Gujarat Technological University

M. Pharm.
Semester – II

Structure for Second Semester of Master of Pharmacy Course

Sr. No.	Subject	Teaching Scheme		Marking Scheme			
		Credits		Theory		Practical	
		Theory	Practical	Ext	Intl	Ext	Intl
1.	Research Methodology	07	-	80	20	--	--
2.	Subject Specialization of Paper – III	07	08	80	20	80	20
3.	Subject Specialization of Paper – IV	08	--	80	20	--	--
	Total	**22**	**08**				

Gujarat Technological University

Master of Pharmacy

Semester – II

Paper code -2920001

Research Methodology

(Common to all discipline)

Theory

(Four hours per week, 7 credits)

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 use in research –
    A. Qualities 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.
6. The Research Report Paper writing/ thesis writing
    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.
    4. Methology-subject, apparatus, instrumentation & procedure.
    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
8. Cost analysis of the project – cost incurred on raw materials-
    Procedure, instrumentations and clinical trials.
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
2. Practical Introduction o copyright. - Gavin Mcfarlane
3. Thesis projects in Science & Engineering – Richard M. Davis.
4. Scientist in legal Systems- Ann labor science
5. Thesis & Assignment – Jonathan Anderson
6. Writing a technical paper- Donald Menzel
7. Effective Business Report Writing –Leland Brown
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
12. Documentation – Genesis & Development 3792.
13. Manual for evaluation of industrial projects-United Nations
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:

1. **Remingtons** "Pharmaceutical Sciences" 19th edition.
2. **Lachman "**The theory and Practice of Industrial Pharmacy" 3rd edition.
3. Pharmaceutics "The Science of Dosage form design" **by Aulton**
4. Pharmaceutical dispensing **by Husa**.
5. Modern pharmaceutics **by G. S. Banker.**
6. Encyclopedia of pharmaceutical technology Volumes: 1 to 19.
7. Pharmaceutical dissolution testing **by Banaker.**
8. United States Pharmacopeia.
9. Drug stability (Principles and Practices) **by Jens. T. Carstensen.**

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.

Gujarat Technological University
Master of Pharmacy
Semester – II
Paper code -2920103
Specialization paper - III
Pharmacometrics and Methods of biological evaluation of drugs

Theory
(Six hours per week, 7 credits)

1. Biological standardization, general principles, Scope and limitation of bio-assay, bioassay of some official drugs.
2. Preclinical drug evaluation of its biological activity, potency and toxicity-Toxicity test in animals including acute, sub-acute and chronic toxicity, ED50 and LD50 determination, special toxicity test like teratogenecity and mutagenecity. Various guidelines for toxicity studies. Animal experiments assessing safety of packaging materials.
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.
7. General and local Anesthetics, Sedatives and Hypnotics, Antiepileptics, Psychopharmacological agents, Analgesics, Anti-inflammatory agents, Anti-Parkinson's drugs, CNS Stimulants.
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.
6. Evaluation of the effect of psychotropic drugs on condition avoidance response.
7. Evaluation of the compulsive behavior (stereotypy) induced by apomorphine and its modification by chlorpromazine in mice.
8. Evaluation of anxiolytic (antianxiety) effect of diazepam in mice using elevated plus-maze apparatus.
9. Study the effect of caffeine in human volunteers.
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.
12. Evaluation of the analgesic potency of drug by thermal method.
13. Evaluation of analgesic effect of morphine in mice using hot plate method.
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.
8. Handbook of Experimental Pharmacology- Goyal R.K.
9. Handbook of Experimental Pharmacology- Kulkarni S.K.

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 (etiology, 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, Diarrhea, 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
7. Pharmacotherapy- A Pathophysiological Approach-Joseph T. Dipiro.
8. Lewis's Pharmacology – James Crossland – Churchil Livingston
9. Modern Pharmacology with Clinical Applications- Craig, Charles R.
10. Principles of Pharmacology--H. L. Sharma

Gujarat Technological University
Master of Pharmacy
Semester – II
Paper code -2920101
Specialization paper - III
Advanced Organic Chemistry - II

Theory
(Six hours per week, 7 credits)

1. Detailed study of individual reactions - allylic rearrangement, Amdt ester synthesis-Bayer-Villiger rearrangement, benzillic acid rearrangement – Curtius rearrangement-Dimorth rearrangement, Heck reaction, Lossen –Schmidt rearrangement, Pinner reaction, Reformatsky reaction, Sharpless oxidation, Suzuki reaction, Sonogashira reaction, Swern oxidation, Vilsmeir Haack reaction.
2. Stereochemistry and Chiral Techniques.
    a. Principles of stereochemistry including geometric isomerism, optical isomerism and conformational isomerism.
    b. Stereochemistry of compounds with asymmetric plane.
    c. Concept of chiral drugs, resolution of racemic mixtures, racemic switches, asymmetric synthesis of following drugs: Vit.C, Nifedipine, Atenolol, Ethambutol, Omeprazole, Ampicillin and Thalidomide.
    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

Specialization paper - III
Advanced Organic Chemistry - II
Practical
(Six hours per week, 8 credits)

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

Reference Books:

1. March Jerry– Advance Organic Chemistry - Reaction Mechanism and Strucutre, McGraw-Hill International Book Company
2. F. A. Carey and R. J. Sundberg – Advance Organic Chemistry Part – A & B, Plenum Press.
3. Clayden Greeves and others – Organic Chemistry, Oxford University Press.
4. Jie Jack Li - Name Reactions, Springer
5. Eliel – Stereochemistry of Carbon Compounds
6. S. Warren - Designing Organic Synthesis, Wiley India Ltd.
7. P. T. Anastas and J. C. Warner – Green Chemistry theory and Practice, Oxford University Press.
8. C. Oliver Kappe and others – Practical Microwave Synthesis for Organic Chemist, Willey Interscience.
9. G. B. Sergeev – Nanochemistry, Elsevier publication\

Gujarat Technological University

Master of Pharmacy

Semester – II

Paper code -2920201

Specialization paper - IV

Drug Design and Discovery

Theory
(Six hours per week, 8 credits)

1. General Introduction to drug discovery concept/process and importance of drug design approaches in drug discovery.
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
5. Quantitative Structure Activity Relationship QSAR- brief introduction to various methods of QSAR – Physicochemical parameters – lipophilic, electronic and steric. 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:

1. Ariens – Drug Design, vol. VII, Academic Press.
2. H Smith & H J William – Introduction to the Principal of Drug Design, John Wright & Sons Ltd.
3. Burgers Medicinal Chemistry – The Basis of Medicinal Chemistry by Manfred S. Wolff, Part – I , John Wiley & Sons

4. Copmuter assisted Drug Design by Edward C. Olson (America Chemical Society, ACD symposium series 112).
5. W. O. Foye - Principles of Medicinal Chemistry, Lipincott Williams and Wilkins.
6. C. Hansch and Leo - Comprehensive Medicinal Chemistry Vol. 4, Pergamon Press.
7. Molecular Modeling in Drug Design by Cohen N. C.
8. C. G. Wermuth - The Practice of Medicinal Chemistry, Elsevier publication.
9. E. H. Kerns and L. Di - Drug like properties, concepts, structure design and methods, Academic Press.

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 maping, 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.
4. Quality control Tests for Tablets, Capsules, Injections, Ointments and Suppositories.
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:

1. Harry G Brittain, Spectroscopy of Pharmaceutical Solids, Drugs andPharmSci.Series,Vol. 160, Taylor and Francis, 2006 N.Y.
2. S. Ahuja, Modern Pharmaceutical Analysis

3. Lena Ohannesian and Anthony J. Streeter, Hand Book of Pharmaceutical Analysis, Pharm Sci. series, Vol. 117, Maarcel Dekker Inc., N.Y
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).
6. Cosmetic and toilet goods – methods of sampling IS 3958 of Indian Standards Institution (BIS).
7. Methods of sampling and test for various cosmetics as laid down by Indian Standard Institution (BIS).
8. Indian Pharmacopoeia,Vol. I and Vol. II - 1996.The Controller of Publications; New Delhi, Govt. of India,
9. The International Pharmacopoeia Vol 1,2,3,4, 3rd Edition General methods of analysis and quality specifications for pharmaceutical substances, excipients, dosage forms.
10. Quality Assurance of Pharmaceuticals – A compendium of guidelines and related materials Vol.1 and Vol.2, WHO, (1999)
11. Basic tests for pharmaceutical substances – WHO (1988)
12. Basic tests for pharmaceutical dosage forms – WHO (1991)
13. Phytochemical Methods by J.B.Haroborne
14. Pharmacopoeal standards for Ayurvedic Formulation (Council of Research in Indian Medicine & Homeopathy)

Gujarat Technological University
Master of Pharmacy
Semester – II
Paper code -2920204
Specialization paper - IV
Regulatory Affairs and New Drug Application

Theory
(Six hours per week, 8 credits)

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
10. Standard institutes & certification agencies like ISI, BSS, ASTM, SO, WHO, US-FDA, UK-MCA, TGA
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
14. Drug Regulatory Agencies-Historical perspectives, organization structure activities & responsibilities: India, US, EU, Japan, ICH
15. Study of compendia – Evolution, Study of parts of compendia like: Policies, General notices, Monographs, Comparative picture of IP, USP, BP, EP&GP

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
2. Mittal B.M., A Textbook of Forensic Pharmacy, 9th Ed., Vallabh Prakashan
3. Deshpande S.W., Drugs and Cosmetic Act.1940.
4. Gnarino Richard A, New Drug Approval Process, 3rd Ed., Marcel Dekker Inc.
5. P. Warayan, Intellectual Property Laws, Eastern Law House.
6. Drug and Cosmetic Act 1940, Eastern Book company by Vijay Malic, 11th Ed. Patents for Medicine, by N. B. Zareri, Indian Drug Manufacturers Association (IDMA)
7. Ira R. Bery, "Introduction to the Pharmaceutical Regulatory Process", Drugs and Pharm Sci. Series, Vol. 144, Marcel Dekker Inc., N.Y.
8. The Drugs and Cosmetic Act 1940 – Vijay Malik

9. Indian Pharmacopoeia, Vol. 1-3, 2007.The Indian Pharmacopoeia commission, Gahaziabad, Govt. of India.
10. The International Pharmacopoeia Vol 1, 2,3,4,5 3rd Editions
11. Pollution Control Act, 1974
12. Prevention of Food Adulteration Act 1954
13. Industrial Development & Regulation Act 1951
14. Consumer Protection Act 1986
15."WHO Expert Committee on specification on Pharmaceutical Preparation"34th report, Geneva, World Health Organisation, 1996 (WHO Technical Report Series, No. 863
16. Quality Assurance of Pharmaceuticals – A compendium of guidelines and related materials Vol.1 and Vol.2, WHO, (1999)
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.

Gujarat Technological University
Master of Pharmacy
Semester – II
Paper code -2920105
Specialization paper – III
Advanced Analytical Pharmacognosy

Theory
(Six hours per week, 7 credits)

1. Standardization of herbal medicines, traditional and folklore remedies,/ preparation and their quality, safety and efficacy assessment and intended use for acceptance by FDA.
2. Stability testing of natural products, procedures, predictable chemical and galenical changes, technical limitation, testing methods and combination products.
3. Marine Pharmacognosy
4. Principles of Ayurveda and standardization of formulation of Ayurvedic dosage form as per Ayurvedic and Herbal Pharmacopoeia.
5. Regulatory and safety measures with herbal, Ayurvedic and other drugs of traditional origin.

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 (15^{th} ed)
2. Wallis T.E, Practical Pharmacognosy, J & A Churchill Ltd.
3. Wagner H., Bladt S. and Zgainski, Plant Drug Analysis Springer, Verlag, New York.
4. Peach K. and Tracey M.V., Modern Methods of Plant Analysis, 1-4, Narosa Publisher House, N.D.
5. Kalia A. N – Textbook of Industrial Pharmacognosy.
6. Handa S.S & Kaul K.L., Supplement to cultivation and utilization of medicinal plants, 1996.
7. R.D. Chaudhary, Herbal Drugs Industry, Eastern Publishers, New Delhi.
8. Clark, E.C.G., Isolation and Identification of Drugs, The Pharmaceutics Press, London.
9. Brain K.R., and Turner R.D., The Practical Evaluation of Phytopharmaceutics, Wrigth-Scientechnics Bristol.
10. WHO Publication.
11. The Ayurvedic Pharmacopoeia of India, Part I, (Vol. I–V) , part II (I & II) Govt. of India, Ministry of Health and Family Welfare, Dept. of Indian Systems of Medicine and Homeopathy, New Delhi 2008.

12. Indian Herbal Pharmacopoeia, revised new edition 2002, Published by RRL, Jammu and IDMA, Mumbai – 2002
13. British Herbal Pharmacopoeia, Published by British Herbal Medicines Association 1996.
14. Ayurvedic Formulary of India, Vol. I and II, Ministry of Health, New Delhi.
15. Stahl E, Thin Layer Chromatography – A Laboratory Hand Book, Springer – Verlag Berlin.
16. Steimser Richard – Folk Medicines
17. Rao Ramchandra – Encyclopedia of Indian Medicine Vol. I

Gujarat Technological University
Master of Pharmacy
Semester – II
Paper code -2920205
Specialization paper – IV
Advances in Pharmaceutical Science
Theory
(Six hours per week, 8 credits)

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-malerial
    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 (15^{th} ed)
4. Kalia A. N – Textbook of Industrial Pharmacognosy.
5. Handa S.S & Kaul K.L. – Supplement to cultivation and utilization of medicinal plants, 1996.
6. Govil J. N, Singh V.K, Siddiqui N. T– Recent Progress in Medicinal plants, Vol., 1-25, , Studim Press , LLC USA.
7. Brunreton J– Pharmacognosy and Phytochemistry of medicinal Plants, (2^{nd} ed.), Intercept limited, Newyork, 1999.
8. Robbers J. E, Speedie M. K, Tyler V. E– Pharmacognosy and Pharmacobiotechnology, William and wikins, USA, 2005.
9. Bhat S. V, Nagasampagi B. A, Meenakshi S– Chemistry of Natural Products, Narosa Publishing House.
10. Robbers J. E, Tyler V. E– Herbs of Choice, Haworth Press In. USA-2002.
11. Reinhold L– Progress in Phytochemistry.
12. Wealth of India,Raw Materia

Gujarat Technological University
Master of Pharmacy
Semester – II
Paper code -2920106
Specialization paper - III
Applied Pharmacotherapeutics - I
Theory
(Six hours per week, 7 credits)

Pathophysiology, Diagnosis & Pharmacotherapeutic management of following acute and chronic diseases and disorders

Basic Concepts of Pathophysiology and Pharmacotherapeutics

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 (hyperthyriodism and hypothyroidism), parathyroid diseases, hyperlipidemia and Adrenocortical dysfunction.

Specialization paper - III
Applied Pharmacotherapeutics - I
Practical
(Six hours per week, 8 credits)

- Each student has to undergo compulsory Hospital postings for understanding and gaining knowledge of Pathophysiology, Diagnosis & Pharmacotherapeutic management of various diseases and disorders.
- It is mandatory that each student has to maintain a record of at least 15 case studies based on the theory topics

ASSIGNMENTS

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

References Books:

1 Clinical Pharmacy and Therapeutics. Roger Walker and Clive Edwards, Churchill Livingstone publication

2 Text Book of Therapeutics: Drug and Disease Management. 7th Edition. Editors: Eric T. Herfindal and Dick R. Gourley, Williams and Wilkins

3 Pathology & Therapeutics for Pharmacists. Russel. J. Greene and Normal F. Harris. Chapman & Hall, London/ Glasgow/ Madras.

4 Robbins Pathologic Basis of Disease. Cartran, Kumar, Collins, W.B.Saunders. Latest edition.

5 Applied Therapeutics: The Clinical Use or Drugs Eds. Brian S.Katcher, Lioyd Yee Young, Marry Anne Koda-Kimble, Applied Therapeutics Inc. Spokane. Latest Edition.

6 Pharmacotherapy: A Pathophysiologic approach – Joseph T. Dipiro et al. Appleton & Lange

7 Harrisons Principles of Internal Medicine. Medical Toxicology (Ellen Horns)

8 Davidson's Principle and Practice of Medicine, Eds. Christopher R. W., Edwards & Ian A.D. Boucher ELBS with Chu0rchill Living stone. Edinburgh. Latest Edition.

9 Avery's Drug Treatment, 4th End, 1997 Adis International Limited

10 Relevant review articles from recent medical and pharmaceutical literature.

Gujarat Technological University

Master of Pharmacy

Semester – II

Paper code -2920206

Specialization paper - IV

Clinical Research and Regulatory Affairs

Theory

(Six hours per week, 8 credits)

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
2. Allen Cato, Lynda Sutton Clinical Drug Trials and Tribulations Second Edition, Revised and Expanded. Marcel Dekker, Inc. 2002
3. Deborah Rosenbaum, Michelle Dresser. Clinical Research Coordinator Handbook Second Edition Practical Clinical Trials Series GCP Tools and Techniques Interpharm/CRC New York Washington, D.C.© 2002
4. Tamas Bartfai, Graham V. Lees. Drug Discovery from Bedside to Wall Street. Elsevier Academic Press. London 2006
5. Ronald D. Mann, Elizabeth B. Andrews. Pharmacovigilance. John Wiley & Sons Ltd, 2002
6. Shayne C. Gad. Drug Safety Evaluation. A John Wiley & Sons, Inc., Publication
7. Bert Spilker. Guide to Clinical Trials.
8. Sandy Weinberg. Guidebook For Drug Regulatory Submissions. A John Wiley & Sons, inc.,2009
9. Duolao Wang and Ameet Bakhai Clinical Trials A Practical Guide to Design, Analysis, and Reporting. Remedica 2006
10. Textbook of Clinical Trial edited by David Machin, Simon Day and Sylvan Green, March 2005, John Wiley and Sons.
11. Principals of Clinical Research edited by Giovanna di Ignazio, Di Giovanna and Haynes.
12. Clinical Data Management edited by R K Rondels, S A Varley, C F Webbs. Second Edition, 2000, Wiley Publications.
13. Various Guidelines like:
    - ✓ ICH – GCP- International Conference on Harmonisation of Technical requirements for registration of pharmaceuticals for human use. ICH Harmonised Tripartite Guideline. Guideline for Good Clinical Practice. E6 1996.
    - ✓ ICMR Guideline – Ethical Guidelines for Biomedical Research on Human Subjects.
    - ✓ Indian GCP – Central Drugs Standard Control Organization. Good Clinical Practices – Guidelines for Clinical Trials on Pharmacuetical Products in India. New Delhi: Ministry of Health; 2001.

    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 **20Hrs**

3. Analytical methods for the analysis of protein and its product: Amino acid sequence analysis, HPLC,Tryptic maping, 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. **6Hrs**

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 **02Hrs**

Specialization paper – III
Pharmaceutical Analysis II
Practical
(Six hours per week, 8 credits)

1. Determination of active constituents in crude drugs. e.g. Caffiene 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.
4. Assay of Ibuprofen Tablet I.P., Tolbutamide Tablet I.P., Calcium Lactate and Ferrous Fumerate I.P.
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:

1. Harry G Brittain, Spectroscopy of Pharmaceutical Solids, Drugs and Pharm Sci.Series, Vol. 160, Taylor and Francis, 2006 N.Y.
2. Lena Ohannesian and Anthony J. Streeter, Hand Book of Pharmaceutical Analysis, Pharm Sci. series, Vol. 117, Maarcel Dekker Inc., N.Y
3. Peptide and Protein Drug Analysis, by Reid,(Marcel Dekker).
4. Pharmaceutical Analysis – Modern Methods – Part A, Part B, James W. Munson – 2001.
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,
7. The International Pharmacopoeia Vol 1,2,3,4, 3rd Edition General methods of analysis and quality specifications for pharmaceutical substances, excipients, dosage forms.
8. Quality Assurance of Pharmaceuticals – A compendium of guidelines and related materials Vol.1 and Vol.2, WHO, (1999)
9. Basic tests for pharmaceutical substances – WHO (1988)
10. Basic tests for pharmaceutical dosage forms – WHO (1991)
11. Phytochemical Methods by J.B.Haroborne
12. Pharmacopoeial standards for Ayurvedic Formulation (Council of Research in Indian
13. 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.
17. Indian Herbal Pharmacopoeia, Vol.1&2, RRL, IDMA, 1998, 2000.
18. Ayurvedic Formulary of India.
19. British Herbal Pharmacopoeia.

Gujarat Technological University
Master of Pharmacy
Semester – II
Paper code -2920207
Specialization paper – IV
PHARMACEUTICAL ANALYSIS SPECIALISATION
QUALITY CONTROL & QUALITY ASSURANCE
Theory
(Six hours per week, 8 credits)

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 Laboratoy 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**

6) Regulatory aspects of Pharmaceuticals and Bulk Manufacturing, WHO Certification Globalization of Drug Industry, Patent regime. **3 Hrs**

Reference Books:

1. Sidney H. Willig, "Good Manufacturing Practices for Pharmaceuticals", Drugs and Pharm. Sci. Series, Vol. 109, Marcel Dekker Inc., N.Y.
2. S. Weinberg, “Good Laboratory Practice Regulation” Drugs and Pharm. Sci. Series, Vol. 124, 2nd Ed., Maracel Dekker Inc., N.Y.
3. WHO’s “Drug” Bulletins
4. GMP practices for pharmaceutical-James Swarbrick.

5. Gnarino Richard A, New Drug Approval Process, 3 rd Ed., Marcel Dekker Inc.
6. Ira R. Bery, “Introduction to the Pharmaceutical Regulatory Process”, Drugs and Pharm Sci. Series, Vol. 144, Marcel Dekker Inc., N.Y.
7. ICH guide lines
8. Drug stability: Principles and practices by Jens T. Carstensen
9. Stability Testing of Drug Products by W.Grimm. .
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

Gujarat Technological University
Master of Pharmacy
Semester – II
Paper code -2920108
Subject of Specialization paper –III
Industrial Pharmacy Paper-III
Theory
(Six hours per week, 7 Credits)

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. **10 Hrs.**
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 **12 Hrs.**
3) **Packaging components and its evaluation**: **10 Hrs.**
   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. **08 Hrs.**
5) **Stability Study as per** I.P., ICH, other regulatory requirements **12 Hrs.**

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:

1. Pharmaceutics "The Science of Dosage Form Design" by Aulton.
2. Encyclopedia of Pharmaceutical Technology Volumes: 1 to 19.
3. Remington's Pharmaceutical Sciences 19th edition.
4. Modern Pharmaceutics by G.S.Banker
5. Yie W. Chien, Novel Drug Delivery Systems, Drugs and Pharm. Sci. Series, Vol.14, Marcel Dekker Inc .N.Y.
6. The Theory and Practice of Industrial Pharmacy by Leon Lachman.
7. Pharmaceutical Production Facilities, Design and applications by Graham C. Cole.
8. International Pharmaceutical Product Registration by Anthony C. Cartwright.
9. Encyclopedia of Controlled Drug Delivery Volumes 1 and 2 by Banker Gilbert
10. Pharmaceutical dosage forms, Parenterals medications: Vol. 1 & 2 by Avis Kenneth
11. Drug stability (Principles and Practices) **by Jens. T. Carstensen.**
12. Stability of drug and dosage forms by Yoskioka.
13. Pharmaceutical dosage forms, Aerosol systems by Lachman L., Liberman H.
14. Pharmaceutical dosage forms, Disperse systems by Lachman L., Liberman H.

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, parentrals, semisolids etc.

Gujarat Technological University
Master of Pharmacy
Semester – II
Paper code -2920208
Subject of Specialization paper –IV
Industrial Pharmacy Paper-IV
Theory
(Six hours per week, 8 Credits)

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.**
5. Concepts in validation, validation of manufacturing and analytical equipments. Process validation in production of pharmaceuticals.
   Electronic records (21CFR11) **10 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.**
8. Study of compendia – Evolution, Study of parts of compendia like: Policies, General notices, Monographs, Comparative picture of IP, USP, BP, EP&GP **07 Hrs.**

Reference Books:

1. S. H. Willig, M.M.Tuckeman and W.S.Hitchings, "Good Manufacturing Practices for Pharmaceuticals", Drugs and Pharm. Sci. Series, Vol. 16, Marcel Dekker Inc., N.Y.
2. B. T. Loftus & R. A. Nash, "Pharmaceutical Process Validation", Drugs and Pharm Sci. Series, Vol. 23, Marcel Dekker Inc., N.Y.
3. S. Bolton, "Pharmaceutical Statistics: Practical & Clinical Applications", Drugs and Pharm. Sci. Series, Vol. 25, Marcel Dekker Inc., N.Y.
4. G.S, Banker & C.T. Rhodes, "Modern Pharmaceutics", Drugs and Pharm. Sci. Series, Vol. 7, Marcel Dekker Inc., N.Y.
5. The guidance documents shall be procured from the website of the respective Government.