DEPARTMENT OF PHARMACEUTICAL SCIENCES

M. PHARM. – PHARMACEUTICS

COURSE STRUCTURE (w. e. f. 2011-12)

Course No.	Title	L(h)	T(h)	P(h)	C
I SEMESTER					
	THEORY				
MPS1101	Advanced Instrumental Analysis (AIA)	3	1	0	4
MPS1103	Product Development & Formulation (PDF)	3	0	0	3
MPS1105	Physical Pharmaceutics (PP)	3	0	0	3
	LAB				
MPS1102	Product Development & Formulation Lab	0	0	6	4
	BREADTH				
MMA1101	Applied Science: Biostatistics	3	0	0	3
	Breadth Paper	3	0	0	3
	Total	**15**	**1**	**6**	**20**
	Total Hours	**22**			
II SEMESTER					
	THEORY				
MPS2101	Biopharmaceutics & Pharmacokinetics (BP)	3	0	0	3
MPS2103	Advanced Drug Delivery System (ADDS)	3	0	0	3
MPS2105	Novel Drug Delivery System (NDDS)	3	0	0	3
	ELECTIVE(ANY ONE)				
MPS2141 **MPSE101** **MCR3101**	Clinical Research – Ethics and Design Fermentation Technology & Bioinformatics Pharmacovigilance	3	0	0	3
	LAB				
MPS2102	Physical Pharmaceutics Lab	0	0	6	4
MPS2104	Biopharmaceutics Lab	0	0	6	4
	Total	**12**	**0**	**12**	**20**
	Total Hours	**24**			
III SEMESTER					
MPS3101	THESIS	-	-	-	**15**
IV SEMESTER					
MPS4101	THESIS	-	-	-	**20**

Total Credit - 75

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)

1. Analytical Application of Absorption Spectra: 3h
   Absorptiometric assay of Organic Compounds, Structural Analysis.
2. Infrared Spectrophotometry: 6h
   Qualitative uses; Interpretation of I.R. Spectra, Quantitative analysis.
3. NMR-Spectroscopy: 8h
   The NMR-Signal, Instrumentation practical consideration, chemical shift, spin-spin coupling, Structure elucidation, investigation of dynamic properties of molecules, quantitative analysis.
4. Mass Spectrometry: 8h
   Theory instrumentation, practical consideration, structure elucidation, detection of impurities, quantitative analysis, application to determination of structure, the gas chromatograph mass spectrometer combination.
5. Optical Rotatory Dispersion: 3h
   Terminology Plain Curves, Rotatory dispersion of ketones, The Axial Haloketone Rule, Octant Rule.
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). 8h
7. Theory, Instrumentation and Applications of: 8h
   Thermogravimetric Analysis (TGA), Differential thermal analysis (DTA), Differential Scanning Calorimeter (DSC), X ray Diffraction(XRD).

BOOKS RECOMMENDED:

1. Practical Pharmaceutical Chemistry (part II) by Beckett and Stenlake.
2. Optical Rotatory Dispersion by C. D.jerassi (For ORD).
3. Indian Pharmaceutical (Biological & Microbiological Assay).
4. British Pharmaceutical (Biological & Microbiological Assay).
5. UV and Visible Spectroscopy, Chemical Application-C.N. R. Rao.
6. Spectrometric identification of organic compound- Silverstein.
7. Chemical application of IR spectroscopy – C.N.R. Rao.
8. Physical Methods of Organic Chemistry- Weissberger.
9. Interpretation of Mass Spectra of organic compounds-B. Kienicz, C. Djerassi.
10. Application of NMR Spectra to Organic Chemistry-Jackmann.
11. Instrumental Methods of Analysis- Willard.
12. Applications of Absorption spectroscopy of organic compounds – John R. Dyer.
13. Pharmaceutical Experiments on isolated preparations by the staff of the Department of Pharmacology, University of Edinburg.
14. Pharmacological Techniques in Drug evaluation, Vol. 1&2 by Peter E. Siegler, J.H. Meyer.
15. Lewis Pharmacology- James Crossland.
16. Fundamental of Experimental Pharmacology- M.N. Ghosh.
17. Indian Pharmacopoeia.
18. British Pharmacopoeia.
19. United States Pharmacopoeia .
20. Assay of Vitamins by Haskmi

MPS1103: PRODUCT DEVELOPMENT & FORMULATION (3 CREDITS)

Pre-Formulation:

A consideration of physio-chemical charecterstics of medicinal agents in their dosage form.

Physical characteristics:

Particle size, polymorphism, crystal form, solubility, Interfacial tension, Salt formation,wettingof 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.
4. Advance in Pharm. Sciences by bean & Beckett.
5. Pharmaceutical technology by Parrot.

Solubility in systems containing Surface-Active agents:
Theory of micelles formation, physical methods of investigation of Micellar solution, factors influencing critical Micelle concentration.Theory of Mechanism of solubilization. Phase equilibria in systems containing surface-active agents, factors involved in the formation of solubilized pharmaceutical products, formulation of solubilized products, containing vitamins and Hormones.

Complexation:
Metal complex, organic molecular complex, conclusion compounds, crystalline structure of complexs, 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, lubricantion of dye-wall.Adhesion and cohesion of particles during granulation of grandles.Bonding during compression and strength of tablet, factors affecting strength of teblet.

Diffusion and Dissolution:
Steady state diffusion, measurement of diffusion coefficient, Dissolution: Dissolution rate, dissolution of tablets and granules, Hixon-Crowell Cube root law in dissolution of powder. Drug release from polymer and granular matrices.

Diffusion principles in Biological systems:
Gastro-intestinal absorption of drugs, pH partition hypothesis. Modification of the pH partion principles, percutaneous absorption, Buccal absorption, uterine diffusion.

Books recommended:

1. Advances in Pharmaceutical Sciences (Vol. I-IV) by Bean, Backett & Carless (Section A)
2. Theory of Pharmaceutical Systems (Vol. I & II) by Carstensen (section B)
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

1. Wagner : Biopharmaceutics & Relevant Pharmacokinetics, Drug Intelligence Publication, 1971.
2. Swarbrick:Current Concepts in Pharmaceutical Sciences (Biopharmaceutics), Lea & Febiger, 1970.
3. Swarbrick: Current Concepts in Pharmaceutical Sciences (Dosage Form Design & Bioavailability), Lea & Febiger, 1973.
4. Niazi: Text Book of Biopharmaceutics & Clinical Pharmacokinetics, Appleton Century Crofts, 1979.
5. Evans et al.: Applied Pharmacokinetics (Principles of Therapeutic Drug Monitoring), Applied Therapeutics, 1980.
6. Gibaldi & Perrier: Pharmacokinetics, 2nd ed. (Revised & Expanded), Marcel Dekker (series in Drugs & Pharmaceutical Sciences – vol. 15), 1982.
7. Gibaldi: Biopharmaceutics & Clinical Pharmacokinetics, 3rd ed., Lea & Febiger, 1984.
8. Ritschel: Graphical Approach to Clinical Pharmacokinetics, 2nd ed., Prous Publishers, 1984.
9. Notari: Biopharmaceutics & Clinical Pharmacokinetics (an introduction), 4th ed. (Revised & Expanded), Marcel Dekker, 1987.
10. Rowland & Tozer : Clinical Pharmacokinetics (Concepts & Applications), 3rd ed., Lea & Febiger – Waverly, 1995.
11. Macheras et al: Biopharmaceutics of Orally Administered Drug, Ellis Horwood (series in Pharmaceutical Technology), 1995.
12. Welling & Tse: Pharmacokinetics (Regulatory, Industrial, Academic Perspectives), 2nd ed., Marcel Dekker (series in Drugs & Pharmaceutical Sciences-vol. 67), 1995.
13. Shargel & Yu: Applied Biopharmaceutics & Pharmacokinetics, 4th ed., Appleton & Lange, 1999.
14. Ratkowsky et al. : "Cross-Over Experiments: Design, Analysis & Applications," Marcel Dekker (series in Statistics: Textbooks and Monograph- Vol. 135)

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
3. Principles Involved in the Development of Intra-Muscular- and Implantable-Sustained-Release Therapeutic systems.

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

1. Robinson & Lee, Eds: Controlled Drug Delivery (Fundamentals & Applications), 2nd ed. (Revised & Expanded), Marcel Dekker (series in Drugs & Pharmaceutical Sciences- Vol. 29), 1987.
2. Chien: Novel Drug Delivery Systems (Fundamentals, Developmental Concepts & Biomedical Assessments), Marcel Dekker (series in Drug & Pharmaceutical Sciences- Vol. 14), 1982.
3. Benita, Ed.: Microencapsulation (Methods & Industrial Applications), Marcel Dekker (series in Drugs & Pharmaceutical Sciences- Vol. 73), 1996.
4. Rolland, Ed: Pharmaceutical Particulate Carriers (Therapeutic Applications), Marcel Dekker (series in Drugs & Pharmaceutical Sciences- Vol. 61), 1993.
5. Cohen & Bernstein, Eds. : Microparticulate Delivery Systems for the Delivery of Proteins & Vaccines, Marcel Dekker (series in Drugs & Pharmaceutical Sciences- Vol. 77), 1996.
6. Betagiri, Jenkins & Parsons : Liposomes Drug Delivery Systems, Technomatic, 1993.
7. McCulloch & Shalaby, Eds: Tailored Polymeric Materials for Controlled Delivery Systems, ACS Symposium Series 709 (American Chemical Society), 1998.
8. Gebelein & Carraher, Jr. : Polymeric Materials in Medication, Plenum Press (series in Polymer Science & Technology- Vol. 32), 1985.
9. McGinity, Ed.: Aqueous Polymeric Coatings for Pharmaceutical Dosage Forms, Marcel Dekker (series in Drugs & Pharmaceutical Sciences- Vol. 36), 1989.
10. Jain, Ed. : Advances in Controlled and Novel Drug Delivery, CBS Publishers, 1999.
11. Wise, Ed.: Biopolymeric Controlled Release Systems, Vol. 1, CRC Presss, 1984.

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
6. Intravaginal –, Intrauterine-, and Intraurethral- Drug Delivery Devices.
7. Dental Drug Delivery System

BOOKS RECOMMENDED

1. Banker and Rhodes, Eds.: "Modern Pharmaceutics," 3rd ed.(Revised & Expanded), Marcel Dekker {series in Drugs and Pharmaceutical Sciences –Vol. 72), 1996.
2. Ansel et al.: "Pharmaceutical Dosage Forms and Drug Delivery System", 7th ed. (International Student Edition, Indian Reprint), Lippincott Williams & Wilkins, 2000.
3. Gebelein & Carraher, Jr., Eds.: "Polymeric Materials in Medication," Plenum Press (Polymer Sci. & Biotechnology- Vol. 32), 1985.
4. McGinity, Ed.: "Aqueous Polymoric Coating for Pharmaceutical Dosage Forms", Marcel Dekker (series in Drugs and Pharmaceutical Sciences –Vol.36), 1989.
5. Chien : "Novel Drug Delivery System (Fundamentals, Developmental Concepts & Biomedical Assessments)," Marcel Dekker (series in Drugs and Pharmaceutical Sciences -Vol. 14), 1982.
6. Robinson and Lee, Eds., "Controlled Drug Delivery: Fundamentals & Applications," 2nd ed. (Revised & Expanded), Marcel Dekker (series in Drugs and Pharmaceutical Sciences –Vol. 29), 1987.
7. Jain, Ed.: "Advances in Controlled & Novel Drug Delivery," CBS Publishers & Distributors, 2000.
8. Potts and Guy, Eds.: "Mechanisms of Transdermal Drug Delivery," Marcel Dekker (series in Drugs and Pharmaceutical Sciences -Vol. 83), 1997.

MPSE101: FERMENTATION TECHNOLOGY AND BIOINFORMATICS

(3 CREDITS)

I. A. Design of Fermentor and Fermentation Technology

Requirement of an ideal Fermetor, 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 B_{12}, 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.
a. Principles of Fermentation Technology by Stanbury, whittaker & Hall, Permagon Press.
b. Fundamental of Biochemical Engg. Bailey & Ollis.
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.
j. Bioinformatics : A Practical Guide to analysis of Genes and Proteins by A.D. Baxevanis, B.F.F. Oulette Editors.

MPS2141: CLINICAL RESEARCH – ETHICS & DESIGN (3 CREDITS)

1. Clinical Research – Introduction, History, Present & Future Scenario 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
5. Regulations – Schedule Y, 21CFR part 11, 50, 54, 56, 310, 312, Drug Registration: Introduction, U.S regulation, Japan regulation, U.K regulation, Indian regulation, Ethnic Insures in drug Registration. 4h
6. Study Participants – Sponsor, Investigator, Volunteer, Contract Research Organization, Data Safety & Monitoring Board 3h
7. Ethics – Principles & Practices --- History, Ethical Principles, Clinical Trial Regulations, Declaration of Helsinki, Ethics Committee, Informed Consent, Investigator's Responsibilities, Vulnerable populations 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
15. Study Report – Interpretation, Report & Retention of data/report 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.
2. Clinical Pharmacotherapeutics- edited by Kamalesh Kholi. Elsevier Publication.
3. Statistical Methods for Clinical Trials, by Mark X Norleans, Marcel and Dekker, Inc, New York, 2001.

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

- Contracting out pharmacovigilance 3h
- 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

1. Pharmacovigilance (2nd Edition) – Ronald D. Mann & Elizabeth B. Andrews, John Wiley & Sons
2. Pharmacovigilance from A to Z - Barton L. Cobert & Pierre Biron, Blackwell Science
3. Good Pharmacovigilance Practice – MHRA
4. Manual of Drug Safety and Pharmacovigilance – Barton L. Cobert, Jones & Bartlett Publishers
5. Dictionary of Pharmacovigilance – Amer Alghabban, Pahrmaceutical Press
6. An Introduction to Pharmacovigilance – Waller, Patrick; John Wiley & Sons
7. Pharmacovigilance (2nd Edition) – Ronald D. Mann & Elizabeth B. Andrews, John Wiley & Sons
8. Pharmacovigilance from A to Z - Barton L. Cobert & Pierre Biron, Blackwell Science
9. Good Pharmacovigilance Practice – MHRA
10. Manual of Drug Safety and Pharmacovigilance – Barton L. Cobert, Jones & Bartlett Publishers
11. Dictionary of Pharmacovigilance – Amer Alghabban, Pahrmaceutical Press
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**

MMA1101: BIOSTATISTICS (3 Credits)

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

2. **Sampling Methods** 4h
   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** 6h
   Statistical estimation – point and confidence interval estimations, Introduction of statistical hypothesis and testing, comparison of population mean with sample means, comparing two sample mans, 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** 6h
   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** 4h
   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**: 4h
   '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**: 2h
   Chi square test- Testing of goodness of fit, testing of independence, Test of homogeneity; Wilcoxon signed rank test; McNemar test

9. **Computer Applications & Practicals:** 2h
   Introduction of statistical software – SPSS with practical exercises

BOOKS RECOMMENDED:

1. Statistical issues in Drug Development by Stephen Senn, 1997, published by John Wiley and Sons Inc.
2. Practical and Clinical Applications 3rd Edn. Sandord Bolton, 1997 Marcel Dekkar Inc, Newyork.
3. Non parametric statistics for Behavioral Sciences by Sidney Siegel; 1956, McGraw Hills, New Delhi.
4. Design and Analysis of Bioavailability and Bioequivalence Studies – 2nd Edn. By Shein-Chung Chow and Jen-Pei Liu, 2000, Marcel Dekkar Inc, Newyork.
5. Computer Applications and Practicals: Introduction of softwares – SPSS/SAS and practical exercises.

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.
   c. Immunoassay Methods Evaluation: Protocol outline, objective & preparation, evaluation of precision, standard tracer, sensitivity, evaluation of accuracy, antibody characteristics, monitoring, reaction conditions, clinical evaluation.

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 2h

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. 7h

BOOKS RECOMMENDED :

1. Biological standardization by J.H. Burn, D.J. Finney & L.G. Goodwin.
2. I.P. & B.P.
3. Screening Methods in Pharmacology by R.A. Turner. Vol. I & II Academic Press, New York and London.
4. Evaluation of drug activities by Laurence & Bacherce.
5. Methods in Pharmacology by Arnold Schwartz.
6. Selected topics on Experiment Pharmacology by Issha G. Kamat, Dadkar, N.K. & Seth, UK.
7. Fundamental of Experimental Pharmacology, by M..N. Ghosh. Scientific Book Agency, Calcutta.
8. Pharmacological Experiment on intact preparation by Churchill Livingstone
9. Drug Discovery and evaluation by H.G. Vogel & W.H. Vogel. Springer Verlag, Berlin Heideleberg.
10. Animal Model in Toxicology by Shayne Cox Gad & Christopher P, Chengelis.
11. Principles & Methods of Toxicology by Hays.
12. CRC Handbook of Toxicology by Derelako & Hollinger.
13. Handbook of Experimental Pharmacology by S.S. Kulkarni. Vallabh Prakashen, Delhi.
14. Pharmacological Experiments on Intact and Isolated preparations, Edinburgh University Pharmacology Staff, Livingstone.
15. Goodman and Gilman's The Pharmacological basis of Therapeutics – Ninth edition, Editors. A. G. Gilman, J. G. Hardman, L. E. Limbiod, P. B. Melineff, R. W. Rudder, Macmillan Publishing Co. Inc. – Latest edition.
16. Clinical Pharmacotherapecutics, edited by Kamalesh Kohli, Elsevier Publication.