

# A.N.U M.PHARMACY (CEUTICS) SYALLABUS (WITH EFFECT FROM 2012-2013)

## I/II M.PHARMACY (1<sup>ST</sup> SEMESTER) MPH103T ADVANCED PHARMACEUTICAL TECHNOLOGY (THEORY)

### **UNIT –1 Preformulation Studies:**

Goals of preformulation, Preformulation parameters, methodology; Solid State Properties, derived & flow properties of Powders, Solubility and Partition coefficient , stability, drug- excipient compatibility studies.

### **UNIT –2 Diffusion and Dissolution:**

**Diffusion:** Steady state diffusion procedures and apparatus. Diffusion principles in biological systems, thermodynamics of diffusion.

**Dissolution:** Basic theories of dissolution, dissolution models. Sink conditions in dissolution and their importance. *In-vitro* and *In-vivo* correlations.

### **UNIT – 3 Polymer Science:**

Types of Polymers, Properties of Polymers, thermodynamics of polymer solution, phase separation, polymers in solid state. Applications of polymers in Pharmaceutical formulations.

### **UNIT – 4 Formulation Development:**

#### **a) Solid Dosage Forms:**

**Tablets:** Types of Tablets, manufacture, production and evaluation of tablets.

**Improved Production techniques for tablets:** New Materials, processes, equipments, improvements in high shear mixers, compression machines, coating machines, coating techniques in tablet technology.

**Capsules:** Manufacture, production and evaluation of hard and soft gelatin capsules.

#### **b) Powder Dosage Forms:**

Formulation development and manufacture of powder dosage form for internal and external use including inhalation dosage forms.

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### **UNIT : 5 Forlulation Development : Liquid and Semi-Solid Dosage Forms.**

Recent advances in the formulation of monophasic liquid dosage forms, suspensions, dry syrups and semi-solid dosage forms. Theories of Emulsification, Stability testing of Emulsions. Preparation and evaluation of Multiple and Micro Emulsions.

#### **b) Parenteral Dosage Forms:**

Advances in the formulating materials, filling machines and sterilizer's for parenterals. Manufacture, production techniques for small and large volume parenterals and quality control of Parenterals.

### **UNIT – 6**

#### **Kinetics and Drug Stability:**

Stability calculations, rate equation, kinetics of drug decompositions, strategy of stability testing, methods of stabilization, methods of accelerated stability testing in dosage forms. Freeze-thaw methods, centrifugal methods, temperature and humidity control.

### **UNIT – 7**

#### **Rheology:**

Theoretical considerations, instrumentation, rheological properties of disperse systems and semi-solids.

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### I/II M.PHARMACY (1<sup>ST</sup> SEMESTER) MPH104P ADVANCED PHARMACEUTICAL TECHNOLOGY (PRACTICALS)

#### \*1. **Preformulation Studies:**

1. Determination of flow properties of lactose granules and effect of glidant concentration on flow properties.
2. Preparation and evaluation of Paracetamol crystals.

#### 2. **Diffusion and Dissolution:**

- 1) Diffusion studies on Paracetamol Suspension using Egg Semi permeable membrane.
- 2) Development of dissolution medium for a poorly soluble drug and dissolution studies on marketed tablet.
- \*3) Evaluation of drug release from immediate and sustained release tablets.

#### 3. **Polymer Science:**

- 1) Determination of Mark-Houwink parameters for HPMC Polymer.

#### 4. **Formulation Development:**

- \*1) Preparation of Paracetamol tablets by wet granulation technique.
- \*2) In process Quality Control Tests For Tablets.
- 3) Preparation & Evaluation of Capsules.
- 4) Preparation of Suspension using different Suspending Agents and its Evaluation.
- 5) Preparation of liquid Paraffin Emulsion and determination of the Effect of homogenization on globule size distribution.
- 6) Preparation & Evaluation of Sodium Nitrate Ampoules.
- \*7) Evaluation of Drug Release from Semisolid preparation.

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### 5. Kinetics and Drug Stability:

- \*1) Accelerated stability studies of Aspirin.  
(Effect temperature on rate of Hydrolysis of Aspirin & Determination of Shelf life).
- 2) Determination of Energy of Activation of Ethyl acetate.
- 3) Determination of First Order Rate constant for the decomposition of Hydrogen Peroxide.

### 6. Rheology:

- \*1) Determination of Viscosity of given samples using Brook Field Viscometers.
- \*2) Studies on Rheological Properties of selected liquids (NACMC in water).

### REFERENCE BOOKS :

- 01 Cole, Pharmaceutical Production Facilities
- 02 H A Liberman, Pharm.Dosage forms (Tablets) Vol-1, 2, 3
- 03 Libermann & Lachman, Theory and Practics of Industrial Pharmacy
- 04 Remingtons Pharmaceutical Sciences
- 05. Walsh Sterile Dosage Forms
- 06. Martin, Physical Pharmacy
- 07. Banker, Modern Pharmaceutics
- 08. ME Alton, The science and practice pharmaceutical dosage forms.
- 09 H.A.Libermann, Pharmaceutical Dosage forms : Disperese Systems (Volume-1 & 2)
- 10. H.A.Libermann Pharmaceutical Dosage forms - Parenteral Medications
- 11. Francoise Nielloud Pharmaceutical Emulsions and suspensions
- 12. James Swarbrick, Encyclopedia of Pharmaceutical Technology Set 2nd end 2002
- 13. Alderman, Pharmaceutical Powder compaction technology

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**I/II M.PHARMACY (1<sup>ST</sup> SEMESTER)  
ADVANCED PHARMACEUTICAL TECHNOLOGY (THEORY)  
MODEL QUESTION PAPER**

TIME: 3HOURS

MAX MARKS: 70

**ALL QUESTIONS CARRY EQUAL MARKS**

**ANSWER ANY FIVE QUESTIONS**

- 1) a) Give a detailed procedure and methods for carrying out Preformulation studies for the development of a dosage form.  
b) Enumerate the role of flow properties in the formulation of solid dosage form and techniques for their measurement.
- 2) a) State and Explain Fick's laws of Diffusion.  
b) Explain the theories of dissolution with their merits & drawbacks.
- 3) a) Give the classification of Polymers with suitable examples. Write about the Pharmaceutical applications of Polymers.  
b) Write about the number average molecular weight and weight average molecular weight of polymers. Explain the significance of Mark-Houwink Equation.
- 4) a) Explain different granulation techniques for the preparation of tablets.  
b) Explain how sugar coating of tablets is carried out.
- 5) a) With the help of neat sketch explain the production of soft gelatin capsules.  
b) Explain the quality control tests to be carried out for capsules.
- 6) a) Explain the theories of emulsification. Add a note on preparation of multiple emulsions.  
b) Write about the official quality control tests to be performed for Parenterals.
- 7) a) Mention the significance of Arrhenius equation in the stability testing. What are its drawbacks. Explain the determination of shelf life of drug product by accelerated stability testing.  
b) A drug product is having an initial concentration of 5.0 mg/ml and found to degrade by first order. It was found that concentration remaining after 20 months is 4.2 mg/ml. It will be ineffective if it loses 30% of its initial concentration. Report the half life and shelf life of the product.

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**I/II M.PHARMACY (1<sup>ST</sup> SEMESTER)  
MODEL QUESTION PAPER (PRACTICALS)**

Time: 6 hrs

Max Marks: 70

1. Synopsis : 15 Marks
- \*2. Major Experiment : 25 Marks
3. Minor Experiment : 15 Marks
4. Viva-voce : 15 Marks

Note : Total sessional marks is 30 (20 for practical sessional plus 10 marks for regularity, promptness, viva-voce and record maintenance).

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### **I/II M.PHARMACY (1<sup>ST</sup> SEMESTER) MPH105T INDUSTRIAL PHARMACY (THEORY)**

**UNIT – 1** A detailed study involving machinery and theory of Pharmaceutical unit operations like Milling, Mixing, Filtration, Drying, Sterilization and Humidity & Air conditioning.

**UNIT – 2 Packaging Technology:**

Packaging materials, Closures And Containers, Unit Dose Packaging, Blister Packing, Strip Packing. FDA regulations for packaging of Tablets, Capsules, Ointments and Aerosols.

**UNIT – 3 Pilot plant and scale-up techniques:**

Significance, pilot study of some important dosage forms such as Tablets, Capsules and Liquid Orals. Discussion on Important Parameters such as Formulas, Equipments, Product Uniformity and Stability, Raw Material Process and Physical Layouts, Personnel Requirements and Reporting Responsibilities.

**UNIT – 4 Quality Assurance:**

Process control- sources and control of quality variation – statistical quality control- Dosage form control, specification –Testing programme and Methods.

**UNIT – 5 Production Management:**

Production organization, objectives and policies.

Good manufacturing practices: Layout of buildings, services, equipment and their maintenance. Materials management, Handling and transportation. Inventory management and control, production and planning control. Sales forecasting, Budget and cost control, Industrial and personal relationship. Safety and health in Pharmaceutical Industry.

**UNIT – 6 Theories of compaction and compression:** Compression, consolidation strength of granules, compression and consolidation under high loads, effect of friction, distribution of forces in compaction, force volume relationships, Heckel plots, compaction profiles, energy involved in compaction, strength of tablet, crushing strength, friability, lamination, instrumentation of tablet machines.

**Unit : 7 ISO 9000 and 1400 Validation :** Sailable features, total quality management and productivity, process products and equipment and

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instrument validation.

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- 02 H A Liberman, Pharm.Dosage forms (Tablets) Vol-1, 2, 3
- 03 Libermann & Lachman, Theory and Practics of Industrial Pharmacy
- 04 H.A.Libermann, Pharmaceutical Dosage forms : Disperese Systems  
(Volume-1 & 2)
05. Francoise Nielloud Pharmaceutical Emulsions and suspensions
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I/II M.PHARMACY (1<sup>ST</sup> SEMESTER)  
INDUSTRIAL PHARMACY (THEORY)  
MODEL QUESTION PAPER

**TIME: 3HOURS**

**MAX MARKS: 70**

ALL QUESTIONS CARRY EQUAL MARKS

ANSWER ANY FIVE QUESTIONS

1. Suggest a suitable dryer for the production of Tablet Granules and explain its principle, working and applications in the Pharmaceutical Industry.
2. Explain the theory of Wet Bulb Temperature. Write a brief note on Psychrometric chart in determining humidity.
3. Write short notes on
  - a) Distribution of forces in compaction.
  - b) Heckel plots.
  - c) Instrumentation in tablet Machine.
4. Explain the significance of Pilot plant and scale up studies and write about the parameters involved in the scale up process of tablets with a neat layout.
5.
  - a) Give the classification of packaging materials used for Pharmaceuticals and mention their relative merits and demerits.
  - b) Write briefly about FDA regulations for packaging of Tablets and Capsules.
6. Write short notes on
  - a) Good Manufacturing Practices
  - b) Inventory management
7. Mention the advantages of Statistical Quality Control. Describe its implementation with suitable examples. Mention the significance of quality control charts.

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### I/II M.PHARMACY (2<sup>ND</sup> SEMESTER) **MPH109T** ADVANCES IN DRUG DELIVERY SYSTEMS (THEORY)

#### UNIT – 1

Basic concepts of sustained and controlled drug delivery systems. Terminology of sustained drug delivery system, controlled release systems, delayed release systems, repeat action systems and site specific systems. Advantages and Disadvantages of SR/CR release systems. Drug candidate selection for SR/CR dosage forms. Dosage calculations, Physico chemical and biological factors influencing the design of SR/CR dosage forms.

#### UNIT- 2

- a) Classification of oral controlled drug delivery systems. Design, fabrication, evaluation and applications of oral controlled drug delivery systems.
- b) Micro encapsulation: Definition, objectives of microencapsulation. Release & Stability kinetics, materials used for microencapsulation, various approaches for the preparation of microcapsules, evaluation & application of microencapsulation.

#### UNIT- 3 Design, fabrication, evaluation and applications of

- a) Bioadhesive drug delivery systems.
- b) Protein and peptide drug delivery systems.
- c) Gastro retentive drug delivery systems.
- d) Colon specific drug delivery systems.

#### UNIT- 4 Design, fabrication, evaluation and applications of

- a) Transdermal therapeutic systems, Sonophoresis & Iontophoresis.
- b) Implantable Therapeutic systems.

UNIT- 5 An introduction to site specific drug delivery systems. Different mechanism of drug targetting, relative merits and demerits of drug targetting. Their design, fabrication, characterization and applications of the following:

- a) Parenteral drug delivery systems.
- b) Liposomes and Neosomes.
- c) Resealed Erythrocytes.

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- d) Nanoparticles.
- e) Monoclonal antibodies.

UNIT- 6 A brief review of mechanism of drug delivery design , fabrication and applications of the following site specific drug delivery systems.

- a) Drug Delivery to Respiratory System.
- b) Drug Delivery to Brain.
- c) Occular Drug Delivery.
- d) Drug Targetting to Neoplastic Diseases.

UNIT : 7 A brief review of mechanism of drug delivery to widely dispersed cells

- a) Macrophages,
- b) Lymphatic Cells
- c) Lysosomal Storage Diseases.

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### I/II M.PHARMACY (2<sup>nd</sup> SEMESTER) **MPH110P** ADVANCES IN DRUG DELIVERY SYSTEMS (PRACTICALS)

- \*1. Preparation and Evaluation of Oral Controlled Release Matrix Tablets by Wet Granulation.
2. Preparation and Evaluation of Oral Controlled release tablets by direct compression.
3. Preparation and Evaluation of co-evaporates for Oral Controlled drug delivery.
- \*4. Preparation and Evaluation of Floating matrix tablets.
- \*5. Preparation and Evaluation of Microspheres by Ionic gelation (Alginate beads)
6. Preparation and Evaluation of Microcapsules by emulsion – solvent evaporation Technique.
7. Preparation and Evaluation of Microcapsules by co-acervation and phase separation Technique.
- \*8. Preparation and Evaluation of Muco adhesive microspheres.
9. Preparation and Evaluation of Transdermal patches using HMPC.
10. Preparation and Evaluation of Transdermal patches using Ethyl Cellulose and Isopropyl Alcohol.
- \*11. Preparation and Evaluation of sustained release pellets by Pan Coating Technique.
12. Preparation and Evaluation of Niosomes by Film Hydration Technique.

## **A.N.U M.PHARMACY (CEUTICS) SYALLABUS (WITH EFFECT FROM 2012-2013)**

### REFERENCE BOOKS :

01. Chien, Novel Drug Delivery System
02. Chien, Nasal and Systemic Drug Delivery
03. Schreier, Drug Targeting Technology
04. H.Bisgaard, Drug Delivery to the Lung
05. Praveen S Tyle, Specialised Drug Delivery Systems
06. Praveen S Tyle, Controlled and Novel Drug Delivery
07. Russel O Potts, Mechanisms of Trnsdermal drug delivery
08. D J Beagley, Drug Delivery to the Brain
09. Johnson & L L Yod, Drug Delivery System
10. Rawlines, Manual of Lab Pharmacokinetics
11. N.K.Jain, Novel and Control drug delivery
12. S P Vyas and Khar, Targetted and control drug delivery
13. Mathiowitz, Encyclopedia of control drug delivery Vol. 1 & 2
14. N.K.Jain, Progress in control and novel drug delivery

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I/II M.PHARMACY (2<sup>nd</sup> SEMESTER)  
ADVANCES IN DRUG DELIVERY SYSTEMS (THEORY)  
MODEL QUESTION PAPER

**TIME: 3HOURS**

**MAX MARKS: 70**

ALL QUESTIONS CARRY EQUAL MARKS

ANSWER ANY FIVE QUESTIONS

1. a) Explain how loading dose and maintenance dose are to be calculated in the design of sustained release dosage forms.  
b) Explain in detail about the Physico chemical factors influencing the design of sustained release dosage forms.
2. a) Explain the mechanism of drug release from the dissolution, diffusion and osmotic pressure controlled Oral drug delivery systems.  
b) Enumerate in detail about various approaches for the preparation of micro capsules.
3. a) Explain the mechanism of bioadhesion. Explain in detail about formulation and evaluation of bioadhesive drug delivery systems.  
b) Write a note Colon specific drug delivery systems .
4. a) What are the objectives of drug targetting. Explain about various mechanisms of drug targetting.  
b) Explain about various approaches of drug targetting to brain.
5. Explain the Kinetics of drug absorption through skin. What are various approaches of TDDS and explain with examples any two in detail.
6. a) How do you distinguish between liposomes and niosomes. Write in detail about their methods of preparation.  
b) What are the advantages of rescaled erythrocytes. Explain the applications of resealed erythrocytes in drug targetting.
7. Write short notes on
  - a) Protein and peptide drugdelivery
  - b) Monoclonal antibodies.

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## I/II M.PHARMACY (2<sup>ND</sup> SEMESTER) MODEL QUESTION PAPER (PRACTICALS)

Time: 6 hrs

Max Marks: 70

- |     |                  |            |
|-----|------------------|------------|
| 1.  | Synopsis         | : 15 Marks |
| *2. | Major Experiment | : 25 Marks |
| 3.  | Minor Experiment | : 15 Marks |
| 4.  | Viva-voce        | : 15 Marks |

Note : Total sessional marks is 30 (20 for practical sessional plus 10 marks for regularity, promptness, viva-voce and record maintenance).

**I/II M. PHARMACY (2<sup>nd</sup> SEMESTER) MPH111T  
ADVANCED BIO-PHARMACEUTICS AND PHARMACOKINETICS (THEORY)**

**UNIT : 1 Bio-availability, Bioequivalence and Therapeutic Equivalence :**

- a) Mechanisms of drug absorption, pH-partition theory and limitations, Physico-chemical properties affecting bioavailability, dissolution, surface area, adsorption, complexation and polymorphism. Techniques of enhancing dissolution rate. Formulation factors affecting bioavailability of drugs in dosage forms of Tablets, capsules, parenterals, liquid orals and topical dosage forms. Designing of bioavailability studies and interpretation of results.
- b) Bioequivalence, pharmaceutical equivalents, bioinequivalency and types of therapeutic equivalence and its regulations.

**UNIT : 2 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 pharmacokinetics parameters pertaining to

- i. Absorption :** (Wherever applicable) 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 :** Over all 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



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### **UNIT : 3 Drug Elimination :**

- a) Drug Metabolism - sites of metabolism, pathways of drug metabolism, factors affecting drug metabolism (genetic, species and environmental).
- b) Concept of Clearance : Organ clearance, total clearance, hepatic clearance, gutwall clearance, lung clearance and renal clearance. Non invasive methods of estimating Pharmacokinetic parameters with emphasis on salivary and urinary compartments.

**UNIT : 4 Non-linear Pharmacokinetics :** Concepts of linear and non linear Pharmacokinetics, Michaelis-Mention Kinetics characteristics. Basic kinetic parameters, possible causes of non induction, non linear binding, non linearity of pharmacological responses.

**UNIT : 5 Time dependent Pharmacokinetics :** Introduction, classification, physiologically induced time dependency, types of biological rhythms, Chronopharmacokinetics.

**UNIT : 6 Clinical Pharmacokinetics :** Altered kinetics in pregnancy, child birth, infants and geriatrics. Kinetics in G.I. disease, malabsorption syndrome, Liver, Cardiac, Renal and pulmonary disease stages.

**UNIT : 7 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.

**I/II M.PHARMACY (2<sup>nd</sup> SEMESTER) MPH112P  
ADVANCED BIO-PHARMACEUTICS AND PHARMACOKINETICS  
(PRACTICALS)**

- \*01. Effect of binder concentration on the dissolution rate testing of paracetamol tablet.
- \*02. Effect of lubricant concentration on the dissolution rate testing of piroxicam tablet.
03. Effect of particle size of paracetamol on the dissolution rate testing of paracetamol tablet.
04. Effect of polymorphism on the dissolution rate testing of Ibuprofen
05. Effect of pH on the dissolution rate testing of diclofenac sodium tablet
- \*06. Effect of pH on the partition coefficient of Ibuprofen.
07. Estimation of protein drug binding by equilibrium dialysis method.
08. Estimation of renal creatinine by COCKROFT-GUALT method
- \*09. Dissolution rate testing of diclofenac sodium SR tablet.
10. Determination of basic pharmacokinetics
11. Determination of area under the curve (AUC) by trapezoid method
12. Determination of mean residence time (MRT) and mean absorption time (MAT) by non compartmental approach.
13. Estimation of absorption rate constant ( $K_a$ ) by method of residuals
14. Estimation of absorption rate constant ( $K_a$ ) by Wangner-Nelson method.
15. Estimation of Pharmacokinetic parameter of a drug administered by IV Bolus by two compartmental method.
- \*16. Estimation of sulpha methoxazole in the blood.
17. Estimation of Bioavailability parameters from four types of dosage form
18. Estimation of elimination rate constant ( $K_e$ ) and elimination half life ( $t_{1/2}$ ) from plasma drug concentration-time profile and urinary excretion data.
19. Determination of elimination rate constant ( $K_e$ ) and elimination half life ( $t_{1/2}$ ) of ciprofloxacin HCl by urinary excretion.

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### **REFERENCE BOOKS**

01. Applied Biopharmaceutics and Pharmacokinetics Leon Shargel
02. Biopharmaceutics and clinical pharmacokinetics :  
An introduction R.E. Notari
03. Clinical Pharmacokinetics Rowland & Towzer
04. Pharmacokinetics Milo Gibaldi
05. Introduction to Biopharmaceutics & Pharmacokinetics Tipnis
06. Remington's Pharmaceutical Sciences, manual  
of lab Pharmacokinetics Rawlins
07. Handbook of Drug Interactions : A clinical and Forensic Guide, Ashraf  
Mozayani, Lionel P.Raymon, Human Press, Totowa, New Jersey, 2004
08. Modern pharmaceutics : Banker

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**I/II M.PHARMACY (2<sup>nd</sup> SEMESTER)  
ADVANCED BIO-PHARMACEUTICS AND PHARMACOKINETICS  
(PRACTICALS)**

**MODEL QUESTION PAPER**

TIME: 3HOURS

MAX MARKS: 70

**ALL QUESTIONS CARRY EQUAL MARKS**

**ANSWER ANY FIVE QUESTIONS**

1. a) Discuss about the experimental designs used for carrying out bioavailability studies.  
b) Explain the role of pH partition theory in the absorption of drugs and what are its limitations ?
2. a) What is a compartment ? What are the advantages and disadvantages of the compartment modeling ?  
b) What are the methods available for the determination of absorption rate constant and explain the method of residuals. Mention its limitation.
3. a) Write about the factors effecting renal clearance of drugs.  
b) What are chronopharmacokinetics and discuss their implications?
4. What are the causes for non-linearity ? How will you detect non-linearity ? Explain Michaelis Menten equation and its application for the calculation of  $K_m$ , and  $V_{max}$ .
5. a) Enlist the various factors affecting drug metabolism.  
b) Write in detail about the techniques for enhancing the dissolution rate of drugs.
6. a) Enumerate in detail about pharmacokinetic and pharmacodynamic drug interactions with suitable examples.  
b) Write about the altered kinetics in the case of malabsorption syndrome and liver disease.
7. Write short notes on
  - a) Mean residence time and volume of distribution ( $V_d$ )
  - b) Dosage regimens.

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**I/II M.PHARMACY (2<sup>ND</sup> SEMESTER)  
MODEL QUESTION PAPER (PRACTICALS)**

Time: 6 hrs

Max Marks: 70

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| 1.  | Synopsis         | : 15 Marks |
| *2. | Major Experiment | : 25 Marks |
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