# DEPARTMENT OF PHARMACEUTICAL SCIENCES
## M. PHARM. – PHARMACEUTICS
### COURSE STRUCTURE (w. e. f. 2011-12)

### I SEMESTER

<table>
<thead>
<tr>
<th>Course No.</th>
<th>Title</th>
<th>L(h)</th>
<th>T(h)</th>
<th>P(h)</th>
<th>C</th>
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</thead>
<tbody>
<tr>
<td>MPS1101</td>
<td>Advanced Instrumental Analysis (AIA)</td>
<td>3</td>
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<tr>
<td>MPS1103</td>
<td>Product Development &amp; Formulation (PDF)</td>
<td>3</td>
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**Total Hours**: 22

### II SEMESTER

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<td>MPSE101</td>
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**Total Hours**: 24

### III SEMESTER

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### IV SEMESTER

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<th>P(h)</th>
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**Total Credit**: 75

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Note:
- L: Lecture; T: Tutorial; P: Practical; C: Credit
- MPS: M. Pharm. Pharmaceutical Sciences Core
- MPSE: M. Pharm. Pharmaceutical Sciences ELECTIVE
- MMA: Mathematics
- MCR: M.S. Pharmaceutical Sciences Core
M. PHARM I SEMESTER

MPS1101: ADVANCED INSTRUMENTAL ANALYSIS (AIA) (4 CREDITS)

2. Infrared Spectrophotometry: Qualitative uses; Interpretation of I.R. Spectra, Quantitative analysis.
4. Mass Spectrometry: Theory instrumentation, practical consideration, structure elucidation, detection of impurities, quantitative analysis, application to determination of structure, the gas chromatograph mass spectrometer combination.
6. Recent trends in chromatography with reference to analysis of drugs and related substances: HPLC, UPLC, HPTLC, GC and hyphenated techniques (LC-MS/ LC-MS/MS).

BOOKS RECOMMENDED:
1. Practical Pharmaceutical Chemistry (part II) by Beckett and Stenlake.
2. Optical Rotatory Dispersion by C. Djerassi (For ORD).
3. Indian Pharmaceutical (Biological & Microbiological Assay).
10. Application of NMR Spectra to Organic Chemistry-Jackmann.
11. Instrumental Methods of Analysis- Willard.
13. Pharmaceutical Experiments on isolated preparations by the staff of the Department of Pharmacology, University of Edinburg.
15. Lewis Pharmacology- James Crossland.
17. Indian Pharmacopoeia.
20. Assay of Vitamins by Haskmi
MPS1103: PRODUCT DEVELOPMENT & FORMULATION (3 CREDITS)

Pre-Formulation:
A consideration of physio-chemical characteristics of medicinal agents in their dosage form.

Physical characteristics:
Particle size, polymorphism, crystal form, solubility, Interfacial tension, Salt formation, wetting of solids, flow characteristics, compressibility, Rheology, Partition coefficient.

Chemical Characteristics:
Degradation-Hydrolytic, oxidative, reductive, photolytic.

Biopharmaceutical Characteristics:
Liquid solubility, dissociation constant, dissolution rate, bulk solubility and diffusibility in diffusion layer, drug stability in G.I.track, complexation.

Stability Testing & Dating of Solid and Liquid Dosage Forms:
Difference in approaches for stability testing of solid and liquids, Kinetic principles, Physical & Chemical stability testing of Pharmaceutical dosage forms and packages.

Quality Control- Process & Dosage forms:
Sources of variations, control of variation-material control and manufacturing control. Statistical quality control- sampling, testing programme and methods.

Pilot Plant Scale-up Techniques:
Evaluation of formula, equipments, raw materials, process, stability, uniformity. Techniques related to tablets including coating, capsules, liquid dosage forms & semi-solid dosage forms.

Antioxidants Preservatives Colorants and flavourants

Product Development Approach for the following Dosage Forms:
Tablets, Capsules, Sustained release Medication, Injectables Ointments.

Introduction to CTD

Books Recommended:
1. Remington’s Pharmaceutical Sciences by Osol et.el.
2. Theory & Practice of Industrial Pharmacy by Lachman.
3. Pharmaceutics of Solids and Solid dosage form by Cartensens.
5. Pharmaceutical technology by Parrot.
MPS1105: PHYSICAL PHARMACEUTICS (3 CREDITS)

**Solubility in systems containing Surface-Active agents:**

**Complexation:**
Metal complex, organic molecular complex, conclusion compounds, crystalline structure of complexes, hydrophobic interactions, analysis of complex. Protein binding and complexation influencing the drug action. Thermodynamic treatment of stability constants.

**Rheology of Powders:**
Basic properties of powders, fundamental properties of powder relation to flow properties. Evaluation, flow properties of powder systems.

**Rheology Application and Practice:**
Factors affecting rheological properties, Rheology and product design, Rheology and Pharmaceutical Processing, Biological application

**Solid Dispersion:**
Introduction and classification, Mechanism of formation, methods of analysis, pharmaceutical applications.

**Physics of Tablet Compression:** Solid behavior under compression: Transmission of forces through power, distribution of forces within the power mass, Dye wall pressure, Effect of pressure on relative volume, lubricant ion of dye-wall. Adhesion and cohesion of particles during granulation of granules. Bonding during compression and strength of tablet, factors affecting strength of tablet.

**Diffusion and Dissolution:**

**Diffusion principles in Biological systems:**

**Books recommended:**
1. Advances in Pharmaceutical Sciences (Vol. I-IV) by Bean, Backett & Carless (Section A)
3. Physical Pharmacy by Martin, Swarbrick & Cammarata (Sec. A & B)
4. The theory & Practice of Industrial Pharmacy by Lachman, Lieberman, Kanig, (Sec. A & B )
5. Physical & Technical Pharmacy by Burlage, Lee & Rising.
MPS1002: PRODUCT DEVELOPMENT & FORMULATION LAB. (4 CREDITS)

A systemic approach of development of Pharmaceutically acceptable dosage forms of various categories of drugs.
M.PHARM (II SEMESTER)

MPS2101: BIOPHARMACEUTICS & PHARMACOKINETICS (3 CREDITS)

I. BIOPHARMACEUTICAL CONSIDERATIONS IN DRUG PRODUCT DESIGN

1. Factors Influencing Dosage Form Design:
   i) Rate-Limiting step in Drug Absorption
   ii) Biopharmaceutical Aspects
   iii) Patient Considerations
   iv) Manufacturing Considerations

2. Factors Influencing Drug Dissolution/Bioavailability:
   i) Physico-Chemical
   ii) Pharmaceutical, and
   iii) Formulation

3. Rate-Limiting Step in Bioavailability:
   i) Disintegration – in vitro, in-vivo
   ii) in-vitro Dissolution Testing
   iii) in-vitro Dissolution to in-vivo Absorption correlation including its failure.
   iv) Dissolution Testing in lieu of Bioavailability Studies.

II. BIOAVAILABILITY & BIOEQUIVALENCE

1. Definitions of Related Terms (*UG)
2. Purpose of Bioavailability Studies (* UG)
3. Relative & Absolute Bioavailability
4. Bioavailability Assessment
5. Bioequivalence Studies
   i) Design of Study    ii) Statistical Evaluation
6. Waiver of in-vivo Bioavailability & Bioequivalence
7. Ranking of Drugs and Several Formulations of the Drug

III. DRUG DISTRIBUTION & ELIMINATION

1. Physiological Factors Influencing Drug Distribution
2. Protein Binding
3. Volume of Distribution
4. Physiological Approach to Drug Elimination
5. Clearance Concepts
6. Dependence of Drug Elimination Kinetics on Clearance & Distribution

IV. PHARMACOKINETICS (based on Plasma & Urinary Excretion Data of Intact Drug)

1. Compartmental Approach:
   i) One Compartmental Model
   ii) Two Compartmental Model
2. **Nonlinear (Dose Dependent) Pharmacokinetics:**

   i) Michaelis-Menten Concept
   
   ii) Pharmacokinetics of Drugs under Such Situations
       (one compartment model – single dose):
       
       a) Intravenous Administration, and
       
       b) First-Order Absorption
   
   iii) Time-Dependent Pharmacokinetics
   
   iv) Nonlinear Pharmacokinetics due to Protein Binding
   
   v) Pitfalls in Pharmacokinetic Modelling

**BOOKS RECOMMENDED**

MPS2103: ADVANCED DRUG DELIVERY SYSTEMS (3 CREDITS)

I. Fundamentals of Controlled-Release Drug Administration
   1. Rationale of / for the Development of Controlled Drug-Release Systems
   2. Potential benefits & limitations
   3. Factors influencing Design & Performance
   4. Design and Fabrication (including Prodrug Approach)
   5. Mechanisms of Drug-Release including Rate-Determining Parameters.
   6. Characterization & Evaluation

II. Parenteral Controlled-Release Drug Delivery Systems
   1. Significance & ideal Carrier Requirements
   2. Various Approaches available

III. Colloidal Drug Delivery System & Targeted Drug Delivery System

IV. Microparticulate Drug Delivery Devices
   1. Microparticulate Carriers
   2. Design & Fabrication of:
      - Microspheric and modified microspheric
      - Liposome based carrier systems.

V. Veterinary Drug Delivery System

BOOKS RECOMMENDED

MPS2105: NOVEL DRUG DELIVERY SYSTEMS (3 CREDITS)
(Pharmaceutics)

Development of Modern Drug Delivery Systems under following heads:

- Fundamentals & Basic Concepts involved,
- Approaches Available,
- Mechanisms of Drug Release,
- Formulation- Design & Optimization, and
- Characterization including Potential Applications & Future Prospects (if any):

With special reference to under mentioned delivery systems.

1. Transdermal Drug Delivery Systems (TDDS) including Iotophoresis & Phonophoresis
2. Osmotic – Pump Delivery
3. Occular Administration
4. Nasal & Pulmonary Drug Devices
5. Buccals/ Mucoadhesives
7. Dental Drug Delivery System

BOOKS RECOMMENDED
MPSE101: FERMENTATION TECHNOLOGY AND BIOINFORMATICS

(3 CREDITS)

I. A. Design of Fermentor and Fermentation Technology

Requirement of an ideal Fermentor, Types of Bio-reactors, Design of Bio-reactors, Discussion on various operations involved e.g. Aeration, Agitation, Defoaming. Operation of Continuous and Batch Fermentation, Principles of operation of CSTR as Chemostat and Turbidostat.

B Development of Fermentation Medium

Discussion on Synthetic and Natural Media, Types of natural media. Interactions of Ingredients. Incompatibility in Culture, Sterilization problems of media on large scales.

C. Strain Improvement

Selection, Mutation types, Mutagenic agents. Mutant isolation, Basic steps of r-DNA Techniques, Recombinant Microorganism.

II Biotechnological Products

Immunodiagnostic agents and different products. Production and formulation with reference to ELISA, Insulin, Interferon, Vit B₁₂, L-lysine, Hepatitis B and Growth Hormones.

III Introduction to Bioinformatics:

Biological Data Resources on Internet and its retrieval system. Human Genome project. Introduction to drug design using Bioinformatics.

Books :

a. Biochemical Engineering by Aiba.
b. Fermentation Microbiology & Biotechnology by Mansi & Bryce.
e. Comprehensive Biotechnology Vol I & II by Murray –Moo-Young.
f. Industrial Microbiology by Reed & Reed.
g. Microbial Technology by Peppler & Peppler.
h. Developing Bioinformatics Computer Scales by C.Gibas, P. Jambeck.
# MPS2141: CLINICAL RESEARCH – ETHICS & DESIGN (3 CREDITS)

   2h

2. Drug Development – Discovery, Screening, Formulation, Preclinical, Various Phases (Phase I to Phase IV) of Clinical Study, Clinical & Product Registration  
   3h

3. BA/BE Studies  
   1h

4. Investigational New Drug & New Drug Application  
   1h

   4h

6. Study Participants – Sponsor, Investigator, Volunteer, Contract Research Organization, Data Safety & Monitoring Board  
   3h

   4h

8. Study Setup – Feasibility assessment, Site selection, Budget proposal  
   2h

9. Study Monitoring – Monitoring Responsibilities: Type of monitoring visits, Site Initiation, Interim Monitoring, Site close out, monitoring activities, Monitoring methods, Problem solving, Writing monitoring reports  
   8h

10. Investigational Product Management – Accountability, Distribution  
    2h

11. Study Design & Planning – Design, Study Protocol, Case Report Form, Quality of Life, Study Plan, Study Flow Chart, Investigator Selection, Clinical Trial Application  
    5h

12. Organization – Contracts & Agreements, Liability & Insurance, Financial Disclosure, Clinical Trial Committees, Logistics & Clinical Laboratory  
    3h

13. Study Conduct – Essential Documents, Subject Recruitment, Randomization & Blinding, Investigational Product Management, Clinical Trial Supplies  
    3h

14. Safety Reporting – Adverse Events, Serious Adverse Events, Adverse Drug Reactions, Patient Care in Clinical Research, Pharmacovigilance  
    2h

    2h

## Books Recommended

1. Principal and practice of Pharmaceutical Medicine edited by Andrew j Fleteher, Lionel D Edwards, Anthony W Fox, Peter Stonier Published by John Wiley & sons Ltd.
MCR3101: PHARMACOVIGILANCE (3 CREDITS)

1. Pharmacovigilance –
i) Drug related problems in health care
   Types and mechanisms of ADRs, Risk factors for ADRs, Drug – drug interactions,
   Other causes of drug related problems, Drugs in pregnancy and lactation,
   Management of patients affected by ADRs, Medication errors 5h

ii) Clinical manifestations of ADRs 5h
   Drug related diseases affecting different organ systems (Brief Overview since covered
   in Clinical Pharmacology)

iii) Spontaneous reporting 5h
   Organization, Setting up and running a PhV centre, Patient reporting, Managing
   individual case report forms, Terminologies, Feed back to reporters, Case assessment,
   Signal analysis and follow up, Root cause analysis of medication errors

iv) Epidemiological Methods 5h
   Drug utilization studies, Cohort event monitoring, Cohort studies,
   Case control studies, Longitudinal databases of patient records

v) Collection and management of safety data during clinical trials: 5h
   Need for good quality safety information, Definition of good safety information,
   Differing regulations concerning safety data collection requirements, Designing a
   system to collect good quality information

vi) Post-marketing drug safety: Differences in clinical and post-marketing drug safety 4h

vii). Reporting to the Regulatory Authorities:

   5h
   Individual case safety reports, Periodic safety update reports, Answering queries
   from regulatory authorities, Updating product labelling – emphasis on safety changes,
   Safety reporting requirements, Safety report sources, Follow up of safety reports,
   Electronic safety reporting – Oracle & other software program available, Safety file
   retentions

viii) Global pharmacovigilance and safety standards 3h
   • Background and introduction to pharmacovigilance
   • The WHO and safety reporting
   • CIOMS – function and purpose
   • ICH – composition and guidelines
   • MedRA

ix) Understanding signals and benefit-risk determinations 3h
   • Definition of a signal
   • Type of signal
   • Who should be involved in signal detection process?
   • Conducting signal detection in clinical and post-marketing surveillance
   • Defining the signal in relation to risk/benefit
   • Definitions of risk/benefit – FDA and EU perspective
   • Risk/benefit assessments – who does this and where does the information go?
   • Safety assessments and risk/benefit – frequency and reporting
• Changes in risk/benefit – how to manage and review existing profile

x) Standard operating procedures (SOPs) in relation to pharmacovigilance 3h
  • Types of SOPs required
  • Production and sign off of SOPs
  • SOP maintenance
  • SOP training

xi) The role of the qualified person (QP) 3h
  • Contract versus permanent.
  • Essential attributes of the QP
  • The duties of the QP
  • What the QP must do
  • Internal audits of the company pharmacovigilance activities

xii) Audit 3h
  • Contracting out pharmacovigilance
  • Preparation for a regulatory inspection
  • Scope of the pharmacovigilance inspection
  • Conduct of the pharmacovigilance inspection
  • The pharmacovigilance inspection report
  • When things go wrong
  • Corrective actions following a pharmacovigilance inspection

Books
2. Pharmacovigilance from A to Z - Barton L. Cobert & Pierre Biron, Blackwell Science
3. Good Pharmacovigilance Practice – MHRA
6. An Introduction to Pharmacovigilance – Waller, Patrick; John Wiley & Sons
8. Pharmacovigilance from A to Z - Barton L. Cobert & Pierre Biron, Blackwell Science
9. Good Pharmacovigilance Practice – MHRA
12. An Introduction to Pharmacovigilance – Waller, Patrick; John Wiley & Sons
MPS2102: Physical Pharmaceutics Lab (4 CREDITS)

Experiments illustrating the principles discussed in MPS1005 Physical Pharmaceutics.

MPS2104: Biopharmaceutics Lab (4 CREDITS)

Experiments illustrating the principles discussed in theory papers covered in MPS2101 Biopharmaceutics & Pharmacokinetics.
M. PHARM III SEMESTER (15 CREDITS)

MPS3101: Thesis:
- Thesis Seminar

M. PHARM IV SEMESTER (20 CREDITS)

MPS4101: Thesis:
- Presentation, Submission and Viva-Voce
BREADTH PAPERS

MMA1101: BIOSTATISTICS     (3 Credits)

1. **Introduction:**
   Relevance and the scope of Statistics.
   Difference between ‘Descriptive’ and ‘Inferential’ Statistics; Relationship between them

2. **Sampling Methods**
   Introduction of sampling, probability and non probability sampling, sampling procedures – simple random, stratified, systematic, cluster and multistage sampling, concept of sampling distribution.

3. **Statistical Inference**
   Statistical estimation – point and confidence interval estimations, Introduction of statistical hypothesis and testing, comparison of population mean with sample means, comparing two sample means, comparison of population proportion with sample proportions, comparing two sample proportions, comparison of more than two samples, introduction of non parametric statistical tests.

4. **Correlation and linear regression**
   Introduction of correlation & regression concepts, estimation of correlation coefficient, regression coefficients, assumption of tests of hypothesis in linear regression, variance of sample estimates of the parameters, confidence intervals in regression analysis, non linear regressions, weighted and transformations in regression analysis, application of linear regressions - standard curves in drug analysis and drug stability studies, analysis of covariance.

5. **Concepts of Inferential Statistics**
   Basics of Statistical Inference
   Sampling distribution
   Estimation – Point estimation, Interval estimation
   Parameter, Statistic, Concept of a hypothesis, Research Hypothesis, Null Hypothesis, Level of Significance, Comparison of means of two samples, Comparison of sample proportion with population proportion, Comparison of two sample proportions,
   Degrees of Freedom, Critical Value, Table value, Type I and Type II errors, Rules for rejection & acceptance of Null Hypothesis, Standard Error

6. **Inferential Statistics - Parametric Test:**
   ‘t’ test – Comparison of sample mean with the population mean, Comparison of means of two independent samples, Comparison of two correlated samples
   ‘Z’ test – different applications
   Annova – one way annova: ‘F’ test

7. **Quality control:**
   Introduction, control charts, acceptance sampling and operating characteristic curves, statistical procedures in Assay.Department, establishing in-house limits, some statistical aspects of quality and the “Barr Decision”.

8. **Inferential Statistics - Non-parametric test:**
   Chi square test- Testing of goodness of fit, testing of independence, Test of homogeneity; Wilcoxon signed rank test; McNemar test
9. **Computer Applications & Practicals:**
   Introduction of statistical software – SPSS with practical exercises

**BOOKS RECOMMENDED:**


**Text Books**

1. Pharmaceutical Statistics
MPS1003: BIOLOGICAL STANDARDIZATION & PHARMACOLOGICAL SCREENING (3 Credits)

1. Laboratory Animals 7h.
   a. Commonly used laboratory, transgenic and other genetically prone animal models (viz. nude mice SH rats etc.)
   b. Techniques of blood collection, anesthesia & euthanasia of experiment animals.
   c. Maintenance & breeding of laboratory animals.
   d. Regulation and ethics requirements.
   e. Guidelines & regulatory agencies – CPCSEA, OECD, FDA ICH, FHSA, EPA, EEC, WHO, etc.
   f. Importance of alternative experimental models, its advantages & disadvantages.

2. Principles of Biological Standardization 4h.
   a. Methods of biological assay, principles of biological assays with certain examples as per IP and BP.
   b. Development of new bioassay methods.

3. Immunoassay 5h
   a. General principles of immunoassay, Theoretical basis, Optimization of immunoassay, Heterogenous immunoassay system, Homogenous immuno system.
   b. Production of immunoassay reagent: Introduction, receptors or binders, unlabelled ligands Calibrators, Labelled ligands and receptor, Separation technique, buffers.

4. Organization of screening for the Pharmacological activity of new substances with emphasis on evaluation using in-vivo, in-vitro, ex-vivo, in-situ, in silico and other possible animal alternative models. 18h.
   a. General Principles & safety pharmacology procedure.
   b. CVS Pharmacology – Antihypertensive, Anti arrhythmics, Vasodilators, disentail.
   c. CNS Pharmacology – behavioral & muscle co-ordination, CNS stimulants, anti-epileptics, Nootropics.
   d. Drugs for Neurodegenerative diseases, like parkinsonism, Alzheimers, multiple sclerosis.
   e. Drugs acting on ANS.
   f. Respiratory Pharmacology – Anti-asthmatics, COPD, Anti-allergic & Mucoactives.
   g. Reproductive Pharmacology – Aphrodisiacs & antifertility agents.
   h. Analgesics, anti-inflammatory & antipyretics.
   i. G.I.T. – Anti-ulcer, anti-emetics, anti-diarrhoeal & laxatives.
   j. Anti-cancer agents.
   k. Metabolic disorders like anti-diabetics, anti-hyperlipidemic, anti-obesity, hepatoprotective.
   l. Models in drug absorption & metabolism.
   m. Immuno Pharmacology – specific (cell & hormonal mediated) & non-specific methods.
   n. Screening of free radical scavenging activity.
   o. Acute, Sub-acute & Chronic toxicity test.
5. Clinical pharmacology and pharmacodynamics: clinical study design, documentation, presentation and interpretation  

6. Clinical trials: definition, phase I – IV studies, design documentation, presentation and interpretation, statistical analysis of clinical data, factorial design, guidelines as per Indian and other regulatory authorities.

BOOKS RECOMMENDED:

2. I.P. & B.P.
6. Selected topics on Experiment Pharmacology by Issha G. Kamat, Dadkar, N.K. & Seth, UK.
8. Pharmacological Experiment on intact preparation by Churchill Livingstone
11. Principles & Methods of Toxicology by Hays.
12. CRC Handbook of Toxicology by Derelako & Hollinger.