## Gujarat Technological University

**M. Pharm.**  
**Semester – II**

Structure for Second Semester of Master of Pharmacy Course

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<th>Sr. No.</th>
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1. Research—Meaning, purpose, Types, (Educational, Clinical, Experimental, Historical descriptive, Basic applied and Patent oriented Research) objective of Research
2. Literature survey—Use of Library, books and journals—Medlines—Internet, Patent Search, and reprints of articles as a source for Literature survey.
3. Selecting a problem and preparing Research proposals
4. Methods and tools used in research—
   A. Qualitative studies, quantitative studies
   B. Simple data organization descriptive data analysis,
   C. Limitation & sources of Error
   D. Inquiries in form of Questionnaire, etc.
5. Documentation—
   A. “How” of documentation
   B. Techniques of documentation
   C. Importance of documentation
   D. Use of computer packages in documentation.
   Different parts of the Research paper
   1. Title—Title of project with authors name
   2. Abstract—Statement of the problem, Background list in brief and Purpose and scope.
   3. Key Words.
   5. Results—tables, graphs, figures & statistical presentation
   6. Discussion support or non support of hypothesis, practical & theoretical Implications
   7. Conclusion
   8. Acknowledgements.
   9. References
   10. Errata
   11. Importance of Spell check for entire project
   12. Uses of footnotes
7. Presentation (especially for oral presentation)
   Importance, types different skills, contained, format of model, introduction, Poster, Gestures, eye contact, facial, expressions, stage, fright, volume—pitch, speed, pause & language, Visual aids & seating, Questionnaire
9. Sources for procurement research grants—international agencies, Government and private bodies.
10. Industrial-institution interaction—Industrial projects, their, feasibility reports. Interaction with industries.
References Books:

1. Research in Education- John V. Best, John V. Kahn 7th edition
2. Presentation skills - Michael Hallon- Indian Society for Institute education
3. Practical Introduction o copyright. - Gavin Mcfarlane
4. Scientist in legal Systems- Ann labor science
6. Writing a technical paper- Donald Menzel
8. Protection of industrial Property rights- P. Das & Gokul Das
9. Spelling for the millions- Edna Furmess
10. Preparation for publication – King Edward Hospital Fund for London
11. Information Technology – The Hindu speaks
14. Manual for the preparation of industrial feasibility studies
Gujarat Technological University
Master of Pharmacy
Semester – II
Paper code -2920102
Specialization paper - III
Novel Drug Delivery System Part-I
Theory
(Six hours per week, 7 credits)

1. Recent Innovations in Conventional Dosage Forms – including site specific and time release modulation.
   e.g.: Tablets: Osmotic, Colon target, Gastro-retentive, Buccal, and Sublingual.
       Capsules: Modified release,
       Semi-solids:
       Parenterals:
       Powders: Particle coating, Taste-masking,
       Liquids:

2. Packaging components and its evaluation: factors affecting selection,
   Types and classification, Primary and secondary and regulatory aspects.
   Contribution in stability of the dosage forms.

Subject of Specialization paper - III
Novel Drug Delivery System Part-I
Practical
(Six hours per week, 8 credits)

Laboratory examination including oral and practical examination in general course illustrative of theory section in the syllabus.

References Books:

3. Pharmaceutics “The Science of Dosage form design” by Aulton
4. Pharmaceutical dispensing by Husa.
5. Modern pharmaceutics by G. S. Banker.
7. Pharmaceutical dissolution testing by Banaker.
Gujarat Technological University
Master of Pharmacy
Semester – II
Paper code -2920202
Specialization paper - IV
Global Regulatory Requirements

Theory
(Six hours per week, 8 credits)

1. Validation of Pharmaceutical Processes, equipments/apparatus, basic concept in analytical method development for dosage forms., Computer System validation, ERP and SAP systems.

2. Basics in Drug approval process with reference to:
Orange book, Freedom of information, IIG, DMF, Historical aspects with Various phases of drug development and approval.

3. IND, NDA, ANDA , Concept of para I to IV, exclusivity: Content, format and Application.

4. Brief and comparative introduction to various regulatory agencies:
USFDA, MCA, TGA, MHRA, ANVISA, CTD, WHO, ICH, SUPAC etc.

Reference Book:
The guidance documents shall be procured from the website of the respective Government.
1. Biological standardization, general principles, Scope and limitation of bio-assay, bioassay of some official drugs.
3. Pyrogens: Sources, Chemistry and properties of bacterial pyrogens and endotoxins, Official pyrogen tests
4. Microbiological assay of antibiotics and vitamins.
5. Biological evaluation of drugs–Screening and evaluation (including principles of screening, development of models for diseases: In vivo models / In vitro models / cell line study) techniques of the following:
6. Parasympathomimetics, Parasympathetic blocking agents, Sympathomimetics, Sympathetic blocking agents, Ganglion stimulants and blockers, Neuromuscular stimulants and blockers.
8. Cardiotonics, Anti-hypertensive drugs, Anti-arrhythmic drugs, Drugs used in Ischemic Heart Diseases, Drugs used in Atherosclerosis.
9. Drugs used in Peptic Ulcer, Respiratory disorders, Hormone and Endocrine disorders. Anti fertility agents and diuretics.
10. Various models for Cataract, glaucoma, inflammatory bowel disease

Specialization paper - III
Pharmacometrics and Methods of biological evaluation of drugs
Practical
(Six hours per week, 8 credits)

1. **Bioassays of drugs**: Bioassay of agonists (Graphical, Matching, 3 Point, 4 point method) and Bioassay of antagonists using various isolated preparations.
2. **Toxicity studies**
3. **Evaluation of drugs based on theory syllabus.**
**Illustrative examples**

Evaluation of the antiepileptic activity of drug using maximum electro convulsive shock seizures (M. E. S.) and chemical induced convulsions methods.

1. Determination of the time required for induction and recovery from anesthesia for various volatile general anesthetics.
2. Evaluation of the effect of pentobarbitone sodium and diazepam in mice.
3. Evaluation of the effect of various tranquilizers and sedatives on motor co-ordination by rota rod test in mice.
4. Evaluation of the effects of drugs on spontaneous motor activity and to evaluate their nature as CNS stimulants or depressants.
5. Evaluation of the antiparkinsonian activity of drugs by pheno-thiazine induced catatonia.
7. Evaluation of the compulsive behavior (stereotypy) induced by apomorphine and its modification by chlorpromazine in mice.
10. Evaluation of the effect of cimetidine in drug induced gastric (peptic) and duodenal ulcers and hyper secretion of gastric acid in rats.
11. Evaluation of the antisecretory and ulcer protective effect of cimetidine in pylorus-ligated rats.
14. Evaluation of the analgesic effect of drugs by acetic acid induced writhing method in mice.
15. Evaluation of the anti-inflammatory property of indomethacin against carrageenan-induced acute paw oedema in rats.
16. Evaluation of the effects of various drugs (diuretics) on the output of the urine in rats.

**References Books:**

1. Screening methods in pharmacology (vol I & II)–R.A. Turner
2. Drug Discovery and Evaluation in Pharmacology assay: Vogel
3. Design and analysis of animal studies in pharmaceutical development, Chow, Shein, Ching.
4. Evaluation of Drug Activity: Pharmacometrics D.R. Laurence
5. Animal and Clinical pharmacologic Techniques in Drug Evaluation-Nodine and Siegler
6. Pharmacology and Toxicology- Kale S.R.
7. Fundamentals of experimental Pharmacology- Ghosh M.N.
Gujarat Technological University
Master of Pharmacy
Semester – II
Paper code -2920203
Specialization paper - IV
Pharmacotherapeutics

Theory
(Six hours per week, 8 credits)

Important disorders/conditions (etioloogy, pathophysiology, complications, diagnosis, Prognosis), their control and management with special emphasis on pharmacology of drugs (mechanism of action, ADME, therapeutics use, and adverse effects, toxicities and possible drug interaction) of the following:

1. Central Nervous system: Neurodegenerative Disorders (Parkinson’s disease, Alzheimer’s disease, Huntington’s chorea, Spasticity), behavioral disorder-(Anxiety, Insomnia, Depression and Mania), Psychoses, Epilepsy, Migraine
2. Cardiovascular and hemopoeitic system; Hypertension, Acute Coronary Syndrome, Angina Pectoris, Atherosclerosis, Congestive Heart Failure, Arrhythmias, Thromboembolic disorder, Anaemia
3. Endocrine system: Disorders of thyroid gland and Parathyroid gland, Diabetes, Adrenocortical dysfunction
4. Gastro-intestinal System: Peptic Ulcer, Inflammatory Bowel Disease, Vomiting, Achlorhydria, Constipation, Diarrhoea, Liver diseases
5. Respiratory system: Bronchial Asthma, Chronic Obstructive Pulmonary Disease (COPD), Allergic Rhinitis, Common cold & Cough, Cystic fibrosis
6. Urogenital system: Renal Failure, Infertility, Benign Prostatic Hypertrophy, Dysmenorrhea, Menopause
7. Disorders of eye: Glaucoma

Reference Books:

1. Principles of Pharmacology –The Pathophysiologic Basic –Golan David E.
2. Pharmacological Basis of Therapeutics-Goodman and Gilman
3. Pharmacology-Rang and Dale
4. Essentials of Pharmacotherapeutics-F.S. Barar
5. Principles of Pharmacology – Paul L. Munson
6. Pharmacology and Pharmacotherapeutics-R.S.Satoskar
8. Lewis’s Pharmacology – James Crossland – Churchill Livingston
9. Modern Pharmacology with Clinical Applications- Craig, Charles R.

2. Stereochemistry and Chiral Techniques.
   a. Principles of stereochemistry including geometric isomerism, optical isomerism and conformational isomerism.
   b. Stereochemistry of compounds with asymmetric plane.
   d. Role of stereochemistry in pharmacokinetics and pharmacodynamics

3. Synthon Approach:
   Definition, terms and abbreviation, rules and guidelines used in synthesis of following drugs.
   Pyrimethamine, Ibuprofen, Diclofenac, Rosiglitazone, Cetirizine, Ciprofloxacin, Captropil, and Losartan

4. Green Chemistry: Solvent free reaction, water as a solvent, ionic liquids, supercritical liquids, supported reagents and catalyst.

5. Introduction to microwave reactions, ultrasound reactions, nanochemistry

Reference Books:
4. Jie Jack Li - Name Reactions, Springer
5. Eliel – Stereochemistry of Carbon Compounds
6. S. Warren - Designing Organic Synthesis, Wiley India Ltd.
9. G. B. Sergeev – Nanochemistry, Elsevier publication

2. Various targets for drug action and theory of drug action – agonist, antagonism/blockers and enzyme inhibition (IC50, EC50 concept) - an overview

3. A general study of stereochemistry and physicochemical properties of the drug/drug-like molecules and their importance in drug action. Correlation between physicochemical properties and drug action, establishing structure activity relationship (SAR) and its analysis. Isosterism and bio-isosterism as guides to structural variations and Prodrug design its application in lead optimization.

4. Various approaches to drug discovery

   
   Detail study on Hansch LFER model, Free Wilson analysis and mixed approach. Various basic statistical methods useful in QSAR development.
   
   a. 3D QSAR – importance and various models (COMFA, MSA, HASL, Apex 3D, DISCO, GFA) used for it.

6. Computer Aided Drug Design (CADD) – Molecular modeling
   
   a. Basic concepts of computational chemistry like Quantum Mechanics, Molecular Mechanics, Force Field, Energy minimization, Conformational generation and analysis, geometry optimization, Molecular Dynamics
   
   b. Ligand based drug design, Analogue approach, Pharmacophore Mapping, importance of ligand shape and Excluded volume techniques, Artificial intelligence methods.
   
   c. Structure based drug design, requirement of SBDD, utilization of target structure derived from NMR and X-ray Crystallography techniques, understanding of drug–receptor/enzyme/target interactions, preparation of protein/target along with active site analysis, docking process, various docking methods. De-novo drug design.
   
   d. Drug design based on antagonism and enzyme inhibition. Various software used in CADD

7. Virtual screening of huge compound databases by using Pharmacophore mapping as well as docking methods

8. Pharmacokinetics (Absorption, Distribution, Metabolism Elimination i.e. ADME) in drug discovery.

References Books:

2. H Smith & H J William – Introduction to the Principal of Drug Design, John Wright & Sons Ltd.
7. Molecular Modeling in Drug Design by Cohen N. C.
8. C. G. Wermuth - The Practice of Medicinal Chemistry, Elsevier publication.
Gujarat Technological University
Master of Pharmacy
Semester – II
Paper code -2920104
Specialization paper - III
Modern Pharmaceutical Analysis

Theory
(Six hours per week, 7 credits)

1. Application of analytical methods to product obtained through genetic engineering, Amino acid sequence analysis, Tryptic mapping, ion exchange amino acid analysis, isoelectric focusing etc.
2. Regulatory requirement in pharmaceutical analysis – US-FDA, ICH
3. Solid state analysis of drug substance including related substances, and impurities present in drugs and their effect on drug stability and therapeutic action.
4. Applications of various analytical techniques in preformulation analysis and its importance.
5. Analysis of solid oral dosage form
6. Analysis of injectable dosage form
7. Compendial testing
8. Automated analysis
9. Compendial methods for evaluation of crude drug and herbal formulation
10. Quality control of radio pharmaceuticals and radio chemical method in analysis.
11. Analysis of cosmetics

Specialization paper - III
Modern Pharmaceutical Analysis
Practical
(Six hours per week, 8 credits)

1. Assay of Ibuprofen Tablet I.P., Tolbutamide Tablet I.P., Calcium Lactate and Ferrous Fumerate I.P.
2. Determination of Water in Sorbitol, Sodium Citrate & Ampicillin.
3. Determination of Total Chloride in Thiamine Chloride Hydrochloride.
5. Detection and Determination of Preservatives, Antioxidants and Colouring materials in Pharmaceuticals.
6. Determination of related substances in Albendazole, Amiloride, Metronidazole,
7. Betamethazone, Carbamazepine, Diclofenac, Ephedrine, Ibuprofen, Paracetamol, Eucalyptus oil, Phenylbarbitone and Sulphafurazone, Rifampicin as per I.P.
   Determination of active constituents in crude drugs. E.G. Caffiene from tea powder, curcumin from curcuma longa, quinine from cinchona bark etc.
8. Quality Control tests for some herbal formulations.
9. Quality Control tests for some cosmetics.

References Books:

2. S. Ahuja, Modern Pharmaceutical Analysis
4. Peptide and Protein Drug Analysis, by Reid, (Marcel Dekker).
5. Classification of cosmetics raw materials and adjuncts IS 3958 of Indian Standards Institution (BIS).
7. Methods of sampling and test for various cosmetics as laid down by Indian Standard Institution (BIS).
13. Phytochemical Methods by J.B.Haroborne
14. Pharmacopoeal standards for Ayurvedic Formulation (Council of Research in Indian Medicine & Homeopathy)
A) REGULATORY AFFAIRS
1. Legislation to regulate the profession of pharmacy – The Pharmacy Act 1948.
2. Legislation to regulate, import, manufacture distribution and sales of drugs, cosmetics- The Drugs & Cosmetic Act 1940 & rules 1945 with amendments.
3. Regulatory aspects of pharmaceutical and bulk drug manufacture and biotechnology derived product.
4. Quality safety and legislation for cosmetic and herbal products.
5. Aims, objects and salient features of following legislations governing Pharmaceutical Industry-
6. Pollution Control Act
7. Prevention of Food Adulteration Act 1954
8. Industrial Development & Regulation Act 1951
9. Consumer Protection Act
11. Drug Master File (Case Study-3 examples)
12. Material Safety Data Sheet (MSDS) preparation
13. Industrial Safety & Health Guide lines for filing in countries like US & EU

B) Approval of New drugs:
Investigational New Drug (IND) submission, format & content of IND, content of Investigator Brochure, general consideration of New Drug Approval (NDA), specific requirements, content & format of NDA, manufacturing control requirement of NDA.

References Books:
1. Drugs and Cosmetics Laws by Krishnan Arora, Professional Book Publishers, New Delhi
3. Deshpande S.W., Drugs and Cosmetic Act,1940.
8. The Drugs and Cosmetic Act 1940 – Vijay Malik
10. The International Pharmacopoeia Vol 1, 2,3,4,5 3rd Editions
11. Pollution Control Act, 1974
13. Industrial Development & Regulation Act 1951
17. A.C. Cartwright and Brian Mathews, "International Pharmaceutical Registration" Taylor and Francis Ltd. UK, 2002
18. United State Pharmacopoeia (USP) 32,NF27, 2009
19. Industrial Health and Safety, Dr. A.M. Sarma, Himalaya Publication.
Specialization paper - III
Advanced Analytical Pharmacognosy
Practicals
(Six hours per week, 8 credits)

Practical exercises based on the relevant topics mentioned in theory syllabus.

References Books:

1. Evans W. C – Trease and Evans pharmacognosy (15th ed)
2. Wallis T.E, Practical Pharmacognosy, J & A Churchill Ltd.
4. Peach K. and Tracey M.V., Modern Methods of Plant Analysis, 1-4, Narosa Publisher House, N.D.
10. WHO Publication.
13. British Herbal Pharmacopoeia, Published by British Herbal Medicines Association 1996.
16. Steimser Richard – Folk Medicines
1. Neutraceuticals from herbal sources
2. Insecticides and pesticides from natural sources
3. Phytochemical screening technique
4. Advances drug from natural sources of following categories:
   a) Antidiabetic
   b) Cardiotonic
   c) Immunomodulators
   d) Anti-inflammatory
   e) Anti-ulcer
   f) Anti-malarial
   g) Diuretics
   h) Anti-oxidant
   i) Urolithiatics
   j) Anti-lipidemic
   k) Brain tonic
   l) Hepatoprotective
   m) Anti-cancer
   n) Anti-AIDS

References Books:

1. Chatterjee T. K – Herbal options
2. Journals-
   a. Indian Drugs
   b. Indian Journal of Pharmaceutical Education
   c. Planta Medica
3. Evans W. C – Trease and Evans pharmacognosy (15th ed)
12. Wealth of India,Raw Materia
Pathophysiology, Diagnosis & Pharmacotherapeutic management of following acute and chronic diseases and disorders

1. Cardiovascular
   - Hypertension, angina pectoris, congestive heart failure, myocardial infarction, cardiac arrhythmias.
2. Gastrointestinal
   - Peptic ulcer disease, Inflammatory Bowel diseases, hepatitis, cirrhosis, nausea and vomiting, constipation and diarrhea.
3. Respiratory
   - Chronic obstructive pulmonary disease, bronchial asthma, cystic fibrosis.
4. CNS
   - Epilepsy, Parkinsonism, schizophrenia, migraine, Alzheimer disease, Huntington’s chorea, Spasticity), behavioral disorder-(Anxiety, Insomnia, Depression and Mania)
5. Endocrine
   - Endocrinal disorders including Diabetes mellitus, thyroid (hyperthyroidism and hypothyroidism), parathyroid diseases, hyperlipidemia and Adrenocortical dysfunction.

ASSIGNMENTS

The students are required to submit a minimum of two written assignments selected from the topics given to them.
References Books:

7. Harrisons Principles of Internal Medicine. Medical Toxicology (Ellen Horns)
10. Relevant review articles from recent medical and pharmaceutical literature.
1. Introduction to Drug Discovery and drug Development
2. Clinical trials
   - Introduction and designing
   - Various phases of clinical trials
   - Post Marketing surveillance – methods
   - Principles of sampling
   - Inclusion and exclusion criteria
   - Methods of allocation and randomization
   - Informed consent process
   - Monitoring treatment outcome
   - Termination of trial
   - Safety monitoring in clinical trials
3. Documents in clinical study
   - Investigator Brochure (IB),
   - Protocol & Amendment in Protocol ,
   - Case Report Form (CRF),
   - Informed Consent Form (ICF),
   - Content of Clinical Trial Report
   - Essential Documents in Clinical Trial
4. Data Management in clinical Research
5. Ethical guidelines in clinical research
   - History
   - ICH-GCP & its Principles
   - Indian GCP (CDSCO Guidelines)
   - ICMR Guidelines - Ethical Guidelines for Biomedical Research on Human Subjects
   - Schedule Y
6. Roles & Responsibility of various clinical trial personnel as per ICH GCP
   - Sponsor
   - Investigator
   - Monitor
   - Auditors
7. Institution Ethics Committee / Independent Ethics Committee
8. Quality Assurance in clinical Research
9. BA/BE studies: Introduction, Regulatory requirements and methodology
10. Clinical Trial Application in India
    - Import & Export of Drug in India
11. Investigational New Drug application (IND)
12. Abbreviated New Drug Application (ANDA)
13. New Drug Application (NDA)
ASSIGNMENTS

The students are required to submit a minimum of two written assignments selected from the topics given to them.

References Books:

1. Rick NG. Drugs From Discovery To Approval. John Wiley & Sons, Inc 2004
13. Various Guidelines like:
   ✓ ICMR Guideline – Ethical Guidelines for Biomedical Research on Human Subjects.

Schedule Y
Gujarat Technological University
Master of Pharmacy
Semester – II
Paper code -2920107
Specialization paper – III
PHARMACEUTICAL ANALYSIS SPECIALISATION
PHARMACEUTICAL ANALYSIS II
Theory
(Six hours per week, 7 credits)

1. Preparation of drug samples for analysis: Pharmaceutical samples, fundamental theories controlling preparation techniques, specific sample preparation techniques. 04 Hrs

2. A detailed study of the principles, instrumentations and applications in drug analysis of: GC-MS, LC-MS with reference to drug metabolism, toxicologic and forensic studies, diagnosis of disease state, quantification of drugs in biological samples, counter current chromatography; Super critical fluid chromatography and size exclusion chromatography 20 Hrs

3. Analytical methods for the analysis of protein and its product: Amino acid sequence analysis, HPLC, Tryptic mapping, ion exchange amino acid analysis, isoelectric focusing and other electrophoretic techniques. 7 Hrs

4. A detailed study of the various principles and procedure involved in the quantitative analysis of pharmaceutical preparations and dosage forms containing the following groups of drugs included in I.P. (Biological and microbiological methods excluded)
   (a) Analgesics and Antipyretics
   (b) Sedatives & Tranquillizers
   (c) Antihypertensives
   (d) Antihistaminics
   (e) Cardiovascular drugs
   (f) Antidiabetics 7 Hrs

5. Solid state analysis of drug substance including a detailed study on related substances and impurities present in drugs and their effect on drug stability and therapeutic action. ICH guidelines for impurity and related substances determination in drugs. 6 Hrs

6. Methods of systematic phytochemical analysis including extraction and identification of plant constituents using chromatographic techniques. Quality control of crude drugs: proximate analysis including ash and extractive values, crude fibre content, U.V. and fluorescence analysis of powdered drugs. WHO guidelines for the quality control of raw materials used in herbal formulations. Analysis of official formulations derived from crude drugs including some Ayurvedic preparations. 14 Hrs

7. Automated analysis 02 Hrs
Specialization paper – III
Pharmaceutical Analysis II
Practical
(Six hours per week, 8 credits)
1. Determination of active constituents in crude drugs. e.g. Caffeine from tea powder, curcumin from curcuma longa, quinine from cinchona bark etc.
2. Determination of extractive values of crude drugs.
3. Determination of Rf values of different amino acids and alkaloids.
5. Quality control Tests for Tablets, Capsules, Injections, Ointments and Suppositories.
7. Determination of related substances in Albendazole, Amiloride, Metronidazole, Betamethazone, Carbamazepine, Diclofenac, Ephedrine, Ibuprofen, Paracetamol, Eucalyptus oil, Phenylbarbitone and Sulphafurazone, Rifampicin as per I.P.
8. Quality Control tests for some herbal formulations.

References Books:

3. Peptide and Protein Drug Analysis, by Reid,(Marcel Dekker).
5. A text book of Pharmaceutical analysis by K.A.Conners (John Wiley)
6. Indian Pharmacopoeia,Vol. I and Vol. II - 2010.The Controller of Publications; New Delhi, Govt. of India,
11. Phytochemical Methods by J.B.Harborne
12. Pharmacopoeial standards for Ayurvedic Formulation (Council of Research in Indian Medicine & Homeopathy)
14. ICH guideline for impurity determination and stability studies.
15. WHO guide lines for the quality control of Herbal plant materials.
16. The Practical evaluation of phytopharmaceutical by Brain & Turner.
18. Ayurvedic Formulary of India.
1) **Drug Regulatory Affairs**- Harmonization of regulatory requirements including ICH activity. Regulatory requirements of different regions applicable to pharmaceutical developments, manufacturing, quality control on finished products, extended release products, biopharmaceutical and bioequivalence assessment and good clinical practices and Comparison with regulation in India. Filing of INDA, NDA and ANDA for approval and registration.

   **15 Hrs**

2) **Stability Testing**- Role of stability testing, stability test guidelines and Regulatory requirements. Protocol of stability testing including testing under different climatic zones and conditions. Conduct of stability testing. Presentation and recording of stability data, Interpretation of data, determination of shelf life. Stability test equipment and recent developments in this area.

   **15 Hrs**

3) **Documentation**- Importance of documentation, statutory requirements and procedure for documentation, critical examination of documents.

   **2 Hrs**

4) **GMP of Pharmaceuticals**- Current GMP in manufacturing, processing, packaging of drugs. GMP for finished products. General provision, organization and personnel, building and facilities, equipment, control of components and drug product, container and closures, production and process, packaging and labeling, laboratory and control of records and reports.

   **15 Hrs**

5) **Good Laboratory Practice**- Current GLP in manufacturing, responsibilities. General provision, organization and personnel, building and facilities, equipment, control of components and drug product, laboratory and control of records and reports, Non-clinical testing, Controls on animal house, Application of Computers in Quality control Laboratory.

   **10 Hrs**


   **3 Hrs**

**Reference Books:**

3. WHO’s “Drug” Bulletins
4. GMP practices for pharmaceutical-James Swarbrick.
7. ICH guide lines
8. Drug stability: Principles and practices by Jens T. Carstensen
10. Stability of Drugs and Dosage Forms by Yoshioka and Stella.
11. A.C. Cartwright and Brian Mathews, “International Pharmaceutical Registration” Taylor and Francis Ltd. UK, 2002
1) **Legislative requirements** as per drug & cosmetic act for obtaining manufacturing licenses for different categories of pharmaceutical products. Approval formalities as per factory act, excise and WHO GMP certification scheme, etc.  

2) Aims, objects and salient features of following legislations governing Pharmaceutical Industry-Pollution control act, Prevention of Food Adulteration Act 1954, Industrial Development & Regulation Act 1951, Consumer Protection Act  

3) **Packaging components and its evaluation:**  
Factors affecting selection, Types and classification, Primary and secondary and regulatory aspects, Contribution in stability of the dosage forms  
**Films for Flexible Packages:** Types of films, materials used for film production, production and evaluation of Oriented and Non-oriented, Stretchable films and Laminates.  
**Strip Packaging:** Significance of Strip Packing, advantages, economics and limitation of Strip Packing, Strip Packing machinery, films employed in Strip Packing (including composites and laminates) and evaluation of films and strips packs.  
**Blister Packaging:** Blister packing materials, significance of Blister packing, advantages, economics and limitation of blister packing, blister packing machinery, various types of blister packages, and evaluation of blister package.  
**Sterile Product Packaging:** General principles of packaging of sterile products. Various types of containers used for sterile products including small volume and large volume parenterals. Types of closures used for the sterile products. Sterile product filling and sealing machinery i.e. ampoule filling and sealing machine. Limitations and merits of various packages. Evaluation of the sterile product packages.  
**In-process quality control tests** for various dosage forms including packaging and labeling operations.  

4) **Disperse systems:** General consideration and recent advances in disperse system technology with main emphasis on pharmaceutical suspensions and emulsions, Quality control of disperse systems  
**Aerosols:** General considerations, recent developments, study of various components of aerosol system, formulation, aerosol filling processes and machinery, Quality control of aerosols.  
**Parenterals:** General considerations, recent developments, formulation, stabilization and manufacturing of small and large volume parenterals, production of injectable grade water, environmental controls and design consideration for parenteral production facility, freeze drying. In process quality control.  
**Semisolid dosage forms:** General considerations, recent developments, formulation and large scale production of various types of semi solid dosage forms, factors affecting release of drugs from semisolid dosage forms. Quality control of semisolid dosage forms.  

5) **Stability Study as per** I.P., ICH, other regulatory requirements
6) **SUPAC guidelines** for different dosage forms like; Immediate release, Modified release, semisolid, etc. including equipments amendment. BACPAC guidelines for active pharmaceutical ingredients. 08 Hrs.

**Reference Books:**
4. Modern Pharmaceutics by G.S.Banker
6. The Theory and Practice of Industrial Pharmacy by Leon Lachman.
9. Encyclopedia of Controlled Drug Delivery Volumes 1 and 2 by Banker Gilbert

**Practicals**
*(Six hours per week, 8 Credits)*

Practical exercises formulated bases on the topics mentioned in the theory such as Accelerated stability analysis, Packaging testing and evaluation, Case studies of different acts, Disperse system, parenterals, semisolids etc.
1. Basic concepts of quality assurance, Requirements of CGMP/GLP, ISO 9000 series, OHSAS 14000, Quality audits etc. 08 Hrs.

2. Precision, accuracy and biases, sampling and operating characteristic curves, sampling plans, statistical inference in estimation of hypothesis testing, statistical procedure in assay development. 04 Hrs.

3. Brief introduction to general requirements of health regulatory agencies such as USFDA, MCC, TGA, MHRA, ANVISA, eCTD, WHO, ICH 12 Hrs.

4. Preparation of documents for new drug application and export registration. Clinical study and basic concepts of Good clinical practice. 03 Hrs.


6. Introduction to orange book, freedom of information (FOI), inactive ingredient guide (IIG), Drug master file (DMF), open part of DMF, codes of therapeutic equivalency, CDER, CBER. 08 Hrs.

7. Regulatory aspects of pharmaceutical and bulk drug manufacture and biotechnology derived product. 08 Hrs.


Reference Books:

5. The guidance documents shall be procured from the website of the respective Government.