# SYLLABUS

## (2007-2008)

# MASTER OF PHARMACY

## (Pharmaceutics)

**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.

## First Year 2nd Semester

### ADVANCED PHARMACETICS –I (MPY-201 Pcs)

### (Biopharmaceutics and Pharmacokinetics)

**1. Therapeutic response and toxicity-** Concentration and response, therapeutic concentration range, therapeutic index, therapeutic window, factors affecting plasma concentration and toxicity.

**2. Compartment modeling – C**onsideration of one, two and multiple compartment models on intravenous administration, intravenous infusion and first order absorption in multiple dosing.

**3. Kinetics of multiple dosing**: Dosing regimens, loading and maintenance dose, one and two compartment models intravenous administration and first order absorption in multiple dosing

**4. Non-linear pharmacokinetics –** Recognition of non linearity, circadian rhythm and chronopharmacokinetics, other resions for non-linearity, one and two compartment open model with Michaelis - Menton kinetics, determination of $K_m$ and Vm, non – linear tissue binding constants.

**5. Physiological pharmacokinetics models**- Concepts, physiologic pharmacokinetic model with binding blood flow- limited versus diffusion-limited model, application and limitation of physiologic pharmacokinetic models, mean time (MRT) statistical moment theory, Mean absorption time (MAT) Mean Dissolution time (MDT).

**6. Clinical Pharmacokinetics –** Concepts, absorption distribution and renal excretion, hepatic clearance and elimination, Disposition and absorption kinetics intravenous dose, constant i.v. infusion , extra vascular dose, metabolic kinetics. Interrelationship between Phrmacokinetic parameters and physiological variables and inhibition of metabolism.

**7. Bioavailability and Bioequivalence**- Objective, significance and factors affecting on bioavailability and bioequivalence, study design and assessment methods for bioavailability and bioequivalence, correlation of in-vitro dissolution in vivo bioavailability, statistical concepts in estimation of bioavailability and bioequivalence, regulatory requirements.

## Books and References Recommended:


1. Notary R.E., "**Biopharmaceutics and Clinical Pharmacokinetics-an introduction**", Marcel Dekker inc., New York.
2. Gibaldi, M., **Biopharmaceutics and Clinical Pharmacokinetics**" Marcel Dekker Inc., New York.
1. Shargel, L.and Andrew, B.C., "**Applied Biopharmaceutics and Pharmacokinetics"**, Prentice-Hall International, Inc.
2. Smith, R. and Steward, J., "**Text book of Biopharmaceutical Analysis**" Lea and Febiger, Philadelphia.
3. Rowland, M. and Tozer, T.N., "**Clinical Pharmacokinetics-Concept and Applications**", B.I. Wavery Pvt. Ltd. ( Lea& Febiger), New Delhi.
4. Swarbick, J. " **Current concept in the Pharm. Sci., Dosage form design and Bioavailability,** Marcel Dekker, Inc., NY.
5. Gibaldi, M. and Perrier, D., "**Pharmacokinetics",** Marcel Dekker, Inc. NY.
6. Banker, G.S. and Rhodes C., ***Modern Pharmaceutics.*** Marcel Dekker Inc. NY.
7. Aulton, M.E., "**Pharmaceutics- The science of doses form design",** Churchill Livingstone, London.

## ADAVENCE PHARMACEUTICS – II (MPY-202 Pcs)

## (Novel Drug Delivery System – I)

## Theory

1. **Controlled Drug Delivery Systems -** :
   - i Concepts and Rationale
   - ii Classification of controlled release systems
   - iii Carriers for CDDS
   - iv Design and evaluation
   - v Release Kinetics
2. **Microencapsulation**
   - i General considerations
   - ii Various techniques employed for microencapsulation
   - iii Evaluation and Application
3. **Transdermal Drug Delivery System (TDDS)**
   - i General considerations , Basic Components,
   - ii Different approaches
   - iii Methods of enhancements of percutaneous absorption
   - iv Evaluations and applications of TDDS
4. **Implants and Inserts**
   - i General considerations, Mechanism of drug release
   - ii Various approaches and Devices
   - iii Applications
5. **Osmotically Regulated Systems**
   - i General considerations
   - ii Classifications and development of Osmotic Pumps
   - iii Applications
6. **General considerations and Applications of following Drug Delivery System**
   - i Bioadhesive and mucoadhesive drug delivery
   - ii Nasopulmonary Drug delivery
   - iii Occular drug delivery
   - iv Pro-drug
7. **Colon – Specific drug delivery**
   - i General considerations,
   - ii Various approaches and applications
8. **An overview of oral controlled drug delivery**

**Book and References Recommended**


1. Jain, N. K., "**Controlled & Novel drug delivery",** CBS Publishers & distributors, New Delhi.
2. Jain, N. K., "**Advances in Controlled & Novel drug delivery",** CBS Publishers & distributors, New Delhi
3. Vyas , S. P. and Khar, R. K. "**Controlled drug delivery – Concepts & Advances**", Vallabh Prakashn, Delhi
4. Vyas, S. P. and Khar, R. K, "**Targeted & Controlled drug delivery Novel Carrier Systems**", CBS Publishers, New Delhi.
5. Mathiowitz, E., "**Encyclopedia of Controlled drug delivery"** Vol - 1 & II, John Wiley & Sons, Canada
6. Swarbick , J. and Boyln, J ., "**Encyclopedia of pharmaceutical technology"** Vol. 1- III, Marcel Dekker , Inc ., New York.
7. Jones, D. A., "**Transdeermal & related drug delivery system**", Marcel Dekker , Inc ., NY.
8. Robinson, J. R. and Lee,. H., "**Controlled drug delivery fundamentals & applications"** Marcel Dekker , Inc., New York.
9. Chein , Y. W. , "**Transdermal controlled systemic medications"** Marcel Dekker, Inc., New York .
10. Hillery , A . and Llyod, A. W., "**Drug delivery & Targetting",** Taylor & Francis, London
11. Deasy, P. B., "**Microencapsulations & related drug processes**" Marcel Dekker, Inc., New York.

## ADAVENCE PHARMACEUTICS – III (MPY-203 Pcs)
## (Novel Drug Delivery System – II)

# Theory

1. **Molecular basis of targeted drug delivery.**

2. **General Considerations, Methods of Preparation, Characterization and Applications of following drug Delivery Systems:**
   i. Liposomes
   ii. Niosomes
   iii. Resealed Erythrocytes
   iv. Nnoparticles
   v. Solid Lipid Nanoparticles
   vi. Dendrimers
   vii. Multiple emulsions
   viii. Submicron emulsion

**3. An overview and Applications of following Drug Delivery Systems:**
   i. Aquasomes
   ii. Pharmacosomes
   iii. Transfersomes
   iv. Liquid Crystals
   v. Magnetically modulated drug delivery
   vi. Peptide and Protein drug Delivery

**Book and References Recommended**


1. Jain, N. K., "**Controlled & Novel drug delivery",** CBS Publishers & distributors, New Delhi.
2. Jain, N. K., "**Advances in Controlled & Novel drug delivery",** CBS Publishers & distributors, New Delhi
3. Vyas , S. P. and Khar, R. K. "**Controlled drug delivery – Concepts & Advances**", Vallabh Prakashn, Delhi
4. Vyas, S. P. and Khar, R. K, "**Targeted & Controlled drug delivery Novel Carrier Systems**", CBS Publishers, New Delhi.
5. Mathiowitz, E., "**Encyclopedia of Controlled drug delivery"** Vol - 1 & II, John Wiley & Sons, Canada
6. Swarbick , J. and Boyln, J ., "**Encyclopedia of pharmaceutical technology"** Vol. 1- III, Marcel Dekker , Inc ., New York.
7. Jones, D. A., "**Transdeermal & related drug delivery system**", Marcel Dekker , Inc ., NY.
8. Robinson, J. R. and Lee,. H., "**Controlled drug delivery fundamentals & applications"** Marcel Dekker , Inc., New York.

9. Chein , Y. W. , "**Transdermal controlled systemic medications"** Marcel Dekker, Inc., New York .
10. Hillery , A . and Llyod, A. W., "**Drug delivery & Targetting",** Taylor & Francis, London
11. Deasy, P. B., "**Microencapsulations & related drug processes**" Marcel Dekker, Inc., New York.

# Pharmaceutical packaging technology

## (MPY-204 Pcs)

1. Concepts in Pharmaceutical Packaging.
2. The packaging function.
3. Regulatory aspects of Pharmaceutical Packaging, Package system.
4. Package design Research.
5. Packaging materials with special reference to:
   Glass, Plastics, metals and polymers.
6. Control of Packaging materials.
7. Ancillary materials used in packaging.
8. Types and Testing of containers and closers.
9. Pharmacopoeial tests and specifications closure systems
10. Types of Packaging with special reference to- Blister, strip, Sachet, Child resistant and Tamper evident packaging.
11. Packaging of Parenteral, Ophthalmics and aerosols.
12. Stability of packages and packaging materials.
13. Sterilization of packaging materials.
14. Printing and decoration of labels and packages.
15. Package Testing.
16. Defects in packaging.

## Books and References Recommended:


1. Swarbrick, J. and Boyran, J. C., **"Encyclopedia of Pharmaceutical Technology"** Vol.1-3, Marcel Dekkar, Inc., New York.
2. Deen,D.A. Evans , E.R. and Hall., I.H., **"Pharmaceutical Packaging Technology**" Tylor and Francis. London.
3. Banker, G.S. and Rhodes C., ***Modern Pharmaceutics.*** Marcel Dekker Inc. NY.
4. Aulton, M.E., "**Pharmaceutics- The science of doses form design",** Churchill Livingstone, London.
5. Lachmen, L. & Lieberman, H.A**.,** ***"Theory and Practice of Industrial Pharmacy",*** Verghese publishing house, Bombay
6. Gennaro, A.R., Remington's "**The Science and practice of Pharmacy",** Lippincot, Wiliams & Wilkins, Philadelphia