Validation Standard Operating Procedures: A Step by Step Guide for Achieving Compliance in the Pharmaceutical, Medical Device, and Biotech Industries, Syed Imtiaz Haider
7. Pharmaceutical Equipment Validation: The Ultimate Qualification Handbook, Phillip A. Cloud, Interpharm Press
8. Validation of Pharmaceutical Processes: Sterile Products, Frederick J. Carlton (Ed.) and James Agalloco (Ed.), Marcel Dekker, 2nd Ed.
9. Analytical Method validation and Instrument Performance Verification by Churg Chan, Heiman Lam, Y.C. Lee, Yue. Zhang, Wiley Inter Science.

**JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD**

**I Year – I Sem M. Pharm. (PM & RA)**

**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.)
2. Simultaneous estimation of multi component containing formulations by UV spectrophotometry
3. Experiment base on HPLC (Isocratic and gradient) Techniques – (2 experiments)
4. Incompatibility studies, identification and functional groups – Determination by FTIR (2 experiments)
5. Separation and calculation of Rf values by using paper chromatography, TLC, HPTLC Technique (2-3 experiments)
6. Calibration of glasswares
7. Calibration of pH meter
8. Calibration of UV-Visible spectrophotometer
9. Calibration of FTIR spectrophotometer
10. Calibration of HPLC instrument

**JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD**

**I Year – I Sem M. Pharm. (PM & RA)**

**PHARMACEUTICAL MANAGEMENT LAB**

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