

August 2011

[KZ 4267]

Sub. Code : 4267

**THIRD B.PHARM. EXAMINATION**

**Paper I - FORMULATIVE PHARMACY AND BIOPHARMACEUTICS**

*Q.P. Code : 564267*

**Time : Three hours**

**Maximum: 100 Marks**

**Answer ALL questions.**

**I. LONG ESSAYS**

**(2 x 20 = 40)**

1. a) Preparation, evaluation and applications of nanoparticles.  
b) Physico chemical factors affecting the bio availability of drugs.
2. a) Discuss the protocols followed in the preformulation studies.  
b) Explain the bioequivalence testing procedures.

**II. SHORT NOTES**

**(8 x 5 = 40)**

1. Evaluation of microcapsules.
2. Osmotic drug delivery systems.
3. Protocol followed for the stability testing of pharmaceutical products.
4. Types of machinery employed for compression of tablets.
5. Compartmental models and its significance.
6. Film defects and its rectification.
7. Hard gelatin capsules.
8. Discuss the different types of prolonged action pharmaceuticals with suitable examples.

**III. SHORT ANSWERS**

**(10 x 2 = 20)**

1. Polymorphism.
2. Biological half life.
3. Co- acervation and phase separation.
4. Slugging.
5. Mean kinetic temperature.
7. Base absorption.
8. Racemisation.
9. Chipping and lamination.
10. Grades of gelatin used for the preparation of capsules.

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February 2012

(LA 4267)

Sub. Code: 4267

**FOURTH B.PHARM. EXAMINATION**

**Paper I – FORMULATIVE PHARMACY AND BIOPHARMACEUTICS**

*Q.P. Code : 564267*

**Time: Three Hours**

**Maximum: 100 marks**

**Answer ALL questions**

**I. Elaborate on:**

**(2 x 20 = 40)**

1. Define Pharmacokinetics. Explain pharmacokinetics and pharmacodynamic parameters in plasma level curve.
2. Differentiate hard and soft gelatin capsules. Explain the method of manufacturing of soft gelatin capsule by rotary die process.

**II. Write notes on:**

**(8 x 5 = 40)**

1. Processing problems of tablet dosage form.
2. Disintegration test for tablet dosage form.
3. Film coating.
4. Importance of microencapsulation in pharmacy.
5. Explain ODDS.
6. Explain Nanoparticals.
7. Explain Bioequivalency testing.
8. Write advantage and limitation of PAP'S.

**III. Short Answers:**

**(10 x 2 = 20)**

1. Define Bioavailability.
2. Define Biopharmaceutics.
3. Write size of hard gelatin capsules.
4. Classification of Liposomes.
5. Importance of tablet coating.
6. Classification of different types of tablets.
7. Write microencapsulation techniques.
8. Storage of capsule dosage forms.
9. Write chemical properties of drugs.
10. Organoleptic property.

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(LB 4267)

AUGUST 2012

Sub. Code: 4267

**FOURTH YEAR B.PHARM. EXAM**  
**Paper I – FORMULATIVE PHARMACY**  
**AND BIOPHARMACEUTICS**  
*Q.P. Code : 564267*

**Time: Three Hours**

**Maximum: 100 marks**

**(180 Min) Answer ALL questions in the same order.**

**I. Elaborate on:**

**Pages Time Marks**  
**(Max.)(Max.)(Max.)**

- |  |    |    |    |
|--|----|----|----|
| 1. Discuss in detail about the physicochemical properties that affect the formulation, stability and bioavailability of drugs in dosage forms. | 19 | 33 | 20 |
| 2. Explain about the types, Formulation, defects and manufacturing of tablets in large scale production.                                       | 19 | 33 | 20 |

**II. Write notes on:**

- |   |   |   |   |
|---|---|---|---|
| 1. Evaluation of tablets.                                     | 3 | 8 | 5 |
| 2. Hard gelatin capsules.                                     | 3 | 8 | 5 |
| 3. Microencapsulation by co – acervation phase separation.    | 3 | 8 | 5 |
| 4. Techniques used in design of prolonged action dosage form. | 3 | 8 | 5 |
| 5. Method of preparation of Liposomes.                        | 3 | 8 | 5 |
| 6. Factors affecting the absorption of drug.                  | 3 | 8 | 5 |
| 7. Pharmacokinetic parameters.                                | 3 | 8 | 5 |
| 8. Methods used in coating of tablets.                        | 3 | 8 | 5 |

**III. Short Answers:**

- |                                      |   |   |   |
|--------------------------------------|---|---|---|
| 1. Name the enteric coated polymers. | 1 | 5 | 2 |
| 2. Microencapsulation.               | 1 | 5 | 2 |
| 3. Soft gelatin capsule.             | 1 | 5 | 2 |
| 4. Define Nanoparticles.             | 1 | 5 | 2 |
| 5. Dental cones.                     | 1 | 5 | 2 |
| 6. Implants.                         | 1 | 5 | 2 |
| 7. Renal clearance.                  | 1 | 5 | 2 |
| 8. Bioavailability.                  | 1 | 5 | 2 |
| 9. Spray congealing.                 | 1 | 5 | 2 |
| 10. Spinhaler.                       | 1 | 5 | 2 |

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**(LC 4267)**

**FEBRUARY 2013**

**Sub. Code: 4267**

**FOURTH YEAR B.PHARM. EXAM  
Paper I – FORMULATIVE PHARMACY  
AND BIOPHARMACEUTICS**

***Q.P. Code: 564267***

**Time: Three Hours  
(180 Min)**

**Maximum: 100 marks**

**I. Elaborate on: (2x20=40)**

1. Discuss about Benefits, Limitations, Types and Evaluation of Prolonged action Pharmaceuticals.
2. Explain in detail about Osmotic Drug Delivery System.

**II. Write notes on: (8x5=40)**

1. Physical properties in formulation.
2. Oxidation.
3. Capsule Filling.
4. Multi orifice centrifugation.
5. Tablet Excipients.
6. Advantages of Transdermal Drug Delivery System.
7. Absorption Rate constant.
8. Renal clearance.

**III. Short Answers: (10x2=20)**

1. Absolute Bioavailability.
2. Diluents.
3. Backing Membrane.
4. Minim per gram factor.
5. Seal coating.
6. Types of Granulation.
7. New Drug Delivery Systems.
8. Dental cones.
9. Gastric Residence Time.
10. Advantages of Tablet coating.

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**(LD 4267)**

**AUGUST 2013**

**Sub. Code: 4267**

**FOURTH YEAR B.PHARM. EXAM**

**PAPER I – FORMULATIVE PHARMACY AND BIOPHARMACEUTICS**

***Q.P. Code: 564267***

**Time: Three Hours**

**Maximum: 100 marks**

**I. Elaborate on:**

**(2X20=40)**

1. What are Preformulation Studies? Explain what physicochemical properties of the drugs are determined in preformulation studies and their importance.
2. Write on the different types of transdermal drug delivery systems and their evaluation.

**II. Write notes on:**

**(8X5=40)**

1. Different types of tablets
2. Quality control tests on hard gelatin capsules
3. Film forming formulations in tablet film coating
4. Design of oral sustained release products
5. Pan coating
6. Bioequivalency testing
7. Dosage form considerations in gastrointestinal absorption
8. Factors affecting stability of drug dosage forms

**III. Short Answers on:**

**(10X2=20)**

1. Components of a rotary punching machine
2. Define bioavailability
3. Diluents used in tableting
4. Storage Conditions to be maintained in standard stability testing
5. What is a fluidized bed processor?
6. What is meant by orange peel effect in tablet coating?
7. Name tablet hardness testers
8. Relationship between biological half life and elimination rate constant in IV bolus dosing following one compartment model
9. Materials required for liposome preparation
10. What is an implant?

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**(LE 4267)**

**FEBRUARY 2014**

**Sub. Code: 4267**

**FOURTH YEAR B.PHARM. EXAM**

**PAPER I – FORMULATIVE PHARMACY AND BIOPHARMACEUTICS**

***Q.P. Code: 564267***

**Time: Three Hours**

**Maximum: 100 marks**

**I. Elaborate on:**

**(2X20=40)**

1. Discuss about the bioavailability and bioequivalence testing.
2. Discuss about the quality control testing of tablets.

**II. Write notes on:**

**(8X5=40)**

1. Solubility
2. Chemical degradation
3. Materials for production of hard gelatin capsules
4. Spray drying – Spray congealing
5. Defects in tablets manufacturing
6. Liposome
7. Drug elimination
8. Clearance

**III. Short Answers on:**

**(10X2=20)**

1. Precompression
2. Polymorphism
3. Wetting
4. Size of hard gelatin capsules
5. Enteric coating
6. Apparent volume of distribution
7. Methods of microencapsulation
8. Hypodermic tablets
9. Biopharmaceutics
10. Application of nanoparticles

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(LF 4267)

AUGUST 2014

Sub. Code: 4267

**FOURTH YEAR B.PHARM. EXAM**  
**PAPER I – FORMULATIVE PHARMACY AND BIOPHARMACEUTICS**

*Q.P. Code: 564267*

**Time: Three Hours**

**Maximum: 100 marks**

**I. Essay:** (2X20=40)

1. Explain about the coating of tablets with examples.
2. Discuss about advantages, Preparation and Evaluation of Transdermal Drug Delivery System.

**II. Short notes:** (8X5=40)

1. Dissolution
2. Stability testing protocol for various pharmaceutical products
3. Quality control test for capsules
4. Types and importance of microencapsulation in pharmacy
5. Evaluation of prolonged action pharmaceutical.
6. Determination of bioavailability
7. Compartment models
8. Rate of drug absorption after oral administration.

**III. Short Answers:** (10X2=20)

1. Novel Drug Delivery System
2. Nano particles
3. Capping and Lamination
4. Osmotic drug delivery system
5. Poor flow of granules
6. Shape of soft gelatin capsules
7. Factors affecting absorption of drugs
8. Preformulation
9. Types of tablets
10. Types of tablets compression machine

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**(LG 4267)**

**FEBRUARY 2015**

**Sub. Code: 4267**

**FOURTH YEAR B.PHARM. EXAMINATION  
PAPER I – FORMULATIVE PHARMACY AND BIOPHARMACEUTICS**

***Q.P. Code: 564267***

**Time: Three hours**

**Maximum: 100 marks**

**I. Essay:** **(2 x 20 = 40)**

1. Discuss about the Absorption of drug and factors affecting drug absorption.
2. Briefly explain about the Formulation, granulation and manufacture of tablets.

**II. Short notes:** **(8 x 5 = 40)**

1. Organoleptic property and their effect on formulation
2. Stability testing
3. Soft gelatin capsules
4. Air suspension techniques for microencapsulation
5. Nanoparticles
6. What is bloom strength? Explain how it is determined?
7. Drug distribution
8. Advantages and disadvantages of capsule dosage forms

**III. Short answers:** **(10 x 2 = 20)**

1. Important of density in preformulation
2. Hydrolysis
3. Storages of capsule dosage form
4. Types of microcapsules
5. Bioavailability
6. Pharmacokinetics
7. Biological half life
8. Defects in film coating
9. Transdermal drug delivery
10. Advantages of liposome

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**B.PHARM. DEGREE EXAMINATION**

**FOURTH YEAR**

**PAPER I – FORMULATIVE PHARMACY AND BIOPHARMACEUTICS**

*Q.P. Code: 564267*

**Time : Three Hours**

**Maximum : 100 marks**

**Answer All Questions**

**I. Essay:**

**(2 x 20 = 40)**

1. What are pre-formulation studies? Explain about physiochemical properties of the drugs that are determined in pre-formulation studies and their importance.
2. Write a note on objectives of tablet coating. Explain the different types of coating and evaluation of coated tablets.

**II. Short notes :**

**(8 x 5 = 40)**

1. Liposomes.
2. Drug elimination
3. Hard gelatin capsules.
4. Microencapsulation by co-acervation phase separation.
5. Techniques used in design of prolonged action dosage form.
6. Write preparation and application of nanoparticles.
7. Factors affecting drug absorption.
8. Invitro - invivo correlation.

**III. Short answers:**

**(10 x 2 = 20)**

1. Total body clearance.
2. Composition of soft gelatin capsules.
3. Coating materials in microcapsules.
4. Define pharmacokinetics.
5. Renal clearance.
6. Spray drying.
7. Bioequivalency testing.
8. What is bloom strength?
9. Classification of different types of tablets.
10. Anti-oxidants.

(LI 4267)

FEBRUARY 2016

Sub. Code: 4267

**FOURTH YEAR B.PHARM. EXAMINATION**  
**PAPER I – FORMULATIVE PHARMACY AND BIO-PHARMACEUTICS**

***Q.P. Code: 564267***

**Time: Three hours**

**Maximum: 100 Marks**

**I. Essay:** **(2 x 20 = 40)**

1. Differentiate hard and soft gelatin Capsules. Discuss about the material used in capsule. Explain the method of manufacturing of soft gelatin capsule by rotary die process.
2. Write on the different types of Transdermal drug delivery systems and their evaluation.

**II. Short notes:** **(8 x 5 = 40)**

1. Processing problems of tablet dosage form.
2. Write advantages and limitation of Prolonged Action Pharmaceuticals.
3. Spray drying –Spray congealing.
4. Pan coating.
5. Apparent volume of distribution and total body clearance.
6. Bioequivalency testing.
7. Discuss the application of stability studies.
8. Polymorphism and its influence in the formulation of solid dosage form.

**III. Short answers:** **(10 x 2 = 20)**

1. Importance of tablet coating.
2. Write microencapsulation techniques.
3. Storage of capsule dosage forms.
4. Write chemical properties of drugs.
5. Organoleptic property.
6. Classification of liposomes.
7. Define Bio-pharmaceutics.
8. Solubility.
9. Slugging.
10. Biological half life.

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(LJ 4267)

AUGUST 2016

Sub. Code: 4267

**FOURTH YEAR B.PHARM. EXAMINATION  
PAPER I – FORMULATIVE PHARMACY AND BIOPHARMACEUTICS**

***Q.P. Code: 564267***

**Time: Three hours**

**Maximum: 100 Marks**

**I. Essay:**

**(2 x 20 = 40)**

1. Give an account of stability testing protocol for various pharmaceutical products. How drug products can be stabilized from the influence of oxidation?
2. Explain about Bio-availability testing.

**II. Short notes:**

**(8 x 5 = 40)**

1. Study of particle size and density of drugs in preformulation studies.
2. Soft gelatin capsule shell and content.
3. Coacervation phase separation.
4. Tablet excipients.
5. Formulation of film coating solutions.
6. Benefits and limitations of prolonged action Pharmaceuticals.
7. Osmotic drug delivery systems.
8. Biological factors influencing gastrointestinal absorption of drugs.

**III. Short answers:**

**(10 x 2 = 20)**

1. Significance of drug solubility.
2. Quality control tests on capsules.
3. Methods of microencapsulate liquids.
4. Sticking and picking in film coated tablets.
5. Difference between prolonged (sustained) release and controlled release drug delivery systems.
6. Properties of drugs suitable for transdermal drug delivery systems.
7. Raw materials required for liposomes.
8. Apparent volume of distribution.
9. Parameters affecting drug dissolution.
10. Dissolution testing apparatuses.

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(LK 4267)

FEBRUARY 2017

Sub. Code: 4267

**B.PHARM. EXAMINATION  
FOURTH YEAR  
PAPER I – FORMULATIVE PHARMACY AND BIOPHARMACEUTICS**

*Q.P. Code: 564267*

**Time: Three hours**

**Maximum: 100 Marks**

**I. Elaborate on:**

**(2 x 20 = 40)**

1. Describe the study of physical properties and solubility analysis of drugs in pre-formulation studies.
2. Explain the types and construction of oral prolonged action pharmaceuticals.

**II. Write notes on:**

**(8 x 5 = 40)**

1. Degradation of drugs in pharmaceutical dosage forms with examples.
2. Evaluation of capsules.
3. Multiorifice centrifugation.
4. Tablet compression machine.
5. Types of tablet coating.
6. Transdermal drug delivery systems.
7. Physicochemical factors affecting oral absorption of drugs.
8. Disintegration test on tablets.

**III. Short answers on:**

**(10 x 2 = 20)**

1. Significance of crystallinity and polymorphism of drugs.
2. Buccal and sublingual tablets.
3. Applications of nanoparticles.
4. Superdisintegrants.
5. Dry granulation in tablet production.
6. Reasons for weight variation of tablets.
7. Hepatic first pass and bioavailability.
8. Characteristics of gelatin for capsule shell production.
9. Renal clearance.
10. Plasticizers.

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(LL 4267)

AUGUST 2017

Sub. Code: 4267

**B.PHARM. DEGREE EXAMINATION  
FOURTH YEAR  
PAPER I – FORMULATIVE PHARMACY AND BIO-PHARMACEUTICS**

***Q.P. Code: 564267***

**Time: Three hours**

**Maximum: 100 Marks**

**I. Elaborate on:** **(2 x 20 = 40)**

1. Define Absorption. Explain the physico chemical factors affecting Drug Absorption.
2. Write in detail the method of preparation of Liposomes and its applications.

**II. Write notes on:** **(8 x 5 = 40)**

1. Influence of Chemical properties of drug in the development of Pharmaceutical dosage form.
2. Processing problems of Tablet dosage form.
3. Wurster air suspension technique.
4. Alzet Osmotic pump.
5. Types and components of transdermal patches.
6. Nanoparticles.
7. Pharmacokinetic parameters.
8. Evaluation of capsules.

**III. Short answers on:** **(10 x 2 = 20)**

1. Objectives of pre-formulation study.
2. Importance of solubility.
3. Binders and dis-integrants.
4. Double compression.
5. Steps involved in sugar coating.
6. Orange peel effect.
7. Basic components of osmotic system.
8. Compartment model.
9. Endocytosis.
10. Bioavailability and bioequivalence.

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THE TAMIL NADU DR. M.G.R. MEDICAL UNIVERSITY

(LM 4267)

FEBRUARY 2018

Sub. Code: 4267

**B.PHARM. DEGREE EXAMINATION  
FOURTH YEAR  
PAPER I – FORMULATIVE PHARMACY AND BIO-PHARMACEUTICS**

*Q.P. Code: 564267*

**Time: Three hours**

**Maximum: 100 Marks**

**I. Elaborate on:**

**(2 x 20 = 40)**

1. Explain in detail about Osmotic drug delivery system.
2. Enlist methods for preparation of microencapsules. Explain air suspension process in detail. Give evaluation test for microencapsules.

**II. Write notes on:**

**(8 x 5 = 40)**

1. Design of oral sustained release products.
2. Classification of different types of tablets.
3. Manufacturing of soft gelatin capsules by rotary die process.
4. Evaluation of tablets.
5. Stability testing protocol for various pharmaceutical products.
6. Compartment models and its significance.
7. Discuss granulation technology on large-scale by various techniques.
8. Discuss the factors affecting bio-availability of a drug.

**III. Short answers on:**

**(10 x 2 = 20)**

1. Backing membrane.
2. Classification of liposome on the basis of structural parameters.
3. Seal coating.
4. Potential advantages of TDDS.
5. Quality control test for capsules.
6. Biological half-life.
7. Anti-oxidants.
8. Organoleptic property and their effect on formulation.
9. Slugging.
10. Processing problems of tablet dosage form.

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THE TAMIL NADU DR. M.G.R. MEDICAL UNIVERSITY

(LN 4267)

AUGUST 2018

Sub. Code: 4267

**B.PHARM. DEGREE EXAMINATION  
FOURTH YEAR  
PAPER I – FORMULATIVE PHARMACY AND BIO-PHARMACEUTICS**

*Q.P. Code: 564267*

**Time: Three hours**

**Maximum: 100 Marks**

**I. Elaborate on:** (2 x 20 = 40)

1. Explain in detail the various physiochemical factors and their effect on formulation, stability and bioavailability of dosage form.
2. Discuss various components of Transdermal drug delivery system.

**II. Write notes on:** (8 x 5 = 40)

1. Accelerated stability studies and stability study protocol.
2. Quality control tests for tablets.
3. Manufacturing of soft gelatin capsule.
4. Types of prolonged action dosage form.
5. Formulation of nanoparticles.
6. Microencapsulation techniques.
7. Method of preparation of liposomes.
8. Osmotic drug delivery system.

**III. Short answers on:** (10 x 2 = 20)

1. Direct compression.
2. Enteric coating.
3. Sublingual tablets.
4. Disintegrants.
5. Matrix system.
6.  $C_{max}$  and  $T_{max}$ .
7. Plasma protein binding.
8. AUC.
9. Clearance.
10. Bioequivalence.

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**B.PHARM. DEGREE EXAMINATION**  
**FOURTH YEAR**  
**PAPER I – FORMULATIVE PHARMACY AND BIO-PHARMACEUTICS**

*Q.P. Code: 564267*

**Time: Three hours**

**Maximum: 100 Marks**

**I. Elaborate on:**

**(2 x 20 = 40)**

1. Write the advantages and limitation of prolonged action pharmaceuticals. Write about two method of preparation and evaluation of prolonged action pharmaceuticals.
2. Write the goals of pre-formulation studies. Explain the physical properties of drugs in pre-formulation studies and their importance.

**II. Write notes on:**

**(8 x 5 = 40)**

1. Methods to enhance the solubility of poorly soluble drugs.
2. Microencapsulation by air suspension technique.
3. Dissolution testing.
4. Drug excipient compatibility studies.
5. Physico-chemical factors affecting drug absorption.
6. Evaluation of transdermal patches.
7. Filling of Hard capsules.
8. Accelerated stability studies.

**III. Short answers on:**

**(10 x 2 = 20)**

1. Permeation enhancers.
2. Biopharmaceutics.
3. Partition co-efficient.
4. Polymorphism.
5. Various sizes of hard capsule.
6. Renal clearance.
7. Nanoparticles.
8. Bloom strength.
9. Elementary osmotic pump.
10. Organoleptic additives.

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THE TAMIL NADU DR. M.G.R. MEDICAL UNIVERSITY

(LP 4267)

AUGUST 2019

Sub. Code: 4267

**B.PHARM. DEGREE EXAMINATION  
FOURTH YEAR  
PAPER I – FORMULATIVE PHARMACY AND BIO-PHARMACEUTICS**

*Q.P. Code: 564267*

**Time: Three hours**

**Maximum: 100 Marks**

**I. Elaborate on:**

**(2 x 20 = 40)**

1. Discuss the pharmaceutical and biological factors that affect absorption of drugs.
2. Explain about Bio-availability and Bio-equivalency studies.

**II. Write notes on:**

**(8 x 5 = 40)**

1. Physical factors of drug that affect stability of dosage form.
2. Accelerated stability studies.
3. Processing problems in tablet manufacturing.
4. Film coating of tablets.
5. Hard gelatin capsule.
6. Benefits and limitation of sustained release preparations.
7. Osmotic drug delivery system.
8. Preparation of microspheres.

**III. Short answers on:**

**(10 x 2 = 20)**

1. Dental cone.
2. Excipients for tablet manufacturing.
3. Dry granulation in tablet production.
4. Composition of soft gelatin capsules.
5. Bloom strength.
6. Benefits of nanoparticles.
7. Enteric coating.
8. Drug elimination.
9. Pharmacokinetic parameters.
10. Compartment models.

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THE TAMIL NADU DR. M.G.R. MEDICAL UNIVERSITY

(LQ 4267)

FEBRUARY 2020

Sub. Code: 4267

**B.PHARM. DEGREE EXAMINATION  
FOURTH YEAR  
PAPER I – FORMULATIVE PHARMACY AND BIO-PHARMACEUTICS**

*Q.P. Code: 564267*

**Time: Three hours**

**Maximum: 100 Marks**

**I. Elaborate on:** (2 x 20 = 40)

1. Define Bio-pharmaceutics. Discuss the various factors influencing the drug absorption in biological milieu.
2. Explain the chemical properties influence the stability of pharmaceutical formulation. Discuss the stability testing protocol followed for the biological products.

**II. Write notes on:** (8 x 5 = 40)

1. Quality control of hard gelatin capsules.
2. Process followed for the bio-equivalency testing.
3. Different types of granulation techniques adopted in tablet manufacturing.
4. Sugar coating process.
5. Nanoparticles.
6. Processing problems of tablets and its rectification.
7. Biological half-life and Elimination rate constant.
8. Multi-orifice centrifugation method used in microencapsulation.

**III. Short answers on:** (10 x 2 = 20)

1. Bio availability.
2. Phase separation.
3. Bridging and filling.
4. Different types of dissolution apparatus.
5. Compartment models.
6. Diffusion mechanism.
7. Liposomes.
8. Rat hole formation.
9. Process variables of film coating.
10. Osmosis.

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