SYLLABUS

(2007-2008)

MASTER OF PHARMACY

(Pharmacology)

Rajiv Gandhi Proudyogiki Vishwavidyalaya
(University of Technology of Madhya Pradesh)
Airport Bypass Road, Gandhinagar,
Bhopal.

INDEX

First Year 1st Semester
MODERN ANALYTICAL TECHNIQUES (MPY 101)

Theory

1. Theory, Instrumentation, Methods and Applications of VU Spectrophotometer.
2. Theory and Instrumentation of IR and FT-IR, its advantage and applications in Structural elucidation.
3. NMR, C^{13} NMR, Origin of spectra, Chemical shifts, Spin-spin coupling, Coupling constant, Instrumentation and application for Structural elucidation.
4. Mass spectra, Instrumentation, Fragmentation pattern and applications for Structural elucidation. Application of GC-Mass, HPLC-Mass for complex mixtures.
5. Theory, Instrumentation and application for the following:
    i) Fluorescence
    ii) X – Ray crystallography
    iii) Atomic spectroscopy
    iv) Ultra centrifugation
    v) ESR
    vi) Liquid Scintillation spectrometry
    vii) Auto radio grapy
6. Separation Techniques; Fundamental principles, Basic instrumentation, Qualitative and Quantitative Pharmaceutical applications of Gas-liquid Chromatography, HPLC, HPTLC, Gel Chromatography, Electrophoresis and Ion-pair Chromatography.
7. General Principle, instrumentation and application of optical rotatory dispersion (ORD) and Circular dichroism (CD).
8. Immunoassay Techniques: Enzyme and Radioimmunoassay techniques. Theory, Methods and applications.
9. Thermal methods: Thermo Gravimetry (TG), Differential Scanning Calorimetry (DSC), Differential Thermal Analysis (DTA).
10. Principles and application of light, Phase contrast, Scanning and Transmission electron microscopy, Cytometry and Flow cytometry.

Books and References Recommended:

1. Florey**, Analytical Profiles of Drugs**, Vol.1-16.
2. Sinder, **Text Book of HPLC.**
3. McLafferty**, Mass Spectrometry.**
4. Rao,C.N., **Ultraviolet Visible Spectroscopy for Chemical Application**.
5. Silverstein, Basseler, Morril, **Spectophotometrc Identification of Organic Compounds.**
6. Rao,C.N., **Chemical Application of Infrared Spectroscopy.**
7. Weissberger, **Physical Methods in Organic Chemistry.**
8. Kiencz, B. and Dierasi, C., **Interpretation of Mass Spectra of Organic Compounds.**
9. Jackmann, **Application of NMR Spectra to Organic Compounds.**
10. Willard, Merrit and Dean, I**nstrumental Methods of Analysis.**
11. Elliel, E.L., **Stereochemistry of Carbon Compounds.**
12. Naahod, P., **Physical Methods of Structure Determination**.
13. Stahl, **Thin Layer Chromatography**.
14. Ewing, **Instrumental Methods of Chemical Analysis.**
15. Block and Durrum, **Paper Chromatography and Electrophoresis**.
16. Remington's **Pharmaceutical Sciences.**
17. Sirmer, **Spectroscopic Analysis.**

BIOTECHNOLOGY & BIOINFORMATICS (MPY 102)

1. **Genetics:** Structure & Function of DNA, DNA Replication & Repair, Expression of Genetic Information: Structure & Function of RNA, Transcription, Genetic code, Translation, Post translational modification.

2. **Recombinant DNA Technology:** Constructing Recombinant DNA molecules Restriction enzymes, Vectors, Gene Cloning, Genomic libraries, Polymerase Chain reaction – based DNA cloning, Restriction mapping, Blotting techniques, DNA sequencing, Pharmaceutical applications of recombinant DNA.

3. **Gene Therapy:** General Introduction, Potential target diseases for Gene therapy, Gene transfer methods, Clinical studies, Pharmaceutical production & Regulation.

4. **Basics of Immunology, Monoclonal antibodies & Hybridoma technology & its Applications.**

    - **Vaccines –** Conventional vaccines, Modern Vaccine technologies, Genetically improved live vaccines, Genetically improved subunit vaccines, Pharmaceutical considerations.

5. **Fundamentals of Cell biology:**

    - **Cell organization and plasma membrane:** Transport of substances across the membrane.
    - **Cellular reproduction:** The Cell cycle, Mitosis & Meiosis, Apoptosis.
    - **Cell Signaling:** Communication between cells and their environment

6. **Molecular biology of cancer:** Causes of Cancer & Genetics of Cancer, New strategies for combating cancer.

7. **Molecular, Structural and Chemical Biology in pharmaceutical research:** Molecular biology of disease and invivo transgenic models, Genomic protein targets and recombinant therapeutics, Structural biology and rational drug design, Chemical biology and Molecular diversity, Gene therapy & DNA/ RNA targeted therapeutics. Future of pharmaceutical research.

8. **Introduction to Bioinformatics:** Biological databases, Sequence analysis, Protein structure, Genetic and physical mapping, Application of bioinformatics in pharmaceutical industries.

9. **Biostatistics** – Graphical representation of Data, Descriptive statistics, Normal distribution, Probability distribution, Sampling & Sampling plans.

Recommended Readings

1. Lehninger *.,* ***Principles of Biochemistry***
2. Karp, G.,***Cell & Molecular Biology***.
3. Crommelin, D.J., A., and Sindelar R.D., ***Pharmaceutical Biotechnology***.
4. Templeton N.S., and Lasic. D.D., ***Gene Therapy.***
5. Benjamin Lewin, ***Genes****.*
6. Watson and Trooze, ***Recombinant DNA Techniques***
7. Lesk., ***Introduction to Bioinformatiics****.*
8. Watson, ***Molecular Biology of cell****.*
9. Old and Primrose, ***Principles of Gene Manipulations.***
10. Watson, J.D., Gilman, M*., **Recombinant DNA Technology***
11. Baxevanis, A.D., Frana, Duelette, B.F*.,**Bioinformatics***
12. Alberts, B., Johnson, A., Lewin, J., Raff, M., Roberts, K., Walter, P*.,* ***molecular biology of the cell***
13. Paul, W.E*, **Fundamentals of Immunology***
14. Klug, W.S., Cummings, M.R., ***Essentials of Genetics***
15. Glick, B.R., Pasternak, J.J., ***Molecular Biotechnology***
16. Walker, J.M., Ripley, R., ***Molecular biology and Biotechnology***
17. Bolton, S***., Pharmaceutical Statistics.***

DRA, INTELLECTUAL PROPERTY RIGHTS AND QUALITY ASSURANCE (MPY -103)

Theory

1. Requirements of GMP, CGMP, GLP, USFDA, WHO guidelines and ISO 9000 Series.
2. Drugs and Cosmetics Acts and Rules, Drug Regulatory Affairs.
3. Documentation – Protocols, Forms and Maintenance of records in Pharmaceutical industry.
4. Clinical Trials and toxicological evaluation of drugs. Preparation of documents for New Drug Approval and Export Registration.
5. Processing and its application, Intellectual Property Rights (Patent, Copy right and Trade marks).
6. Sewage disposal and Pollution control.
7. Concepts in Validation, Validation of manufacturing, Analytical and Process validation and its Application.
8. Basic concept of Quality Control and Quality Assurance systems, Source and Control of Quality variation of Raw materials, Containers, Closures, Personnel, Environmental, etc.
9. In process quality control tests, IPQC problems in Pharmaceutical industries. ICH Guidelines
10. Sampling plans, Sampling and Characteristic curves.
11. Master formula generation and Maintenance, Standard Operating Procedure (SOP) for different dosage forms.

Books and References Recommended:

1. Willing, Tuckerman and Hitching, **Good Manufacturing Practices for Pharmaceuticals.**
2. **Drugs and Cosmetic Acts and Rules.**
3. Bharathi, **Drugs and Pharmacy Laws in India.**
4. Patel, **Industrial Microbiology.**
5. Loftus, B.T. and Nash,R.A., **Pharmaceutical Process Validation**.
6. Bolton, S., **Pharmaceutical Statistics**.
7. Banker, G.S. and Rhodes, C.T., **Modern Pharmaceutics**.
8. OPPI, **Quality Assurance.**
9. Carletiori, **Validation of Aseptic Pharmaceutical Process.**
10. Garfield, **Quality Assurance Principles for Analytical Laboratories**.
11. **Indian Pharmacopoeia.**
12. **British Pharmacopoeia.**
13. **United State Pharmacopoeia.**

PRODUCT DEVELOPMENT AND FORMULATION (MPY-104)

Theory

1. **Preformulation studies:** Study of physical, chemical and pharmaceutical factors influencing formulation of drugs.
2. **Formulation additives:** Study of formulation additives, Drug – Excipient, Excipient - Excipient interactions and Incompatibilities.
3. **Solubilization:** Theory of solubilization, methods of solubility enhancement and factor influencing solubility. Solids dispersion.
4. **Dissolution Technology:** Design of dissolution apparatus, dissolution media, dissolution testing of different types of dosage formulations, data interpretation, *in-vitro* and *in-vivo* correlation**.**
5. **Tablets:** Recent advances in tablet technology and automation in manufacturing process, formulation and evaluation of dispersible, effervescent, floating and multilayers tablets.
6. **Formulation consideration and evaluation:** Parenterals and Ophthalmics.
7. **Polymers:** Classification, General method of synthesis, Properties, Characterization, Evaluation and Application in pharmacy. A detail account of biodegradable polymers.
8. **Nutraceuticals:** Introduction, formulations, uses, recent developments and law governing nutraceuticals.
9. **Pharmaceutical packaging:** Packaging materials, type and tests of containers and closures, Pilot plant scale up technique.
10. **Drug stability:** Stability study programmes for formulations. Determination of Expiry date (shelf life) and Overage calculations. Stability indicating assays and ICH guidelines for stability.
11. **OptimizationTechniques:** Computers in pharmacy, Optimization techniques, Computer aided drug formulations.

Books and References Recommended:

1. Swarbrick, J. and Boyran, J. C., **Encyclopedia of Pharmaceutical Technology"** Vol.1-3, Marcel Dekkar, Inc., New York.
2. Gennaro, A.R., Remington's "**The Science and practice of Pharmacy",** Lippincot, Wiliams & Wilkins, Philadelphia.
3. Aulton, M.E., "**Pharmaceutics- The science of doses form design",** Churchill Livingstone, London.
4. Carstersen, J.T., "**Drug stability: Principal & practice**", Marcel Dekker, Inc., NY
5. Banker and Rhodes, ***Modern Pharmaceutics.*** Marcel Dekker Inc. NY.
6. Liium, L. and Davis, S.S.**, "Polymers in controlled drug delivery", Wright Bristol.**
7. Kibbe**, " Hand book of Pharmaceutical Excipients.,** Pharmaceutical Press, London.
8. Lachmen, L. & Lieberman, H.A**.," *Theory and Practice of Industrial Pharmacy",*** Verghese publishing house, Bombay.
9. Martin**, *Physical Pharmacy*.**
10. Lieberman, H.A. & Lachmen, L**.," Pharmaceutical Dosage forms –Dispersed Systems''** Vol.1-3 ,Marcel Dekker, Inc., NY.
11. Avise, K. E. & Lachmen, L., **" Pharmaceutical Dosage forms –"Parenteral Medications''** Vol.1-3 ,Marcel Dekker, Inc., NY.
12. Lieberman, H.A. & Lachmen, L**.," Pharmaceutical Dosage forms –Tablets''** Vol.1-3 ,Marcel Dekker, Inc., NY.
13. Yalkowsky,S.H." **Techniques of Solubilization of drugs**"**,** Marcel Dekker, Inc., NY.

M. Pharm (Pharmacology) II semester

Advanced Pharmacology – I (MPY-201 Pcl)

1. **Introduction to Pharmacokinetics**

   Biological half-life, Area under curve, Apparent volume of distribution, Concept of drug clearance, Drug disposition.

   Compartment models and their limitations–one compartment open model and multi compartment models. Kinetics of i.v infusion and multiple dose regimens.

   Physiological factors related to drug absorption.

   Drug distribution and protein binding.

   Bioavailability and bioequivalence.
2. The Basics of Drug Interactions
3. Therapeutic Drug Monitoring

   Introduction, Necessity of TDM, Criteria for valid TDM, Essential for effective TDM, Organization of TDM service, Effectiveness of TDM.
4. Drug Selection, Dosage regimen design, Pharmacokinetics of the drug, Patient compliance, Evaluation of patient's response, Measurement of serum drug concentration, monitoring dosing, Determination of dose frequency, Dosing of drugs in elderly.
5. Analytical aspects of TDM, Use of HPLC and Immunoassays in TDM.
6. TDM of selected individual drugs. Aminoglycosides, Carbamazepine, Theophylline, Digoxin, Phenytoin, Methotrexate, Lithium, Valproic acid.

Book and Reference Recommended:

1. Applied Biopharmaceutics and Pharmacokinetics by Leon Shargel and B.C. Andrew
2. Therapeutic Drug Monitoring and Clinical Biochemistry by Mike Halworth and Nigel Capps.
3. Biopharmaceutics and Pharmacokinetics by Robert E. Notari
4. Pharmaceutics and Pharmacy Practice by Gilbert S. Banker
5. Remington's Pharmaceutical Sciences.
6. Dissolution, Bioavailability and Bioequivalence by Abdou
7. Drug Disposition and Pharmacokinetics by Stephen H. Curry
8. Pharmacokinetics by Milo Gilbaldi and Donald Perrier 2nd Edn Marcel Dekker Inc New York 1982.
9. Simkin: Handbook of TDM
10. Goodman and Gilman's The Pharmacological Basis of Therapeutics. McGraw Hill.
11. Principles of drug Action. The basis of Pharmacology by Goldstein A, Arrow. L. and Kalman, S.M. 2nd Ed, John Wiley and Sons Inc. New York, 1974.
12. Clinical Pharmacokinetics. Concept and applications by Rowland M and Tozer 3rd ed. Lea and Febiger Philadelphia.
13. Pharmacokinetics for Pharmaceutical Scientists Wagner J.G. Technomic. Inc. Lancaster P. A. 1993.
14. Applied Pharmacokinetics, Principles of Therapeutic Drug Monitoring by Evans W.E., Schentag J.J. and Jusko W.J. 3rd Ed. Applied Therapeutics Inc. Vancouvers H.A.

Advanced Pharmacology – II (MPY-202 Pcl)

1. Care, Handling and breeding techniques of laboratory animals. Regulations for laboratory animal care and ethical requirements. CPCSEA guidelines for performing experiments on animals. Alternatives to animal studies.
2. Preclinical evaluation of following categories of drugs
    - Sedatives, hypnotics, anxiolytics, antidepressant, antipsychotics, antiparkinsonism agent, analgesics, antipyretics.
    - Anti-inflammatory agents, Anticonvulsants, local anaesthetics, CNS stimulants.
    - Antiulcer agents, laxatives, bronchodilators, antitussives
    - Diuretics
    - Histamine antagonists
    - Muscle relaxants, Anticholinesterases, anticholinergics, adrenolytics.
    - Hypoglycemics, antifertility agent, androgens.
    - Antithyroid agent, Dermatological agents, antitumor agents.
    - Anthelmintics, Antimalarials, Antileprotics.
3. *In vitro* testing of drugs. Animal cell lines and their uses. Limitations of *in vitro* testing of drugs.

Book and Reference Recommended

1. Kulkarni, S.K. Handbook of Experimental Pharmacology, (Vallabh Prakashan, Delhi).
2. Gohsh, M.N. Fundamentals of Experimental Pharmacology, (Scientific Book Agency, Calcutta).
3. Sheth, U.K., Dadkar, N.K. and Kamat, U.G. Selected Topics in Experimental Pharmacology, (Kothari Book Depot, Bombay)
4. Perry, W.L.M. Pharmacological Experiments on Isolated Preparations, (E & S Livingstone, London)
5. Lawarence, D.R. and Bacharach, A.L. Evaluation of Drug Activities: Pharmacometrics, (Academic Press, London)
6. Turner, R.A. Screening Methods in Pharmacology, (Academic Press, London)
7. Thompson, E.B. Drug Bioscreening, (VCH, New York)
8. Vogel, H.G. and Vogel W.H. Drug Discovery and Evaluation Pharmacological assay, (Springer New York)
9. Burn, J.H. Practical Pharmacology, (Blackwell Scientific Co. Oxford).

Advanced Pharmacology – III (MPY-203 Pcl)

1. Clinical evaluation of New Drugs. Organization, Ethics and Protocol for Clinical trials. Drug Registration.
2. **General Principles of Toxicology:** General Reproductive Toxicology, Carcinogenicity, Mutagenicity, Teratogenicity and Immunotoxicology.
3. Clinical pharmacology of drugs used in the treatment of following diseases
    a. **CVS diseases:** Hypertension, Congestive cardiac failure, Angina Pectoris, Acute Myocardial Infarction, Cardiac Arrhythmia, Atherosclerosis, Peripheral Vascular disorders, Coagulation disorders.
    b. Pain management, Pain pathways, NSAIDS, Local anesthetics, Prostaglandins, Leukotrienes and Platelet Activating Factor.
    c. **Immunopharmacology:** AIDS, Drug Allergy, Tissue transplantation, Immunostimulants, Immunosuppressants, vaccines and Sera.
    d. **Gastrointestinal diseases:** Peptic Ulcer, Nausea and Vomiting, diarrhea and Constipation.
    e. **Renal disease:** Acute and Chronic Renal failure
    f. **Respiratory disease:** Asthma, Chromic Obstructive Pulmonary Edema, Pulmonary Embolism.
    g. **Hepatic disorder:** Cirrhosis, Hepatitis.
    h. **Infectious Disease:** General guidelines for rational use of antibiotics. Resistance to antibiotics. Respiratory tract infections, Meningitis, Gastroentritis, Pneumonia, Bacterial Endocarditis, Septicemia, Otitis media, Urinary tract infection, Tuberculosis, Leprosy, Protozoal infection, HIV and Opportunistic infections, Fungal Infections.
    i. **Neoplastic disorders:** General principles of Cancer chemotherapy, Chemotherapy of Lung, Breast, Head and Neck Cancer, Leukemia, Liver and Prostate cancer.

Book and Reference Recommended

1. Roger and Walker, Clinical Pharmacy and Therapeutics. Churchill Livingston Publication.
2. Dipiro, J.L. Pharmacotherapy: A Pathopysiological Approach. (Elsevier).
3. Russle, T.G. Pathology and Therapeutics for Pharmacists: A basis for Clinical Pharmacy Practice. (Chapman and Hall Publication).
4. Herfindal, E.T. and Hirschman, J.L. Clinical Pharmacy and Therapeutics. Williams & Wilkins, London.
5. Davidson's Principles and Practice of Medicine. Churchill Livingston Eighteenth Edition.
6. Harrisons Principles of Internal Medicine. Vol. I & II 14th Edn. Int. McGraw Hills.
7. Oxford Medicine, Blackwell Science
8. Panda, U.N. Textbook of Medicine, CBS.
9. Niesink, R.J.M., De Vries, J. and Hollingers, M.A. Toxicology, Principles and Applications, CRC Press 1996.
10. Amdur, M.O., Duol, J. and Klassen, C.D. Casarett and Doull's Toxicology.
11. Gupta, P.K. and Salunkhe, D.K. Modern Toxicology, Vol–I, II and III (Metropolitan, New Delhi)
12. James Crossland. Lewis Pharmacology, Churchill Livingston, London.
13. Goodman and Gilman. The Pharmacological basis of Therapeutics, Pergamon Press, New York.

Advanced Pharmacology – IV (MPY-204 Pcl)

1. Molecular mechanism of drug action. Receptor Occupancy and Cellular Signaling systems, such as G-Proteins, Cyclic nucleotides, Calcium and Phosphatidyl inositol, Ionic channel and their modulators.
2. Endogenous bioactive molecules as TNF-α, Interleukins, Process of Apoptosis, Arachidonic acid metabolites, COX-2 regulators and their role in inflammation.
3. Recent trends on different classes of receptors and drug acting on them.
    a) Cholinergic receptors
    b) Dopamine receptors
    c) Serotonin receptors
    d) Hormone receptors
    e) GABA receptors
    f) Opioid receptors
    g) Purinergic receptors
    h) Glutamate receptors
4. Neurosteroids, Nitric Oxide
5. Endothelium derived vascular substances (NO, endothelins) and their modulators. Pharmacology of Atrial Peptides, Reactive Oxygen intermediates, Anti oxidants and their therapeutic implications.
6. Fc receptors on T and B-lymphocytes, Antibody Dependent and Cellular Cytotoxicity.
7. Concept of gene therapy and recent development in the treatment of various hereditary diseases. Transgenic mouse and its applications. Human genome mapping and its potential in drug research.
8. General Principles of Clinical Laboratory tests.

Book and Reference Recommended:

1. Katzung, B.G. Basic and Clinical Pharmacology (Lange Medical Publication, California)
2. Barar, F.S.K. Essentials of Pharmacotherapeutics (S. Chand & Co, New Delhi)
3. Bowman, W.C. and Rand, M.J. Textbook of Pharmacology (Blackwell, Oxford)
4. Craig, C.R. and Stitzel, B.E. Modern Pharmacology (Little Brown & Co. Boston)
5. Drill, V.A. Pharmacology in Medicine (McGraw Hill Co. New York)
6. Goodman and Gilman. Pharmacological Basis of Therapeutics (Mc Graw Hill)
7. Rang, H.P. and Dale, M.M. Pharmacology (Churchill Livingston, U.K.)
8. Bacq, Z.M. and Capek. Fundamentals of Biochemical Pharmacology
9. Melmon, K.L. and Morelli. Clinical Pharmacology Basic Principles of Therapeutics (Macmillan New York).