MAULANA ABUL KALAM AZAD UNIVERSITY OF TECHNOLOGY, WEST BENGAL
Syllabus of M. PHARM Industrial Pharmacy
Effective from academic session 21-22

**Curriculum structure**

<table>
<thead>
<tr>
<th>Course Code</th>
<th>Course</th>
<th>Credit Hours</th>
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<th>Hrs./w k</th>
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<tr>
<td><strong>SEMESTER I</strong></td>
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<tr>
<td>MIP101</td>
<td>Modern Pharmaceutical Analytical Techniques</td>
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<td>MIP 102</td>
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<td>MIP 103</td>
<td>Novel drug delivery systems</td>
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<td>MIP 104</td>
<td>Intellectual Property Rights</td>
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<td>MIP191</td>
<td>Industrial Pharmacy Practical I</td>
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<td>MIP 181</td>
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<td><strong>SEMESTER II</strong></td>
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<td>MIP201</td>
<td>Advanced Biopharmaceutics and Pharmacokinetics</td>
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<td>Scale up and Technology Transfer</td>
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INDUSTRIAL PHARMACY (MIP)
MODERN PHARMACEUTICAL ANALYTICAL TECHNIQUES
(MIP 101)

Scope
This subject deals with various advanced analytical instrumental techniques for
identification, characterization and quantification of drugs. Instruments dealt are
NMR, Mass spectrometer, IR, HPLC, GC etc.

Objectives
After completion of course student is able to know,
   □ The analysis of various drugs in single and combination dosage forms
   □ Theoretical and practical skills of the instruments

THEORY 60 HOURS


IR spectroscopy: Theory, Modes of Molecular vibrations, Sample handling, Instrumentation of Dispersive and Fourier – Transform IR Spectrometer, Factors affecting vibrational frequencies and Applications of IR spectroscopy

Spectrofluorimetry: Theory of Fluorescence, Factors affecting fluorescence, Quenchers, Instrumentation and Applications of fluorescence spectrophotometer.

Flame emission spectroscopy and Atomic absorption spectroscopy: Principle, Instrumentation, Interferences and Applications.

2. NMR spectroscopy: Quantum numbers and their role in NMR, Principle, Instrumentation, Solvent requirement in NMR, Relaxation process, NMR signals in various compounds, Chemical shift, Factors influencing chemical shift, Spin-Spin coupling, Coupling constant, Nuclear magnetic double resonance, Brief outline of principles of FT–NMR and 13C NMR. Applications of NMR spectroscopy.

4 Chromatography: Principle, apparatus, instrumentation, chromatographic parameters, factors affecting resolution and applications of the following:
   a) Paper chromatography
   b) Thin Layer chromatography
   c) Ion exchange chromatography
   d) Column chromatography
   e) Gas chromatography
   f) High Performance Liquid chromatography
   g) Affinity chromatography

5 Electrophoresis: Principle, Instrumentation, Working conditions, factors affecting separation and applications of the following:
   a) Paper electrophoresis
   b) Gel electrophoresis
   c) Capillary electrophoresis
   d) Zone electrophoresis
   e) Moving boundary electrophoresis
   f) Iso electric focusing

X ray Crystallography: Production of X rays, Different X ray methods, Bragg’s law, Rotating crystal technique, X ray powder technique, Types of crystals and applications of X-ray diffraction.

6. Immunological Assays: Radioimmunology assay (RIA), ELISA (Theory & practical) and knowledge on Bioluminescence assays.

REFERENCES
Scope
This course is designed to impart knowledge and skills necessary to train the students on par with the routine of Industrial activities in R&D and F&D.

Objectives
On completion of this course it is expected that students will be able to understand:
- The scheduled activities in a Pharmaceutical firm.
- The pre formulation studies of pilot batches of pharmaceutical industry.
- The significance of dissolution and product stability

THEORY 60 Hrs

1. Preformulation Studies: Molecular optimization of APIs (drug substances), crystal morphology and variations, powder flow, structure modification, drug-excipient compatibility studies, methods of determination. 12 Hrs

2. Formulation Additives: Study of different formulation additives, factors influencing their incorporation, role of formulation development and processing, new developments in excipient science. Design of experiments - factorial design for product and process development. 12 Hrs

3. Solubility: Importance, experimental determination, phase-solubility analysis, pH-solubility profile, solubility techniques to improve solubility and utilization of analytical methods - cosolvency, salt formation, complexation, solid dispersion, micellar solubilization and hydrotropy. 12 Hrs

4. Dissolution: Theories, mechanisms of dissolution, in-vitro dissolution testing models - sink and non-sink. Factors influencing dissolution and intrinsic dissolution studies. Dissolution test apparatus - designs, dissolution testing for conventional and controlled release products. Data handling and correction factor. Biorelevant media, in-vitro and in-vivo correlations, levels of correlations. 12 Hrs

REFERENCES
17. Encyclopaedia of Pharm. Technology, Vol I – III.
NOVEL DRUG DELIVERY SYSTEMS
(MIP 103)

Scope
This course is designed to impart knowledge and skills necessary to train the students in the area of novel drug delivery systems.

Objective
On completion of this course it is expected that students will be able to understand,
- The need, concept, design and evaluation of various customized, sustained and controlled release dosage forms.
- To formulate and evaluate various novel drug delivery systems

THEORY
60 Hrs

1. Concept & Models for NDDS: Classification of rate controlled drug delivery systems (DDS), rate programmed release, activation modulated & feedback regulated DDS, effect of system parameters in controlled drug delivery, computation of desired release rate and dose for controlled release DDS, pharmacokinetic design for DDS – intermittent, zero order & first order release.


2. Study of Various DDS: Concepts, design, formulation & evaluation of controlled release oral DDS, Mucoadhesive DDS (buccal, nasal, pulmonary) Pulsatile, colon specific, liquid sustained release systems, Ocular delivery systems

3. Transdermal Drug Delivery Systems: Theory, design, formulation & evaluation including iontophoresis and other latest developments in skin delivery systems.

4. Sub Micron Cosmeceuticals: Biology, formulation science and evaluation of various cosmetics for skin, hair, nail, eye etc and it’s regulatory aspects.

12 Hrs

08 Hrs

04 Hrs


7 Biotechnology in Drug Delivery Systems: Brief review of major areas - recombinant DNA technology, monoclonal antibodies, gene therapy.

8 New trends for Personalized Medicine: Introduction, Definition, Pharmacogenetics, Categories of Patients for Personalized Medicines: Customized drug delivery systems, Bioelectronic Medicines, 3D printing of pharmaceuticals, Telepharmacy.

REFERENCES
3. Transdermal Controlled Systemic Medications, YW Chein, Vol 31, Marcel Dekker, NY.
INTELLECTUAL PROPERTY RIGHTS
(MIP 104)

Scope
This course is designed to impart knowledge and skills necessary to train the students to be on par with the routine of industrial activities in drug regulatory affairs.

Objectives
On completion of this course it is expected that students will be able to understand,
  □ Assist in Regulatory Audit process.
  □ Establish regulatory guidelines for drug and drug products
  □ The Regulatory requirements for contract research organization

THEORY 60 Hrs

1. Definition, Need for patenting, Types of Patents, Conditions to be satisfied by an invention to be patentable, Introduction to patent search. Parts of patents. Filling of patents. The essential elements of patent; Guidelines for preparation of laboratory note book, Non-obviousness in Patent. 12 Hrs

2 Role of GATT, TRIPS, and WIPO 12 Hrs

3 Brief introduction to Trademark protection and WHO Patents. IPR’s and its types, Major bodies regulating Indian Pharmaceutical sector. 12 Hrs

4 Brief introduction to CDSCO. WHO, USFDA, EMEA, TGA, MHRA, MCC, ANVISA 12 Hrs

5 Regulatory requirements for contract research organization. Regulations for Biosimilars. 12 Hrs

REFERENCES:
2. Applied Production and Operation Management By Evans, Anderson and Williams
3. GMP for pharmaceuticals Material Management by K.K. Ahuja Published by CBS publishers
4. ISO 9000–Norms and explanations
5. GMP for pharmaceuticals– Willing S.H. Marcel and Dekker
1. Analysis of pharmacopoeial compounds and their formulations by UV Vis spectrophotometer
2. Simultaneous estimation of multi component containing formulations by UV spectrophotometry
3. Experiments based on HPLC / GC
4. Estimation of riboflavin/quinine sulphate by fluorimetry
5. Estimation of sodium/potassium by flame photometry
6. Effect of surfactants on the solubility of drugs.
7. Effect of pH on the solubility of drugs.
8. Stability testing of solution and solid dosage forms for photo degradation.
9. Stability studies of drugs in dosage forms at 25 °C, 60% RH and 40 °C, 75% RH.
10. Compatibility evaluation of drugs and excipients (DSC & FTIR).
11. Preparation and evaluation of different polymeric membranes.
12. Formulation and evaluation of sustained release oral matrix tablet/oral reservoir system.
13. Formulation and evaluation of microspheres / microcapsules.
14. Formulation and evaluation of transdermal drug delivery systems.
15. Design and evaluation of face wash, body-wash, creams, lotions, shampoo, toothpaste, lipstick.
17. Preparation and evaluation of Liposome delivery system.
ADVANCED BIOPHARMACEUTICS & PHARMACOKINETICS
(MIP 201)

Scope
This course is designed to impart knowledge and skills necessary for dose calculations, dose adjustments and to apply Biopharmaceutics theories in practical problem solving.

Objectives
On completion of this course it is expected that students will be able to understand,

- The basic concepts in Biopharmaceutics and pharmacokinetics.
- The use of raw data and derive the pharmacokinetic models and parameters the best describe the process of drug absorption, distribution, metabolism and elimination.
- To critically evaluate Biopharmaceutics studies involving drug product equivalency.
- To design and evaluate dosage regimens of the drugs using pharmacokinetic and biopharmaceutic parameters.

THEORY 60 Hrs

1. Drug Absorption From The Gastrointestinal Tract: 12 Hrs

2. Biopharmaceutic Considerations in Drug Product Design and In Vitro Drug Product Performance: 12 Hrs
   Introduction, Biopharmaceutic Factors Affecting Drug Bioavailability, Rate-Limiting Steps in Drug Absorption, Physicochemical Nature of the


REFERENCES

2. Biopharmaceutics and Pharmacokinetics, A. Treatise, D. M. Brahmankar and Sunil B. Jaiswal, Vallab Prakashan, Pitampura, Delhi
4. Textbook of Biopharmaceutics and Pharmacokinetics, Dr. Shobha Rani R. Hiremath, Prism Book
SCALE UP AND TECHNOLOGY TRANSFER  
(MIP 202)

Scope
This course is designed to impart knowledge and skills necessary to train the students to be on scale up, technology transfer process and industrial safety issues.

Objectives:
On completion of this course it is expected that students will be able to understand,
- Manage the scale up process in pharmaceutical industry.
- Assist in technology transfer.
- To establish safety guidelines, which prevent industrial hazards.

THEORY 60 Hrs

1. Pilot plant design: Basic requirements for design, facility, equipment selection, for tablets, capsules, liquid orals, parenteral and semisolid preparations.

   Scale up: Importance, Technology transfer from R & D to pilot plant to plant scale, process scale up for tablets, capsules, liquid orals, semisolids, parenteral, NDDS products – stress on formula, equipments, product uniformity, stability, raw materials, physical layout, input, in-process and finished product specifications, problems encountered during transfer of technology

2 Validation: General concepts, types, procedures & protocols, documentation, VMF. Analytical method validation, cleaning validation and vendor qualification.


4 Process validation: Importance, validation of mixing, granulation, drying, compression, tablet coating, liquid filling and sealing, sterilization, water process systems, environmental control.
Industrial safety: Hazards – fire, mechanical, electrical, chemical and pharmaceutical, Monitoring & prevention systems, Hrs industrial effluent testing & treatment. Control of environmental pollution.

REFERENCES
1. Pharmaceutical process validation, JR Berry, Nash, Vol 57, Marcel Dekker, NY.
3. Pharmaceutical project management, T.Kennedy, Vol 86, Marcel Dekker, NY.
5. Tablet machine instruments in pharmaceuticals, PR Watt, John Wiloy.
6. Pharmaceutical dosage forms, Tablets, Vol 1, 2, 3 by Lachman, Lieberman, Marcel Dekker, NY.
7. Pharmaceutical dosage forms, Parenteral medications, Vol 1, 2 by K.E. Avis, Marcel Dekker, NY.
8. Dispersed system Vol 1, 2, 3 by Lachman, Lieberman, Marcel Dekker, NY.
PHARMACEUTICAL PRODUCTION TECHNOLOGY  
(MIP 203)

Scope
This course is designed to impart knowledge and skills necessary to train the students to be on par with the routine of Industrial activities in Production

Objectives
On completion of this course it is expected that students will be able to understand,

□ Handle the scheduled activities in a Pharmaceutical firm.
□ Manage the production of large batches of pharmaceutical formulations.

THEORY 60 Hrs

Improved Tablet Production: Tablet production process, unit 12 Hrs
1. operation improvements, granulation and pelletization equipments, continuous and batch mixing, rapid mixing granulators, rota granulators, spheronizers and marumerisers, and other specialized granulation and drying equipments. Problems encountered.


2 Parenteral Production: Area planning & environmental control, wall and floor treatment, fixtures and machineries, change rooms, personnel flow, utilities & utilities equipment location, engineering and maintenance.

3 Lyophilization & Spray drying Technology: Principles, 12 Hrs
process, freeze-drying and spray drying equipments.

4 Capsule Production: Production process, improved capsule manufacturing and filling machines for hard and soft gelatin capsules. Layout and problems encountered.
Disperse Systems Production: Production processes, applications of mixers, mills, disperse equipments including fine solids dispersion, problems encountered.

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Packaging Technology: Types of packaging materials, machinery, labeling, package printing for different dosage forms.


REFERENCES

1. The Theory & Practice of Industrial Pharmacy, L. Lachman, Varghese Publ, Bombay.
2. Modern Pharmaceutics by Banker, Vol 72, Marcel Dekker, NY.
3. Pharmaceutical Dosage Forms, Vol 1, 2, 3 by Lachman, Lieberman, Marcel Dekker, NY.
4. Pharmaceutical Dosage Forms, Parenteral medications, Vol 1, 2 by K.E. Avis, Marcel Dekker, NY.
6. Dispersed System Vol 1, 2, 3 by Lachman, Lieberman, Marcel Dekker, NY.
7. Product design and testing of polymeric materials by N.P. Chezerisionoff.
10. Quality Control of Packaging Materials in Pharmaceutical Industry, Kharburn, Marcel Dekker, NY.
12. Tablet Machine Instrumentation In Pharmaceuticals, PR Watt, Ellis Horwoods, UK.
ENTREPRENEURSHIP MANAGEMENT
(MIP 204)

Scope
This course is designed to impart knowledge and skills necessary to train the students on entrepreneurship management.

Objectives:
On completion of this course it is expected that students will be able to understand,
  ▪ The Role of enterprise in national and global economy
  ▪ Dynamics of motivation and concepts of entrepreneurship
  ▪ Demands and challenges of Growth Strategies And Networking

THEORY 60 Hrs

2. Entrepreneur: Entrepreneurial motivation - dynamics of motivation. Entrepreneurial competency -Concepts. Developing Entrepreneurial competencies - requirements and understanding the process of entrepreneurship development, self-awareness, interpersonal skills, creativity, assertiveness, achievement, factors affecting entrepreneur role. 12 Hrs


Preparing Project Proposal To Start On New Enterprise

Project work – Feasibility report; Planning, resource mobilisation and implementation.

REFERENCES

INDUSTRIAL PHARMACY PRACTICAL - II
(MIP 291)

1. Improvement of dissolution characteristics of slightly soluble drug by Solid dispersion technique.
2. Comparison of dissolution of two different marketed products /brands
3. Protein binding studies of a highly protein bound drug & poorly protein bound drug
5. Pharmacokinetic and IVIVC data analysis by WinnolineR software
6. In vitro cell studies for permeability and metabolism
7. Formulation and evaluation of tablets
8. Formulation and evaluation of capsules
9. Formulation and evaluation of injections
10. Formulation and evaluation of emulsion
11. Formulation and evaluation of suspension.
12. Formulation and evaluation of enteric coating tablets.
13. Preparation and evaluation of a freeze dried formulation.