STRUCTURE FOR THEORY & PRACTICAL PAPERS
WITH CONTACT HOURS PER WEEK AND CREDIT POINTS FOR
MASTER DEGREE IN PHARMACEUTICAL TEHCOLOGY (M. PHARMA) IN PHARMACEUTICS

SEMESTER-I

A. THEORY							
SL. NO.	**CODE**	**THEORY**	**CONTACTS (PERIODS/WEEK)**				**CREDITS**
			L	**T**	**P**	**TOTAL**	
01	MPT-106	Dosage form design parameters & pharmaceutical product development	**4**				3
02	MBS-101	Bio-Statistics (Common paper)	**4**				2
03	MPT-101	Modern Pharmaceutical Analytical Techniques (Common paper)	**4**				3
04	MPT-116	Bio-pahramceutics & pharmacokinetics	**3**				2
Sessional							
05	MPT-181	Seminar					1
06	MPT-196	Pharmaceutical Technology Lab.			**4**		3
	MPT-191	Pharmaceutical Analysis Lab.			**4**		3
							17

FULL MARKS FOR PAPER WITH 2 / 3 CREDIT POINT = 100

FULL MARKS FOR PAPER WITH 1 CREDIT POINT = 50

FULL MARKS FOR PAPER WITH 5 CREDIT POINT = 200

FULL MARKS FOR PAPER WITH 9 CREDIT POINT = 300

SEMISTER-II

A. THEORY							
SL. NO.	**CODE**	**THEORY**	**CONTACTS (PERIODS/WEEK)**				**CREDITS**
			L	**T**	**P**	**TOTAL**	
01	MPT-206(1)	Drug Delivery System	**3**				2
02	MPT-209	Pharmaceutical Bio-technology	**4**				3
03	MPT-212	Process validation & CGMP (Common paper)	**4**				3
04	MPT-206(2)	Physical Pharmaceutics	**2**				1
Sessional							
05	MPT-281	Seminar					1
06	MPT-296	Bio-pharmaceutics Lab.			**4**		2
							13

SEMISTER-III

A. THEORY							
SL. NO.	**CODE**	**THEORY**	**CONTACTS (PERIODS/WEEK)**				**CREDITS**
			L	**T**	**P**	**TOTAL**	
01	MPT-314	Research Method & Clinical Trials	**3**				2
02	MPT-391	Synopsis					5
03	MPT-392	Presentation					3
							10

SEMISTER-IV

A. THEORY							
SL. NO.	**CODE**	**THEORY**	**CONTACTS (PERIODS/WEEK)**				**CREDITS**
			L	**T**	**P**	**TOTAL**	
01	MPT-496	Thesis					9
02	MPT-496(1)	Defence of Thesis					3
							12

The Synopsis and presentation of 1st semester and Thesis and Defence of Thesis in 4th Semester should be assessed in presence of External Examiner(s). The Final Credit should be awarded to the student of the above mentioned subjects by both the internal and external examiners.

SYLLABUS FOR M. PHARM IN PHARMACEUTICS

SEMESTER-I

DOSAGE FORM DESIGN PARAMETERS & DEVELOPMENT OF PHARMACEUTICAL PRODUCT

Code : MPT-106
Contact : 4L
Credits: 3
Full marks : 100

A] 1. Physicochemical aspects

a) pKa
b) Partition Coefficient
c) Solubility
d) Solid state characterization and physical behaviour of drugs
e) Reaction kinetics and mechanisms

2. Biological aspects

a) Role of physicochemical parameters on drug absorption and their implications.
b) Routes of administrations and implication on bio-availability.
c) Physicochemical aspects of drugs and first pass metabolism.

B] 1. Pre-formulation studies :

Preformulation testing, preformulation trials, in-vitro and in-vivo trials, preformulation worksheet

2. Stages in product development and evaluation, product development functions, Data required for product development, formulation factors.
3. Pilot Plant Scale up. Importance and technique involved.

Bio-Statistics

Code : MBS-101
Contact : 4L
Credits: 2
Full marks : 100

1. ***An introduction to statistics and bio-statistics collection and organisation of data:*** Graphical and pictorial presentation of data, measures of central tendency and dispersion, sampling techniques, sample size, coefficient of variation, mean error, relative error, precision and accuracy.

2. ***Probability:*** Definition and probability distributions, normal, binominal and polynominal distributions, continuous data distribution, fiducial limits, pobit and logit analysis.

3. ***Regression***: Linear regression and correlation, curvilinear regression method of least squares, curve fitting, multiple regression and correlation, significance of correlation and regression.

4. ***Parametric tests*** **:** Testing hypothesis, types of errors, tests of significance based on normal distribution, test of significance for correlation coefficients.

5. ***Non-parametric tests*** **:** Data characteristics and non-parametric procedures, chi-square test, sign test, Wilcoxon sign rank test, goodness of fit Mann-Whitney etc.

6. ***Experimental design:*** Randomization in completely randomized and latin square designs, factorial design, cross over and parallel design, bio-availability and bio-equivalence.

7. ***Techniques:*** Bioassay dose effect, relationships, LD_{50}, ED_{50}, probability calculations, Statistical quality control, shewhart control charts, statistical procedures in assay development.

MODERN PHARMACEUTICAL ANALYTICAL TECHNIQUES

Code : MPT-101
Contact : 4L
Credits: 3
Full marks : 100

1. Principles of separation and applications of TLC. Column chromatography. Paper chromatography, Ion exchange chromatography, Counter current chromatography, G.C., DCCC, HPTLC & HPLC and electrophoresis.

2. Infrared spectroscopy

Introduction: The IR absorption process; the modes of vibration bond properties and absorption trends. The Hook's Law & calculations of frequencies for different types of bonds; coupled interactions; hydrogen bonding; radiation source, sample handling, qualitative and quantitative applications and introduction about FT-IR

3. Ultraviolet spectroscopy :

Introduction: The nature of electronic excitation, the origin of UV band structure; principle of absorption spectroscopy; Beer and Lambert's Law, Chromophore s ® s*, h®s*,p® p*, h® p*, transitions; shifts reagents effects of substituents; effect of conjugation' confirmations and geometry; calculation of Lamda maxima, effect of solvents, qualitative and quantitative applications

4. Nuclear Magnetic Resonance spectroscopy :

A. 1H NMR Spectroscopy: Principle, Instrumentation techniques. Chemical equivalence, spin-spin coupling, The origin of spin-spin splitting, Pascal triangle, the coupling constant chemical shift reagents Pharm. application including interpretation of Proton-NMR spectra.

B. 13C NMR Spectroscopy: Peak assignments, off resonance decoupling, selective proton decoupling, chemical shift equivalence, chemical shifts and spin coupling.

5. Mass Spectrometry:

Basic principle and theory involved, Instrumentation, types of ions, fragmentation, rearrangements; mass spectra of representative compounds, recognition of molecular ion peak, chemical ionization mass spectrometry, field desorption mass spectrometry, mass spectrometry, fast atom bombardment mass spectrometry.

6. Thermal analysis:

Introduction to various thermal methods of analysis, basic principle and theory; differential thermal analysis and differential scanning calorimetry and micro calorimetry. Different types of calorimeters and micro calorimeters.

7. Pharmacological evaluation of drugs in biological fluids: Bioassay.
8. Microbiological assays.

9. Radioimmunoassays.

10. Quantitative microscopy of herbal drugs. Lycopodium spore method, stomatal number, stomatal index, palisade ratio, vein-islet number, and vein-termination number.

Bio-pharmaceutics & Pharmacokinetics

Code : MPT-116
Contact : 3L

Credits: 2

Full marks : 100

1. Introduction, concentration time profile, plotting the data, different fluid compartments and blood flow rates compartment models.

2. Protein and tissues binding, factors effecting protein binding kinetics of protein binding, determination of rate constants and different plots (direct, scatchard and reciprocal), significance volume of distribution, implications and in vitro methodologies.

3. *Pharmacokinetic characterization of drugs :* Absorption rate constants (Wagner-Nelson, Loo-Reigeiman methods) Limitations, lag-time, pharmacokinetics in presence of lag-time, Flip-flop model.

4. Drug disposition, renal clearance, mechanism of clearance, clearance ratio, determination of clearance, hepatic clearance, % drug metabolized, relationship between blood flow, intrinsic clearance, hepatic clearance and protein binding, different volumes of distribution, significance and integration kinetics.

5. Pharmacokinetics of multiple dosing, dosage regimen design based on mean average, minimum and maximum, plasma serum concentrations, limited fluctuation methods, Repeated one point method, Dosage adjustment in disease patients.

6. Nonlinear pharmacokinetics, direct, linear and orbit graph methods of dosing. Non-linear pharmacokinetics due to drug-protein binding.

7. Bio-availability and variations in blood leveis, disease states on bio-availability, bio-availability and biologic response, pharmacodynamic models.
8. In-vitro and in-vivo co-relations.
9. Animal models, Factors influencing the bio-availability of disposition of drugs and application of this information to optimize the therapy.
10. BA/BE, absorption in drug development

<u>Books Recommended</u> :

1. Milo Gibaldi and Donald Perrier, “Pharmacokinetics”, Drugs and Pharm. Sci. Series, Vol. 15, Marcel Dekker Inc., N.Y.
2. J.C.Wagner, “Fundamentals of Clinical Pharmacokinetics”, Drug Intelligence Publications, Hamilton, 1975.
3. Bert N. LaDu, “Fundamentals of Drug Metabolism & Disposition”, Waverley Press Inc., Baltimore, 1972.
4. T.Z.Lsaky, “Intestinal Absorption & Malabsorption”, Raven Press, N.Y., 1975.
5. J.T.Carstensen, “Theory of Pharm.Systems”, Vols. 1-3, Academic Press, N.Y.
6. H.S. Beans, A.H.Beckett and J.E.Caraless, “Advances in Pharm.Sci.”,Vol.1 to 4

7. J.T.Carstensen, “Drug Stability : Principles and Practices”, Drugs and Pharm. Sci. Series, Vol. 43, Marcel Dekker Inc., N.Y.

Pharmaceutical Technology Lab : (4 hr. per week)

Code : MPT-196
Contact : 3L

Credits: 2

Full marks : 100

1. Experiment based on pre-formulation studies of dosage form.
2. Preparation and evaluation of sustained release dosage form, transdermal drug delivery system, micro-capsules, micro-emulsions, solid dispersion of drug in polymer and ocular dosage form.
3. Dissolution studies of different dosage forms and in-vivo and in-vitro co-relation studies.

Pharmaceutical Analysis Lab. (4 hr per week)

Code : MPT-191
Contact : 3L

Credits: 2

Full marks : 100

1. Practical based on instrumental methods of analysis. A sufficient training will be given through exercises using different kinds of spectral analysis.
2. Microbial analysis of Vitamins and Anti-biotics
3. Pharmacological Bioassay of some drugs.

SEMESTER-II

Drug delivery System

Code : MPT-206(1)
Contact : 3L

Credits: 2

Full marks : 100

1. Biopharmaceutic and pharmacokinetic aspects of PO CRDDS. Computation of desired release rate and dose for CR, release DDS. Pharmacokinetic design for DDS, Intermittent zero order and first order rlease.
2. Mathematical models for novel drug delivery systems: Membrane diffusion, diffusion controlled, biodegradable, osmotic pumps.
3. Peroral controlled-release delivery: Case studies.
4. Transdermal / Skin drug delivery systems: Principles of skin permeation, sorption promoters, pharmacokinetics of skin permeation, development and evaluation of transdermal devices.
5. Transdermal controlled: Release delivery, case studies (both iontophoresis and passive diffusion and combination approaches)
6. Parenteral drug delivery: Selection, design and development, polymer microspheres and dispersed DDS.
7. Strategies and design, in-vitro / in-vivo considerations, factor effecting controlled release drug delivery systems.
8. Protein/peptide drug delivery systems, enzyme, epithelial/endothelial barriers, pharmacokinetics, different routes of delivery, practical considerations.
9. Drug targeting: Microspheres, nanoparticles, brain specific delivery, liposomes, monoclonal antibodies.
10. Localized drug delivery systems case studies.
11. Drug delivery strategies: Case studies, drug delivery systems and drug development.
12. Flow sheet diagram for the manufacturing of infusion fluids as per recent GMP guidelines.

Books Recommended :

1. Joseph R. Robinson, "Sustained and Controlled Release Drug Delivery Systems", Drugs & Pharm. Sci. Series, Vol. 6, Marcel Dekker Inc., N.Y.
2. Yie W. Chien, "Novel Drug Delivery Systems", Drugs and Pharm. Sci. Series, Vol. 14, Marcel Dekker Inc., N.Y.
3. J.N.Nixon, "Microencapsulation",Drugs and Pharm. Sci. Series, Vol. 3, Marcel Dekker Inc., N.Y.
4. G. Jolles and R.H.Wooldridge, "Drug Design - Faact or Fantasy?" Academic Press, 1984.
5. J.R.Robinson and Vincent H.L. Lee, "Controlled Drug Delivery", Drugs and Pharm. Sci. Series, Vol.29, Marcel Dekker Inc., N.Y.
6. R.L.Juliano, "Drug Delivery Systems", Oxford University Press, Oxford, 1980.
7. M.I.Gutcho, Microcapsules and Microencapsulation Techniques, Noyes Data Corporation, 1976.
8. E.B.Roche, "Design of Biopharmaceutical Properties through prodrug and analogs", Am. Pharm. Assoc. Academy of Pharm. Sci., 1977.
9. Lisbeth, Illum & Stanley S. Davis : "Polymers in Controlled Drug Delivery", Wright, Bristol (1987).

Pharmaceutical Bio-technology

Code : MPT-209
Contact : 4L

Credits: 3

Full marks : 100

1. Systems and methods of molecular biology: Introduction to genetic engineering and biotechnology, genes and gene expression, bacteria, bacteriophage, yeasts, animal cells, use of mutants, genetic analysis of mutants, genetic recombination, complementation.
2. Gene cloning: Nucleic acid isolation cloning vectors (some examples), enzymes used in molecular cloning, cloning methods (some examples)
3. Gene expression: Gene expression, some examples in E. coli in baculovirus in mammalian cells.
4. Fermentation technology: Design, operation and characteristics of fermentation processes, cell growth and production regulation, product biosynthesis and accumulation, instrumentation and bio-process control.
5. Industrial enzymes in drug development: Penicillin amidase, carbohydrase enzymes, chymosin from calf stomach, future directions.
6. Antibiotic biosynthesis genes and their use in developing new antibiotic from micro organisms. Methods for isolating new antibiotics, genetic systems and molecular tools for analysis of antibiotic, bio-synthesis, cloning and analysis of antibiotic biosynthesis genes, genetically engineered hybrid antibiotics.
7. Second generation molecules via site-specific gene alteration, second generation protein program design, examples of engineered proteins of therapeutic potential, methods of protein drug delivery future perspective.
8. Prospects in gene therapy, Potential approach to gene therapy, somatic cell gene transfer, prospects and limitations.
9. Biotechnology in pharmaceutical industry: Major areas for biotechnology in the pharmaceutical industry such as antibiotics, sexual re-combination, recombinant DNA technology, monoclonal antibody, regulatory proteins (human insulin, interferon, therapeutic peptides) commercial aspects, priorities for future biotechnological research.
10. Sterilization and sterility testing : principle, validation of different sterilization processes, methods, industrial sterilizer, air handling unit and sterility testing of different types of dosage form.

Books Recommended :

1. J.D.Watson, "Molecular Biology of the cell".
2. J.D.Watson and Tooze, "Recombinant DNA techniques" : A short course.
3. Benjamin Levin, "Genes V".
4. Peppler, "Microbial Technology" I & II.
5. Old & Primrose, "Genetic Manipulations"
6. I.P. 1996, Vol.-I & II

PROCESS VALIDATION AND CGMP

Code : MPT-212
Contact : 4L

Credits: 3

Full marks : 100

1. Basic concepts of quality assurance, Requirements of CGMP/GLP, ISO 9000 series, Quality audits etc.
2. Precision, accuracy and biases, sampling and operating characteristic curves, sampling plans, statistical inference in estimation of hypothesis testing, statistical procedure in assay development.
3. Development of new analytical method and its validation.
4. In-process quality control tests for various dosage forms including packaging and labeling operations.
5. Brief introduction to general requirements of health regulatory agencies such as US FDA, WHO etc. Preparation of documents for new drug application and export registration.
6. History and various phases of drug development and drug approval, Investigational New drug (IND), New Drug Application (NDA) (Phase I-IV): content and format, Abbreviated new drug application (ANDA), Content, development flow sheet and format, exclusivity, concept of paragraph I to IV, Clinical study and basic concepts of Good clinical practice.
7. Concepts in validation, validation of manufacturing and analytical equipment. Process validation in production of pharmaceuticals. Electronic records (21CFR11)
8. Introduction to orange book, freedom of information (FOI), inactive ingredient guide (IIG), Drug master file (DMF), open part of DMF, codes of therapeutic equivalency, CDER, CBER

Books Recommended:

1. S. H. Willig, M.M.Tuckeman and W.S.Hitchings, "Good Manufacturing Practices for Pharmaceuticals", Drugs and Pharm. Sci. Series, Vol. 16, Marcel Dekker Inc., N.Y.
2. B.T.Loftus & R.A.Nash, "Pharmaceutical Process Validation", Drugs and Pharm Sci. Series, Vol. 23, Maarcel Dekker Inc., N.Y.
3. S. Bolton, "Pharmaceutical Statistics : Practical & Clinical Applications", Drugs and Pharm. Sci. Series, Vol. 25, Marcel Dekker Inc., N.Y.
4. G.S, Banker & C.T.Rhodes, "Modern Pharmaceutics", Drugs and Pharm. Sci. Series, Vol. 7, Maracel Dekker Inc., N.Y.

PHYSICAL PHARAMCEUTICS

Code : MPT-206(2)
Contact : 2L

Credits: 1

Full marks : 50

1. SOLIDS

Particle characterization by size, shape and surface of individual particle and for contacted particle. Handling of solids, pharmaceutical granulation, compression and compaction properties of binary mixtures, lubricant sensitivity, characterization of granules and compacts, physics of tablet compression, Heckel plot, direct compression, advanced tablet coating techniques

2. DISSOLUTION:

Theory of dissolution, concept of drug release, Dissolution test apparatus: different designs, factors affecting dissolution rate. Dissolution of different dosage forms: solids, suspensions, topicals, suppositories and controlled release systems.

3. SURFACTANT SYSTEM

Phase behaviour of surfactant in binary and ternary systems. Factors affecting phase behaviour, Micellization; micelle structure, shape, size factors affecting CMC and miclle size, thermodynamics and kinetics of micelle formation. Pharmaceutical aspects of solubilization, solubilization in non-aqueous system, interactions with polymers and oppositely charged species. Hydrotrophy in pharmaceuticals, surfactants in emulsions and suspensions. Biological implications of surfactants; effect on: dissolution of drugs, permeability of membranes, drug absorption, antibacterial activity.

4. Drug delivery gels, synthetic hydrogels-their preparation. Diffusion properties of swollen hydrogels, methods of modifying release kinetics.

Bio-pharmaceutics Lab :

Code : MPT-296

Credits: 2

Full marks : 100

Contact hour : 60 hr per semester

Experiment based on bio-availability studies of different drug formulations.

SEMESTER - III

Research Methodology and Clinical Trials

Code : MPT-314

Credits: 2

Full marks :

Contact hour : 3 hr per week

Information technology: subject classification and cataloguing, literature searches, data bases electronic and libraries, referencing and bibliographies, electronic communications.

- Good clinical practice.
- Good Laboratory Practice
- Ethics including consent and insurance
- Adverse drug reaction surveillance
- Randomization
- Clinical trial design
- Data management/statistics
- Protocol preparation
- Case record forms
- Evaluation of Reports and Report Writing
- International guidelines for Clinical Research
- Use of unregistered medicines for Research

INSTRUCTIONS

1. Each Semester will consist of a minimum of 15 weeks instructions :
2. Internal assessment of Theoreticals (30%) will be based on two class tests of 10 marks in each of the theory subject during each semester and 10 marks for class attendance of student in each subject.
3. Internal assessment of practicals (30%) will be based on day to day attendance, viva, laboratory record etc. There will be no separate class test in practicals. The question papers of university examinations shall be set by both the internal and external examiners. The choice in question papers shall be restricted to 25% only. Complete coverage of prescribed syllabus in university question papers is desired.
4. A minimum of 75% attendance in theory and practical classes is compulsory.
5. A student has to get minimum 45% mark in theory and 50% marks in practical separately to pass the subject.
6. Pass mark in aggregate will be 50% of the total marks.
7. A student will secure 1st class if he/she obtains 60% of total marks and 1st class with honours, if he/she obtains 75% of the total marks.
8. A student will be promoted to next higher semester with a maximum of two back papers (including practical).
9. A student will get a maximum of 4 yrs. time from the date of admission to complete the degree course.

PRECIES OF TOTAL GRADES IN M. PHARMACY PROGRAMME
(PHARMACEUTICS, PHARMACEUTICAL CHEMISTRY & PHARMACOLOGY)

SEMESTER	MINIMUM	MAXIMUM
SEM I		17
SEM II		13
SEM III		10
SEM IV		12
TOTAL CREDIT		**52**

NOTE: THE ENTIRE COURSE HAS BEEN DESIGNED ON THE BASIS OF AICTE & JADAVPUR UNIVERSITY, BIT, MESRA & PILANI COURSE STRUCTURE. THIS IS TO BE CONSIDERED AT THE TIME OF FINALISATION OF THE CURRICULUM.