

M.Pharm.Semester-I to IV

Prospectus No. 20121429

संत गाडगे बाबा अमरावती विद्यापीठ  
SANT GADGE BABA AMRAVATI UNIVERSITY

आयुर्विज्ञान विद्याशाखा  
(FACULTY OF MEDICINE)

अभ्यासक्रमिका  
औषधिनिर्माण पदव्युत्तर परीक्षा

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**PROSPECTUS**

OF

MASTER OF PHARMACY (PHARMACEUTICS) EXAMINATIONS

SEMESTER-I & III, WINTER-2011

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Subject Code : MPH-201

Subject : NOVEL DRUG DELIVERY SYSTEM

THEORY: 60 Hours (4 hrs. /week)

## SECTION-A

**1. SUSTAINED AND CONTROLLED RELEASE DRUG DELIVERY SYSTEMS**

Introduction; Rationale of SRDDS; Advantages and Disadvantages of SRDDS; Factors influencing the design and performances of SRDDS: A) Physicochemical properties of a drug influencing design and performance; B) Biological factors influencing design and performance of SRDDS. Different Micro- encapsulation processes. Introduction, Design and Development of oral controlled release drug administration: Dissolution controlled, Diffusion controlled (Reservoir devices, Matrix devices), Membrane permeation controlled, Osmotic pressure controlled, Gel diffusion controlled, pH controlled, Ion - exchange controlled delivery systems.

**2. POLYMER SCIENCE**

Introduction, Polymer-classification, Applications of Polymers in formulation of controlled drug delivery systems, Biodegradable and Nonbiodegradable polymers, Properties of following commonly used polymers- Starch, Gelatin, Chitosan, Albumin, Cellulose derivatives and Poloxamers.

**3. TRANSDERMAL DRUG DELIVERY SYSTEMS**

Permeation through skin, Factors affecting permeation, Basic components of TDDS, Formulation approaches used in development of TDDS and their evaluation, Permeation enhancers.

**4. MUCOADHESIVE DRUG DELIVERY SYSTEMS**

Introduction, 1) Buccal drug delivery system: Concepts, Advantages and Disadvantages, Structure of oral mucosa, Trans-mucosal permeability, Permeability enhancers, *in vitro* and *in vivo* methods for Buccal absorption; 2) Nasal Drug Delivery Systems: Introduction, Physiology of nose, Fundamentals of nasal absorption, Distribution of drug in the nasal cavity, Enhancement in absorption, *in vitro* and *in vivo* methods for determination of nasal absorption.

## SECTION-B

**5. OCCULAR DRUG DELIVERY SYSTEMS**

Formulation and evaluation of ocular controlled drug delivery systems, ophthalmic inserts and *in situ* gels.

**6. TARGETED DRUG DELIVERY SYSTEMS**

Concepts, Advantages and Disadvantages, Targeting of drugs

through nanoparticles, liposomes, resealed erythrocytes, microspheres, magnetic microspheres, monoclonal antibodies, pulsatile drug delivery. Study on colon targeting. Biosome.

**7. Protein & Peptide Drug Delivery System**

Physical aspects, biochemistry of protein drug (structure, properties & stability), barrier to transport & pharmacokinetics, different routes of delivery.

**8. Intrauterine Drug Delivery Systems**

Development of intrauterine devices (IUDs), copper IUDs, hormone-releasing IUDs.

## REFERENCE BOOKS:

1. Encyclopedia of controlled delivery; By Edith Mathiowitz, Published by Wiley Interscience Publication, John Wiley and sons, Inc, New York / Chichester / Weinheim.
2. Controlled and Novel Drug Delivery; By N.K.Jain, CBS Publishers and Distributors, New Delhi, First edition, 1997 (reprint in 2001).
3. Controlled Drug Delivery - Concepts and Advances; By S.P.Vyas and R.K.Khar, Vallabh Prakashan, New Delhi, First edition, 2002.
4. Remington's Pharmaceutical Sciences.
5. Novel drug delivery system; By Y.M.Chien, Marcel Dekker, Inc.
6. Controlled Drug Delivery - Fundamentals and Applications, 2nd edition; By Joseph R.Robinson and Vincent H.L.Lee.
7. Pharmaceutical Dosage forms, disperse system: Volume 1, By Herbert A.Libermann et.al, Marcel Dekker, Inc.
8. Pharmaceutical Dosage forms: Tablets Volume II, Herbert A.Libermann et.al, Marcer Dekker, Inc.
9. Bentley's Textbook of Pharmaceutics; By E.A.Rawline, ELBS Publications.
10. Microencapsulation and Related Drug Process; By Patric B.Deasy.

Subject code: MPH-202

Subject : BIOPHARMACEUTICS AND PHARMACOKINETICS

THEORY 60 Hours (4 hrs. /week)

## SECTION-A

**1. ABSORPTION OF DRUGS**

Definition, Structure of cell membrane and composition, Gastrointestinal absorption – Mechanism, Factors affecting drug absorption: Biological, Physiological, Physico-Chemical and Pharmaceutical dosage form factors; Methods of determining absorption: *In Vitro* and *In Vivo* methods.

**2. DISTRIBUTION OF DRUGS**

Definition, Distribution in blood and other fluids: cellular distribution, drug penetration to CNS, placental transfer of drugs and blood flow, Factors affecting drug distribution, Volume of distribution,

3. **PROTEIN BINDING**

Plasma protein binding: factors affecting, significance and kinetics of protein binding.

4. **METABOLISM OF DRUGS**

Definition, brief overview of Phase I (Oxidative, reductive and hydrolytic reactions) and Phase II reactions (Conjugation) of Biotransformation. Factors affecting biotransformation.

**SECTION- B**

5. **EXCRETION OF DRUGS**

Definition, Renal and non-renal excretion, Concept of clearance - Renal clearance, Organ clearance & Hepatic clearance.

6. **BASIC CONCEPTS OF PHARMACOKINETICS**

Basic considerations, Pharmacokinetic models, Compartment modeling: one compartment model - IV bolus, IV infusion, Extra-vascular; Multi Compartment models; Two compartment model - IV bolus, IV infusion, Extra-vascular, Three Compartment model in brief.

7. **NON-LINEAR PHARMACOKINETICS**

Cause of non-linearity, Michaelis-Menten equation, Estimation of  $K_m$  and  $V_{max}$ .

8. **DOSAGE REGIMEN**

Concept of loading dose & maintenance dose, Multiple dosing with respect to I.V. and oral route, Adjustment of dosage in renal and hepatic impairment, Individualization of therapy, Therapeutic Drug Monitoring.

9. Application of Pharmacokinetics in Novel drug delivery systems. BCS Classification of drugs.

**REFERENCE BOOKS:**

1. Biopharmaceutics and clinical Pharmacokinetics By Milo Gibaldi.
2. Remington's Pharmaceutical Sciences; By Mack publishing company, Pennsylvania.
3. Pharmacokinetics; By Milo Gibaldi, Donald Perrier; Marcel Dekker, Inc.
4. Handbook of clinical Pharmacokinetics; By Milo Gibaldi and Laurie Prescott by ADIS Health Science Press.
5. Biopharmaceutics and Pharmacokinetics; By Robert E. Notari.
6. Biopharmaceutics; By Swarbrick.
7. Biopharmaceutics and Pharmacokinetics- A Treatise; By

D.M.Brahmankar and Sunil B.Jaiswal., Vallabh Prakashan Pitampura, Delhi.

8. Clinical Pharmacokinetics, Concepts and Applications; By Malcolm Rowland and Thomas N.Tozer. Lea and Febiger, Philadelphia, 1995.
9. Dissolution, Bioavailability and Bioequivalence; By Abdou.H.M., Mack Publishing Company, Pennsylvania, 1989.
10. Biopharmaceutics and Clinical Pharmacokinetics- An introduction; 4th edition, Revised and expanded By Robert. E. Notari, Marcel Dekker Inc, New York and Basel, 1987.
11. Encyclopedia of Pharmaceutical Technology, Vol 13, James Swarbrick, James. C.Boylan. Marcel Dekker Inc, New York, 1996.

**Subject code : MPH-203**

**Subject : INDUSTRIAL PHARMACY**

**THEORY :60 Hours (4 hrs./week)**

**SECTION-A**

1. **PREFORMULATION**

Introduction, organoleptic properties, purity, particle size, shape, and surface area. Solubilisation, surfactants and its importance, temperature, pH, co-solvency; Techniques for the study of crystal properties and polymorphism. Physicochemical characteristics of new drug molecules with respect to different dosage forms.

2. **COMPACTION AND COMPRESSION**

Compaction of powders with particular reference to distribution and measurement of forces within the powder mass undergoing compression including- physics of tablet compression; Effect of particle size, moisture content, lubrication etc on strength of tablets.

3. **PILOT PLANT SCALE UP TECHNIQUES**

Significance of pilot plant scale up study and large scale manufacturing techniques (formula, equipment, process, stability and quality control) of some important dosage forms such as tablets, capsules, injections, liquid orals, semisolids, ophthalmic products, emulsions including multiple emulsions.

4. **SOLID DOSAGE FORMS:**

Recent advances in tablet and capsule technology like double compression, direct compression, lubrication and binding agents, extrusion and spheronization,; oral drug delivery systems, e.g., matrix controlled, osmotic pressure controlled, membrane permeation controlled, pH controlled, ion-exchange controlled, gel diffusion controlled, hydro-dynamically balanced systems, modulation of GI transit time, gastro-retentive systems

**SECTION- B****5. COATING OF SOLID DOSAGE FORMS:**

Aqueous and non-aqueous film coating, polymers, process controls, coating equipment, coating pans, Accela-cota, Hi-coater, Dria-Coater and metering devices and spray systems, particle coating methods; advances in microencapsulation techniques.

**6. OPTIMIZATION TECHNIQUES IN PHARMACEUTICAL FORMULATION AND PROCESSING**

Concept of optimization, Optimization parameters, Classical optimization, Statistical design, and Optimization methods.

**7. METHODS OF ENHANCING BIOAVAILABILITY**

Solubilization, Prodrugs, and enhancement of dissolution characteristics, cyclodextrin, permeation enhancer, solid dispersion, surfactant, bioavailability enhancers.

**8. Optimization & Pilot plant scale up techniques for Tablets & Capsules- an overview.**

Automation & Effluent testing and Treatment in Pharmaceutical industries.

**REFERENCE BOOKS:**

1. Theory and Practice of Industrial Pharmacy By Lachmann and Libermann.
2. Pharmaceutical dosage forms: Tablets Vol. 1-3 by Leon Lachmann.
3. Pharmaceutical Dosage forms: Disperse systems, Vol, 1-2; By Leon Lachmann.
4. Pharmaceutical Dosage forms: Parenteral medications Vol. 1-2; Leon Lachmann.
5. Modern Pharmaceutics; By Gillbert and S. Banker.
6. Remington's Pharmaceutical Sciences.
7. Advances in Pharmaceutical Sciences Vol. 1-5; By H.S. Bean & A.H. Beckett.
8. Physical Pharmacy; By Alfred martin
9. Bentley's Textbook of Pharmaceutics – Rawbins.
10. Good manufacturing practices for Pharmaceuticals: A plan for total quality control, Second edition; By Sidney H. Willig.
11. Drug formulation manual; By D.P.S. Kohli and D.H. Shah. Eastern publishers, New Delhi.
12. Pharmaceutical Preformulations; By J.J. Wells.

**Subject code : MPH-204**

**Subject : ADVANCED PHARMACEUTICS AND COSMETOLOGY**

**THEORY : 60 Hours (4 hrs./week)**

**SECTION-A****1. STERILIZATION PROCESS**

Principle, Advantages, Disadvantages, Applications of different sterilization methods, equipments. Sterility testing: Principle, general procedure, control tests, sterility testing of some preparations like parenterals and ophthalmic preparation, ampoules, vials, syringes and needles.

**2. STABILITY TESTING**

Physicochemical and biological factors affecting stability of drugs, Methods to find out degradation pathways, Determination of shelf life by accelerated stability testing, Overages.

**3. BIOAVAILABILITY AND BIOEQUIVALENCE STUDIES**

Definition, Objective of bioavailability, Parameters of bioavailability, Determination of AUC. Estimating absorption rate of drugs; Measurement of bioavailability- Pharmacokinetic methods and Pharmacodynamic methods. Drug dissolution rate & bioavailability. *In vitro* drug dissolution testing models. In-vitro in-vivo correlation. Definitions: Bio equivalence, Chemical equivalence, Therapeutic equivalence, Pharmaceutical equivalence; Testing of bioequivalence of dosage forms.

**SECTION- B****4. MICROMERITICS AND RHEOLOGY**

A detailed account of micromeritics and rheology including apparatus involved in this area and their application in pharmacy.

**5. MANUFACTURING TECHNIQUES AND EVALUATION OF COSMETICS**

Manufacturing of Cosmetics like creams, powders, compacts, shampoo, lipstick liquids, foam, aerosol cosmetics and their Performance, physicochemical and microbiological evaluation. Design and Assessment of preservative systems for cosmetics, valuation of preservatives in cosmetic products and factors affecting activity of preservatives.

**6. PACKAGING OF PHARMACEUTICALS**

Desirable features and a detailed study of different types of Pharmaceutical containers and closures (Glass, Plastics and Rubber), including their merits and demerits; selection and evaluation of Pharmaceutical packaging materials.

**REFERENCE BOOKS:**

1. Theory and Practice of Industrial Pharmacy By Lachmann and Libermann.

2. Modern Pharmaceutics; By Gillbert and S. Banker.
3. Remington's Pharmaceutical Sciences.
4. Advances in Pharmaceutical Sciences Vol. 1-5; By H.S. Bean & A.H. Beckett.
5. Physical Pharmacy; By Alfred martin
6. Bentley's Textbook of Pharmaceutics – Rawbins.
7. Pharmaceutical Preformulations; By J.J. Wells.
8. Harry's Cosmeticology.
9. Textbook of Cosmeticology by B.M.Mittial.
10. Textbook of Cosmeticology by P.P.Sharma.

**Subject code : MPH-205**

**Subject : SELECTED TOPICS IN PHARMACEUTICS**

**THEORY : 60 Hours (4 hrs. /week)**

#### SECTION-A

1. **EXCIPIENTS IN PHARMACEUTICAL FORMULATIONS:**  
Introduction to excipients and their importance in pharmaceutical and cosmetic industry; specialized type of excipients used in tablets such as directly compressible excipients and super disintegrants; surfactants in disperse systems, taste masking excipients, colors, flavours, sweetening agents, gel and film forming agents, solubilizers, their evaluation methods, quality control and material safety data sheet.
2. **PARENTERAL DOSAGE FORMS:**  
Formulation, stabilization and manufacture of small and large volume, parenterals, evaluation and quality control; injectable controlled release formulations, long acting contraceptive formulations, implantable drug delivery systems.
3. **COLLOIDAL AND DISPERSE SYSTEMS:**  
Specialized pharmaceutical emulsions like multiple emulsion, microemulsions, nanoemulsions, injectable emulsions; suspensions, reconstituted suspensions nanosuspensions, and gels; quality assurance of dispersed systems.
4. **SURFACTANT SYSTEM**  
Introduction, micellization, thermodynamics and kinetics of micelle formation, classification., Pharmaceutical aspects of Solubilization, Solubilization in non-aqueous system, interactions with polymers and oppositely charged species. Surfactants in emulsions and suspensions. drug absorption, antibacterial activity.

#### SECTION-B

5. **Techniques of solubilization:**  
Mechanisms for enhancing solubility such as chemical modification,

micellar solubilization, cosolvency, complexation, hydrotrophy, and dielectric constant modification.

#### 6. **PACKAGING DEVELOPMENT:**

- i) Glass containers for Pharmaceuticals:  
Glass types, their manufacture chemical performances testing and quality control.
  - ii) Plastics containers for pharmaceuticals:  
Classification of plastics, plastic polymers and their physico-chemical, mechanical and biological properties: Additives and fabrication processes, plastic container for parenteral and transfusion sterile drip kits. Quality control testing and biological toxicity.
  - iii) Paper and paperboard : Types of paper, folding cartons, quality control testing to paper and paperboard.
  - iv) Metal containers: Aluminum and tinplate drums collapsible tubes and Aerosol containers, Lacquering, coating and lining.
  - v) Caps and Closures:  
Types caps closure liners, child resistant caps, and Elastomeric closures for parenterals, classification of elastomers, physical chemical and biological properties and their quality control.
  - vi) Labels and labeling:  
Types of labels, adhesives, inject and barcoding.
7. **Corrugated and solid fibre boards and boxes:** Types of corrugation methods and types of box design and Quality control. Transit worthiness of package: Hazards, mechanical climatic during transit, Laboratory testing methods.

#### **REFERENCE BOOKS**

1. Carstensen, Pharmaceutical principles of solid dosage forms, CRC.
2. Pharmaceutical dosage forms: Parenteral, Lachman, Libermann, and Avis, Vol. I & II Marcel Dekker.
3. Lachman, Lieberman, Pharmaceutical dosage forms: Dispersed systems Vol. I, II, Marcel-Dekker
4. Ray and Weller, Handbook of Pharmaceutical Excipients, Pharmaceutical Press.
5. Pharmaceutical dosage forms: Parenteral, Lachman, Libermann, and Avis, Vol. I & II Marcel Dekker.
6. Park, Controlled Drug Delivery – Challenges and Strategies, CRC.
7. Handbook of Package Engineering by Joseph. F. Handlon.
8. Packaging Materials & Containers by F.A. Paine
9. Industrial Packaging by Fried man & Kipness.
10. Packaging of Pharmaceuticals, C.F. Ross
11. Packaging laws & Regulation, Chowdhary & Subramanian

**Subject code : MPH - 206**

**Subject : LABORATORY COURSE-2**

**Practical 8 hrs./week (Minimum 20 practical should be conducted)**

1. Preparation and evaluation of microcapsules/micro spheres by different techniques.
2. Study on diffusion of drugs through various polymer membranes.
3. Study on In-vitro dissolution of various sustained release formulations of marketed products.
4. Preparation of matrix tablets using various polymers, like polyvinyl alcohol, polyvinyl pyrrolidone etc., and studying their release patterns.
5. Preparation of various polymer films, loading of drugs and studying the release Pattern.
6. Film coating of drug pellets for granules with sodium CMC and the study on In Vitro dissolution.
7. Preparation and evaluation of following drug delivery systems:
  - a. Fast dissolving tablets
  - b. Gels
8. Preparation of various drug formulations by solid dispersion technique and their evaluation. (Minimum Two Practical)
9. Formulations based on the cosmetics like vanishing cream, talcum powder, tooth paste, coconut oil shampoo, paste depilatory, nail polish, lipstick etc. (Minimum two Practical)
10. Other formulations based on the theory topics.
11. Pre-formulation study of tablets.
12. Studying the stability of suspensions using the data on sedimentation volume and degree of flocculation.
13. Determinations of flow properties of powders by Angle of repose and flow through an orifice with, and without glidants.(Minimum Two Practical)
14. Comparison of dissolution studies of two different marketed products.
15. Calculation  $k_a$ ,  $k_e$ ,  $t_{1/2}$ ,  $C_{max}$ ,  $T_{max}$ .
16. Calculation of AUC and bioequivalence from the given data for two drugs.
17. In vitro absorption studies.
18. To study the pharmacokinetics of suitable drug after oral administration. (Minimum Two Practical)
19. Extent of plasma-protein binding studies on the same drug (i.e. highly and poorly protein bound drug ) at different concentrations.
20. Accelerated stability study
21. Experiment based on the theory topics.

**RECOMMENDED BOOKS:**

All books mentioned as reference books for theory should be used.

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# INDEX

## M.Pharm. (Pharmaceutics) Semester-I & IV (Prospectus No.20121429)

Sr. No.	Subject	Page No.
1.	Special Note for Information of the students	1 - 2
2.	Direction No. 22 of 2010	3 - 20
<b>Semester-I</b>		
3.	Research Methodology & Biostatistics	21 - 24
4.	Biotechnology and Bioinformatics	24 - 25
5.	Quality Control of Pharmaceutical Products	25 - 26
6.	Drug Regulatory Affairs	27 - 28
7.	Product Development and Formulation	28 - 29
8.	Laboratory Course -I	30
<b>Semester-II</b>		
8.	Advanced Industrial Pharmacy –I	31 - 32
9.	Advanced Industrial Pharmacy –II	32 - 33
10.	Pharmaceutical Process Validation and Production Management	34 - 35
11.	Selected Topics in Industrial Pharmacy –I	35
12.	Selected Topics in Industrial Pharmacy –II	36 - 37
13.	Laboratory Course –II	37 - 38
<b>Semester-III</b>		
14.	Seminar on research envisaged for dissertation	NIL
15.	Seminar on recent trends in Pharm. Sciences	NIL
<b>Semester-IV</b>		
16.	Dissertation	NIL
17.	Seminar on Dissertation	NIL
18.	Viva-Voce	NIL