SYLLABUS

(2007-2008)

MASTER OF PHARMACY

(Pharmacognosy)

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 (Pharmacognosy) II Semester

PHARMACOGNOSY PAPER I (MPY 201 Pcg)

PHYTOTHERAPEUTIC MATERIALS

- Chemistry of herbal medicines - Study of extraction, isolation, chemical properties, structure and biosynthesis of chemical components in herbal medicines with the objective to use modern science and technology to study the relationship between chemical components and properties of herbal medicines.
- Problems encountered in and prospects of discovering new drugs from plants. Natural substance as raw materials in drug synthesis, Biomedicinals of recent discovery.
- Emerging plant Drugs - A review of medicinal plant with antiprotozoal, antihepatotoxic anticancer antihypertensive, antidiabetic, anti-inflammatory CNS affecting and antiviral drugs, antioxidants & immuno modulating agents.
- Recent trends in utilization of vegetable laxative bitters and sweeteners natural coloring materials A comparative study of principles of Ayurvedic, Unani, Siddha and Chinese and Kempo medicines A review of current status of plants in alternative system of medicine.
- Information and applications of herbs and herbal formulations available in Indian and International market. Profile of important herbs for their Phytoconstituents, analytical profile and marker components.
- Technologies for the processing of medicinal plant for dosage forms.

Books Recommended:

01. Trease and Evans "Pharmacognosy", W.B. Sunders Publication – 2002.
02. Varro, E. Tyler, "Pharmacognosy", 9th Edition, Lea & Febiger – 1998.
03 Wallis, T.E. "Text Book of Pharmacognosy", 5th Edition, CBS Publishers and Distributors – 2002.
04. Cutler, G. Horace "Biologically Active Natural Products Agrochemicals, CRC Press, New York.
05. Sim, Medicinal Plant Alkaloids.
06. Sim, Medicinal Plant Glycosids.
07. Wagner, Economic and Medicinal Plants Vol. I to IV.
08. Wagner, Pharmacognosy, Phytochemistry and Medicinal Plants.
09. Schwartz, Screening Methods in Pharmacognosy.
10. Harborne, Phytochemical Screening.

PHARMACOGNOSY PAPER II (MPY-202 Pcg)

HERBAL DRUG TECHNOLOGY

- Herbal remedies philosophy concepts and bases of herbal medicine, WHO guideline regarding efficacy safety and toxicity of herbal medicines regulatory requirements as per European community, other regulatory authority, Indian Scenario and US. Potential of exploiting Indian herbal medicines,
- Factor effecting herb quality – An overview for procurement and storage of drugs. Quality control considerations, Pesticide residue, heavy metal and microbial contamination.
- Evaluation and standardization of herbal drugs / formulation by pharmacognostic and analytical methods.
- Quantitative microscopy as applied drugs evaluation and procedures of microtome sectioning procedure, preparations of biological materials for examination by electronic microscope
- Herbal formulations – Quality assurance in new materials, manufacturing of important herbal powders, granules, capsules, tablets, liquids formulations, gel, creams, ointments and other dosage forms. Stability and Biopharmaceutics considerations drug interactions and therapeutic incompatibilities of herbal constituents / formulations.
- Dosage forms in Indian system of medicines- Method of preparations of various Ayurvedic dosage forms, Scope of developing modern manufacturing techniques, approaches for stability and quality control, comparative study of Ayurvedic technology for formulation of dosage forms with modern technology of herbal formulations.
- Herbal cosmetics- Formulation consideration, study of cosmetic materials of herbs, hair dyes sunscreen, shampoo, lotion, creams etc.
- Natural flavour and flavour constituents- Use of natural flavours as flavouring agents. Concept of aromatherapy, important essential oils in aromatherapy.
- Neutraceuticals, cosmeceuticals and functional foods- Health benefits fo food supplements and functional foods, phytopharmaceuticals as cosmetics, phytosomes.

Books Recommended:

01. Patykar, K.D. “Herbal Cosmetics & Ancient India: With Treatise on Planta Cosmetic, Indian Book Centre & Publishers.
02. Asharam Vaidhya, “Herbal Indian Perfumes & Cosmetics”, Indian Books Centre & Publishers.
03. Herbal Cosmetics and Ayurvedic Medicines (EOU)
04. Paranjpe P., Herbs for Beauty: Revealing Ayurvedic Treasures.
05. Ayurvedic Pharmacopoeia, Vol. I, II & III, Gowthom Medicone Pvt. Ltd., Chennai.
06. Choudhary R.D., “Practical Approach to Industrial Pharmacognosy, Herbal Drug Industry, Eastern Publishers, New Delhi – 1996.
07. Karnik P., Pharmaceutical Standard of Herbal Plants, Syndicate Publishing Co.
08. Sammbamurthy et al “Medicinal Plants in Industry”, Question Bank, CBS Publishers & Distributors.
09. C.K. Atal, Cultivation of Medicinal Plants.
10. C.K.Atal, Cultivation of Aromatic Plants.

PHARMACOGNOSY PAPER III (MPY 203 Pcg)

CULTIVATION OF DRUGS

- Exogenous and endogenic factors influencing production of crude drugs plant growth regulators and their application in pharmacy. Disease management of medicinal and aromatic plants.
- Profiles for commercial cultivation technology/and post harvest care of following medicinal plants- Ashwagandha, Periwinkle, Medicinal Yams, Ergot, Guggal, Belladonna, Senna, Rauwolfia, Opium Poppy, Psyllium, Steroid bearing Solariums Ammimajus, Ipecac, Datura, Aloe, Henbane, Digitalis, Saffron.
- Technology for commercial scale cultivation and processing for commercial exploitation aromatic plants Lemongrass Gerenium, Basil, Palmrosa, Vetiver, Patchouli, Japanese Mint Rose, Hops, Jasmine, Sandal, Dill, Celery, Anise, Davana ,mentha..
- Extraction and utilization of Biomedicinal, Occurrence methodology for extraction and chemistry of sennosides, digoxin, ginsengoside, solasodine, berberine, quinine, ergot alkaloids, taxol, withanolides, podophylotoxin, emetine, atropine.
- Profile for Manufacture and commerce of pharmaceutical aids - Papain, Pectin, pharmaceutical gums and their derivatives, starch and its derivatives.

Books Recommended:

01. Jackson, P. Betty, “Atlas of Miscroscopy of Medicinal Plants: Culinary Herbs and Spices, CBS Publisher and Distributor.
02. Harbourne, Phytochemical Methods.
03. Handa H.S., Indian Herbal Pharmacopoeia.
04. Bilgrami et al, “Phytochemistry & Plant Taxonomy, CBS Publisher & Distributor, New Delhi.
05. Wagner H, and Baldts, “Plant Drug Analysis: A Thin Layer Chromatography”.
06. Karnik “Pharmaceutical Standard of Herbal Plants”.
07. Rajpal V, “Standardization of Botanicals” Gowtham Medicone Pvt. Ltd., Chennai.
08. Thin Layer Chromatography by Stahl.

PHARMACOGNOSY PAPER IV (MPY 204 Pcg)

MEDICINAL PLANT BIOTECHNOLOGY

- Historical perspectives, prospects, for development of plant biotechnology as source of medicinal agents. Application in pharmacy and allied fields.
- Types, techniques, nutritional requirement and growth of plant tissue culture. Organogenesis and embryogenesis. Protoplast fusion and cultures.
- Biotechnology of micropropagation of medicinal and aromatic plants.
- Genetic stability of tissue cultures.
- Secondary metabolism in tissue cultures with emphasis on production of medicinal agents and its impact. Screening and selection of high yielding cell lines. Effect of cultural practices, precursors and elicitors on production of biomedicinals.
- Biotransformation, bioreactors for pilot and large scale cultures of plant cells, cellular totipotency, cryopreservation and retention of biosynthetic potential in cell cultures.
- Immobilized plant cells culture system, immobilization techniques, and effect of immobilization on secondary metabolism and realization of chemosynthetic potential in immobilized cells.
- Hairy roots and multiple shoots culture and their applications. Industrially potential cell systems of different types. Development of transgenic plants
- Techniques employed in elucidation of biosynthetic pathways, Biogenesis of tropane, quinoline, imidazole, isoquinoline and indole alkaloids, sterols, anthraquinone and saponin glycosides, Flavanoids and isoprenoids compounds of pharmaceutical significance.

Books Recommended:

01. Khan, A. Irfan, “Role of Biotechnology in Medicinal and Aromatic Plants, Vol. I to VIIII., Ukaaz Publication – 2002.
02. Vyas & Dixit, “Pharmaceutical Biotechnology”, CBS Publisher – 1998.
03. Doyle, Alan & Griffith, J, “Cell & Tissue Culture: Laboratory Procedures in Biotechnology. John Willey & Sons.
04. Gamborg, O.L. & Philip G.C, “Plant Cell, Tissue & Organ Culture: Fundamental Methods, Narosa Publication – 1998.
05. Purohit S.S. “Biotechnology: Fundamentals & Application” Agro Bios India – 2001.
06. Scheepler, A. Judith and Gambier M Rossa “Biotechnological Explorations: Applying the Fundamentals” ASM Press, Washington D.C.
07. Pullock Mackaryee, Quality Control of Herbal Drugs.