



Name :

Roll No. :

Invigilator's Signature :

**CS/M.PHARM/SEM-1/MPT-106/2012-13
2012**

**DOSAGE FORM DESIGN PERMETERS AND
PHARMACEUTICAL PRODUCT DEVELOPMENT**

Time Allotted : 3 Hours

Full Marks : 70

The figures in the margin indicate full marks.

*Candidates are required to give their answers in their own words
as far as practicable.*

GROUP - A

(Multiple Choice Type Questions)

1. Choose the correct alternatives for any *ten* of the following :

10 × 1 = 10

- i) Parts of solvent required to dissolve one part of solute in case of sparingly soluble drugs is
 - a) 1 - 10
 - b) 10 - 30
 - c) 30 - 100
 - d) 100 - 1000.
- ii) Coulter-counter is used to measure
 - a) particle size
 - b) particle shape
 - c) surface area
 - d) particle volume.
- iii) If the pKa of aspirin is 5.6, what fraction of drug would be ionized at pH 8.6 ?
 - a) 80%
 - b) 90%
 - c) 99%
 - d) 99.9%.



- iv) Spray dried lactose is widely used as
 - a) Diluent in direct compression
 - b) superdisintegrant
 - c) binder
 - d) none of these.
- v) Poorly soluble drugs are poor candidates to make controlled release device, because
 - a) their absorption is pH dependent
 - b) they are highly ionised
 - c) their absorption is dissolution rate limited
 - d) none of these.
- vi) Powder flow will be excellent if angle of repose is
 - a) $30^\circ - 40^\circ$
 - b) $25^\circ - 30^\circ$
 - c) $< 25^\circ$
 - d) $> 40^\circ$.
- vii) Which of the ampicillin polymorphs has the higher bioavailability ?
 - a) Anhydrous
 - b) Monohydrate
 - c) Dehydrate
 - d) Trihydrate.
- viii) Which category drug as per BCS cannot be given by oral route ?
 - a) Class-I
 - b) Class-II
 - c) Class-III
 - d) Class-IV.
- ix) Bulk density is determined by
 - a) Mercury displacement
 - b) Helium displacement
 - c) Nitrogen absorption
 - d) none of these.



- x) Particle surface area can be measured by
- Noyes-Whitney equation
 - Fick's first law
 - BET equation for adsorption
 - None of these.
- xi) Differential Thermal Analysis is used for investigation of
- Polymorphism
 - Dissolution rate
 - Solubility
 - None of these.
- xii) Absorption of griseofulvin is
- increased due to micronization
 - decreased due to micronization
 - unaltered due to micronization
 - Permeation rate limited.

GROUP - B

(Short Answer Type Questions)

Answer any *three* of the following. $3 \times 5 = 15$

- Write a note on Diffuse Reflectance Spectroscopy.
- Describe the different 'Level of Correlations' in IV-IVC.
- Write a note on Polymorphism and its significance in Preformulation study.
- How partition coefficient is determined ? What is its importance in Pre-formulation studies ?
- Explain BSC of drugs with special reference to bio-waiver policy.



GROUP - C

(Long Answer Type Questions)

Answer any *three* of the following. $3 \times 15 = 45$

7. Briefly explain the different stages of product development for regulated market.
8. a) What do you mean by order of the reaction ? Discuss one method by which order of reaction can be determined. What is understood by hydrolytic degradation ? What are the measures to be applied to prevent the effects of hydrolysis ?
- b) A formulation was found to degrade following 1st order kinetics. The initial concentration was 1000 units/ml. The specific rate constant K at 25°C was found to be 2.01×10^{-5} /hr. Calculate the expiration data of product based on 10% degradation is allowed.
- $(2 + 3 + 2 + 3) + 5$
9. Describe pilot plant scale up studies used for tablet dosage form by dry granulation method (only for uncoated tablet).
10. How will you measure solubility and partition coefficient of an Investigational New Drug during preformulation trials ? Describe the permeation studies to be performed on a new drug preformulation trial.
- $(3 + 3) + 9$
11. Discuss the effect of route of administration of drugs and its implication on bioavailability.