Master of Pharmacy
(Industrial Pharmacy)
M. Pharm

Curriculum
(2014-2016)

JIWAJI UNIVERSITY, GWALIOR
<table>
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<tr>
<th>Sem No.</th>
<th>Paper Code</th>
<th>Subject Name</th>
<th>Periods (Per week)</th>
<th>Maximum Marks (Theory)</th>
<th>Maximum Marks (Practical)</th>
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<td>MP-102</td>
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<td>MP-104</td>
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<td>MIP-202</td>
<td>Advances in drug delivery system</td>
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|         | MIP-203    | Industrial Process Validation & Production
Management | 4       |           | 25        | 75             |           |                | 100          |
|         | MIP-204    | Advanced Quality Control                          | 4       |           | 25        | 75             |           |                | 100          |
|         | MIP-205    | Lab (Practical)                                   |           | 16*       |           |                | 50        | 150            | 200          |

- Practicals based on theory subjects

| III     | MIP-301    | Dissertation – I  
(Synopsis, Literature Review, Research envisaged, Seminar Presentation) | Sessional (Internal) | End. Sem. Exam |
|         |           |                                                  | 100                 | Dissertation | Seminar | Viva-voce |
|         |           |                                                  |                     | 150          | 75      | 75        | 400          |
|         | MIP-401    | Dissertation – II  
(Experimental Work, Seminar Presentation) | Sessional (Internal) | End. Sem. Exam |
|         |           |                                                  | 100                 | Dissertation | Seminar | Viva-voce |
|         |           |                                                  |                     | 150          | 75      | 75        | 400          |
|         | MIP-204    |                                                  |                     | Total        | 400     |
|         | MIP-205    |                                                  |                     | Total        | 2000    |

GRAND TOTAL

2000
SEMESTER I

Subject code: MP-101
Subject: ADVANCED ANALYTICAL TECHNIQUES

1. Separation Techniques: Classification, principles, theory, instrumentation and application of chromatographic methods- Gas chromatography (derivatisation methods, column efficiency parameters), Gas-liquid chromatography, HPLC, HPTLC, Size Exclusion chromatography, GC-MS, LC-MS, Ion Pair and Ion Exchange Chromatography and Supercritical Fluid Chromatography.


3. Infra Red (IR) Spectroscopy: Basic principle, Interaction of infrared radiation with organic molecules and its effect on bonds. Instrumentation, IR spectrophotometers, Sample preparation and handling. Interpretation of IR spectra, Fermi Resonance, Qualitative and quantitative applications of IR.


6. Thermal Methods: Theory, Instrumentations and applications of Thermogravimetric Analysis (TGA) and Differential Thermal Analysis (DTA), Differential Scanning Calorimetry (DSC).

RECOMMENDED BOOKS:

Subject code: MP-102
Subject: RESEARCH METHODOLOGY AND BIOSTATISTICS

RESEARCH METHODOLOGY
1. Introduction: Meaning of research, purpose of research and types of research (clinical, experimental, basic, applied and patent oriented research), objective of research.
3. Preparing a research proposal: Selecting a problem and preparing a research proposal for different types of research, sources of procurements of grants.
5. Research report/paper writing/thesis writing / poster presentation: Different parts of research report or paper
   - Title—title of project with authors name
   - Abstract—Statement of the problem, Background list in brief, Purpose and Scope
- Key words
- Methodology-subject, apparatus/instrumentation and procedure
- Results-tables, graphs, figures and statistical presentation
- Discussion-support or non-support to hypothesis. Practical and theoretical implications
- Acknowledgements
- References
- Errata
- Importance of spell check
- Use of foot notes

BIOSTATISTICS
1. Descriptive Statistics: Classification and properties of variable, median and mean, standard deviation, Graphic representation of data.
2. Estimation and Hypothesis testing: Null Hypothesis, confidence level, concept of hypothesis testing & types of error, Student t" test, Chi-Square test.
3. Analysis of Variance: Analysis of variance (one way and two way), Repeated measures designs, factorial designs, univariate ANOVA post hoc tests, analysis of covariance (ANCOVA), repeated measures analysis, multiple regression, and power analysis

RECOMMENDED BOOKS:

Subject code: MP-103
Subject: DRUG REGULATORY AFFAIRS (DRA)

1. Legislation to regulate the profession of pharmacy – The Pharmacy Act 1948.

2. Aims, objects and salient features of following legislations governing Pharmaceutical Industry-
   - Industrial Development and Regulation Act 1951
   - Prevention of Food Adulteration Act 1954
   - Consumer Protection Act
   - Pollution and Environment Control Act

3. Intellectual Property Rights Law:
   - Indian Patent Act 1970 and amendments there under,
   - Copyright (Indian) Act
   - Guidelines for filing patents in countries like US & UK
   - ICH guidelines for clinical trials, therapeutic drugs monitoring drugs and bioequivalence.

4. Drug Master File, Master Formula Record and DMF, Standard Operating Procedures (SOP) for different dosage forms.


6. Good Clinical Practice Guideline, Good Laboratory Practice Guidelines, GMP Guidelines

7. New Drug Application

RECOMMENDED BOOKS:

2. Drugs and Cosmetics Laws by Krishnan Arora, Professional Book Publishers, New Delhi
5. Deshpande S.W., Drugs and Cosmetic Act.1940
7. GLP regulation by Alen Hirsch Vol 38 Marcel Decker series.

Subject code: MP-104
Subject: FORMULATION AND DEVELOPMENT

1. **Preformulation Studies**: Goal of preformulation methodology, solid state properties, partition coefficient, solubility, dissolution, crystal form and stability, Thermal Analysis, X-ray diffraction:-Techniques to generate and characterize amorphous and crystalline forms, compatibility tests, dissolution of drug substances and dosage, factors influencing formulation of drugs.

2. **Excipients**: Overview of excipients used in drug formulation (mainly cyclodextrin, ion exchange resins, film coating materials, superdisintegrants, directly compressible vehicles, surfactants, thickeners), Drug-excipient and package-excipient interactions.


5. **Dissolution Techniques**: Concept and importance of dissolution, Dissolution apparatus and dissolution media, Dissolution model like Hixson-Crowell, Higuchi’s Model, Drug release modeling through polymer matrix and lamimates, Concept of membrane controlled delivery and its importance in dosage form design.

6. **Formulation considerations**: Tablets, Parenterals and Ophthalmics.

8. **Optimization Techniques**: Formulation and Processing Optimization parameters, statistical design, and other application.

9. **Quality Assurance**: Concept of quality control and quality assurance, Quality control of raw materials and pharmaceutical process and finished products.

**RECOMMENDED BOOKS:**


8. Carstensen, Drug Stability : Principles and practices, Marcel Dekker Inc


11. Martin, Physical Pharmacy
SEMESTER II – INDUSTRIAL PHARMACY

Subject code: MPIP-201

Subject: ADVANCED INDUSTRIAL PHARMACY

1. Tablet Production system design: Introduction, Principle, Benefits of improved Tablet production system, Material Handling, processing step combination or elimination, Unit operation improvements, Role of Computer process Control.


RECOMMENDED BOOKS:

1. B.S. Banker. Modern Pharmaceutics, Marcel Dekker.
3. Lachman, Theory and Practice of Industrial Pharmacy, Lea and Febiger.
7. Ghebre, sellasie, Pharmaceutical Polletization technology, Marcel Dekker.

Subject code: MPIP-202

Subject : ADVANCES IN DRUG DELIVERY SYSTEM

1. Fundamentals of controlled release drug delivery systems: Fundamentals and Rationale of Sustained / controlled drug delivery, factors influencing the design and performance of sustained/ Controlled release products, Drug Targeting, Pharmacokinetic / Pharmacodynamic basis of controlled drug delivery systems.

2. Oral drug delivery: Formulation, fabrication and evaluation of various oral controlled drug delivery systems including dissolution and diffusion controlled delivery systems, gastro retentive, colon targeted and pulsatile drug delivery, Osmotic pumps.

3. Parenteral controlled release system: Scope, terminology and techniques used, injectable controlled release formulations, Implantable drug delivery, microspheres, liposomes and their evaluation.


5. Transdermal drug delivery system: Permeation through skin including mechanism, permeation enhances, In-vitro skin permeation, technologies for developing transdermal drug delivery system, mechanism of release kinetics, evaluation of transdermal drug delivery systems.

6. Ocular Drug Delivery: Transport of drugs through ocular tissues, approaches to improve ocular drug delivery.
7. **Site specific drug delivery system:** Active and passive targeting, resealed erythrocyte, monoclonal antibodies, drug targeting by particulate carrier system, drug targeting to brain, lung and colon.

**RECOMMENDED BOOKS:**


Subject code: MPIP-203

Subject: **INDUSTRIAL PROCESS VALIDATION AND PRODUCTION MANAGEMENT**

1. **Introduction:** Definition, regulatory history of process validation, regulatory basis of process validation.

2. **Organisation:** Structure, corresponding departments, scope of validation work, protocol and documentation.


4. **Validation of solid dosage form:** Definition and control of process variables, guidelines for process validation of solid dosage form, validation of raw material and analytical methods.

5. **Prospective process validation:** Introduction, Organization and documentation. Formulation development and development of manufacturing capability Scale up studies, qualification trials master product documents. Experimental design and analysis.

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6. **Retrospective process validation:** Process, validation strategies. Selection and evaluation of historical data.


8. **Analytical methods validation:** Assay validation during development phase. Retrospective and prospective analytical methods validation.


10. **Safety management:** Industrial hazards due to fire, accident, mechanical and electrical equipment, chemicals and pharmaceutical safety measures.


**RECOMMENDED BOOKS:**

3. Balchandra and Nambudri. Production Management-Text and cases. Prentice Hall of India
Subject code: MPIP-204
Subject: ADVANCED QUALITY CONTROL


2. Good manufacturing practices: GMP in manufacturing processing and quality control of drugs, control of facility, personal, production and process controls, packaging and labeling controls, documents, WHO GMP guidelines. Good clinical practice (GCP), Good laboratory practice (GLP), Good Pharmacy practice (GPP)

3. Pharmaceutical Validation: Definition & concept of validation, validation of building, equipments, instruments and facilities, process validation, cleaning –validation, validation master plan, Documents and formats.

4. ICH Stability Guidelines, Schedule M and Schedule Y

5. Quality control of Biological products: International Biological standards, safety testing of pharmaceutical Quality control of antibiotics.

6. Sterile Pharmaceutical Products: GMP aspects related to sterile products- General guidelines, personnel, building and premises, equipment, sanitation, processing, sterilization, Quality control and validation, Documentation

7. Designing safety into the laboratory: Laboratory accident and First aid for chemical burns and accident, egress, hazard zoning, emergency facilities, Hazards: slippery spill of Hazardous substances and their handling. Laboratory design-safety aspect: storage of laboratory chemicals, laboratory design; Principle of chemical storage; inventory control; segregation.

RECOMMENDED BOOKS:

1. Pharmaceutical Quality Assurance, MA Potdar, Nirali Prakashan, Pune
4. Pharmaceutical Process Validation; By F. R., Berory and Robert A. Nash
5. Quality Control of Packaging material in the Pharmaceutical Industry: Kenneth Harburn, Marcel Dekker.
7. Encyclopaedia of pharmaceutical technology, Marcel and Dekker
8. Achieving sterility in medical and pharmaceutical products – N.A. Halls, Marcel and Dekker


Subject code: MIP-205  Lab Work (Practicals based on theory)