M. Pharm.

(PHARMACEUTICS)

COURSE STRUCTURE
### First Semester

<table>
<thead>
<tr>
<th>S. NO.</th>
<th>CODE</th>
<th>SUBJECT</th>
<th>TEACHING SCHEME</th>
<th>CREDITS</th>
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<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td>LECTURES</td>
<td>TUTORIALS</td>
</tr>
<tr>
<td>1</td>
<td>MPH 1001</td>
<td>Modern Analytical Techniques</td>
<td>4</td>
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<td>MPH 1002</td>
<td>Product Development</td>
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<td>3</td>
<td>MPH 1003</td>
<td>Drug Regulatory Affairs Intellectual Property Rights</td>
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<td>4</td>
<td>MPH 1008</td>
<td>Advanced Pharmaceutics-I</td>
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<tr>
<td>5</td>
<td>MPH 1009</td>
<td>Advances In Drug Delivery Systems-I</td>
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<td>6</td>
<td>MPH 1081</td>
<td>Modern Analytical Techniques</td>
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<td>7</td>
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<td>Product Development</td>
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<td>8</td>
<td>MPH 1085</td>
<td>Advances In Drug Delivery Systems-I</td>
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### Second Semester

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<td>LECTURES</td>
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<td>1</td>
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<td>4</td>
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<td>1</td>
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<td>Synopsis of the Proposed Research Work</td>
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<td>2</td>
<td>MPH 3082</td>
<td>Dissertation- Interim Evaluation</td>
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Total
### Fourth Semester

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M. Pharm.
(PHARMACEUTICS)

DETAILED SYLLABUS
# MPH 1001: MODERN ANALYTICAL TECHNIQUES

**Credits: 04**

**Objective:** To impart basic knowledge of spectroscopy (UV, IR, NMR and MASS), chromatography (Paper, TLC, HPLC, column, HPTLC), XRD and basic instruments. They have theoretical as well as practical aspects of the same. The subject is taught in such a way that they can develop analytical methods for any drug also they can characterize any organic compounds on the basis of above techniques which they utilize in their research.

<table>
<thead>
<tr>
<th>Module No.</th>
<th>Content</th>
<th>Teaching Hours</th>
</tr>
</thead>
<tbody>
<tr>
<td>I</td>
<td><strong>UV-Visible Spectroscopy:</strong> Principle of UV-Visible Spectroscopy, Chromophores and their interaction with UV-visible radiation and their utilization in qualitative and quantitative analysis of drug molecules. Woodward-Fieser rule and its applications. <strong>Infrared Spectroscopy:</strong> Infrared radiation and its interaction with organic molecules, vibrational mode of bonds, instrumentation and applications, effect of hydrogen bonding and conjugation on absorption bands, interpretation of IR spectra, FTIR and ATR. Principles and application of light, phase contrast, scanning and transmission. Electron microscopy.</td>
<td>17</td>
</tr>
<tr>
<td>II</td>
<td><strong>Nuclear Magnetic Resonance Spectroscopy:</strong> Magnetic properties of nuclei, field and precession, chemical shift concept, isotopic nuclei, reference standards and solvents. $^1$H NMR spectra, multiplicity, coupling constants, integration of signals, interpretation of spectra, decoupling-double resonance and shift reagent methods. Principles of FT-NMR, Free induction decay, average time domain and frequency domain signals. Spin-spin and spin-lattice relaxation phenomenon. Proton noise decoupled spectra. $^{13}$C NMR spectra, their interpretation and application. Nuclear overhauser Effect, APT and DEPT techniques. Introduction of 2D NMR techniques, COSY with application.</td>
<td>17</td>
</tr>
<tr>
<td>III</td>
<td><strong>Mass Spectrometry:</strong> Basic principles and brief outline of instrumentation. Ion formation, molecular ion, metastable ion, fragmentation process in relation to molecular structure and functional groups, relative abundance of isotopes, chemical ionization, API, FAB, ESI, Maldy and GC-MS. <strong>Chromatographic Techniques:</strong> Principles of separation and application of Column, Paper, Thin layer, GLC, HPLC and HPTLC; Instrumentation, preparative and micro pore columns, Reverse phase columns, mobile phase selection and detectors, Size exclusion chromatography, Affinity chromatography, Electrophoresis. Thermal Methods: Thermogravimetry (TG), Differential thermal Analysis (DTA) and Differential Scanning Calorimetry (DSC) - Basic principles, outline of instrumentation and applications in Pharmacy.</td>
<td>18</td>
</tr>
</tbody>
</table>

**Outcome:** The students would be able to perform research work utilizing these techniques.

**Books Recommended**

- George, S., Steroid Analysis in Pharmaceutical Industry.
MPH 1081: MODERN ANALYTICAL TECHNIQUES

Credits: 02  
Semester I  
L–T–P: 0–0–4

**OBJECTIVE:** To impart basic practical knowledge of UV and IR spectroscopy, chromatography (Paper, TLC, HPLC,) and basic instruments. The subject is taught in such a way that they can develop analytical method for any drug also they can characterize any organic compounds on the basis of above techniques which they utilize in their research.

**Practicals based on theory syllabus.**

**OUTCOME:** The students would be able to do research work on the basis of above techniques.
**MPH 1002: PRODUCT DEVELOPMENT**

**Credits: 04**

**Semester I**

**L–T–P: 4–0–0**

**OBJECTIVE:** The course is designed to make students familiar with the resources of drug **information**, preformulation study, drug-drug interaction, drug-excipients interaction and interaction with packaging materials and regulatory issues of excipients.

<table>
<thead>
<tr>
<th>Module No.</th>
<th>Content</th>
<th>Teaching Hours</th>
</tr>
</thead>
</table>
| I          | a) Drug information resources, Study of status of Indian Pharmaceutical Industry, Global Pharmaceutical Industry  
            b) Stages in product development – flow charts, acceptance criteria. | 17             |
| II         | Excipients – General consideration factors governing selection, Drug-excipient, & Excipient-excipient interactions, Excipient package interactions, Safety and regulatory issues of excipients | 17             |
| III        | Preformulation studies – Concept including decision trees, Analytical studies, Solid state properties, Physicochemical properties, Stability. | 18             |

**OUTCOME:**

- The students will be able to use drug information resources, preformulation parameters and its application in designing and stability of dosage form and understand the product development process till submission of its report to ANDA.

**Books Recommended**

- Carstensen J., Drug Stability Principles and Practices,
- Otterstatter G., Coloring of Food, Drugs, & Cosmetics, CRC Press, Taylor and Francis, Landon.
- Relevant websites
**MPH 1082: PRODUCT DEVELOPMENT**

**Credits: 02**

**Semester I**

**L–T–P: 0–0–4**

**OBJECTIVE:** The course is designed to make students familiar with the practical aspects of utilizing resources of drug information, preformulation study, drug-drug interaction, drug-excipients interaction and interaction with packaging materials and regulatory issues of excipients

Practicals based on theory syllabus.

**OUTCOME:**
The students will be able to use drug information resources, preformulation parameters in designing stable dosage forms.
**MPH 1003: DRUG REGULATORY AFFAIRS & INTELLECTUAL PROPERTY RIGHTS**

**Credits:** 04  
**Semester:** I  
**L-T-P:** 4–0–0

**OBJECTIVE:** To know about regulatory bodies like ICH, USFDA AND CDSCO, rules and regulation to market a product in India and USA, intellectual property rights and patent procedure.

<table>
<thead>
<tr>
<th>Module No.</th>
<th>Content</th>
<th>Teaching Hours</th>
</tr>
</thead>
</table>
| **I**      | a) Drug & Cosmetics Acts & rules with special reference to schedule Y & M, Drug Regulatory Affairs Requirements of cGMP, GLP, GCP, USFDA, IND, NDA & ANDA (Content & review process)  
b) BA/BE Studies- USFDA, CDSCO & EUDRA guidelines. | 17 |
| **II**     | a) Intellectual Property Rights Processing & its application (patents, Trademarks, Copyrights), Patents Act, Major emphasis on Patents related to:  
- Patentable subject matter  
- Non-Patentable subject matter  
- Criteria for getting a patent  
- Types of patent and its usefulness  
- Filing procedure for patents  
b) Patent cooperation treaty: Introduction & their advantage.  
c) Trade related aspect of intellectual property rights: Introduction & their advantage.  
e) Requirements for factory premises for Medical Devices and In-vitro Diagnostic products in India. | 17 |
| **III**    | a) Concepts in validation, Analytical & Process validation & ISO 9000 Series Basic concepts of Quality Control & quality assurance systems control of quality variation of Raw materials, containers & closures. In process quality control tests,  
b) ICH Guidelines-An introduction of [Q1A (R2), Q3A (R2) & Q6A) guidelines]  
c) Biosimilars: An introduction  
d) Fixed dose combination: USFDA Guideline. | 18 |

**OUTCOME:**

Students will learn about the rules and regulations to market a new drug in India and USAand the procedure for filing of patents.

**Books Recommended:**

- Drugs & Cosmetic Acts & rules.
- Patents Act.
- Factory Act.
- Consumer Protection Act.
- Environmental Protection Act.

- Sharma PP., Validation in Pharmaceutical industry, Vandana publication pvt. Ltd, Delhi.
- Nally JD., Good manufacturing practices for Pharmaceuticals, Informa Healthcare, New York.
- Garfiedl, Quality Assurance Principles for Analytical Laboratories.
- Relevant websites.
MPH 1008: ADVANCED PHARMACEUTICS-I

Credits: 04  Semester I  L–T–P: 4–0–0

OBJECTIVE: To study the principles of solubility, dissolution, diffusion, complexation and stability to optimize the designing of dosage forms.

<table>
<thead>
<tr>
<th>Module No.</th>
<th>Content</th>
<th>Teaching Hours</th>
</tr>
</thead>
<tbody>
<tr>
<td>I</td>
<td>Solubility &amp; Dissolution</td>
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<tr>
<td></td>
<td>(a) <strong>Solubility</strong> – Introduction, Solvent solute interactions, Thermodynamic, Kinetic and intrinsic solubility, Solubility parameter – Hildebrand &amp; Scott equation, Solubility of solids in liquid, Solubility of gases in liquids, Solubility of liquids in liquids, Solubility of solids in solids.</td>
<td>17</td>
</tr>
<tr>
<td></td>
<td>(b) <strong>Dissolution</strong> – Introduction, Intrinsic dissolution rate, Factors affecting dissolution, Noyes whitney equation, Mechanism of dissolution, Zero order and first order release kinetics – Hixon-Crowell, Higuchi Models etc, Measurement of Dissolution rate – methods &amp; apparatus.</td>
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<td></td>
<td>c) In-vitro in-vivo correlation.</td>
<td></td>
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<tr>
<td>II</td>
<td>a) <strong>Diffusion</strong> – Introduction, Mechanism of transport in Pharmaceutical systems, Thermodynamic basis, Ficks laws of diffusion, Diffusion through membranes, Procedures and apparatus to study drug diffusion, pH partition theory and its modifications.</td>
<td>17</td>
</tr>
<tr>
<td></td>
<td>b) <strong>Complexation</strong> – Introduction, Metal complexes, Organic molecular, Complexes, Inclusion compounds, Methods of analysis, Protein binding.</td>
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<tr>
<td>III</td>
<td>Stability testing, Degradative pathways, Stress testing of drug substances, Stability indicating assays, Stability testing protocols, Retest period, Shelf life determination, Photostability testing, Stability of biotechnologicals and phytoPharmaceuticals, Post approval changes (ICH, WHO- guidelines)</td>
<td>18</td>
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</tbody>
</table>

OUTCOME: To utilize the physicochemical principles in formulation development.

Books Recommended:
- Florence, Alexander T; Attwood, David, Physiochemical Principles of Pharmacy, Pharmaceutical Press, London
- Banakar E., Pharmaceutical Dissolution Testing, CRC Press, Taylor & Francis
- Dakshina Murthy Chilukuri, Gangadhar Sunkara, and David Young, Pharmaceutical Product Development: In Vitro-In Vivo Correlation, Informa Healthcare, New York.
- Relevant websites.
MPH 1009: ADVANCES IN DRUG DELIVERY SYSTEMS-I

Credits: 04  
Semester I  
L-T-P: 4–0–0

OBJECTIVE:

To impart knowledge about the advances in drug delivery systems in recent years. Detailed information of biodegradable polymers, controlled drug delivery systems and transdermal drug delivery systems will be given.

<table>
<thead>
<tr>
<th>Module No.</th>
<th>Content</th>
<th>Teaching Hours</th>
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<tbody>
<tr>
<td>I</td>
<td>Biodegradable polymers- A study of Natural synthetic and semi synthetic polymers. Factors affecting biodegradation, Mechanism of biodegradation, Applications.</td>
<td>17</td>
</tr>
<tr>
<td>II</td>
<td>Controlled drug delivery systems- Concept, Rationale, Design, Fabrication and evaluation of Oral, Parenteral,</td>
<td>17</td>
</tr>
</tbody>
</table>
| III        | a) A study of Opthalmic, Dental and IUD CDDS systems.  
b) Transdermal drug delivery systems- Concept, Rationale, Approaches to development, Design, Fabrication and evaluation. | 18 |

OUTCOME:

Students will be able to design controlled drug delivery systems using biodegradable polymers and know about evaluation and applications.

Books Recommended:

- Dean STH, Controlled Release Systems Fabrication Technology, CRC Press, Taylor and Francis, Landon.
- Chasin M. And Langer R., Biodegradable polymers as a drug delivery systems, Informa Healthcare, New York.
- Relevant websites.
MPH 1085: ADVANCES IN DRUG DELIVERY SYSTEMS-I

Credits: 03  Semester I  L–T–P: 0–0–6

OBJECTIVE:

To impart knowledge about the advances in drug delivery systems in recent years. Detailed information of biodegradable polymers, controlled drug delivery systems and transdermal drug delivery systems will be given.

Practicals based on theory syllabus.

OUTCOME:

Students will be able to design controlled drug delivery systems using biodegradable polymers and know about evaluation and applications.
MPH 2007: ADVANCED PHARMACEUTICS-II

Credits: 04  Semester II  L-T-P: 4–0–0

**OBJECTIVE:** To study the Pharmaceutical excipients and their standardisation advances in granulation technology and concept of personalized medicine.

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<thead>
<tr>
<th>Module No.</th>
<th>Content</th>
<th>Teaching Hours</th>
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<tbody>
<tr>
<td>I</td>
<td>Detailed study of Pharmaceutical excipients used in solid, liquid and semi solid dosage forms. Super disintegrants, Directly compressible diluents, Film coating materials, Solublizing agents, Polymers, Standardization of excipients.</td>
<td>17</td>
</tr>
<tr>
<td>II</td>
<td>Industrial processes- Advances in granulation technology- High shear, Low shear granulation, Extrusion/Spheronisation, Effervescent, Melt, Pelletisation, Rapid release, Continuous Fluid bed granulation.</td>
<td>17</td>
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</table>
| III        | a) Design of formulation for pediatric and geriatric population, ADME, Additives, Type of delivery systems, Compliance issues, Package and label design.  
            b) Concept of personalized medicine- need for low & flexible dose products, Fast dissolving, Combination dose systems, Mini tablets, Microdose systems, Implanted devices, Pumps, Microfluidic devices and microchip based technology, Electroactive controlled release films, TelePharmacy, Three dimensional printing. | 18             |

**OUTCOME:** To utilize the above concepts in formulation development.

**Books Recommended:**

- Dean E., Pharmaceutical Packaging Technology, CRC Press, Taylor and Francis, Landon.
- Sellasse IG., Martin C., Pharmaceutical extrusion technology, Informa Healthcare, New York.
- Relevant websites.
MPH 2008: PHARMACEUTICAL PRODUCTION MANAGEMENT

Credits: 04  Semester II  L-T-P: 4–0–0

OBJECTIVE: To study the concepts of pilot plant design, validation and material management in Pharmaceutical production management.

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<tr>
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<tbody>
<tr>
<td>I</td>
<td>Pilot Plant Design: Basic requirement for design, facility, equipment selection for Tablets, Capsules, Liquid orals, Parenterals and semisolid preparations, Plant site selection, layout and organization of Pharmaceutical industries, Quality by Design, Pharmaceutical Development (ICH Q8R2)</td>
<td>17</td>
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<tr>
<td>III</td>
<td>Material Management: Inventories, Inventory management, vendor selection, ABC concept, costing of product and cost control, EOQ, Quality risk management: ICH Q9 &amp; WHO Guidelines. Total quality management, Guide to Pharmaceutical manufacturing facilities.</td>
<td>18</td>
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</tbody>
</table>

OUTCOME: To utilize the above concepts in Pharmaceutical production.

Books Recommended
- Sharma PP., Validation in Pharmaceutical industry, Vandana publication pvt. Ltd, Delhi.
- Levin M., Pharmaceutical process scale up, Informa Healthcare, New York.
- Nally JD., Good manufacturing practices for Pharmaceuticals, Informa Healthcare, New York.
- Otterstatter G., Coloring of Food, Drugs, & Cosmetics, CRC Press, Taylor and Francis, Landon.
- Relevant websites
OBJECTIVE:

To convey the knowledge about the advances in drug delivery systems in recent years. Detailed information about novel approaches such as targeted drug delivery, nanotechnology based formulations will be given.

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<tbody>
<tr>
<td>I</td>
<td>a) Advances in liquid formulation - Multiple emulsions, Micro emulsions, SEDDS, SMEDDS. b) Fast release dosage forms - Concept, Rationale, Design and Evaluation.</td>
<td>17</td>
</tr>
<tr>
<td>II</td>
<td>a) Targeted drug delivery systems - Concept, Types, b) Organ targeting – brain, lung, liver, tumors &amp; lymphatic, Approaches and strategies.</td>
<td>17</td>
</tr>
<tr>
<td>III</td>
<td>a) Nanotechnology based Pharmaceuticals - Rationale, Preparation, Characterization, Evaluation and uses. b) Biotechnology based Pharmaceuticals.</td>
<td>18</td>
</tr>
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</table>

OUTCOME: Students will know the methodologies of designing novel drug delivery systems and their evaluation and applications.

Books Recommended:

- Hauss E., Oral Lipid-Based Formulations: Enhancing the Bioavailability of Poorly Water-Soluble Drugs, Informa Healthcare, New York.
- Dinda SC., Advances in Pharmaceutical technology, PharmMed press, Hyderabad.
- Schreier H, Drug targeting technology, Informa Healthcare, New York.
- Relevant websites
MPH 2083: ADVANCES IN DRUG DELIVERY SYSTEMS-II

Credits: 06  Semester II  L–T–P: 0–0–12

OBJECTIVE:

To learn about the practical aspects of advances in drug delivery systems in recent years. Novel approaches such as targeted drug delivery, nanotechnology based formulations.

Practicals based on theory syllabus.

OUTCOME: Students will be able to use the methodologies of designing novel drug delivery systems and their evaluation.
MPH 2084: SEMINAR
Semester II
L-T-P: 0-0-2

Credits: 01

THIRD SEMESTER

MPH 3081: Synopsis of the Proposed Research Work
MPH 3082: Dissertation- Interim Evaluation

FOURTH SEMESTER

MPH 4081: Dissertation Evaluation