Name : ....

Roll No. : ....

Invigilator's Signature : ....

CS/M.Pharm/SEM-1/MPT-106/2009-10

2009

DOSAGE FORM DESIGN PARAMETERS & 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 :

$$10 \times 1 = 10$$

   i)   Powder flow will be excellent if

      a)   angle of repose is 30°-40°

      b)   angle of repose is 25°-30°

      c)   angle of repose is less than 25°

      d)   angle of respose is more than 40°.

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ii) Micronization of hydrophobic drugs

a) increases dissolution rate

b) decreases dissolution rate

c) causes no alteration in dissolution rate.

iii) Absorption of griseofulvin is

a) dissolution rate limited

b) permeation rate limited

c) perfusion rate limited.

iv) The half life is independent of initial concentration in case of

a) zero order absorption

b) first order absorption

c) mixed order absorption.

v) Particle surface area can be measured by

a) Noyes-Whitney equation

b) Fick's first law

c) BET equation for adsorption.
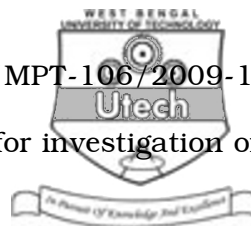
vi) Differential Thermal Analysis is used for investigation of

   a) Polymorphism

   b) Dissolution rate

   c) Solubility.

vii) The stainless steel may react with some acidic materials of pharmaceutical dosage formulations. This problem can be minimized by pre-reacting the stainless steel with

   a) excessive amount of D.M. water

   b) acetic acid or nitric acid solution

   c) potassium permanganate solution

   d) none of these.

viii) BET equation of adsorption theory is used to determine the

   a) surface area of the particle

   b) density of the particle

   c) surface volume of the particle

   d) viscosity of the liquid.

ix) 'Solvates' are

   a)   crystal with liquid in the molecules

   b)   amorphous state

   c)   crystal with water in the molecules

   d)   none of these.

x)   Effect of temperature on the stability of drug is determined by

   a)   Higuchi equation

   b)   Fick's law

   c)   Newton's law

   d)   none of these.

xi)   % compressibility is (when ρ_{tap} = tapped bulk density, ρ_o = bulk density & ρ_t = true density)

   a) $\dfrac{\left(\rho_{tap} - \rho_t\right)}{\rho_{tap}} \propto 100$

   b) $\left(\dfrac{\rho_o - \rho_t}{\rho_t}\right) \propto 100$

   c) $\left(\dfrac{\rho_{tap} - \rho_o}{\rho_{tap}}\right) \propto 100$

   d)   none of these.

xii) A pilot plant has four types of space requirements. These are physical testing area, storage area, standard pilot plant equipment floor space and the fourth one is

    a)   administrative and information processing

    b)   quality assurance

    c)   packaging

    d)   none of these.

GROUP – B
(Short Answer Type Questions)
Answer any *three* of the following.   3 × 5 = 15

2. Describe the routes of administration to bypass first pass metabolism.

3. How will you perform pilot-plant scale up studies of 'suppositories' ?

4. Discuss the physiological aspect of G.I. tract from where weakly acidic drugs are absorded.

5. What do you mean by diffuse reflectance spectroscopy ? Write down the law and equation related to diffuse reflectance spectroscopy. What is the role of it in preformulation trial ? $1\frac{1}{2} + 2 + 1\frac{1}{2}$

6. Describe the role of 'critical path analysis' in pharmaceutical product development.

7. A controlled release formulation of aspirin was prepared and it was found to show a zero-order kinetics with a rate constant of $5 \cdot 0$ mg/ml month^{-1}. Calculate $t_{\frac{1}{2}}$ and shelf life
of the product if dose of the formulation is 50 mg/ml.

GROUP – C
(Long Answer Type Questions)
Answer any *three* of the following. $3 \times 15 = 45$

8. Describe the following : $2 + 6\frac{1}{2} + 6\frac{1}{2}$

   a) Importance of flow property studies.

   b) Different parameters studied to understand the flow ability.

   c) Different factors influencing flow ability.

9. Write notes on the following :

   a) Determination of permeability of drug *in vitro*.

   b) Duties and responsibilities of preformulation co-ordinator. $8 + 7$

10. Write an account on the mechanisms of drug transport across functional membranes with relevant rate equations involved. Also justify the statement, "the use of a large single oral dose of certain drugs is irrational". $13 + 2$

11. What do you mean by Pharmaceutical Product Design ? Describe in detail about the role of "experimental approach to develop a prototype formula for a pharmaceutical product". How do bio-availability studies and developement of validation data influence Pharmaceutical Product Design ? 3 + 5 + 7

12. a) "Drugs in formulation are often required to be buffered for optimum drug stability and drug action. Buffer constituents are the contributing factors in influencing ionic effect. A thorough kinetic study on the influence of ionic strength is therefore, of prime importance." Elaborate on the subject by deducing equations.

   b) In a second order rate study it was found that 30% of the reaction was completed in 12·0 min. How long will it take for 70% completion ? (Two reactants were of same initial concentration, *i.e*, $a = b$) $7\frac{1}{2} + 7\frac{1}{2}$