SCHOOL OF PHARMACY
GURU NANAK INSTITUTIONS TECHNICAL CAMPUS
An Autonomous Institution under UGC

COURSE STRUCTURE
&
SYLLABUS
FOR
MASTER IN PHARMACY
(PHARMACEUTICS)

A Two Year Degree Course in Pharmacy under semester pattern under
(Effective from the academic session 2016-17)
## I YEAR – I SEMESTER COURSE STRUCTURE

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## II YEAR – I SEMESTER COURSE STRUCTURE

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

UNIT I
1. Biological and metabolic factors affecting bioavailability, complexation, dissolution - techniques of enhancing dissolution.
2. Formulation factors affecting bioavailability of drugs in dosage forms of tablets, capsules, parenterals, liquid oral and topical dosage forms.
4. Bioequivalence: Importance equivalency concepts, bio waivers, 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:
   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. Noninvasive 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

UNIT IV
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 express factors affecting the bioavailability and stability of dosage form; they also learn the bioequivalence studies and protocols for bioequivalent studies. They also evaluate the parameters for the disposition, absorption and Michaelis-Menten constants for non-linear kinetics.

TEXT BOOKS
1. Biopharmaceutics and Clinical Pharmacokinetics by Milo Gibaldi.
2. Learn Shargel and ABC yu, Applied Biopharmacokinetics and
5. Text book of Biopharmaceutics and Clinical Pharmacokinetics by Niazi Sarfaraz

RECOMMENDED BOOKS
1. Bio-Pharmaceutics and Pharmacokinetics by V. Venkateshwarlu.
4. Drug drug interactions, scientific and regulatory perspectives by Alber P. G
I Year – I Sem M.Pharm (Pharmaceutics/Pharmaceutical Technology)

ADVANCED PHYSICAL PHARMACEUTICS

Objective: The students shall apply the principles of physical and chemical properties of particle science, polymer science and their use in pharmaceutical dosage forms. They also learn the compression and consolidation parameters for powders and granules. Students also learn about the rheology, disperse systems, dissolution and solubility related 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

UNIT IV

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

TEXT BOOKS
2. Theory and Practice of Tablets – Lachman Vol.4
5. Industrial Pharmacy - Selected Topics , CVS Subramanyam and J Thimmasetty, VallabhaPrakashan Delhi - 2013
REFERENCE BOOKS
1. Dispersive systems I, II, and III
2. Robinson. Controlled Drug Delivery Systems
ADVANCED PHARMACEUTICAL TECHNOLOGY-I

**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.

**UNIT I**

**Preformulation studies:** Goals of Preformulation, preformulation parameters, Polymorphs and Amorphous forms, selection of drugs- solubility, partition coefficient, salt forms, humidity, solid state properties, Particle Size Analysis (Laser Diffraction and Dynamic Light Scattering) drug-excipient compatibility, flow properties, format and content of reports of preformulation, preformulation stability studies (ICH)

**UNIT II**

**Formulation development of solid dosage forms – I:** New materials, excipients science - diluents, disintegrants, superdisintegrants, etc. evaluation of functional properties of excipients, co-processed materials, methods of preparation and evaluation.

**UNIT III**

**Formulation development of solid dosage forms– II:** Coating, coating machines, coating techniques in tablet technology for product development, computerization, inprocess control of tablets, formulation development and manufacture of powder dosage forms for internal use. Microencapsulation- types, methodology, problems encountered.

**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, advances in capsule manufacture, machines, 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:** 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.

**TEXT BOOKS**

1. Pharmaceutics - The Science of Dosage form design by ME Aulton.
6. Pharmaceutical statistics by Bolton
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.
5. Dispensing for Pharmaceutical Students by SJ Carter.
6. Industrial Pharmacy - Selected Topics , CVS Subramanyam and J Thimmasetty, VallabhaPrakashan Delhi - 2013
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, MS, 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
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), $^{13}$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, AnneSchibli
I Year – I Sem M.Pharm(Pharmaceutics/Pharmaceutical Technology)

INTELLECTUAL PROPERTY RIGHTS AND REGULATORY AFFAIRS
(Core Elective I)

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
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
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
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
10. Drugs and Cosmetics act by Vijay Malik
12. fda.org, wipo.int, patentlawlinks.com, hc-sc.gc.ca, ich.org, cder.org
13. Current good manufacturing practices for pharmaceuticals by Manohar A. Potdar
I Year – I Sem. M.Pham. (Pharmaceutics/Pharmaceutical Technology)

PHARMACOEPIDEMIOLOGY, PHARMACOECONOMICS AND PHARMACOVIGILANCE
(Optional Elective – I)

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, causuality 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 pharmacovigilance.
REFERENCES:
I Year – I Sem M.Pharm(Pharmaceutics/Pharmaceutical Technology)

DRUG REGULATORY AFFAIRS (NATIONAL AND INTERNATIONAL)
(Optional Elective – I)

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.SFood & Drug Administration USDMF
b. CanadaTherapeutic 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 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.
TEXT AND REFERENCE BOOKS
1. Original laws published by Govt. of India.
3. Laws of Drugs in India by Hussain.
5. Pharmaceutical Regulatory Affairs - Selected Topics , CVS Subramanyam and J Thimmasetty, VallabhaPrakashan Delhi - 2013
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
I Year – I Sem
M.Pharm(Pharmaceutics/Pharmaceutical Technology)

SEPARATION METHODS
((Optional Elective – I)

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:**

UNIT-IV
i. **Gas Chromatography:**
   - Principles, split-splitless 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 chromatography (GC, HPLC) with principles, instrumentation, identification, development of methodology specific to the components of the mixture, 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) 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 Papers
I Year – I Sem M.Pharm (Pharmaceutics/Pharmaceutical Technology)

PHARMACEUTICAL MANAGEMENT-I
(Optional Elective –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

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.

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
5. Management by Stoner and Freeman; Prentice Hall, New Delhi.
7. Management of Organizational Behavior, Utilizing the Human Resources by Harcey, Paul and Blanchard Kenneth; Prentice Hall of India, New Delhi
10. Management "Global Perspective Heinz Weihrich, Harold Koontz by Tata Mcgraw Hill".
I Year – I Sem M.Pharm (Pharmaceutics/Pharmaceutical Technology)

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
List of experiments

1. Determinates of molecular weight of some selected polymers.
2. Preparation and evaluation of solid dispersions (Immediate 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 1st order and 2nd 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 paracetamol 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.
Objective: The students shall apply the pharmacokinetic and pharmacodynamic principles in the design of CDDS. They also apply the design, evaluation and applications related to oral, parenteral, transdermal, implants, bioadhesives and targeted drug delivery systems.

UNIT 1
Fundamentals of controlled drug delivery systems, pharmacokinetic and pharmacodynamic basis of controlled drug delivery. Design, fabrication, evaluation and applications of the following controlled releasing systems
5. Controlled release oral drug delivery systems
6. Parenteral controlled release drug delivery systems

UNIT II
Design, fabrication, evaluation and applications of the following
d. Implantable Therapeutic systems
e. Transdermal delivery systems
f. Ocular and Intrauterine delivery systems
g. Vaccine delivery: Delivery systems used to promote uptake, absorption enhancers, oral immunization, controlled release microparticles form vaccine development

UNIT III
Biochemical and molecular biology approaches to controlled drug delivery of
b. Bioadhesive drug delivery systems
c. Nasal drug delivery systems
d. Drug delivery to Colon

UNIT IV
Biochemical and molecular biology approaches to control drug delivery of
f. Liposomes
g. Niosomes
h. Microspheres
i. Nanoparticles
j. Resealed erythrocytes

UNIT V
Drug targeting to particular organs
6. Delivery to lungs
7. Delivery to the brain and problems involved
8. Drug targeting in neoplasams

Outcomes: Students will select the drugs for CDDS design of the formulation fabrication of systems of above drug delivery systems with relevant applications.
Text Books
6. Advances in Drug Delivery, Vol 1, 2, 3 by Y.Madhusudan Rao, A.V. Jithan
Objectives: The students shall learn the theory of unit operations, machinery, materials of constructions, qualification of equipments and its utility. The students shall also understand about the objectives and principles of GMP, TQM and effluent analysis and specifications. They also understand the regulatory basis for the validation of analytical methods related to solids, sterile and liquid dosage forms.

UNIT I
Pharmaceutical unit operations: A detailed study involving machinery and theory of Pharmaceutical unit operations like milling, mixing, filtration, and drying.

UNIT II
7. Qualification of equipment (IQ, OQ, PQ)

UNIT III
Production management: Production organization, objectives and policies of good manufacturing practices, layout of buildings, services, equipments and their maintenance, material management, handling and transportation, inventory management and control, production and planning control, Sales forecasting, budget and cost control, industrial and personal relationship. Total Quality Management (TQM)

UNIT IV
Effluent Testing and Treatment: Effluent analysis, specifications and preventive measures water of pollution, solid pollution, air pollution and sound pollution.

UNIT V
Validation: Regulatory basis, validation of analytical methods, and process, in solid dosage forms, sterile products, and liquid dosage forms.

Outcome: The students will explain the machinery involved in milling, mixing, filtration, drying and packing material constructions used in the production of pharmaceutical materials. They also learn salient features of GMP, TQM applicable in industry. They also understand the effluent treatments and prevent the pollution. They also should evaluate the validation of analytical methods and processes.

Text Books
1. The Theory and Practice of industrial Pharmacy by Leon Lachman, Herbert A. Lieberman.
2. Good Manufacturing Practice for Pharmaceuticals by Sidney H. willig.

Recommended Text Books
1. Unit operations of Chemical Engineering by Warren L. McCabe, Julian C. Smith, Peter Harriott.
2. Remington's Science and Practice of Pharmacy by A. Gennaro.
4. CGMP, H.P.P. Sharma
Objective: The students shall understand about the pilot plant and their scale up techniques for manufacturing of tablets capsules, suspensions, emulsions and semisolids. The students also learn the filling of capsules, compression machines, sterilizers for formulation of parenterals and also understand the properties of propellants, DPI, MDI and their quality control. The students also understand about the cosmetics and nutraceuticals.

UNIT I

Pilot plant scale-up techniques used in pharmaceutical manufacturing

1. Pilot plant: Technology transfer from R&D to pilot plant to pilot scale considerations of steps involved with manufacture, layout design, facility, equipment selection of tablets, capsules, suspensions, emulsions & semisolids.

2. Scale up: Importance, Scale up process-size reduction, mixing, blending, granulation, compression, coating involved in tablets, capsules & liquid-liquid mixing.

UNIT II

Formulation development of parenteral dosage forms: Advances in materials and production techniques, filling machines, sterilizers, product layout.

UNIT III

Pharmaceutical Aerosols: Advances in propellants, metered dose inhaler designs, dry powder inhalers, selection of containers and formulation aspects in aerosols formulation, manufacture and quality control.

UNIT IV


b. Nutraceuticals:
   c. Introduction, source, manufacture and analysis of glucosamine and cartinine.
   d. Monographs: General and specific properties of glucosamine & cartinine.
   e. A brief overview of role of nutraceuticals in cancer prevention & cardiovascular disorders.

UNIT V

Aseptic processing operation

a. Introduction, contamination control, microbial environmental monitoring, microbiological testing of water, microbiological air testing, characterization of aseptic process, media and incubation condition, theoretical evaluation of aseptic operations.

b. Air handling systems: Study of AHUs, humidity & temperature control.

Outcomes: students will understand the planning of pilot plant techniques used for all pharmaceutical dosage forms such as tablets, capsules, parenterals, aerosols, cosmetics and nutraceuticals.
Text Books
1. Pharmaceutics - The Science of Dosage form design by ME Aulton.
2. The Theory and Practice of industrial Pharmacy by Leon Lachman, Herbert A. Lieberman.
3. Remington’s Science and Practice of Pharmacy by A. Gennaro.
5. Pharmaceutical Dosage forms - Parenterals (Vol I, II and III) by Avis, Lieberman and Lachman.
6. Scale up techniques – Pharmaceutical process by Michael Levin, Marcel Dekker

Recommended Books
1. Bentley’s Text Book of Pharmaceutics by EA Rawlins.
3. Dispensing for Pharmaceutical Students by SJ Carter.
6. Industrial Pharmacy - Selected Topics, CVS Subramanyam and J Thimmasetty, VallabhaPrakashan Delhi - 2013
GURU NANAK INSTITUTIONS TECHNICAL CAMPUS-AUTONOMOUS
I Year – II Sem M.Pharm (Pharmaceutics/Pharm Tech)

BIOSTATISTICS AND RESEARCH METHODS
(Core Elective- II)

Objective: The student shall know the introduction, scope of biostatistics and Research work, calculation and present of the data. It also informs the students, how the present research work writing and correlating.

UNIT I

UNIT II
Measures of central tendency: computation of means, median and mode from grouped and ungrouped data.
Measure of dispersion: computation of variance, standard deviation, standard error and their coefficients.

UNIT III
Measures of Correlation and Regression: Experimental designing, planning of an experiment, replication and randomization. Probit analysis.
Probability rules: Binomial, Poison and Normal distribution.
Hypothesis testing: Student’s test, Chi square test, Analysis of Variance (ANOVA): 1-way, 2-way, 3-ways

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

UNIT V
The research report paper writing/ thesis writing
Different parts of the research paper
a. Title-Title of project with authors’ name
b. Abstract – Statement of the problem, Background list in brief and purpose and scope
c. Key words
d. Methodology- subject, apparatus, instrumentation and procedure
e. Results – tables, graphs figure and statistical presentation
f. Discussion support or non-support of hypothesis, practical and theoretical implications
g. Conclusion
h. Acknowledgements
i. References
j. Errata
k. Importance of Spell check for entire projects
l. Uses of footnotes
**Outcome:** The student will be known the Biostatistics arrangement, presentation and formation of tables and charts. They also know the correlation and regression & application of different methods, analysis of data and also learn how to write dissertation, thesis and Research paper

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

**Reference Books**
- a. Remington’s Pharmaceutical Sciences
- b. Theory & Practice of Industrial Pharmacy by Lachman
- c. Statistics for business and economics 3rd edition by Vikas books publications
- d. Biostatistics & Computer applications by GN Rao and NK Tiwari
- h. Biostatistics and Computer Applications by G.N. Rao and N.K. Tiwari
- i. Fundamentals of Biostatistics by Khan and Khanum
- j. Research Methodology by RK Khanna bis and SuvasisSaha
- k. Research methods and Quantity methods by G.N.Rao
Objective: The students are going to study about various techniques for screening of drugs for various pharmacological activities and guidelines for handling animals and human and animal ethics for screening of drugs.

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

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

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

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

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

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

Text Books:
- Screening methods in Pharmacology, Vol.-1&2 by Robert A. Turner and Peter Hebborn.
- Principles of clinical research edited by Giovanna di ignazio, Di Giovanna and Haynes

Reference Books:
- ICH of technical requirements for registration of pharmaceuticals for human use, ICH harmonized tripartite guidelines - Guidelines for good clinical practice, E6, May 1996.
- Good clinical practice - Guidelines for Clinical trials on pharmaceutical products in India, Central drug standard control organization, New Delhi, Minister of Health- 2001.
STABILITY OF DRUGS AND DOSAGE FORMS
(Open Elective- II)

Objective: These topics are designed impart a specialized knowledge to preserve the properties of
drugs and dosage forms during manufacture storage and shelf life. The understanding of properties and
evaluation of stability during storage, by solution and solid state against several factors of degradation

UNIT-I
Drug decomposition mechanisms:
1. Hydrolysis and acyltransfers: Nature of reaction, structure and utility, stabilization of
   Pharmaceutical examples.
2. Oxidation: Nature of oxidation, kinetics of oxidation, oxidation pathways of pharmaceutical,
   Interest Inhibition of oxidation
3. Photolysis: Energetics of photolysis, kinetics photolysis, photolytic reactions of pharmaceutical
   interest, prevention of photolytic reactions.

UNIT-II
Solid state chemical decomposition: Kinetic of solids state decomposition, Pharmaceutical examples of
solid state decomposition, Pure drugs, drug excipient and drug-drug interaction in solid state, methods of
stabilization.
Physical stability testing of dosage forms:
Solids – tablets, capsules, powder and granules
Disperse systems
Microbial decomposition
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.
1. cGMP& ICH guidelines for Accelerated stability 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:


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.


Objective - To develop expertise regarding suitability and evaluation of nanomaterials, able to apply the properties to the fabrication of nanopharmaceutical, evaluate the intensity of dosage forms and availability for targeting and controlled delivery.

UNIT I – Introduction to Nanotechnology
   Definition of nanotechnology
   History of nanotechnology
   Unique properties of nanomaterials
   Role of size and size distribution of nanoparticles properties, classification.

UNIT II – Synthesis of Nanomaterials
   Physical, chemical and biological Methods
   Methods for synthesis of
   Gold nanoparticles
   Magnetic nanoparticles
   Polymeric nanoparticles
   Self – assembly structures such as liposomes, micelles, aquasomes and nanoemulsions

UNIT III – Biomedical applications of Nanotechnology
   1. Nanotechnology products used for in vitro diagnostics
   2. Improvements to medical or molecular imaging using nanotechnology
   3. Targeted nanomaterials for diagnostic and therapeutic purpose

Unit IV
Design of nanomaterials for drug delivery, pulmonary and nasal drug delivery, nanomaterials for cancer therapy and cardiovascular diseases. Localized drug delivery systems.

Unit V
Characterization including the principles, size reduction, analysis of nanoparticles, size, PDI, size separation, stability, methods of analysis regarding integrity and release of drugs

Outcomes – The students should be able to select the right kind of materials, able to develop nano formulations with appropriate technologies, evaluate the product related test and for identified diseases
Recommended Books:
1. Nanomedicine and Nanoproducts: Applications, Disposition and Toxicology in the Human body, Eiki Igarashi, CRC press. 2015
2. Nanotechnology and Drug Delivery Volume one and two: Nanoplatforms in Drug Delivery, Jose L.Arias, CRC press
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
iii. 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.
iv. 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- α and β-Carotene, Lycopene, Xanthophylls, lutein
b. Sulfides: Diallylsulfides, Allyl trisulfide.
c. Polyphenolics: Reservetrol
d. Flavonoids- Rutin, Naringin, Quercitin, Anthocyanidins, catechins, Flavones
e. Prebiotates / Probiotics.: Fructo oligosaccharides, Lacto bacillum
f. Phytoestrogens : Isoflavones, daidzein, Geebustin, lignans
g. Tocopherols

UNIT III
I. 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.
II. Measurement of free radicals: Lipid peroxidation products, lipid hydroperoxide, malondialdehyde.

UNIT IV
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.
Antioxidants: Endogenous antioxidants – enzymatic and nonenzymatic antioxidant defence, Superoxide dismutase, catalase, Glutathione peroxidase, Glutathione Vitamin C, Vitamin E, α- Lipoic acid, melatonin
Synthetic antioxidants : Butylated hydroxy Toluene, Butylated hydroxy Anisole.

UNIT V
Food Laws and Regulations; FDA, FPO, MPO, AGMARK. HACCP and GMPs on Food Safety. Adultration of foods.
Regulations and Claims – Current Products: Label Claims, Nutrient Content Claims, Health Claims, Dietary Supplements Claims

Outcome: Helps the student to understand the importance of Neutraceuticals in various common problems with the concept of free radicals
REFERENCES:
1. Dietetics by Sri Lakshmi
2. Role of dietary fibres and neutraceuticals in preventing diseases by K.T Agusti and P.Faizal: BSPunublication.
Objective: To know the pharmaceutical product management, planning, marketing accounts and finance. They also know the Inventory control, concept and techniques to improve production in packaging, marketing, sale and accounting.

UNIT I
Production Management: Fundamentals of production, organization, economic policy, manufacturing economics, production capacities, production lines and job balancing, visible and invisible inputs, methodology of activities. Development of efficient work methods, quality control and management of R&D.
Production planning and control, production processes - mass, job and project; plant location and lay out; work study (preliminary idea only), materials management- purchase, inventory control and store keeping. Productivity management: Concepts, problems, tools and techniques for improvement. Operation research techniques by PERT and CPM.
Considerations for design of large scale manufacturing units including intricate design criteria for units to manufacture sterile and non-sterile products with special reference to tablets, capsules, and injections. Design and development of packaging units including recent advances in packaging techniques for various types of sterile and non-sterile dosage forms. Warehousing design, construction, maintenance and sanitation; good warehousing practice, materials management.

UNIT II
Pharmaceutical Marketing: Evolution of marketing concept; production oriented, sales oriented, promotion oriented and consumer oriented (modern concept); market segmentation; concept of marketing, mix: Role of 7 P’s (Product, Price, Promotion, Place, Physical Evidence, Process, People) in Pharmaceutical Marketing Management, corporate planning & strategy, Pharmaceutical industrial marketing management. Pharmaceutical marketing environment. Product management. E-Pharma Marketing.

UNIT III
Product Planning: Selection of product, new product development and product differentiation, pricing, promotion – personal selling; salesmanship, qualities of salesman, management of sales force, advertising, publicity and window display, channels of distribution. Marketing Research: Definition and importance, Pharmaceutical Marketing Research techniques, marketing information system, pharmaceutical marketing research area. Market Demands and Sales Forecasting: Major concepts in the demand measurement, estimating current demands, geo-demographic analysis, estimating industry sales, market share and future demand, sales forecasting.

UNIT IV
Introduction to financial management, financial planning and control, working capital management, management of fixed assets. Concepts and techniques of financial management decision, concepts in evaluation – time value of money, valuation of a firm’s stock, capital assets pricing model, investment in assets and required returns, risk analysis, financing and dividend policies, capital structure decision, working capital management, management of cash, management of accounts receivable, inventory management. Banking and finance: Service and functions of bank, finance planning and sources of finance, short, intermediate and long term financing, tools of financial analysis, financial ratio analysis, funds analysis and financial forecasting, operating and financial leverages. General principles of insurance. Introduction to financial management, financial planning and control, working capital management, management of fixed assets.
Evaluation of investment decisions by payback period, accounting rate of return, net present value methods, break even analysis.

UNIT V
Accounting & Finance: Financial accounting, GAAP, cost accounting, budgetary control, valuation of inventory and assets, modern trends, role of internal auditing, internal versus external auditing, accounting control and information systems.
Project definition, preparation of feasibility assessment and selection, project reporting, conventional project appraisal; limitations, towards a new framework. Projections, profitability, cost and benefit analysis, appraisal criteria – financial, economic and social. Risk analysis.
Institutional Finance and Project Appraisal: Framework for domestic/ international finance evaluation, project identification, feasibility, appraisal, financial and capital structures, capital market instruments, managing new issues, negotiations with FI, FII, and other market players, issue pricing, SEBI guidelines, syndication of loans including term loans, lease financing.

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

Text and reference books
3. Stock Exchange and Investment Analysis by Briston, R. J.
7. Project Management: A System Approach to Planning Scheduling and Controlling by Harold Kerzner;
8. CRS Publishers and Distributors, Delhi.
16. Principle and Practice of Marketing in India by Memoria C. B.
20. Production and Operations Management by S.N.Chary
## ADVANCED DRUG DELIVERY SYSTEMS LAB

### List of Experiments

1. Study on diffusion of drugs through various polymeric membranes (2 experiments)
2. Formulation and evaluation of sustained release oral matrix tablet (2 experiments)
3. Formulation and evaluation of sustained release oral reservoir system (2 experiments)
4. Formulation and evaluation of microspheres / microencapsules (2 experiments)
5. Study of in-vitro dissolution of various SR products in market (2 experiments)
6. Formulation and evaluation of transdermal films (2 experiments)
7. Formulation and evaluation mucoadhesive system (2 experiments)
8. Preparation and evaluation enteric coated pellets / tablets (2 experiments)
List of Experiments

1. Preparation of four different types of semisolid forms and evaluation of their performance using in vitro diffusion method
2. Evaluation of test sterility for commercial preparations including sterile water for injection and antibiotic injection.
3. Collecting samples of environment of aseptic room and counting the colonies
4. Validation of one unit operation (eg. Mixing) and development of protocol.
5. Comparative evaluation of different marketed products (tablets) of the same API
6. Dissolution studies of drug in three different bio relevant dissolution media
7. Stability study testing of tablet dosage forms (Any two products)