# Curriculum and Syllabi

**Appendix-B**

Course of Study and Scheme of Examination

**M. Pharm. (Pharmaceutics)**

## I – Semester

<table>
<thead>
<tr>
<th>S. No</th>
<th>Sub. Code</th>
<th>Subject</th>
<th>Teaching Hours per Week</th>
<th>Distribution of Marks</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td>Theory</td>
<td>Practical</td>
</tr>
<tr>
<td>1</td>
<td>MPY-101</td>
<td>Modern Analytical Techniques</td>
<td>04</td>
<td>06</td>
</tr>
<tr>
<td>2</td>
<td>MPY-102</td>
<td>Biotechnology &amp; Bioinformatics</td>
<td>04</td>
<td>04</td>
</tr>
<tr>
<td>3</td>
<td>MPY-103</td>
<td>Drug Regulatory Affairs, IPR and Quality Assurance</td>
<td>04</td>
<td>---</td>
</tr>
<tr>
<td>4</td>
<td>MPY-104</td>
<td>Product development &amp; Formulation</td>
<td>04</td>
<td>06</td>
</tr>
<tr>
<td></td>
<td></td>
<td><strong>Total</strong></td>
<td>16</td>
<td>16</td>
</tr>
</tbody>
</table>

## II – Semester

<table>
<thead>
<tr>
<th>Sub. Code</th>
<th>Subject</th>
<th>Teaching Hours per Week</th>
<th>Distribution of Marks</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>Theory</td>
<td>Practic</td>
</tr>
<tr>
<td>1</td>
<td>MPY-201 pcs Advanced Pharmaceutics I (Biopharmaceutics &amp; Pharmacokinetics)</td>
<td>04</td>
<td>--</td>
</tr>
<tr>
<td>2</td>
<td>MPY-202 pcs Advanced Pharmaceutics II (Novel Drug Delivery System I)</td>
<td>04</td>
<td>--</td>
</tr>
<tr>
<td>3</td>
<td>MPY-203 pcs Advanced Pharmaceutics III (Novel Drug Delivery System II)</td>
<td>04</td>
<td>--</td>
</tr>
<tr>
<td>4</td>
<td>MPY-204 pcs Advanced Pharmaceutics IV (Pharmaceutical Packaging Technology)</td>
<td>04</td>
<td>--</td>
</tr>
<tr>
<td>5</td>
<td>* Lab (Practical)</td>
<td>--</td>
<td>16</td>
</tr>
<tr>
<td></td>
<td><strong>Total</strong></td>
<td>16</td>
<td>16</td>
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</tbody>
</table>

*Practical based on theory paper 1 to 4

In second year, third and fourth semester a major research project shall be undertaken by the candidate. A Minor research project has to be undertaken by the candidate in the third semester and evaluation of the same shall be done at the end of the third semester as per the scheme.
**Second Year**

**Third Semester - Mini Project**

<table>
<thead>
<tr>
<th>Seminar/Viva</th>
<th>Project Report</th>
<th>Total</th>
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</thead>
<tbody>
<tr>
<td>100</td>
<td>200</td>
<td>300</td>
</tr>
</tbody>
</table>

**Third and Fourth Semester - Major Research Project**

<table>
<thead>
<tr>
<th>Sessional Work</th>
<th>Thesis exam and Viva-voice</th>
<th>Presentation of Thesis work in the Department</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>200</td>
<td>400</td>
<td>100</td>
<td>700</td>
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</tbody>
</table>

First Year + First Year + Second Year + Second Year = Total
(First Sem.) (Second Sem.) (Third Sem.) (Fourth Sem.)

700 + 700 + 300 + 700 = 2400
SYLLABUS
(2010-2011)

MASTER OF PHARMACY
(Pharmaceutics)

Rajiv Gandhi Proudyogiki Vishwavidyalaya
(University of Technology of Madhya Pradesh)
Airport Bypass Road, Gandhinagar,
Bhopal.
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\textsuperscript{13} NMR, Origin of spectra, Chemical shifts, Spin-spin coupling, Coupling constant, Instrumentation and application for Structural elucidation.
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.

Books and References Recommended:

2. Sinder, Text Book of HPLC.
10. Willard, Merrit and Dean, Instrumental Methods of Analysis.
15. Ewing, Instrumental Methods of Chemical Analysis.
16. Block and Durrum, Paper Chromatography and Electrophoresis.
18. Sirmer, Spectroscopic Analysis.

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.


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**:
   - Cellular reproduction: The Cell cycle, Mitosis & Meiosis, Apoptosis.
   - Cell Signaling: Communication between cells and their environment


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.


**Recommended Readings**

1. Lehninger, *Principles of Biochemistry*
6. Watson and Trooze, *Recombinant DNA Techniques*
7. Lesk., *Introduction to Bioinformatics*.
10. Watson, J.D., Gilman, M., *Recombinant DNA Technology*
13. Paul, W.E, *Fundamentals of Immunology*
DRA, INTELLECTUAL PROPERTY RIGHTS AND QUALITY ASSURANCE

(MPY -103)

THEORY

1. Requirements of GMP, CGMP, GLP, USFDA, WHO guidelines and ISO 9000 Series.
6. Sewage disposal and Pollution control.
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:

3. Bharathi, Drugs and Pharmacy Laws in India.
4. Patel, Industrial Microbiology.
8. OPPI, Quality Assurance.
11. Indian Pharmacopoeia.
1.1.1.1 PRODUCT DEVELOPMENT AND FORMULATION (MPY-104)

1.1.1.0.1.1.1.1 Theory

1. Preformulation studies: Study of physical, chemical and pharmaceutical factors influencing formulation of drugs.
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.
9. Pharmaceutical packaging: Packaging materials, type and tests of containers and closures, Pilot plant scale up technique.
Books and References Recommended:


I Year 1st Semester Syllabus is common for all M. pharm. Courses i.e. it is same as for Pharmaceutical Chemistry.
First Year 2\textsuperscript{nd} Semester

ADVANCED PHARMACETICS -I

(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**  – Consideration 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 reasons for non-linearity, one and two compartment open model with Michaelis - Menten kinetics, determination of $K_m$ and $V_m$, 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 Pharmacokinetic 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:**


ADAVENCE PHARMACEUTICS – II
(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 Ocular 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

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

Pharmaceutical packaging technology

Theory

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.
14. Printing and decoration of labels and packages.
15. Package Testing.

Books and References Recommended: