KRISHNA UNIVERSITY
Course Structure and Syllabus for M. PHARMACY-Pharmaceutics

1	Title of the Course	**M.PHARMACY**
2	Duration of the course	Two years (four semesters)
3	Eligibility criteria for admission	The candidate seeking admission in to M. Pharmacy course should have passed B.Pharmacy degree of any recognised university.
4	In take	18 Seats
5	Mode of Admission	The admission will be through common entrance examination.
6	Objectives of the course	The objective is to train a candidate so as to ensure higher competence in both general and special area of interest and prepare him/her for a career in teaching, research and specialty practice. A candidate must achieve a high degree of professional proficiency in the subject matter and develop competence in research and its methodology as related to the field concerned.
7	Course Requirement	The course shall include Theory, Practicals, Tests, Seminars, Assignments and project work.
8	Course structure and Scheme of Examination	The course will be conducted on credit system and evaluation will be on seven point grading system.
9	Credit System	In this system credits will be allotted to each paper. Each theory paper will be given credits on the basis of number of teaching hours shown against each paper in the following table. One hour of teaching of theory paper in a week will be given one credit. Each practical will be given credits on the basis of number of practical hours shown against each practical in the following table. Two hours of practical paper in a week will be given one credit.
10	Gradation System	The course will be evaluated and the students will be graded on ten point scale with seven letter grades i.e., **O, A, B,C,D,E,F.**
11	Number of working days	In each semester at least ninety working days (15 weeks of six working days) must be dedicated for theory classes, practical classes and seminars.
12	Attendance	The regulations regarding the attendance, condonation will be as per the general regulations adopted by the university.
13	Paper setting and Evaluation Procedures	The regulations regarding the paper setting and evaluation procedures will be as per the general regulations adopted by the university.

15	Seminars and Assignments	**a)** The candidate should deliver two seminars in the First semester and One in the Second semester on the topics allotted. Each seminar shall be evaluated by three teachers of the concerned subject. **b)** At the end of the Second semester each candidate should face the comprehensive viva-voce examination evaluated by an external examiner along with two internal examiners. **c)** The candidate should do two assignments in First semester and one assignment in Second semesters on the topics allotted. Each of the assignment shall be evaluated by two teachers of the concerned subject and average of two shall be the marks secured by the candidate.
16	Submission of Dissertation	**a)** Every candidate shall submit five copies of the dissertation including synopsis at the end of 4^{th} semester. **b)** The dissertation submitted by the candidate shall be evaluated by an External Examiner and the vive-voce examination shall be conducted jointly by the Supervisor, who guided the work and the External Examiner.

SEMESTER-I

Theory

S. No	Subject Code	Name of the Subject	Internal Marks	External Marks	Total Marks	No. of Hours/ week	No. of Credits / week
1.	MPPC 101	Chromatographic Methods of Analysis	30	70	100	6	6
2.	MPPC 102	Advanced Physical Pharmaceutics	30	70	100	6	6
3.	MPPC 103	Intellectual Property Rights & Regulatory Guidelines	30	70	100	6	6
4.	MPPC 104	Preformulation Studies In Product Development	30	70	100	6	6

Practical

1.	MPPC 105	Chromatographic Methods of Analysis	30	70	100	6	6
2.	MPPC 106	Preformulation Studies In Product Development	30	70	100	6	6
3.	MPPC 107	Seminar	50	-	50	3	3
4.	MPPC 108	Assignments	50	-	50	3	3
Total						**42**	**42**

SEMESTER-II

Theory

S. No	Subject Code	Name of the Subject	Internal Marks	External Marks	Total Marks	No. of Hours / week	No. of Credits / week
1.	MPPC 201	Advances In Drug Delivery Systems -I	30	70	100	6	6
2.	MPPC202	Advanced Bio-Pharmaceutics	30	70	100	6	6
3.	MPPC 203	Advanced Pharmacokinetics	30	70	100	6	6
4.	MPPC 204	Advances In Drug Delivery Systems -II	30	70	100	6	6

Practical

1.	MPPC 205	Advances In Drug Delivery Systems -I	30	70	100	6	6
2.	MPPC 206	Advanced Bio-Pharmaceutics	30	70	100	6	6
3.	MPPC 207	Seminar	50	-	50	3	3
4.	MPPC 208	Assignments	50	-	50	3	3
Total						**42**	**42**

SEMESTER-III

S. No	Subject Code	Name of the Subject	Internal Marks	External Marks	Total Marks	No. of Hours/ week	No. of Credits / week
1.	MPPC 301	Dissertation Work					
		a)Seminar-I (literature survey-library)			50	36	36
		b) Seminar-II			50		
		Total				36	36

SEMESTER-IV
Project Work

S. No	Subject Code	Name of the Subject	Internal Marks	External Marks	Total Marks	No. of Hours/ week	No. of Credits / week
1.	MPPC 401	Evaluation of Dissertation Work		150	150	36	36
2.	MPPC 402	Viva-Voce	50		50		
		Total				36	36

TOTAL NUMBER OF CREDITS AT THE END OF COURSE: -----

S.No	SEMESTER	CREDITS
1	1ST SEMESTER	42
2	2ND SEMESTER	42
3	3RD SEMESTER	36
4	4TH SEMESTER	36
	TOTAL	**156**

PROCEDURE TO EVALUATE INTERNAL ASSESSMENT

THEORY

Internal Assessment	15 Marks
Assignment	5 Marks
Seminars	5 Marks
Attendance	5 Marks
Total	**30 Marks**

PRACTICAL (LAB)

Continuous Assessment at the end of each credit			Internal Assessment (consolidation of credits, 2 Exams, mid & Final)	Attendance	Total
Performance	Viva	Record			
10 marks	3 marks	2 marks	10 marks	5 marks	30 marks

* If a student is absent for any experiment, he has to complete it before coming to the next lab class to get the marks.

* Final External lab examiner may give any experiment, in form confined to the syllabus and need not be from the list of experiments.

GRADATION SYSTEM:

Grade points are allotted based on percentage of marks as shown in the table

S.No.	Range of Marks	Grade	Grade Points
1	>85%	O	10.0
2	75% - 85%	A	9.0
3	67% - 74%	B	8.0
4	58% - 66%	C	7.0
5	50% - 57%	D	6.0
6	40% - 49%	E	5.0
7	< 39%	F	0.0

1. Calculation of SGPA (Semester Grade point Average)

   For example if a student gets the grades in one semester A,A,B,B,B,D in six subjects having credits 2(S1) 4(S2) , 4(S3), 4(S4), 4(S5), 2(S6), respectively.
   The SGPA is calculated as follows:

$$\{9(A) \times 2\,(S1) + 9\,(A) \times 4\,(S2) + 8(B) \times 4(S3) + 8(B) \times 4(S4) + 8(B) \times 4(S5) + 6(D) \times 2(S6)\}$$

$$SGPA = \frac{\{2(S1) + 4(S2) + 4(S3) + 4(S4) + 4(S5) + 2(S6)\}}{}$$

$$= \frac{162}{20} = 8.10$$

A student securing 'F' grade there by securing 0.0 grade points has to appear and secure at least 'E' grade at the subsequent examination(s) in that subject.
If a student gets the grades in another semester D,A,B,C,A,E,A in seven subjects having credits 4(S1), 2(S2), 4(S3), 2(S4), 4(S5), 4(S6), 2(S7) respectively.

$$SGPA = \frac{\{6(D) \times 4(S1) + 9(A) \times 2(S2) + 8(B) \times 4(S3) + 7(C) \times 2(S4) + 9(A) \times 4(S5) + 5(E) \times 4(S6) + 9(A) \times 2(S7)\}}{\{4(S1) + 2(S2) + 4(S3) + 2(S4) + 4(S5) + 4(S6) + 2(S7)\}}$$

$$= \frac{162}{22} = 7.36$$

$$CGPA = \frac{(9x2 + 9x4 + 8x4 + 8x4 + 8x4 + 6x2 + 6x4 + 9x2 + 8x4 + 7x2 + 9x4 + 5x4 + 9x2)}{(20+22)}$$

$$= \frac{324}{42} = 7.71$$

3.1) A candidate shall be declared to have passed in a paper if the candidate secures a minimum of 'E' grade in theory and a minimum of 'D' grade in practicals/ project/viva-voce/ industrial training. This includes sessionals wherever applicable. Further, a candidate has to secure a minimum of 5.0 SGPA for a pass in each semester in case of B.E./ B.Tech. /B.Arch. / B.Pharm. /5 year integrated courses and PG Diploma / Diploma/PG in Arts & Commerce Courses, whereas for PG in Engineering, Sciences, Pharmacy/PG. Diplomas in Sciences 5.5 SGPA is the minimum for a pass in each semester. Further, a candidate will b e permitted to choose any paper(s) to appear for improvement in case the candidate fails to secure the minimum prescribed SGPA/ CGPA to enable the candidate to pass at the end of any semester examination.

3.2) Pass/fail shall not be indicated in the marks statement against each individual paper.

3.3) A candidate will be declared to have passed in a course if a candidate secures 5.0 CGPA for B.E./ B.Tech./ B.Arch./ B.Pharmacy and Diploma / PG Diplomas and PG in

Arts & Commerce, while for P.G. in Science, Engineering and Pharmacy and P.G. Diplomas in Sciences 5.5 CGPA has to be secured for a pass in a course.

3.4) Further, classification of successful candidates is based on CGPA as follows.
Distinction – CGPA 8.0 or more
I Class – CGPA 6.5 or more but less than 8.0
II Class – CGPA 5.5 or more but less than 6.5
Pass – CGPA 5.0 or more but Less than 5.5

FIRST SEMESTER

MPPC101: CHROMATOGRAPHIC METHODS OF ANALYSIS:

Unit -I

GC-MS: Principle, instrumentation, sperators used, selected ion monitoring/mass fragmentography and applications

LCMS: Basic principle, instrumentation, ion formation and types, fragmentation processes and patterns, MS/MS detection, ionization sources, detectors employed and applications

Unit II

HPLC and UPLC: Principle, instrumentation, structural types of column packings, optimization of column performance, separation columns, methods of chiral separations, derivatization, RP HPLC, its advantages in bio pharmaceutical analysis, detectors used in HPLC and applications. Principles of UPLC, modifications in UPLC compared to HPLC, advantages and applications.

Unit III

HPTLC: Basic principle, instrumentation, advantages when compared to TLC, method of development and applications in pharmaceutical and phytochemical analysis.
Electrophoresis: Moving boundary electrophoresis, zone electrophoresis, continuous electrophoresis (preparative) and applications.

SCF and Permeation: Theory, instrumentation and specific applications.

Unit IV

Development of analytical method, optimization and validation using Paper and Thin layer chromatography, HPLC, LC-MS, GLC, GC-MS, HPTLC, Capillary electrophoresis for pharmaceutical dosage forms and bulk drugs.

Unit V

Sample Preparation - Analysis of drugs from formulations and biological samples including, selection of biological sample, extraction of drugs by various methods such as Liquid Liquid Extraction (LLE), Solid Phase Extraction (SPE) and Membrane filtration.

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Textbooks:

1. Instrumental methods off analysis by Willad et al, 7th Edition CBS publishers Chennai.
2. A Text Book of Pharmaceutical Analysis (Vol. 1 & 2) - Roger E. Schirmer.
3. Practical Pharmaceutical Chemistry (Vol. 1 & 2) – Beckette & Stenlake.
4. Pharmaceutical Analysis - Modern Methods by J.W.Munson (Marcel Dekker).
5. Packing and stationary phases in chromatographic techniques by Unger KK.

MPPC 102: ADVANCED PHYSICAL PHARMACEUTICS

Unit I

Solids:
Crystal structure
Crystal form -Crystallization and factors affecting crystal form
Polymorphism - Pharmaceutical implications of polymorphism
Crystal hydrates - Pharmaceutical consequences of solvate formation

Dissolution of solid drugs
Biopharmaceutical importance of particle size
Wetting of powders - Contact angle and wettability of solid surfaces and wettability of powders
Solid dispersions -Eutectics and drug identification

Unit II

The solubility of drugs:
Definitions - Expressions of solubility.
Factors influencing solubility: Structural features and aqueous solubility, Hydration and solvation, The effect of simple additives on solubility, The effect of pH on the solubility of ionisable drugs.
Measurement of solubility.
The solubility parameter - Solubility parameters and biological processes
Solubility in mixed solvents.
Solubilization by the use of surfactants, cyclodextrins as solubilising agents.

Unit III

Diffusion: Diffusion, Steady state diffusion, Diffusion through membranes procedures and apparatus for assessing drug diffusion, Biologic Diffusion. Elementary drug release.

Unit IV

Compression of Tablets: The process of compression, Properties of tablets influenced by compression, Measurement of compression force, Nature of materials.

Unit V

Drug stability: The chemical breakdown of drugs, Kinetics of chemical decomposition in solution, Factors influencing drug stability of liquid dosage forms, Factors influencing drug stability of solid dosage forms, Stability testing and calculation of shelf-life.

Text Books and references:

1. Physicochemical Principles of pharmacy 4th Edition, A.T Florence, David Atwood (Unit I and Unit II and V).
2. Martin's Physical Pharmacy and Pharmaceutical Sciences, Edited by Patrick J Sinko (Unit III).
3. Remington, The Science and Practice of Pharmacy 20th Edition (Unit III).
4. Pharmaceutical dosage forms: Tablets- Volume 2 edited by HA. Lieberman. Leo Lachman and Joseph B. Schwartz (Unit IV).
5. Physical Pharmacy by David Atwood and A.T Florence, Pharmaceutical Press (Unit V).

MPPC 103: INTELLECTUAL PROPERTY RIGHTS & REGULATORY GUIDELINES

Unit I

The Patents and Designs Act 1970. Patent discussion with emphases on: Patentable subject matter, Non patentable subject matter, Criteria for getting a patent, Types of patent and its usefulness. Filing procedure for patents, Patent co-operation Treaty. Trade related aspects of IPR.

Unit II

Preparation of documents for Investigational New Drug (IND) - Content and Format of INDs for Phase 1 study of drugs.
Review Process General consideration, content, format and approval of NDA & Abbreviated New Drug Application (ANDA).
Drug Master Files, Site Master Files, Out of specification.

Unit III

International Conference on Harmonization - Quality:

Stability Testing of New Drug Substances and Products (Q1A (R2), Photostability Testing of New Drug Substances and Products (Q1B), Validation of Analytical Procedures: Methodology (Q2B), Evaluation of Stability Data (Q1E).

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Unit IV

FDA guidelines on Biopharmaceutics:

Bioavailability and Bioequivalence Studies for Orally Administered Drug Products - General Considerations
Guidance for Industry - Bioanalytical Method Validation,
Guidance for Industry- Dissolution testing of immediate release Solid Oral Dosage forms
Guidance for Industry-Extended Release Oral Dosage forms: Development, Evaluation and Applications of *In Vitro/In Vivo* Correlations
Waiver of In Vivo Bioavailability and bioequivalence Studies for immediate release solid oral dosage forms based on Biopharmaceutics Classification system

Unit V

FDA Guidelines:
Nonclinical Studies for the Safety Evaluation of Pharmaceutical Excipients.
Food-Effect Bioavailability and Fed Bioequivalence Studies
SUPAC IR - Immediate release solid oral dosage forms: Scale up and approval changes: Chemistry Manufacturing and controls *In Vitro* dissolution testing, and *In Vivo* bioequivalence documentation.

Recommended Books and References:

1. http://www.patentoffice.nic.in/ipr/patent/patents.htm (Unit I)
2. Pharmaceutical Patent Law – John R. Thomas (Unit I)
3. www.fda.gov (Unit III. IV and V)
4. Pharmaceutical dosage forms and drug delivery systems by Howard Ansel et al, International Student Edition (Unit II)
5. New Drug Approval Process – The Global Challenge by Richard a Guarino (Unit II)
6. The CDER Hand Book (NDAs and ANDAs) – (Unit II)

MPPC 104: PREFORMULATION STUDIES IN PRODUCT DEVELOPMENT

Unit I

Pre-Formulation:
A consideration of following 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 and Partition coefficient.
Chemical Characteristics-
Degradation: Hydrolytic, oxidative, reductive and photolytic, Drug-Excipient compatibility studies.

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Biopharmaceutical Characteristics-
Lipid solubility, dissociation constant, dissolution, drug stability in G.I.tract and complexation.

Unit II

Impurity profiling:
Forced degradation studies (Methodology), and Impurity profiling -Definition and sources of impurities: (Impurities associated in with APIs-Organic impurities (Process and Drug-related), Inorganic impurities, Residual solvents; Impurities related to formulation; Formation of impurities on aging).
Guidance for Industry - Impurities in New Drug Substances Q3A; Guidance for Industry Impurities in New Drug Products.Q3B (R2).

Unit III

Development of Stability Indicating Methods:

Introduction, Forced Degradation Studies - Experimental Approach to Forced Degradation Studies
Stability Indicating HPLC Method Development - Method Scope, Preliminary Requirements, Method Development Approach, Method Optimization.

Unit IV

Dissolution Method Development: An Industry Perspective-
Physical and Chemical Properties of API, Dissolution Apparatus Selection, Dissolution Medium Selection, Key Operating Parameters, Method Optimization, Validation, Automated Systems.

Unit V

Product Development Approach for the following Dosage Forms:
Tablets, Capsules, Injectables

Recommended Books and References:

1) Remington's Pharmaceutical Sciences, L.Wiliams & Wilkins, 21st Ed. (Vol. I & II)
2) Theory & Practice of Industrial Pharmacy by Lachman.
3) Pharmaceutics of Solids and Solid dosage forms by J. Cartensen.
4) Advances in Pharm. Sciences by Beckett.
5) Pharmaceutical Technology by Parrot.
6) Pharmaceutical Impurities- A Mini-Review; AAPS PharmSciTech 2002; 3 (2) article 6 (http://www.aapspharmscitech.org).

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7) Pharmaceutical Dissolution testing Edited by J Dressman and Johannes Krämer, Taylor & Francis Group, LLC.
8) Hand Book of Stability Testing in Pharmaceutical Development – Regulations, Methodologies and Best Practices, Edited By Kim Huynh Ba, Springer Publications.
9) FDA/ICH guidelines Q3A and Q3B (R2).

I – Semester - (Practicals)

MPPC 105 - CHROMATOGRAPHIC METHODS OF ANALYSIS – PRACTICLAS

Practicals Based on Theory:

1. Estimation of drugs official in IP by HPLC
2. Bio analytical method development for some drugs by HPLC
3. Estimation of amino acids by TLC

For example -

1. Assay of drugs in the sample using HPLC (minimum 4 experiments).
2. Assay of Paracetamol in the sample using HPTLC.
3. Estimation of amino acids by TLC.
4. Construction of calibration curve for some drugs in rat and human plasma by HPLC (minimum 2 experiments).

MPPC 106 - PREFORMULATION STUDIES IN PRODUCT DEVELOPMENT – PRACTICLAS

Practicals Based on Theory:
For example -

1) Evaluation of flow properties of powders and other samples.
2) Solubility studies of weakly acidic and weakly basic drugs.
3) Forced degradation studies of some drugs.
4) Drug - excipient compatibility studies.
5) Dissolution studies of drug products (both IR and SR) official in IP and other pharmacopoeias (minimum 4 experiments).

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SECOND SEMESTER

MPPC 201: ADVANCES IN DRUG DELIVERY SYSTEMS - I

Unit I

Fundamentals, rationale of sustained/controlled drug delivery, factors influencing the design and performance of sustained/controlled release products, pharmacokinetic/Pharmacodynamic basis of controlled drug delivery

Polymers Used In Controlled Drug Delivery Systems:

Introduction, Polymer-classification, Applications for Polymers in formulation of controlled drug delivery systems, Biodegradable and Natural polymers

Unit II

Design, fabrication, evaluation and applications of the following novel drug delivery systems:

1. Controlled release oral drug delivery
2. Parenteral controlled release drug delivery systems
3. Implantable therapeutic systems.
4. Transdermal therapeutic systems and their recent advances

Unit III

Design, fabrication, evaluation and applications of the following novel drug delivery systems:

1. Ocular and intrauterine delivery systems
2. Bioadhesive drug delivery systems
3. Nasal drug delivery systems

Unit IV

Design, fabrication, evaluation and applications of the particulate drug carriers:

1. Liposomes, Microspheres, Nanoparticles
2. Monoclonal antibodies and Resealed erythrocytes

Unit V

Drug targeting to particular organs:

1. Drug delivery to respiratory system
2. Problems of drug delivery to the brain and targeting to brain
3. Drug targeting in Neoplastic diseases

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Text Books and References:

1. Nasal and Systemic Drug Delivery By Chien
2. Drug Targeting technology By Schreier
3. Drug Delivery to the Lung By H.Bisgaard
4. Specialized Drug Delivery Systems By Praveen. S. Tyle
5. Controlled and Novel Drug Delivery By N.K.Jain
6. Mechanisms of Transdermal drug delivery By Russel. O. Potts
7. Drug Delivery to the Brain By D.J.Beagley
8. Drug Delivery Systems By Johnson and Llyod
9. Novel Drug Delivery Systems By Chien

MPPC 202: ADVANCED BIO-PHARMACEUTICS

Unit I

Physiologic factors related to drug absorption: Routes of drug administration, Nature of cell membranes and passage of drugs across cell membranes. Oral drug absorption: Drug absorption in gastrointestinal tract

Unit II

Biopharmaceutic considerations in drug product design: Rate limiting steps in drug absorption. Pharmaceutic factors affecting drug bioavailability - Disintegration, Dissolution and Solubility, pH - partition theory

Effect of Physicochemical nature of drug on dissolution: solubility, stability, particle size, polymorphism and solvates, salts, prodrugs. Techniques of enhancing dissolution rate

Unit III

Formulation factors affecting bioavailability of drugs in dosage forms of Tablets, capsules, parenterals, liquid orals and topical dosage forms. Effect of excipients on drug absorption

Unit IV

Dissolution and Drug release testing: Dissolution conditions, Compendial methods of dissolution, Meeting dissolution requirements, and Alternative methods of dissolution testing. *In Vitro - In Vivo* Correlation.

Unit V

Bioavailability: Definition and purpose of bioavailability studies, Methods for assessing the bioavailability.

Bioequivalence: Design and Evaluation of bioequivalence studies, evaluation of the data,

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study submission and drug review process, Dissolution profile comparison and Biopharmaceutics Classification System (BCS). Therapeutic equivalence

Text Books and references:

1. Biopharmaceutics and Clinical pharmacokinetics-M. Gibaldi
2. Applied Biopharmaceutics and Pharmacokinetics, 5th Edition by Leon Shargel

MPPC 203: ADVANCED PHARMACOKINETICS

Unit I

Basic concepts of Pharmacokinetics: compartmental models: One two and Non-compartmental approaches to Pharmacokinetics. Recent trends, merits and limitations of these approaches. Application of these models to determine the various pharmacokinetic parameters pertaining to:

i) Absorption: (Wherever applicable) Absorption rate constant, Absorption rate constant, Absorption half life, lag time and extent of absorption, AUC.
ii) Distribution: Apparent volume of distribution and its determination.
iii) Metabolism: Metabolic rate constant
iv) Elimination: Overall apparent elimination rate constant and half-life.

Under the following conditions:

a) Intravenous bolus injection
b) Intravenous infusion
c) Single dose oral administration
d) Multiple dose injections
e) Multiple dosage oral administration

Unit II

Non-linear Pharmacokinetics: Concepts of linear and non-linear Pharmacokinetics, Causes of Non linear pharmacokinetics, Michaelis-Menton kinetics characteristics.

Unit III

Time dependent Pharmacokinetics: Introduction, classification, physiologically induced time dependency: Chronopharmacokinetics.

Unit IV

Drug Metabolism: sites of metabolism, factors affecting drug metabolism (genetic, specie sand environmental).

Unit V

Drug interactions: Kinetics of drug interaction, study of drug-drug interactions mediated through absorption, distribution, metabolism and elimination, Mechanisms of interaction and consequence. Influence of alcohol, smoking, food and beverages on drug action.

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Text Books and references:

1. Biopharmaceutics and Clinical Pharmacokinetics-M. Gibaldi
2. Applied Biopharmaceutics and Pharmacokinetics, 5th Edition By Leon Shargel
3. Biopharmaceutics and Clinical Pharmacokinetics By Notari
4. Clinical Pharmacokinetics - Concepts and Applications by Rowland and Towzer
5. Pharmacokinetics by Milo Gilbaldi and Donald Perrier
6. Remington's Pharmaceutical Sciences, L.Wiliams & Wilkins, 21st Ed. (Vol. I & II)

MPPC- 204: ADVANCES IN DRUG DELIVERY SYSTEMS - II

Unit-I

Cell membranes, epithelial barriers of Drug absorption and physiological factors effecting oral bioavailability:

a. Plasma membrane-Phospholipids bilayer, membrane modulation of fluidity modelsvproteins.
b. Epithlia-cell junctions-structure and role in drug absorption.
c. Transport across cell membranes-efflux transporter systems (multi drug resistance)

Unit-II

Nucleic acid based therapeutic delivery systems: Gene therapy, introduction, (ex vivo & in-vivo gene therapy) potential target diseases for gene therapy (inherited disorder and cancer), gene expression system (viral & non viral gene transfer), gene delivery systems (liposomal), biodistribution and pharmacokinetics

Unit III

Genomics, Proteomics: Definitions of genomics and proteomics and Bioinformatics. Brief Knowledge of Human genome project - Pharmacogenomics-geneticpolymorphisms influencing drug disposition and effect on drug response

Unit IV

Delivery of peptides and proteins/Biotechnology based drugs:

Formulation aspects, Overview of delivery systems, site specific proteins, Stability problems, Evaluation of recombinant proteins. Knowledge of engineered proteins-techniques of getting engineered Proteins by DNA technology. Novel delivery systems of Insulin

Unit V

Vaccine Delivery: Evidence and mechanism of uptake and transport of antigens. Delivery systems used to promote uptake. Absorption enhancers, Lipid carrier systems, oral immunization, controlled release micro particles for vaccine development, single

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dose vaccine delivery systems using biodegradable polymers. Knowledge of peptide based and nucleic acid based vaccines

2-Semester - (Practicals)

MPPC 205-ADVANCES IN DRUG DELIEVRY SYSTMS – PRACTICLAS

1. Preparation of Microcapsules
2. Preparation of Transdermal patches
3. Study of diffusion across Transdermal patches
4. Preparation of Microspheres
5. Preparation of oral matrix tablets using HPMC and other hydrophilic cellulose polymers as release retardant materials and studying their release patterns
6. Study on *In-vitro* dissolution of various sustained release formulations of marketed products

MPPC 206 -ADVANCED BIO PHARMACEUTICS – PRACTICLAS

1. Effect of physicochemical properties on solubility and dissolution of poorly soluble drugs.
   a) pH b) Particle size c) Polymorphism/Recrystallisation
2. Effect of pH on partition-coefficient
3. Effect of formulation excipients on dissolution of drugs from Tablets/Capsules
4. Preparation and evaluation of solid dispersions of poorly water-soluble drugs with hydrophilic carriers
5. Dissolution rate study on IR/SR/CR Products

Problems / calculations in Pharmacokinetics

a) Determination of k_e, $t_{1/2}$ from plasma data
b) Determination of AUC
c) Determination of Renal Clearance
d) Determination of K_e and biological half life from Urinary excretion studies

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