JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD

M.PHARMACY (INDUSTRIAL PHARMACY)

COURSE STRUCTURE AND SYLLABUS

I Year – I Semester

Category	Course Title	Int. marks	Ext. marks	L	P	C
Core Course I	Applied Biopharmaceutics and Pharmacokinetics	25	75	4	--	4
Core Course II	Advanced physical Pharmaceutics	25	75	4	--	4
Core Course III	Industrial Pharmaceutics	25	75	4	--	4
Core Elective I	1. Modern Pharmaceutical Analytical Technique 2. Intellectual Property Rights and Regulatory Affairs	25	75	4	--	4
Open Elective I	1. Pharmacoepidemiology, Pharmacoeconomics and Pharmacovigilance 2. Drug Regulatory Affairs (National & International) 3. Herbal Cosmetic Technology 4. Separation Methods 5. Pharmaceutical Management – I	25	75	4	--	4
Laboratory I	Modern Pharmaceutical Analytical Techniques Lab	25	75	4	--	4
Laboratory II	Advanced Physical Pharmaceutics Lab	25	75	--	4	2
Seminar I	Seminar	50	--	--	4	2
Total Credits				**24**	**8**	**28**

I Year – II Semester

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

II Year - I Semester

Course Title	Int. marks	Ext. marks	L	P	C
Comprehensive Viva-Voce	--	100	--	--	4
Project work Review I	50	--	--	24	12
Total Credits			--	24	**16**

II Year - II Semester

Course Title	Int. marks	Ext. marks	L	P	C
Project work Review II	50	--	--	8	4
Project Evaluation (Viva-Voce)	--	150	--	16	12
Total Credits			**--**	**24**	**16**

JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD

M.Pharm. I Year – I Sem (Industrial Pharmacy)

APPLIED BIOPHARMACEUTICS AND PHARMACOKINETICS

Objective: The student shall know about bioavailability, bioequivalence and factor affecting bioavailability. They also know the pharmacokinetic parameter like drug disposition, absorption, non-linear and time dependant pharmacokinetics. They also know about the drug interactions & problems associated in pharmacokinetic parameters calculations.

UNIT I

a. Biological and metabolic factors affecting bioavailability, complexation, dissolution - techniques of enhancing dissolution.
b. Formulation factors affecting bioavailability of drugs in dosage forms of tablets, capsules, parenterals, liquid orals and topical dosage forms.
c. **Bioavailability :**Importance, dose dependency, AUC, rate and extent, assessment, blood and urine samples, single dose and multiple dose studies, *Invitro- Invivo* Correlation analysis and Levels of Correlations.
d. **Bioequivalence:** Importance equivalency concepts, biowaivers, study designs, protocol, transformation of data, Statistical Criteria as per the Regulations.

UNIT II

Pharmacokinetics – Drug Disposition: compartment models: One, two and non-compartmental approaches to pharmacokinetics. Recent trends, merits and limitations of these approaches. Application of these models to determine the various pharmacokinetic parameters pertaining to:

a. Distribution: Apparent volume of distribution and its determination, factors affecting.
b. Metabolism: Metabolic rate constant, Factors affecting Metabolism
c. Elimination: Over all apparent elimination rate constant, and half life.
   All the above under the following conditions:
   1. Intravenous infusion
   2. Multiple dose injections
d. Non-invasive methods of estimating pharmacokinetics parameters with emphasis on salivary and urinary samples.
e. Concept of clearance: organ, total clearance, hepatic clearance, lung clearance and renal clearance.

UNIT III

Pharmacokinetics – Absorption: Rate constants **–** Zero order, first order,Models of experimental study of absorption (in silico, in vitro, in situ and in vivo) – Absorption half lives, method of residuals, Wagner – Nelson method, Loo - Reigleman method, Analysis of kinetics from urine samples. Pharmacokinetic parameters determination pertaining to: Multiple dosage oral administration

UNIT IV

Non-linear pharmacokinetics: Concepts of linear and non-linear pharmacokinetics, Michaelis-Menton kinetics characteristics. Basic kinetic parameters, possible causes of non-induction, non-linear binding, and non-linearity of pharmacological responses.

Clinical Pharmacokinetics: Altered kinetics in pregnancy, child birth, infants and geriatrics. kinetics in GI disease, malabsorption syndrome, liver, cardiac, renal and pulmonary disease states.

UNIT V

Time dependent pharmacokinetics: Introduction, classification, physiologically induced time dependency: Chronopharmacokinetics - principles, drugs– (amino glycosides, NSAIDS, antihypertensive drug) chemically induced dependency.

Drug Interactions: Kinetics of drug interaction, study of drug-drug interaction mediated through absorption, distribution, metabolism and elimination, mechanisms of interaction and consequence.

❖ Numerical problems associated with all units, if any.

Outcome: students will be able to tell factors affecting the bioavailability and stability of dosage form; they also know the bioequivalence studies and protocols for bioequivalent studies. They also know the parameters for the disposition, absorption and Michaelis-Menton constants for non-linear kinetics.

TEXT BOOKS

1. Biopharmaceutics and Clinical Pharmacokinetics by Milo Gibaldi.
2. Learn Shargel and ABC yu, Applied Biopharmacokinetics and
3. Biopharmaceutics and Pharmacokinetics by C.V.S. Subrahmanyam, Vallabh Prakashan.2010.
4. Basic biopharmaceutics, Sulnil S. Jambhekar and Philip J Brean.
5. Text book of Biopharmaceutics and Clinical Pharmacokinetics by NiaziSarfaraz

RECOMMENDED BOOKS

1. Bio-Pharmaceutics and Pharmacokinetics by V.Venkateshwarlu.
2. Pharmacokinetics.Biopharmaceutics and Clinical pharmacy by Robert E. Notari.
3. Biopharmaceutics and Clinical Pharmacokinetics - An Introduction by Robert E. Notari.
4. Drug drug interactions, scientific and regulatory perspectives by Alber P. G

JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD

M.Pharm. I Year – I Sem (Industrial Pharmacy)

ADVANCED PHYSICAL PHARMACEUTICS

Objective: the students shall know about particle science, polymer science and its use in pharmaceutical dosage forms. They also know the compression and consolidation parameters for powders and granules. Students also know about the rheology, disperse systems, dissolution and solubility parameters for dosage forms.

UNIT I

Polymer science: Classification, properties and characterization of polymers, phase separation, polymers in solid state, preparation of polymer solution, application of polymers in pharmaceutical formulations. Mechanism of biodegradation of biodegradable polymers including controlled drug delivery systems, Mucoadhesive, Hydrodynamically balanced and Transdermal Systems.

UNIT II

Physics of tablet compression: Basic principles of interactions, compression and consolidation, compression and consolidation under high loads, effect of friction, distribution of forces in compaction, force volume relationships, Heckel plots, compaction profiles, energy involved in compaction, Measurement of compression with strain gauges, compression pressure-QA parameters.

UNIT III

Kinetics and drug stability: Stability calculations, rate equations, complex order kinetics, Factors influencing stability, strategy of stability testing, method of stabilization, method of accelerated stability testing in dosage forms, temperature and humidity control, physical stability testing of pharmaceutical products. Photodecomposition, Method, solid state decomposition.

UNIT IV

Theories on stability of disperse systems: Adsorption, wetting, crystal growth mechanisms, physical stability of suspensions and emulsions, drug release from suspension and emulsion formulations. Accelerated stability evaluation of physical stability. Micro emulsions & multiple emulsions, types of viscometer-principle & working.

Viscoelasticity: Theoretical consideration, instrumentation, rheological properties of disperse systems and semisolids. Oscillatory testing, Creep measurement.

UNIT V

Dissolution and solubility: Solubility and solubilization of nonelectrolytes, solubilization by the use of surfactants, cosolvents, complexation, drug derivatisation and solid state manipulation, Mechanisms of Drug release - dissolution, diffusion (Matrix and Reservoir) and swelling controlled (Peppas Model) and dissolution equipment.

Outcome: The students will know particle size analysis method, solid dispersion, physics of tablets, polymer classification and its applications, student will also know the stability calculations, shelf life calculations and accelerated stability studies. They also know the rheology, absorption related to liquids and semi-solid dosage forms. They also know the factors affecting the dissolution and solubility in related to invitro/invivo correlations.

TEXT BOOKS

1. Physical Pharmacy , 4th Edition by Alfred Martin.
2. Theory and Practice of Tablets – Lachman Vol.4
3. Pharmaceutical Dosage forms – Dispasystems Vol. I & II
4. Cartenson “Drug Stability, Marcel Decker Solid state properties, Marcel Dekker.

REFERENCE BOOKS

1. Dispersive systems I, II, and III
2. Robinson. Controlled Drug Delivery Systems

JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD

M.Pharm. I Year – I Sem (Industrial Pharmacy)

INDUSTRIAL PHARMACEUTICS

Objective: This subject is to make the student achieve different parameters and factors that influence the dosage form design:

UNIT 1

a. **Preformulation studies:** Goals of preformulation, preformulation parameters, methodology, solid state manipulation and characterization, solubility and partition coefficient, drug- excipient compatibility.
b. Advances in Pharmaceutical excipients. Excipients selection
c. Packaging development – selection of primary and secondary packaging materials and testing

UNIT II

Pharmaceutical unit operations: A detail study involving machinery and theory of pharmaceutical unit operations like mixing, filtration, drying, and sterilization.

UNIT III

Formulation development of solid and powder dosage forms: Improved production techniques for tablets, new materials, processes, equipment improvements, high shear mixers, compression machines, coating machines, coating techniques in tablet technology for product development and computerization for in process quality control of tablets. Formulation development and manufacture of powder dosage form for internal and external use including inhalation dosage forms.

UNIT IV

Formulation development of soft and hard gelatin capsules : Introduction, production and methods of manufacture, filling equipment and filling operations, formulations, finishing, special techniques, the nature of the capsule shell and capsule, advances in capsule manufacture, processing and control including pharmaceutical aspects, physical stability and packaging.

UNIT V

Optimization techniques in pharmaceutical formulation and processing: Introduction, optimization parameters, statistical design, response surface method, contour diagrams, factorial design, partial factorial design, simplex methods, mixture designs, Placket Burhan method, Box Benken method, applications in pharmaceutical formulation.

.

Outcome:

- Different machinery used for various steps in manufacture of various dosage forms.
- Formulation and evaluation of hard and soft gelatin capsules and their advantages over other dosage forms.

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. Hand book of Pharmaceutical excipients

RECOMMENDED 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.
6. Pharmaceutical Packaging Technology by UK Jain, DC Goupale S Nayak.

JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD

M.Pharm. I Year – I Sem (Industrial Pharmacy) (Core 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
d. Counter – current extraction, solid phase extraction techniques, gel filtration

UNIT II

a. Gas chromatography: Introduction, fundamentals, instrumentation, columns: preparation andoperation, 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 overhausereffect(NOE), ^{13}CNMR spectra and its applications, 2D-NMR, COSY and applications in pharmacy.

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

REFERENCES :

1) 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

M.Pharm. I Year – I Sem (Industrial Pharmacy) (Core Elective -I)

INTELLECTUAL PROPERTY RIGHTS AND REGULATORY AFFAIRS

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.

Intellectual property rights

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), Mandrid Protocol

Regulatory Affairs

Unit IV

a. National Drug Regulatory requirements, National Drug Policy, Drugs and Cosmetics Act and its amendments, overview of schedules, detail study of schedule M and Schedule Y.
b. USFDA, FDA guidelines on IND, NDA and ANDA approvals, and SUPAC changes and understanding on 505 (b) (2) applications

Unit V

a. Requirement of GLP Guidance and recommendation on Dissolution and Bio-equivalence requirement. Types of ANDA filing (Para I, II, III, IV filing). Exclusivities (NCE, NS, NP, NDF, PED, ODE, PC)
b. ICH objectives and Guidelines- stability testing, WHO guidelines, ISOs- Production design, certification. ICH 8(QbD), ICH Q9 and ICHQ10

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

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,5th edition, by Guarino
9. Commercial Manual on Drugs and Cosmetics 2004, 2nd 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,wipo.int,patentlawlinks.com, hc-sc.gc.ca,ich.org,cder.org

Current good manufacturing practices for pharmaceuticals by Manohar A.Potdar

JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD

M.Pharm. I Year – I Sem (Industrial Pharmacy) (Open Elective -I)

PHARMACOEPIDEMIOLOGY, PHARMACOECONOMICS AND PHARMACOVIGILANCE

Objective: This course is designed to impart knowledge and skills in epidemiology, economics and vigilance of various diseases. This will enable the students to understand cost effectiveness in the management of disease and ADRS

Unit-I

Pharmacoepidemiology: Definition and scope: Origin and evaluation of pharmacoepidemiology need for pharmacoepidemiology, aims and applications.

Measurement of outcomes in pharmacoepidemiology Outcome measures and drug use measures Prevalence, incidence and incidence rate. Monetary units, number of prescriptions, units of drugs dispensed, defined daily doses and prescribed daily doses, medication adherence measurement.

Unit-II

Concept of risk in pharmacoepidemiology, Measurement of risk, attributable risk and relative risk, time-risk relationship and odds ratio

Pharmacoepidemiological methods: Includes theoretical aspects of various methods and practical study of various methods with the help of case studies for individual methods Drug utilization review, case reports, case series, surveys of drug use, cross–sectional studies, cohort studies, case control studies, case–cohort studies, meta–analysis studies, spontaneous reporting, prescription event monitoring and record linkage system.

Unit-III

Sources of data for pharmacoepidemiological studies Adhoc data sources and automated data systems.

Selected special applications of pharmacoepidemiology Studies of vaccine safety, hospital pharmacoepidemiology, pharmacoepidemiology and risk management, drug induced birth defects.

Unit-IV

Pharmacoeconomics: Definition, history, need of pharmacoeconomic evaluations Role in formulary management decisions.

Pharmacoeconomic evaluation Outcomes assessment and types of evaluation, includes theoretical aspects of various methods and practical study of various methods with the help of case studies for individual methods: Cost – minimization, cost- benefit, cost – effectiveness, cost utility

Applications of Pharmacoeconomics, Softwares used and case studies

Unit-V

a. Scope, definition and aims of Pharmacovigilance
b. Adverse drug reactions - Classification, Mechanism, predisposing factors, causualilty assessment (different scales used)
c. Reporting, evaluation, monitoring and management of ADRs
d. Role of pharmacist in management of ADRs.

Outcome: At completion of this subject, the students are expected to understand risk of pharmacoepidemiology history and need of pharmacoeconomics and assessment of pharmocovigilance.

REFERENCES:

1. Roger Walker, Clive Edward, Clinical pharmacy & therapeutics, Churchill Livingstone, New York.
2. Principles of drug action the basis of Pharmacology by Goldstein A, Arrow L. and Kalman ,S.M. 2nd edition. John Wiley & Sons. Incl. New York. 1974 Edition. McGraw Hill.
3. G Katzung, Basic and Clinical Pharmacology. Bertram, 9th edn Lange Publications, 2004
4. Goodman & Gilman's The Pharmcological basis of Therapeutics Ed. J.G. Hardman, L.E. Limbird, P.B. Molinoff and R. W. Ruddon. International Edition. McGraw Hill

JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD

M.Pharm. I Year – I Sem (Industrial Pharmacy) (Open Elective -I)

DRUG REGULATORY AFFAIRS (NATIONAL AND INTERNATIONAL)

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

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 (EMEA/ 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.

Outcome:

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

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

M.Pharm. I Year – I Sem (Industrial Pharmacy) (Open Elective -I)

HERBAL COSMETIC TECHNOLOGY

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

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

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. 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

M.Pharm. I Year – I Sem (Industrial Pharmacy) (Open Elective -I)

SEPARATION METHODS

Objectives: The course is designed to import knowledge in the field of various separation techniques in the context of their applications both at laboratory and industry level. The techniques such as GC, HPLC, Electrophoresis etc. Methods allow qualitative and quantitative estimations and thus demand for the development and validation of methods.

UNIT: I

i. **Column Chromatography and Short column chromatography**: Column packing, sample loading, column development, detection.

ii. **Flash chromatography and Vacuum liquid chromatography:** Objectives, optimization studies, selecting column and stationary phases, selecting suitable mobile phases, automated flash chromatography, and reverse phase flash chromatography.

UNIT-II

Sample Preparation - Analysis of drugs from formulations and biological samples including, selection of biological sample, extraction of drugs by various methods such as Liquid -Liquid Extraction (LLE), Solid Phase Extraction (SPE) and Membrane filtration.

UNIT: III

i. **HPLC:** Principles, basic parameters Retention factor, Capacity factor, Selectivity factor, plate number, plate height, resolution, peak shapes, band broadening, Van Deemter equation and curve. Column selection and optimization, column problems, solvents, trouble shooting, sample preparation.

ii. **Method Development and validation:** Introduction, Forced Degradation Studies -Experimental Approach to Forced Degradation Studies. Stability Indicating HPLC Method Development - Method Scope, Preliminary Requirements, Method Development Approach, Method Optimization and validation.

UNIT-IV

i. **Gas Chromatography:** Principles, split-split less injector, head space sampling, columns for GC, detectors, quantification, derivatization techniques.

ii. **Hyphenated techniques:** Introduction to GC-MS and LC-MS techniques and their applications.

UNIT-V

i. **Electrophoresis:** Capillary electrophoresis: Basic principle (zeta potential), instrumentation,different modes of CE, advantages and disadvantages, pharmaceutical applications.

ii. **Counter current chromatography:** Basic principles, droplet counter current chromatography, centrifugal partition chromatography, choice of solvents for SP and MP.

Outcome : The students should describe the separation techniques of choromatography (GC, HPLC) with principles, instrumentation, identification, development of methodology specific to the components of the mixure, including the method validation. The students should be able to explain the separation principles using the advanced techniques such as Flash chromatography and highphenated techniques.

REFERENCES:

1) 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) Methods in Biotechnology, Natural Product Isolation by Sarker, Latif, Gray
13) Methods in Biotechnology, Natural Product Isolation by Richard Canell
14) Various Reviews and Research Paper

JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD

M.Pharm. I Year – I Sem (Industrial Pharmacy) (Open Elective -I)

PHARMACEUTICAL MANAGEMENT-I

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.

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 Mangers; 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.

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

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 th Edition Richard. H. Hall

9. Principles and Methods of Pharmacy Management III rd Edition Harry A. Smith.
10. Management “Global Perspective Heinz Weihrich, Harold Koontz by Tata Mcgraw Hill”.
11. Personnel Management and Industrial Relations by P. C. Tripathi.

JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD

M. Pharm. I Year – I Sem (Industrial Pharmacy)

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. Estimation of multi components formulation by UV of two different methods
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. Interpretation of spectra and structure determination of Mass Spectroscopy
7. Separation of protein drug substances by electrophoresis.
8. Workshop on IR and NMR interpretation
9. Development and evaluation of drugs by derivative spectroscopy.

JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD

M. Pharm. I Year – I Sem (Industrial Pharmacy)

ADVANCED PHYSICAL PHARMACEUTICS LAB

List of experiments

1. Determinates of molecular weight of some selected polymers.
2. Preparation and evaluation of solid dispersions (Immediated release and sustained release)
3. Accelerated stability testing of Aspirin Tablets
4. Stability evaluation of Aspirin at various pH and temperature conditions
5. Determination of I^{st} order and 2^{nd} order rate constant. Half life by Acid / Alkali hydrolysis
6. Preparation and evaluation of multiple emulsions
7. Preparation and evaluation of β-cyclodextrin complexes of some drugs.
8. Generation of dissolution profiles of few dosage forms and application of the data into various kinetic equations. Calculation of Hixon-crowell dissolution rate constant
9. Preparation and dissolution study of paracetmol tablets and comparison with the marketed product.
10. Study of solubility and dissolution for few drugs and their respective salts.
11. Study of drug release from commercial suspension and emulsion dosage forms
12. Viscosity measurement of Newtonian and Non-Newtonian liquids
13. Evaluation of drug-protein binding analysis
14. Assignment of numerical problems, one compartment and two compartment disposition, method of residuals, AUC and evaluation of pharmacokinetic parameters.